

Standard Medicare Part D Formulary Prior Authorization Guidelines

FOREWORD

This document will serve as a reference to assist with administration of clinical and administrative prior authorization (PA) criteria for Part D Standard formulary clients. This document should not be used to determine formulary status or effective date for a PA guideline. To determine formulary status or effective date for a PA guideline, refer to the formulary ASCII and PA ASCII files produced monthly.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ABALOPARATIDE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ABALOPARATIDE	TYMLOS	44231		GPI-10 (3004400500)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

Does the patient have **ONE** of the following diagnoses?
Postmenopausal osteoporosis (ICD-10 M81.0, Group M80.0) in a female
Osteoporosis (ICD-10 Group M80.0) in a male

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

Has the patient received a total of 24 months cumulative treatment with any parathyroid hormone therapy (e.g., Forteo [teriparatide], Tymlos [abaloparatide])?

If yes, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

If no, continue to #3.

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ABALOPARATIDE (PART D)

GUIDELINES FOR USE (CONTINUED)

Does the patient meet **ONE** of the following criteria?

The patient is at high risk for fractures (defined as history of osteoporotic fracture or multiple risk factors for fracture)

The patient has failed or is intolerant to other osteoporosis therapy (e.g., Fosamax [alendronate], Actonel [risedronate])

If yes, **approve for 24 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ABALOPARATIDE (Tymlos)** requires the following rule(s) be met for approval:

The request is for ONE of the following:
- Postmenopausal osteoporosis (a type of bone condition in women after menopause)
- Osteoporosis (a type of bone condition in a male)

You have NOT received a total of 24 months of cumulative treatment with any parathyroid hormone therapy (such as Forteo [teriparatide], Tymlos [abaloparatide])

You meet ONE of the following:
- You are at high risk for fractures (defined as history of osteoporotic fracture [a type of complete or partial break in a bone] or multiple risk factors for fracture)
- You have failed or could not tolerate other available osteoporosis therapy (such as Fosamax [alendronate], Actonel [risedronate])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tymlos.

REFERENCES

Tymlos [Prescribing Information]. Waltham, MA: Radius Health, Inc.; December 2023.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ABALOPARATIDE (PART D)

For Part D use only:

ABALOPARATIDE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	24 MONTHS
Other Criteria	OSTEOPOROSIS: HAS NOT RECEIVED A TOTAL OF 24 MONTHS CUMULATIVE TREATMENT WITH ANY PARATHYROID HORMONE THERAPY.

Part D Effective: 01/01/25 Created: 06/24
Commercial Effective: N/A Client Approval: 06/24 P&T Approval: 01/23

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ABATACEPT - IV (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ABATACEPT/MALTOSE	ORENCIA	33411		GPI-14 (66400010002120)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

NOTE: For requests for the SQ dosage form of Orencia, please see the ABATACEPT - SQ PA guideline.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist
- Orencia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
- The patient had a trial of or contraindication to 3 months of treatment with ONE conventional synthetic DMARD (disease-modifying antirheumatic drug) (e.g., methotrexate at a dosegreater than or equal to 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, sulfasalazine)

  If yes, **approve for 6 months by HICL or GPI-14.**
  APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

  If no, continue to #2.

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ABATACEPT - IV (PART D)

INITIAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (pJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
- The patient is 6 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist
- Orencia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of pJIA

If yes, **approve for 6 months by HICL or GPI-14.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #3.

Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by, or in consultation with a rheumatologist or dermatologist
- Orencia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

If yes, **approve for 6 months by HICL or GPI-14.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #4.

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ABATACEPT - IV (PART D)

INITIAL CRITERIA (CONTINUED)

Is the request for prophylaxis of acute graft versus host disease (aGVHD) and the patient meets **ALL** of the following criteria?

- The patient is 2 years of age or older
- The patient is undergoing hematopoietic stem cell transplantation (HSCT) from a matched OR one allele-mismatched unrelated-donor
- Orencia will be used in combination with a calcineurin inhibitor (e.g., cyclosporine, tacrolimus, pimecrolimus) and methotrexate
- Orencia will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of aGVHD prophylaxis

If yes, **approve for 1 month by HICL or GPI-14.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ABATACEPT - IV (Orencia intravenous)** requires the following rule(s) be met for approval:

The request is for ONE of the following:

- Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
- Moderate to severe polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition in children)
- Psoriatic arthritis (PsA: a type of skin and joint condition)
- Prophylaxis (prevention) of acute graft versus host disease (aGVHD: a short-term type of immune disorder)

If you have moderate to severe rheumatoid arthritis, approval also requires:

- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Orencia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
- You have tried or have a contraindication to (harmful for you to use) 3 months of ONE conventional synthetic DMARD (disease-modifying antirheumatic drug, such as methotrexate at a dose greater than or equal to 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, sulfasalazine)

(Initial denial text continued on next page)

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ABATACEPT - IV (PART D)

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe polyarticular juvenile idiopathic arthritis, approval also requires:
- You are 6 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Orencia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis

If you have psoriatic arthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (skin doctor)
- You will NOT use Orencia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

If the request is for prophylaxis of acute graft versus host disease, approval also requires:
- You are 2 years of age or older
- You are undergoing hematopoietic stem cell transplantation (HSCT: a type of cell transplantation) from a matched OR one allele (version of a gene)-mismatched unrelated-donor
- Orencia will be used in combination with a calcineurin inhibitor (such as cyclosporine, tacrolimus, pimecrolimus) and methotrexate
- You will NOT use Orencia concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of acute graft versus host disease prophylaxis

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ABATACEPT - IV (PART D)

RENEWAL CRITERIA

NOTE: For the diagnosis of acute graft versus host disease (aGVHD), please refer to the Initial Criteria section.

Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
The patient continues to benefit from the medication
Orencia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

If yes, **approve for 12 months by HICL or GPI-14.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #2.

Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (pJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
The patient continues to benefit from the medication
Orencia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of pJIA

If yes, **approve for 12 months by HICL or GPI-14.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #3.

Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
The patient continues to benefit from the medication
Orencia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

If yes, **approve for 12 months by HICL or GPI-14.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the renewal denial text at the end of the guideline.

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RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ABATACEPT - IV (Orencia intravenous)** requires the following rule(s) be met for renewal:
You have ONE of the following:
- Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
- Moderate to severe polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition in children)
- Psoriatic arthritis (PsA: a type of skin and joint condition)

If you have moderate to severe rheumatoid arthritis, renewal also requires:
- You continue to benefit from the medication
- You will NOT use Orencia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis

If you have moderate to severe polyarticular juvenile idiopathic arthritis, renewal also requires:
- You continue to benefit from the medication
- You will NOT use Orencia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis

If you have psoriatic arthritis, renewal also requires:
- You continue to benefit from the medication
- You will NOT use Orencia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the prescribing information and/or Drug Monograph for Orencia.

REFERENCES
Orencia [Prescribing Information]. Princeton, NJ: Bristol-Myers Squibb Company; May 2024.

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ABATACEPT - IV (PART D)

For Part D use only:

ABATACEPT - IV (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: RHEUMATOID ARTHRITIS (RA), POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST.
Coverage Duration	RA, PJIA, PSA: INITIAL: 6 MOS, RENEWAL: 12 MOS. ACUTE GRAFT VERSUS HOST DISEASE (AGVHD): 1 MO.
Other Criteria	INITIAL: ALL INDICATIONS: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION. RA: TRIAL OF OR CONTRAINDICATION TO 3 MONTHS OF TREATMENT WITH ONE CONVENTIONAL SYNTHETIC DMARD (DISEASE-MODIFYING ANTIRHEUMATIC DRUG) - IF PATIENT TRIED METHOTREXATE, THEN TRIAL AT A DOSE GREATER THAN OR EQUAL TO 20 MG PER WEEK OR MAXIMALLY TOLERATED DOSE IS REQUIRED. RENEWAL: RA, PJIA, PSA: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR THE SAME INDICATION.

Created 05/05
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 10/24

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ABATACEPT - SQ (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ABATACEPT	ORENCIA, ORENCIA CLICKJECT	37825		GPI-14 (6640001000D520, 6640001000E520, 6640001000E510, 6640001000E515)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

NOTE: For requests for the IV dosage form of Orencia, please see the ABATACEPT - IV PA guideline.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist
- The patient had a trial of or contraindication to 3 months of treatment with ONE conventional synthetic DMARD (disease-modifying antirheumatic drug) (e.g., methotrexate dose of at least 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, sulfasalazine)
- Orencia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

If yes, **approve for 6 months by HICL or GPI-14 for all strengths.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #2.

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ABATACEPT - SQ (PART D)

INITIAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (pJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
The patient is 2 years of age or older
Therapy is prescribed by or in consultation with a rheumatologist
Orencia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of pJIA

If yes, **approve for 6 months by HICL or GPI-14 for all strengths.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #3.

Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
The patient is 2 years of age or older
Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
Orencia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

If yes, **approve for 6 months by HICL or GPI-14 for all strengths.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ABATACEPT - SQ (Orencia SQ [subcutaneous])** requires the following rule(s) be met for approval:
You have ONE of the following:
Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
Moderate to severe polyarticular juvenile idiopathic arthritis (pJIA: a type ofjoint condition in children)
Psoriatic arthritis (PsA: a type of skin and joint condition)
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ABATACEPT - SQ (PART D)

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe rheumatoid arthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You have tried at least 3 months of or have a contraindication to (harmful for you to use) ONE conventional synthetic DMARD (disease-modifying antirheumatic drug, such as methotrexate at a dose of at least 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, sulfasalazine)
- You will NOT use Orencia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis

If you have moderate to severe polyarticular juvenile idiopathic arthritis, approval also requires:
- You are 2 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Orencia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis

If you have psoriatic arthritis, approval also requires:
- You are 2 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (skin doctor)
- You will NOT use Orencia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ABATACEPT - SQ (PART D)

RENEWAL CRITERIA

Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
- The patient continues to benefit from the medication
- Orencia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

If yes, **approve for 12 months by HICL or GPI-14 for all strengths.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #2.

Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (pJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
- The patient continues to benefit from the medication
- Orencia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of pJIA

If yes, **approve for 12 months by HICL or GPI-14 for all strengths.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #3.

Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
- The patient continues to benefit from the medication
- Orencia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

If yes, **approve for 12 months by HICL or GPI-14 for all strengths.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the renewal denial text at the end of the guideline.

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ABATACEPT - SQ (PART D)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ABATACEPT - SQ (Orencia SQ [subcutaneous])** requires the following rule(s) be met for renewal:
You have ONE of the following:
- Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
- Moderate to severe polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition in children)
- Psoriatic arthritis (PsA: a type of skin and joint condition)

If you have moderate to severe rheumatoid arthritis, renewal also requires:
- You continue to benefit from the medication
- You will NOT use Orencia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis

If you have moderate to severe polyarticular juvenile idiopathic arthritis, renewal also requires:
- You continue to benefit from the medication
- You will NOT use Orencia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis

If you have psoriatic arthritis, renewal also requires:
- You continue to benefit from the medication
- You will NOT use Orencia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Orencia.

REFERENCES
Orencia [Prescribing Information]. Princeton, NJ: Bristol-Myers Squibb Company; May 2024.

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ABATACEPT - SQ (PART D)

For Part D use only:

ABATACEPT - SQ (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: RHEUMATOID ARTHRITIS (RA), POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: RA: TRIAL OF OR CONTRAINDICATION TO 3 MONTHS OF TREATMENT WITH ONE CONVENTIONAL SYNTHETIC DMARD (DISEASE-MODIFYING ANTIRHEUMATIC DRUG) - IF A PATIENT TRIED METHOTREXATE, THEN TRIAL AT A DOSE OF AT LEAST 20 MG PER WEEK OR MAXIMALLY TOLERATED DOSE IS REQUIRED. INITIAL/RENEWAL: ALL INDICATIONS: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION. RENEWAL: RA, PJIA, PSA: CONTINUES TO BENEFIT FROM THE MEDICATION.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ABEMACICLIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ABEMACICLIB	VERZENIO	44537		GPI-10 (2153101000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

Does the patient have a diagnosis of breast cancer (ICD-10 Group C50)?

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

Is the patient's cancer in early stage and the patient meets **ALL** of the following criteria?
- The patient is 18 years of age or older
- The patient's cancer is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive
- Verzenio will be used in combination with endocrine therapy (tamoxifen or an aromatase inhibitor [e.g., anastrozole, letrozole, exemestane]) for adjuvant treatment
- The patient is at high risk of recurrence

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #3.

Is the patient's cancer advanced or metastatic and the patient meets **ALL** of the following criteria?
- The patient is 18 years of age or older
- The patient's cancer is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative

If yes, continue to #4.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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ABEMACICLIB (PART D)

GUIDELINES FOR USE (CONTINUED)

Does the patient meet **ONE** of the following criteria?

- Verzenio will be used in combination with an aromatase inhibitor (e.g., anastrozole, letrozole, exemestane) as initial endocrine-based therapy
- Verzenio will be used in combination with fulvestrant (Faslodex) AND the patient has experienced disease progression following endocrine therapy (e.g., anastrozole, letrozole, tamoxifen)
- Verzenio will be used as monotherapy AND the patient has experienced disease progression following endocrine therapy (e.g., anastrozole, letrozole, tamoxifen) and prior chemotherapy in the metastatic setting

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ABEMACICLIB (Verzenio)** requires the following rules be met for approval:
You have breast cancer
If you have early breast cancer, approval also requires:

- You are 18 years of age or older
- Your cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative, node-positive (cancer that has spread to the lymph nodes)
- Verzenio will be used in combination with endocrine therapy (tamoxifen or an aromatase inhibitor [such as letrozole, anastrozole, exemestane]) for adjuvant (add-on) treatment
- You are at high risk of recurrence (disease returning)

(Denial text continued on next page)

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ABEMACICLIB (PART D)

GUIDELINES FOR USE (CONTINUED)

If you have advanced or metastatic breast cancer, approval also requires:

- You are 18 years of age or older
- Your cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative
- You meet ONE of the following:
  - Verzenio will be used in combination with an aromatase inhibitor (such as letrozole, anastrozole, exemestane) as initial endocrine (hormone)-based therapy
  - Verzenio will be used in combination with fulvestrant (Faslodex), AND you have experienced disease progression following endocrine therapy (a type of hormone-based treatment such as letrozole, anastrozole, tamoxifen)
  - Verzenio will be used as monotherapy (one drug), AND you have experienced disease progression following endocrine therapy (such as letrozole, anastrozole, tamoxifen) and prior chemotherapy (drugs used to treat cancer) in the metastatic setting (cancer that has spread to other parts of the body)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Verzenio.

REFERENCES

Verzenio [Prescribing Information]. Indianapolis, IN. Eli Lilly and Company; February 2025.

For Part D use only:

ABEMACICLIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ABIRATERONE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ABIRATERONE ACETATE	ZYTIGA, ABIRTEGA, ABIRATERONE ACETATE	37571		GPI-10 (2140601020)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

Does the patient have **ONE** of the following diagnoses?
- Metastatic castration-resistant prostate cancer (mCRPC) (ICD-10 Z19.2, C61)
- Metastatic high-risk castration-sensitive prostate cancer (mCSPC) (ICD-10 Z19.1, C61)

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

Will the requested medication be used in combination with prednisone?

If yes, continue to #3.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

Does the patient meet **ONE** of the following criteria?
- The patient had a bilateral orchiectomy
- The patient has a castrate level of testosterone (i.e., less than 50 ng/dL)
- The requested medication will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog (e.g., Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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ABIRATERONE (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ABIRATERONE (Zytiga, Abirtega)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Metastatic castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and no longer responds to testosterone lowering treatment)
- Metastatic high-risk castration-sensitive prostate cancer (mCSPC: prostate cancer that has spread to other parts of the body and may respond to testosterone lowering treatment)

The requested medication will be used in combination with prednisone
You meet ONE of the following:
- You had a bilateral orchiectomy (both testicles have been surgically removed)
- You have a castrate level of testosterone (blood testosterone levels are less than 50 ng/dL)
- The requested medication will be concurrently (at the same time) with a gonadotropin-releasing hormone (GnRH) analog (such as Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Zytiga.

REFERENCES
Zytiga [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; November 2024.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ABIRATERONE (PART D)

For Part D use only:

ABIRATERONE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	METASTATIC HIGH-RISK CASTRATION-SENSITIVE PROSTATE CANCER (MCSPC), METASTATIC CASTRATION-RESISTANT PROSTATE CANCER (MCRPC): 1) RECEIVED A BILATERAL ORCHIECTOMY, 2) CASTRATE LEVEL OF TESTOSTERONE (I.E., LESS THAN 50 NG/DL), OR 3) CONCURRENT USE WITH A GONADOTROPIN RELEASING HORMONE (GNRH) ANALOG

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Effective: 04/07/25 Client Approval: 03/25 P&T Approval: 07/20

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ABIRATERONE SUBMICRONIZED (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ABIRATERONE ACET, SUBMICRONIZED	YONSA	44946		GPI-10 (2140601025)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

Does the patient have a diagnosis of metastatic castration-resistant prostate cancer (mCRPC) (ICD-10 Z19.2, C61) **AND** meet the following criterion?
Yonsa will be used in combination with methylprednisolone

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

Does the patient meet **ONE** of the following criteria?
The patient had a bilateral orchiectomy
The patient has a castrate level of testosterone (i.e., less than 50 ng/dL)
Yonsa will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog (e.g., Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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ABIRATERONE SUBMICRONIZED (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ABIRATERONE SUBMICRONIZED (Yonsa)** requires the following rules be met for approval:

You have metastatic castration-resistant prostate cancer (mCRPC: prostate cancer has spread to other parts of the body and no longer responds to testosterone lowering treatment)

Yonsa will be used in combination with methylprednisolone

You meet ONE of the following:

- You had a bilateral orchiectomy (both testicles have been surgically removed)
- You have a castrate level of testosterone (blood testosterone levels are less than 50 ng/dL)
- Yonsa will be used concurrently (at the same time) with a gonadotropin-releasing hormone (GnRH) analog (such as Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the prescribing information and/or drug monograph for Yonsa.

REFERENCES

Yonsa [Prescribing Information]. Cranbury, NJ: Sun Pharmaceuticals Industries, Inc.; March 2022.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ABIRATERONE SUBMICRONIZED (PART D)

For Part D use only:

ABIRATERONE SUBMICRONIZED (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	METASTATIC CASTRATION-RESISTANT PROSTATE CANCER (MCRPC): 1) RECEIVED A BILATERAL ORCHIECTOMY, 2) CASTRATE LEVEL OF TESTOSTERONE (I.E., LESS THAN 50 NG/DL), OR 3) CONCURRENT USE WITH A GONADOTROPIN RELEASING HORMONE (GNRH) ANALOG.

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 06/18
Client Approval: 06/24
P&T Approval: 01/21

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ABOBOTULINUM TOXIN A BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ABOBOTULINUMTOXINA	DYSPORT	36477		GPI-10 (7440002003)	

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

Is this a pharmacy call?

If yes, continue to #3.
If no, continue to #2.

Is the requested medication going to be filled at a pharmacy?

If yes, continue to #3.
If no, **Refer to plan. (This should be processed under the member's medical benefit)**

Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

If no, continue to #4.

Is the pharmacy dispensing the drug directly to the member or member's representative?

If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

If no, continue to #5.

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ABOBOTULINUM TOXIN A BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

Is the internal HQ code ML500, SFC01, or SUM03?

If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override)
For PAC's: Send an email to plan (reference UNSAD section of PACIP).

If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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ABOBOTULINUM TOXIN A BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

Is the request for the treatment of a cosmetic indication (e.g., wrinkles - glabellar lines, lateral canthal lines, forehead lines) (ICD-10 L98.8, Group L81)?

If yes, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

If no, continue to #2.

Does the patient have a diagnosis of cervical dystonia (spasmodic torticollis or involuntary contracting of the neck muscles) (ICD-10 G24.3) **AND** meet the following criterion?
The patient is 18 years of age or older

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #3.

Does the patient have a diagnosis of spasticity (ICD-10 Group G81.1; G04.1, G11.4, G80.0, G80.1, G80.2) **AND** meet the following criterion?
The patient is 2 years of age or older

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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ABOBOTULINUM TOXIN A BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ABOBOTULINUM TOXIN A (Dysport)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Cervical dystonia (a type of muscle condition)
- Spasticity (stiffness or tightness of the muscles)

If you have cervical dystonia, approval also requires:
- You are 18 years of age or older

If you have spasticity, approval also requires:
- You are 2 years of age or older

NOTE: This medication will not be approved for the treatment of a cosmetic indication (such as wrinkles - glabellar lines, lateral canthal lines, forehead lines).

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Dysport. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Dysport [Prescribing Information]. Cambridge, MA: Ispen Biopharmaceuticals, Inc.;September 2023.

Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed February 26, 2024].

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ABOBOTULINUM TOXIN A BvD (PART D)

For Part D use only:

ABOBOTULINUM TOXIN A (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	COSMETIC DIAGNOSIS.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

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Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 04/21

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ABROCITINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ABROCITINIB	CIBINQO	47767		GPI-10 (9027200500)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of moderate to severe atopic dermatitis (AD) (ICD-10 Group L20) and meet **ALL** of the following criteria?
- The patient is 12 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist, allergist, or immunologist
- Cibinqo will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Eucrisa (crisaborole)]) for the treatment of atopic dermatitis
- The patient had a trial of or contraindication to ONE of the following preferred agents: Dupixent (dupilumab), Rinvoq (upadacitinib)

If yes, continue to #2.

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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ABROCITINIB (PART D)

INITIAL CRITERIA (CONTINUED)

Does the patient have a trial of or contraindication to **ONE** of the following?
- High potency topical corticosteroid (e.g., halobetasol propionate 0.01% lotion, triamcinolone acetonide 0.5% cream or ointment) or a super-high potency topical corticosteroid (e.g., fluocinonide 0.1% cream, clobetasol propionate 0.05% cream or ointment)
- Topical calcineurin inhibitor (e.g., tacrolimus, pimecrolimus)
- Topical PDE-4 inhibitor (e.g., crisaborole [Eucrisa], Adquey [difamilast], Zoryve [roflumilast])
- Topical AhR agonist (e.g., Vtama [tapinarof])
- Topical JAK inhibitor (e.g., ruxolitinib [Opzelura])

If yes, **approve for 6 months by HICL or GPI-10.**
If no, do not approve.

INITIAL DENIAL TEXT: Our guideline named **ABROCITINIB (Cibinqo)** requires the following rule(s) be met for approval:
- You have moderate to severe atopic dermatitis (AD: a type of skin condition)
- You are 12 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
- You will NOT use Cibinqo concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Eucrisa (crisaborole)]) for the treatment of atopic dermatitis
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Dupixent (dupilumab), Rinvoq (upadacitinib)
- You have tried or have a contraindication to (harmful for you to use) ONE of the following:
  - High potency topical corticosteroid (such as halobetasol propionate 0.01% lotion, triamcinolone acetonide 0.5% cream or ointment) or a super-high potency topical corticosteroid (such as fluocinonide 0.1% cream, clobetasol propionate 0.05% cream or ointment)
  - Topical calcineurin inhibitor (such as tacrolimus, pimecrolimus)
  - Topical PDE-4 inhibitor (such as crisaborole [Eucrisa], Adquey [difamilast], Zoryve [roflumilast])
  - Topical aryl hydrocarbon receptor (AhR) agonist (such as Vtama [tapinarof])
  - Topical JAK inhibitor (such as ruxolitinib [Opzelura])

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ABROCITINIB (PART D)

RENEWAL CRITERIA

Does the patient have a diagnosis of moderate to severe atopic dermatitis (AD) (ICD-10 Group L20) and meet **ALL** of the following criteria?
The patient has shown improvement while on Cibinqo
Cibinqo will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Eucrisa (crisaborole)]) for the treatment of atopic dermatitis

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.

RENEWAL DENIAL TEXT: Our guideline named **ABROCITINIB (Cibinqo)** requires the following rule(s) be met for renewal:
You have moderate to severe atopic dermatitis (AD: a type of skin condition)
You have shown improvement while on Cibinqo
You will NOT use Cibinqo concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Eucrisa (crisaborole)]) for the treatment of atopic dermatitis

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RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cibinqo.

REFERENCES

Cibinqo [Prescribing Information]. New York, NY: Pfizer Labs; December 2023.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ABROCITINIB (PART D)

For Part D use only:

ABROCITINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	AD: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST, ALLERGIST, OR IMMUNOLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	AD: INITIAL: 1) TRIAL OF OR CONTRAINDICATION TO ONE OF THE FOLLOWING: (A) HIGH OR SUPER-HIGH POTENCY TOPICAL CORTICOSTEROID, (B) TOPICAL CALCINEURIN INHIBITOR, (C) TOPICAL PDE4 INHIBITOR, (D) TOPICAL AHR AGONIST OR (E) TOPICAL JAK INHIBITOR, AND 2) TRIAL OF OR CONTRAINDICATION TO ONE OF THE FOLLOWING PREFERRED AGENTS: DUPIXENT, RINVOQ. INITIAL/RENEWAL: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION. RENEWAL: IMPROVEMENT WHILE ON THERAPY.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ACALABRUTINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ACALABRUTINIB	CALQUENCE	44607		GPI-10 (2153210300)	
ACALABRUTINIB MALEATE	CALQUENCE	48182		GPI-10 (2153210350)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

Does the patient have a diagnosis of mantle cell lymphoma (MCL) (ICD-10 Group C83.1) **AND** meet the following criterion?
The patient is 18 years of age or older

If yes, continue to #2.
If no, continue to #4.

Is the patient previously untreated and meets **ALL** of the following criteria?
Calquence will be used in combination with bendamustine and rituximab
The patient is ineligible for autologous hematopoietic stem cell transplantation (HSCT)

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #3.

Has the patient received at least one prior therapy (e.g., CHOP [cyclophosphamide, doxorubicin, vincristine, prednisone]-based regimen)?

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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ACALABRUTINIB (PART D)

GUIDELINES FOR USE (CONTINUED)

Does the patient have a diagnosis of chronic lymphocytic leukemia (CLL) (ICD-10 Group C91.1) OR small lymphocytic lymphoma (SLL) (ICD-10 Group C83.0) **AND** meet the following criterion?
The patient is 18 years of age or older

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ACALABRUTINIB (Calquence)** requires the following rules be met for approval:
You have ONE of the following:
- Mantle cell lymphoma (MCL: a type of blood cancer)
- Chronic lymphocytic leukemia (CLL: a type of blood cancer)
- Small lymphocytic lymphoma (SLL: a type of blood cancer)

If you have untreated mantle cell lymphoma, approval also requires:
- You are 18 years of age or older
- Calquence will be used in combination with bendamustine and rituximab
- You are NOT eligible for autologous hematopoietic stem cell transplantation (HSCT: a type of procedure to replace damaged bone marrow with your own healthy blood-forming cells)

If you have treated mantle cell lymphoma, approval also requires:
- You are 18 years of age or older
- You have received at least one prior therapy (such as a CHOP [cyclophosphamide, doxorubicin, vincristine, prednisone]-based regimen)

If you have chronic lymphocytic leukemia or small lymphocytic lymphoma, approval also requires:
- You are 18 years of age or older

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ACALABRUTINIB (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Calquence.

REFERENCES
Calquence [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals; January 2025.

For Part D use only:

ACALABRUTINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

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ACETAMINOPHEN DAILY LIMIT (PART D)

Generic	Brand	HICL	GCN	Exception/other
N/A	N/A	N/A	N/A	N/A

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request then a verbal MRF must be completed. Please check the applicable CS note for processing.

GUIDELINES FOR USE

Is the claim rejecting with any of the following error codes?
NCPDP Reject Code: TQ (Dosage Exceeds Product Labeling Limit)
REJ-38: INGREDIENT CUMULATIVE DAILY DOSAGE EXCEEDS LIMIT

If yes, continue to #2.
If no, guideline does not apply.

Is the patient taking a dose of the requested drug in an amount exceeding 4000mg of acetaminophen per day?

If yes, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.
If no, continue to #3.

Is the requested medication being taken together with other acetaminophen containing product(s) and the combination will exceed 4000mg of acetaminophen per day?

If yes, continue to #4.
If no, **approve for one month, for one fill count, by GPID, for the requested medication. Set override type MAXINGREDIENTDOSE to a value of "Y". NOTE: Include the quantity limit based on any applicable restriction(s):**
The requested drug has a plan limit of **[XX tablets/capsules/mL]** per **[XX]** days.

Will the patient discontinue the concurrent acetaminophen containing drug(s) that place the patient over 4000mg of acetaminophen per day?

If yes, **approve for one month, for one fill count, by GPID, for the requested medication. Set override type MAXINGREDIENTDOSE to a value of "Y". NOTE: Include the quantity limit based on any applicable restriction(s):**
The requested drug has a plan limit of **[XX tablets/capsules/mL]** per **[XX]** days.

If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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ACETAMINOPHEN DAILY LIMIT (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: Our safety program for acetaminophen will cause a claim to deny when the dose of 4000mg of acetaminophen per day is exceeded. The claim will also deny if the requested drug is being used at the same time (concurrently) with other acetaminophen containing product(s) that exceed 4000mg of acetaminophen per day limit. Our safety program named **ACETAMINOPHEN DAILY LIMIT** will allow an approval for the requested drug if the patient will discontinue the concurrent acetaminophen containing drug(s) that cause the daily acetaminophen dose to exceed 4000mg. Please consult your physician if you have any questions about this prescription and work with them to obtain a safe and effective acetaminophen dose.

According to our records, you are taking [INSERT APAP-CONTAINING DRUGS] which totals [TOTAL DAILY APAP DOSE]. We do not have information showing you are reducing or discontinuing the total daily amount of acetaminophen. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

To ensure appropriate use of acetaminophen products and address overuse from a medication safety perspective while preserving patient access to medically necessary drug regimens. The maximum daily dose for an adult is 4000 mg. However, in some people, taking the maximum daily dose or more for an extended period of time can lead to serious liver damage.
A claim may reject at POS due to exceeding the acetaminophen daily limit as a result of concurrent use with other acetaminophen products. An approval is granted if the the concurrent acetaminophen containing product will be discointinued. In some cases, the member's history claim may have an incorrect day supply due to a pharmacy error. This will cause the new claim to reject at POS for exceeding the acetaminophen daily limit. This is addressed in question #3.

REFERENCES

"FDA Drug Safety Communication: Prescription Acetaminophen Products to be Limited to 325mg Per Dosage Unit; Boxed Warning Will Highlight Potential for Severe Liver Failure". January 13, 2011. Available at https://www.fda.gov/Drugs/DrugSafety/ucm239821.htm [Accessed 12/3/18].
"Medicare Part D Overutilization Monitoring System – Updates". October 25, 2013. Available at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoMedicare-Part-D-OMS-Updates-10-25-13.pdf [Accessed 12/3/18].

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/22 Created: 08/19
Commercial Effective: N/A Client Approval: 12/21 P&T Approval: 10/19

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ACOLTREMON (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ACOLTREMON	TRYPTYR	50621		GPI-10 (8680531000)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of dry eye disease (DED) (ICD-10 Group H04.12) and meet **ALL** of the following criteria?
Therapy is prescribed by or in consultation with an ophthalmologist or optometrist
The patient has at least ONE positive diagnostic test (e.g., tear breakup time, tearfilm osmolarity, ocular surface staining, Schirmer test)
The patient had a trial of or contraindication to ONE of the following preferred agents: Xiidra (lifitegrast), Miebo (perfluorohexyloctane)

If yes, **approve for 3 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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ACOLTREMON (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ACOLTREMON (Tryptyr)** requires the following rule(s) be met for approval:
You have dry eye disease (DED: a type of eye condition)
Therapy is prescribed by or in consultation with an ophthalmologist or optometrist (types of eye doctors)
You have at least ONE positive diagnostic test (such as tear breakup time, tear film osmolarity, ocular surface staining, Schirmer test)
You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Xiidra (lifitegrast), Miebo (perfluorohexyloctane)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ACOLTREMON (PART D)

RENEWAL CRITERIA

Does the patient have a diagnosis of dry eye disease (DED) (ICD-10 Group H04.12) **AND** meet the following criterion?
The patient has demonstrated improvement of dry eye disease

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ACOLTREMON (Tryptyr)** requires the following rule(s) be met for renewal:
You have dry eye disease (DED: a type of eye condition)
You have demonstrated improvement of your dry eye disease (the treatment is working)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Tryptyr.

REFERENCES
Tryptyr [Prescribing Information]. Fort Worth, TX: Alcon Laboratories, Inc.; May 2025.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ACOLTREMON (PART D)

For Part D use only:

ACOLTREMON (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	DRY EYE DISEASE: INITIAL: AT LEAST ONE POSITIVE DIAGNOSTIC TEST (E.G., TEAR BREAKUP TIME, TEAR FILM OSMOLARITY, OCULAR SURFACE STAINING, SCHIRMER TEST).
Age Restrictions	N/A
Prescriber Restrictions	DRY EYE DISEASE: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH AN OPHTHALMOLOGIST OR OPTOMETRIST.
Coverage Duration	INITIAL: 3 MO. RENEWAL: 12 MO.
Other Criteria	DRY EYE DISEASE: INITIAL: TRIAL OF OR CONTRAINDICATION TO ONE OF THE FOLLOWING PREFERRED AGENTS: XIIDRA, MIEBO. RENEWAL: IMPROVEMENT OF DRY EYE DISEASE.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ACORAMIDIS (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ACORAMIDIS HCL	ATTRUBY	50022		GPI-10 (4055001030)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of cardiomyopathy of wild-type transthyretin-mediated amyloidosis (ICD-10 E85.82) or variant transthyretin-mediated amyloidosis (ATTR-CM) (ICD-10 E85.4) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a cardiologist, transthyretin amyloidosis (ATTR) specialist, or medical geneticist
- The patient has New York Heart Association (NYHA) Class I, II, or III heart failure
- Attruby will NOT be used concurrently with other ATTR-CM TTR (transthyretin) stabilizers (e.g., tafamidis [Vyndaqel, Vyndamax])

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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ACORAMIDIS (PART D)

INITIAL CRITERIA (CONTINUED)

Is the patient's diagnosis confirmed by **ONE** of the following?
- A bone scan (scintigraphy) strongly positive for myocardial uptake of TC-99m-PYP
  *(**Note:** Strongly positive defined as heart to contralateral lung [H/CL] ratio of at least 1.5 or Grade 2 or greater localization to the heart using the Perugini Grade 1-3 scoring system)*
- A biopsy of tissue of affected organ(s) (cardiac and possibly non-cardiac sites) to confirm amyloid presence AND chemical typing to confirm presence of transthyretin (TTR) protein

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ACORAMIDIS (Attruby)** requires the following rule(s) be met for approval:
- You have cardiomyopathy of wild-type or variant transthyretin-mediated amyloidosis (ATTR-CM: heart disease caused by a build-up of a type of protein)
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor), transthyretin amyloidosis (ATTR) specialist, or medical geneticist (doctor who treats gene disorders)
- You have New York Heart Association (NYHA) Class I, II, or III heart failure (classification of heart failure symptoms)
- You will NOT use Attruby concurrently (at the same time) with other ATTR-CM TTR (transthyretin) stabilizers (such as tafamidis [Vyndaqel, Vyndamax])
- Your diagnosis is confirmed by ONE of the following:
  - A bone scan (scintigraphy) strongly positive for myocardial uptake of TC-99m-PYP (a type of imaging test) (Note: Strongly positive defined as heart to contralateral lung [H/CL] ratio of at least 1.5 or Grade 2 or greater localization to the heart using the Perugini Grade 1-3 scoring system)
  - A biopsy of tissue of the affected organ(s) (removal of cells or tissue from the body for examination) (can be heart or non-heart related organs) to confirm amyloid (type of protein) presence AND chemical typing to confirm presence of transthyretin (TTR) protein

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ACORAMIDIS (PART D)

RENEWAL CRITERIA

Does the patient have a diagnosis of cardiomyopathy of wild-type transthyretin-mediated amyloidosis (ICD-10 E85.82) or variant transthyretin-mediated amyloidosis (ATTR-CM) (ICD-10 E85.4) **AND** meet the following criterion?
Attruby will NOT be used concurrently with other ATTR-CM TTR (transthyretin) stabilizers (e.g., tafamidis [Vyndaqel, Vyndamax])

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ACORAMIDIS (Attruby)** requires the following rule(s) be met for renewal:
You have cardiomyopathy of wild-type or variant transthyretin-mediated amyloidosis (ATTR-CM: heart disease caused by a build-up of a type of protein)
You will NOT use Attruby concurrently (at the same time) with other ATTR-CM TTR (transthyretin) stabilizers (such as tafamidis [Vyndaqel, Vyndamax])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Attruby.

REFERENCES

Attruby [Prescribing Information]. Palo Alto, CA: BridgeBio Pharma Inc.; November 2024.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ACORAMIDIS (PART D)

For Part D use only:

ACORAMIDIS (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	CARDIOMYOPATHY OF WILD TYPE OR VARIANT TRANSTHYRETIN-MEDIATED AMYLOIDOSIS (ATTR-CM): INITIAL: 1) NEW YORK HEART ASSOCIATION (NYHA) CLASS I, II, OR III HEART FAILURE, AND 2) DIAGNOSIS CONFIRMED BY (A) BONE SCAN (SCINTIGRAPHY) STRONGLY POSITIVE FOR MYOCARDIAL UPTAKE OF TC-99M-PYP, OR (B) BIOPSY OF TISSUE OF AFFECTED ORGAN(S) (CARDIAC AND POSSIBLY NON-CARDIAC SITES) TO CONFIRM AMYLOID PRESENCE AND CHEMICAL TYPING TO CONFIRM PRESENCE OF TRANSTHYRETIN (TTR) PROTEIN.
Age Restrictions	N/A
Prescriber Restrictions	ATTR-CM: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST, ATTR SPECIALIST, OR MEDICAL GENETICIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	ATTR-CM: INITIAL/RENEWAL: NO CONCURRENT USE WITH OTHER ATTR-CM TTR STABILIZERS (E.G., TAFAMIDIS).

Created: 12/24
Effective: 04/01/25 Client Approval: 02/25 P&T Approval: 01/25

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ADAGRASIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ADAGRASIB	KRAZATI	48522		GPI-10 (2153241000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

Does the patient have a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
The patient's cancer has a KRAS G12C mutation as determined by an FDA-approved test
The patient has received at least one prior systemic therapy

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #2.

Does the patient have a diagnosis of locally advanced or metastatic colorectal cancer (CRC) (ICD- 10 C19) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
The patient's cancer has a KRAS G12C mutation as determined by an FDA-approved test
Krazati will be used in combination with Erbitux (cetuximab)
The patient has received prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy

If yes, **approve for 12 months by HICL** or GPI-10**.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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ADAGRASIB (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ADAGRASIB (Krazati)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Locally advanced or metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to nearby tissue or lymph nodes or to other parts of the body)
- Locally advanced or metastatic colorectal cancer (CRC; a type of digestive tract cancer that has spread to nearby tissue or lymph nodes or to other parts of the body)

If you have locally advanced or metastatic non-small cell lung cancer, approval also requires:
- You are 18 years of age or older
- Your cancer has a KRAS G12C mutation (a type of abnormal gene) as determined by a Food and Drug Association (FDA)-approved test
- You have received at least one prior systemic therapy

If you have locally advanced or metastatic colorectal cancer, approval also requires:
- You are 18 years of age or older
- Your cancer has a KRAS G12C mutation (a type of abnormal gene) as determined by a Food and Drug Administration (FDA)-approved test
- Krazati will be used in combination with Erbitux (cetuximab)
- You have received prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy (drugs used to treat cancer)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ADAGRASIB (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Krazati.

REFERENCES
Krazati [Prescribing Information]. San Diego, CA: Mirati Therapeutics, Inc., June 2024.

For Part D use only:

ADAGRASIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25 Created: 12/22
Commercial Effective: N/A Client Approval: 08/24 P&T Approval: 07/24

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ADALIMUMAB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ADALIMUMAB	HUMIRA	24800		GPI-10 (6627001500)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

************Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist
- The patient had a trial of or contraindication to 3 months of treatment with ONE conventional synthetic DMARD (disease-modifying antirheumatic drug) (e.g., methotrexate at a dose of at least 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, sulfasalazine)
- Humira will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)],PDE-4 inhibitor) for the treatment of RA

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #2.

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ADALIMUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (pJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
The patient is 2 years of age or older
Therapy is prescribed by or in consultation with a rheumatologist
Humira will NOT be used concurrently with another systemic biologic (e.g., Enbrel [etanercept]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of pJIA

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #3.

Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
Humira will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)],PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #4.

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ADALIMUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist
- Humira will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS
- The patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam)

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #5.

Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
- The patient is 6 years of age or older
- Therapy is prescribed by or in consultation with a gastroenterologist
- Humira will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #6.

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ADALIMUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
- The patient is 5 years of age or older
- Therapy is prescribed by or in consultation with a gastroenterologist
- Humira will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #7.

Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist
- The patient has psoriasis covering 3% or more of body surface area (BSA) OR psoriatic lesions affecting the hands, feet, face, scalp, or genital area
- Humira will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

If yes, continue to #8.
If no, continue to #9.

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ADALIMUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

Does the patient meet **ONE** of the following criteria?
- The patient has had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy)
- The patient has a contraindication or intolerance to both immunosuppressant and PUVA (phototherapy)
- The patient is switching from a different biologic (e.g., Remicade [infliximab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

Does the patient have a diagnosis of moderate to severe hidradenitis suppurativa (HS) (ICD-10 L73.2) and meet **ALL** of the following criteria?
- The patient is 12 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist
- Humira will NOT be used concurrently with another systemic biologic (e.g., Cosentyx [secukinumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of HS

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #10.

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ADALIMUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of non-infectious intermediate, posterior, or panuveitis (ICD-10 Group H44.11) and meet **ALL** of the following criteria?
- The patient is 2 years of age or older
- Therapy is prescribed by or in consultation with an ophthalmologist
- The patient does NOT have isolated anterior uveitis
- Humira will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of uveitis

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ADALIMUMAB (Humira)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
- Moderate to severe polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition in children)
- Psoriatic arthritis (PsA: a type of skin and joint condition)
- Ankylosing spondylitis (AS: a type of joint condition)
- Moderate to severe Crohn's disease (CD: a type of bowel disorder)
- Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
- Moderate to severe plaque psoriasis (PsO: a type of skin condition)
- Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)
- Non-infectious intermediate, posterior, or panuveitis (a type of eye condition)

(Initial denial text continued on next page)

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ADALIMUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe rheumatoid arthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You have tried or have a contraindication to (harmful for you to use) 3 months of treatment with ONE conventional synthetic DMARD (disease-modifying antirheumatic drug, such as methotrexate at a dose of at least 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, sulfasalazine)
- You will NOT use Humira concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis

If you have moderate to severe polyarticular juvenile idiopathic arthritis, approval also requires:
- You are 2 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Humira concurrently (at the same time) with another systemic biologic (such as Enbrel [etanercept]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis

If you have psoriatic arthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
- You will NOT use Humira concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

If you have ankylosing spondylitis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Humira concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis
- You have tried or have a contraindication to (harmful for you to use) an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)

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ADALIMUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe Crohn's disease, approval also requires:
- You are 6 years of age or older
- Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who specializes in digestive conditions)
- You will NOT use Humira concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease

If you have moderate to severe ulcerative colitis, approval also requires:
- You are 5 years of age or older
- Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who specializes in digestive conditions)
- You will NOT use Humira concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

If you have moderate to severe plaque psoriasis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
- You have psoriasis covering 3% or more of body surface area (BSA) or psoriatic lesions (rashes) affecting your hands, feet, face, scalp, or genital area
- You will NOT use Humira concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis
- You meet ONE of the following:
  - You have had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy)
  - You have a contraindication (harmful for you to use) or intolerance (side effect) to both immunosuppressant (a type of drug that decreases the body's immune response) and PUVA (phototherapy)
  - You are switching from a different biologic (such as Remicade [infliximab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication

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ADALIMUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe hidradenitis suppurativa, approval also requires:
- You are 12 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
- You will NOT use Humira concurrently (at the same time) with another systemic biologic (such as Cosentyx [secukinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of hidradenitis suppurativa

If you have non-infectious intermediate, posterior, or panuveitis, approval also requires:
- You are 2 years of age or older
- Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor)
- You do NOT have isolated anterior uveitis (a different type of eye inflammation)
- You will NOT use Humira concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of uveitis

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ADALIMUMAB (PART D)

RENEWAL CRITERIA

Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
The patient continues to benefit from the medication
Humira will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #2.

Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (pJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
The patient continues to benefit from the medication
Humira will NOT be used concurrently with another systemic biologic (e.g., Enbrel [etanercept]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of pJIA

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #3.

Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
The patient continues to benefit from the medication
Humira will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #4.

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ADALIMUMAB (PART D)

RENEWAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
The patient continues to benefit from the medication
Humira will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)],PDE-4 inhibitor) for the treatment of AS

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #5.

Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
The patient continues to benefit from the medication
Humira will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #6.

Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) **AND** meet the following criterion?
Humira will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)],PDE-4 inhibitor) for the treatment of CD

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #7.

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ADALIMUMAB (PART D)

RENEWAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51)
AND meet the following criterion?
Humira will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)],PDE-4 inhibitor) for the treatment of UC

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #8.

Does the patient have a diagnosis of moderate to severe hidradenitis suppurativa (HS) (ICD-10 L73.2) and meet **ALL** of the following criteria?
The patient continues to benefit from the medication
Humira will NOT be used concurrently with another systemic biologic (e.g., Cosentyx [secukinumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) forthe treatment of HS

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #9.

Does the patient have a diagnosis of non-infectious intermediate, posterior, or panuveitis (ICD-10 Group H44.11) and meet **ALL** of the following criteria?
The patient continues to benefit from the medication
Humira will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of uveitis

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the renewal denial text at the end of the guideline.

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ADALIMUMAB (PART D)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ADALIMUMAB (Humira)** requires the following rule(s) be met for renewal:
You have ONE of the following:
- Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
- Moderate to severe polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition in children)
- Psoriatic arthritis (PsA: a type of skin and joint condition)
- Ankylosing spondylitis (AS: a type of joint condition)
- Moderate to severe Crohn's disease (CD: a type of bowel disorder)
- Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
- Moderate to severe plaque psoriasis (PsO: a type of skin condition)
- Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)
- Non-infectious intermediate, posterior, or panuveitis (a type of eye condition)

If you have moderate to severe rheumatoid arthritis, renewal also requires:
- You continue to benefit from the medication
- You will NOT use Humira concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis

If you have moderate to severe polyarticular juvenile idiopathic arthritis, renewal also requires:
- You continue to benefit from the medication
- You will NOT use Humira concurrently (at the same time) with another systemic biologic (such as Enbrel [etanercept]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis

If you have psoriatic arthritis, renewal also requires:
- You continue to benefit from the medication
- You will NOT use Humira concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

(Renewal denial text continued on next page)

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ADALIMUMAB (PART D)

RENEWAL CRITERIA (CONTINUED)

If you have ankylosing spondylitis, renewal also requires:
- You continue to benefit from the medication
- You will NOT use Humira concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis

If you have moderate to severe plaque psoriasis, renewal also requires:
- You continue to benefit from the medication
- You will NOT use Humira concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis

If you have moderate to severe Crohn's disease, renewal also requires:
- You will NOT use Humira concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease

If you have moderate to severe ulcerative colitis, renewal also requires:
- You will NOT use Humira concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

If you have moderate to severe hidradenitis suppurativa, renewal also requires:
- You continue to benefit from the medication
- You will NOT use Humira concurrently (at the same time) with another systemic biologic (such as Cosentyx [secukinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of hidradenitis suppurativa

If you have non-infectious intermediate, posterior, or panuveitis, renewal also requires:
- You continue to benefit from the medication
- You will NOT use Humira concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of uveitis

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ADALIMUMAB (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Humira.

REFERENCES

Humira [Prescribing Information]. North Chicago, IL: AbbVie Inc.; February 2024.

For Part D use only:

ADALIMUMAB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	INITIAL: PLAQUE PSORIASIS (PSO): PSORIASIS COVERING 3 PERCENT OR MORE OF BODY SURFACE AREA OR PSORIATIC LESIONS AFFECTING THE HANDS, FEET, FACE, SCALP, OR GENITAL AREA.
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: RA, PJIA, ANKYLOSING SPONDYLITIS (AS): PRESCRIBED BY OR IN CONSULTATION WITH RHEUMATOLOGIST. PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH DERMATOLOGIST OR RHEUMATOLOGIST. PSO, HIDRADENITIS SUPPURATIVA (HS): PRESCRIBED BY OR IN CONSULTATION WITH DERMATOLOGIST. CROHNS DISEASE (CD), ULCERATIVE COLITIS (UC): PRESCRIBED BY OR IN CONSULTATION WITH GASTROENTEROLOGIST. UVEITIS: PRESCRIBED BY OR IN CONSULTATION WITH OPHTHALMOLOGIST.
Coverage Duration	INITIAL: RA, PSO, PJIA, AS, PSA, CD, UC, UVEITIS: 6 MONTHS, HS: 12 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: RHEUMATOID ARTHRITIS (RA): TRIAL OF OR CONTRAINDICATION TO 3 MONTHS OF TREATMENT WITH ONE CONVENTIONAL SYNTHETIC DMARD (DISEASE-MODIFYING ANTIRHEUMATIC DRUG) - IF PATIENT TRIED METHOTREXATE, THEN TRIAL AT A DOSE OF AT LEAST 20 MG PER WEEK OR MAXIMALLY TOLERATED DOSE IS REQUIRED. AS: TRIAL OF OR CONTRAINDICATION TO AN NSAID. PSO: 1) AT LEAST A 3 MONTH TRIAL OF ONE ORAL IMMUNOSUPPRESSANT (CYCLOSPORINE, METHOTREXATE, TACROLIMUS) OR PUVA (PHOTOTHERAPY), 2) CONTRAINDICATION OR INTOLERANCE TO BOTH IMMUNOSUPPRESSANT AND PUVA, OR 3) PATIENT IS SWITCHING FROM A DIFFERENT BIOLOGIC, PDE-4 INHIBITOR, OR JAK INHIBITOR FOR THE SAME INDICATION. UVEITIS: DOES NOT HAVE ISOLATED ANTERIOR UVEITIS.

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	INITIAL/RENEWAL: ALL INDICATIONS: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION. RENEWAL: RA, POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA), PSA, AS, PSO, HS, UVEITIS: CONTINUES TO BENEFIT FROM THE MEDICATION.

Created: 05/03
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 10/24

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ADALIMUMAB-AATY (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ADALIMUMAB-AATY	YUFLYMA, ADALIMUMAB-AATY	48955		GPI-10 (6627001503)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
Yes	Yes	No	Yes	Yes	No	Yes	Yes	No	Yes	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist
- The patient had a trial of or contraindication to 3 months of treatment with ONE conventional synthetic DMARD (disease-modifying antirheumatic drug) (e.g., methotrexate at a dose of at least 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, sulfasalazine)
- The requested medication will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #2.

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ADALIMUMAB-AATY (PART D)

INITIAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (pJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
- The patient is 2 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist
- The requested medication will NOT be used concurrently with another systemic biologic (e.g., Enbrel [etanercept]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of pJIA

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #3.

Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
- The requested medication will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #4.

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ADALIMUMAB-AATY (PART D)

INITIAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist
- The requested medication will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS
- The patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam)

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #5.

Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
- The patient is 6 years of age or older
- Therapy is prescribed by or in consultation with a gastroenterologist
- The requested medication will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #6.

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ADALIMUMAB-AATY (PART D)

INITIAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a gastroenterologist
- The requested medication will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #7.

Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist
- The patient has psoriasis covering 3% or more of body surface area (BSA) OR psoriatic lesions affecting the hands, feet, face, scalp, or genital area
- The requested medication will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

If yes, continue to #8.
If no, continue to #9.

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ADALIMUMAB-AATY (PART D)

INITIAL CRITERIA (CONTINUED)

Does the patient meet **ONE** of the following criteria?
- The patient has had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy)
- The patient has a contraindication or intolerance to both immunosuppressant and PUVA (phototherapy)
- The patient is switching from a different biologic (e.g., Remicade [infliximab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

Does the patient have a diagnosis of moderate to severe hidradenitis suppurativa (HS) (ICD-10 L73.2) and meet **ALL** of the following criteria?
- The patient is 12 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist
- The requested medication will NOT be used concurrently with another systemic biologic (e.g., Cosentyx [secukinumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of HS

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #10.

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ADALIMUMAB-AATY (PART D)

INITIAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of non-infectious intermediate, posterior, or panuveitis (ICD-10 Group H44.11) and meet **ALL** of the following criteria?
- The patient is 2 years of age or older
- Therapy is prescribed by or in consultation with an ophthalmologist
- The patient does NOT have isolated anterior uveitis
- The requested medication will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of uveitis

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ADALIMUMAB-AATY (Yuflyma)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
- Moderate to severe polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition in children)
- Psoriatic arthritis (PsA: a type of skin and joint condition)
- Ankylosing spondylitis (AS: a type of joint condition)
- Moderate to severe Crohn's disease (CD: a type of bowel disorder)
- Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
- Moderate to severe plaque psoriasis (PsO: a type of skin condition)
- Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)
- Non-infectious intermediate, posterior, or panuveitis (a type of eye condition)

(Initial denial text continued on next page)

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ADALIMUMAB-AATY (PART D)

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe rheumatoid arthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You have tried or have a contraindication to (harmful for you to use) 3 months of treatment with ONE conventional synthetic DMARD (disease-modifying antirheumatic drug, such as methotrexate at a dose of at least 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, sulfasalazine)
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis

If you have moderate to severe polyarticular juvenile idiopathic arthritis, approval also requires:
- You are 2 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Enbrel [etanercept]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis

If you have psoriatic arthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

If you have ankylosing spondylitis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis
- You have tried or have a contraindication to (harmful for you to use) an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)

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ADALIMUMAB-AATY (PART D)

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe Crohn's disease, approval also requires:
- You are 6 years of age or older
- Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who specializes in digestive conditions)
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease

If you have moderate to severe ulcerative colitis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who specializes in digestive conditions)
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

If you have moderate to severe plaque psoriasis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
- You have psoriasis covering 3% or more of body surface area (BSA) or psoriatic lesions (rashes) affecting your hands, feet, face, scalp, or genital area
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis
- You meet ONE of the following:
  - You have had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy)
  - You have a contraindication (harmful for you to use) or intolerance (side effect) to both immunosuppressant (a type of drug that decreases the body's immune response) and PUVA (phototherapy)
  - You are switching from a different biologic (such as Remicade [infliximab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication

(Initial denial text continued on next page)

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ADALIMUMAB-AATY (PART D)

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe hidradenitis suppurativa, approval also requires:
- You are 12 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Cosentyx [secukinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of hidradenitis suppurativa

If you have non-infectious intermediate, posterior, or panuveitis, approval also requires:
- You are 2 years of age or older
- Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor)
- You do NOT have isolated anterior uveitis (a different type of eye inflammation)
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of uveitis

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ADALIMUMAB-AATY (PART D)

RENEWAL CRITERIA

Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
The patient continues to benefit from the medication
The requested medication will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #2.

Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (pJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
The patient continues to benefit from the medication
The requested medication will NOT be used concurrently with another systemic biologic (e.g., Enbrel [etanercept]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of pJIA

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #3.

Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
The patient continues to benefit from the medication
The requested medication will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #4.

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ADALIMUMAB-AATY (PART D)

RENEWAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
The patient continues to benefit from the medication
The requested medication will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #5.

Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
The patient continues to benefit from the medication
The requested medication will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #6.

Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) **AND** meet the following criterion?
The requested medication will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #7.

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ADALIMUMAB-AATY (PART D)

RENEWAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) **AND** meet the following criterion?
The requested medication will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.
If no, continue to #8.

Does the patient have a diagnosis of moderate to severe hidradenitis suppurativa (HS) (ICD-10 L73.2) and meet **ALL** of the following criteria?
The patient continues to benefit from the medication
The requested medication will NOT be used concurrently with another systemic biologic (e.g., Cosentyx [secukinumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of HS

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.
If no, continue to #9.

Does the patient have a diagnosis of non-infectious intermediate, posterior, or panuveitis (ICD-10 Group H44.11) and meet **ALL** of the following criteria?
The patient continues to benefit from the medication
The requested medication will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of uveitis

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.
If no, do not approve.
DENIAL TEXT: See the renewal denial text at the end of the guideline.

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ADALIMUMAB-AATY (PART D)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ADALIMUMAB-AATY (Yuflyma)** requires the following rule(s) be met for renewal:

You have ONE of the following:

- Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
- Moderate to severe polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition in children)
- Psoriatic arthritis (PsA: a type of skin and joint condition)
- Ankylosing spondylitis (AS: a type of joint condition)
- Moderate to severe Crohn's disease (CD: a type of bowel disorder)
- Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
- Moderate to severe plaque psoriasis (PsO: a type of skin condition)
- Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)
- Non-infectious intermediate, posterior, or panuveitis (a type of eye condition)

If you have moderate to severe rheumatoid arthritis, renewal also requires:

- You continue to benefit from the medication
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis

If you have moderate to severe polyarticular juvenile idiopathic arthritis, renewal also requires:

- You continue to benefit from the medication
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Enbrel [etanercept]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis

If you have psoriatic arthritis, renewal also requires:

- You continue to benefit from the medication
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

(Renewal denial text continued on next page)

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ADALIMUMAB-AATY (PART D)

RENEWAL CRITERIA (CONTINUED)

If you have ankylosing spondylitis, renewal also requires:
- You continue to benefit from the medication
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis

If you have moderate to severe plaque psoriasis, renewal also requires:
- You continue to benefit from the medication
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis

If you have moderate to severe Crohn's disease, renewal also requires:
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn’s disease

If you have moderate to severe ulcerative colitis, renewal also requires:
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

If you have moderate to severe hidradenitis suppurativa, renewal also requires:
- You continue to benefit from the medication
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Cosentyx [secukinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of hidradenitis suppurativa

If you have non-infectious intermediate, posterior, or panuveitis, renewal also requires:
- You continue to benefit from the medication
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of uveitis

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ADALIMUMAB-AATY (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Yuflyma.

REFERENCES
Yuflyma [Prescribing Information]. Jersey City, NJ: Celltrion USA, Inc.; November 2025.

For Part D use only:

ADALIMUMAB-AATY (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	INITIAL: PLAQUE PSORIASIS (PSO): PSORIASIS COVERING 3 PERCENT OR MORE OF BODY SURFACE AREA OR PSORIATIC LESIONS AFFECTING THE HANDS, FEET, FACE, SCALP, OR GENITAL AREA.
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: RA, PJIA, ANKYLOSING SPONDYLITIS (AS): PRESCRIBED BY OR IN CONSULTATION WITH RHEUMATOLOGIST. PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH DERMATOLOGIST OR RHEUMATOLOGIST. PSO, HIDRADENITIS SUPPURATIVA (HS): PRESCRIBED BY OR IN CONSULTATION WITH DERMATOLOGIST. CROHNS DISEASE (CD), ULCERATIVE COLITIS (UC): PRESCRIBED BY OR IN CONSULTATION WITH GASTROENTEROLOGIST. UVEITIS: PRESCRIBED BY OR IN CONSULTATION WITH OPHTHALMOLOGIST.
Coverage Duration	INITIAL: RA, PSO, PJIA, AS, PSA, CD, UC, UVEITIS: 6 MONTHS, HS: 12 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: RHEUMATOID ARTHRITIS (RA): TRIAL OF OR CONTRAINDICATION TO 3 MONTHS OF TREATMENT WITH ONE CONVENTIONAL SYNTHETIC DMARD (DISEASE-MODIFYING ANTIRHEUMATIC DRUG) - IF PATIENT TRIED METHOTREXATE, THEN TRIAL AT A DOSE OF AT LEAST 20 MG PER WEEK OR MAXIMALLY TOLERATED DOSE IS REQUIRED. AS: TRIAL OF OR CONTRAINDICATION TO AN NSAID. PSO: 1) AT LEAST A 3 MONTH TRIAL OF ONE ORAL IMMUNOSUPPRESSANT (CYCLOSPORINE, METHOTREXATE, TACROLIMUS) OR PUVA (PHOTOTHERAPY), 2) CONTRAINDICATION OR INTOLERANCE TO BOTH IMMUNOSUPPRESSANT AND PUVA, OR 3) PATIENT IS SWITCHING FROM A DIFFERENT BIOLOGIC, PDE-4 INHIBITOR, OR JAK INHIBITOR FOR THE SAME INDICATION. UVEITIS: DOES NOT HAVE ISOLATED ANTERIOR UVEITIS. INITIAL/RENEWAL: ALL INDICATIONS:

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	NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION. RENEWAL: RA, POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA), PSA, AS, PSO, HS, UVEITIS: CONTINUES TO BENEFIT FROM THE MEDICATION.

Created: 03/25
Effective: 03/28/26 Client Approval: 03/26 P&T Approval: 01/26

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ADALIMUMAB-ADBM (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ADALIMUMAB-ADBM	CYLTEZO	44481		GPI-10 (6627001505)	BRAND ONLY

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist
- The patient had a trial of or contraindication to 3 months of treatment with ONE conventional synthetic DMARD (disease-modifying antirheumatic drug) (e.g., methotrexate at a dose of at least 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, sulfasalazine)
- Cyltezo will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)],PDE-4 inhibitor) for the treatment of RA

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #2.

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ADALIMUMAB-ADBM (PART D)

INITIAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (pJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
The patient is 2 years of age or older
Therapy is prescribed by or in consultation with a rheumatologist
Cyltezo will NOT be used concurrently with another systemic biologic (e.g., Enbrel [etanercept]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of pJIA

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #3.

Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
Cyltezo will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)],PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #4.

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ADALIMUMAB-ADBM (PART D)

INITIAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
Therapy is prescribed by or in consultation with a rheumatologist
Cyltezo will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)],PDE-4 inhibitor) for the treatment of AS
The patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam)

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #5.

Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
The patient is 6 years of age or older
Therapy is prescribed by or in consultation with a gastroenterologist
Cyltezo will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)],PDE-4 inhibitor) for the treatment of CD

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #6.

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ADALIMUMAB-ADBM (PART D)

INITIAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a gastroenterologist
- Cyltezo will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #7.

Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist
- The patient has psoriasis covering 3% or more of body surface area (BSA) OR psoriatic lesions affecting the hands, feet, face, scalp, or genital area
- Cyltezo will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

If yes, continue to #8.
If no, continue to #9.

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ADALIMUMAB-ADBM (PART D)

INITIAL CRITERIA (CONTINUED)

Does the patient meet **ONE** of the following criteria?
- The patient has had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy)
- The patient has a contraindication or intolerance to both immunosuppressant and PUVA (phototherapy)
- The patient is switching from a different biologic (e.g., Remicade [infliximab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

Does the patient have a diagnosis of moderate to severe hidradenitis suppurativa (HS) (ICD-10 L73.2) and meet **ALL** of the following criteria?
- The patient is 12 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist
- Cyltezo will NOT be used concurrently with another systemic biologic (e.g., Cosentyx [secukinumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of HS

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #10.

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ADALIMUMAB-ADBM (PART D)

INITIAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of non-infectious intermediate, posterior, or panuveitis (ICD-10 Group H44.11) and meet **ALL** of the following criteria?
- The patient is 2 years of age or older
- Therapy is prescribed by or in consultation with an ophthalmologist
- The patient does NOT have isolated anterior uveitis
- Cyltezo will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of uveitis

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do no approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ADALIMUMAB-ADBM (Cyltezo)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
- Moderate to severe polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition in children)
- Psoriatic arthritis (PsA: a type of skin and joint condition)
- Ankylosing spondylitis (AS: a type of joint condition)
- Moderate to severe Crohn's disease (CD: a type of bowel disorder)
- Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
- Moderate to severe plaque psoriasis (PsO: a type of skin condition)
- Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)
- Non-infectious intermediate, posterior, or panuveitis (a type of eye condition)

(Initial denial text continued on next page)

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ADALIMUMAB-ADBM (PART D)

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe rheumatoid arthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You have tried at least 3 months of or have a contraindication to (harmful for you to use) ONE conventional synthetic DMARD (disease-modifying antirheumatic drug, such as methotrexate at a dose of at least 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, sulfasalazine)
- You will NOT use Cyltezo concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis

If you have moderate to severe polyarticular juvenile idiopathic arthritis, approval also requires:
- You are 2 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Cyltezo concurrently (at the same time) with another systemic biologic (such as Enbrel [etanercept]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis

If you have psoriatic arthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
- You will NOT use Cyltezo concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

If you have ankylosing spondylitis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Cyltezo concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis
- You have tried or have a contraindication to (harmful for you to use) an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)

(Initial denial text continued on next page)

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ADALIMUMAB-ADBM (PART D)

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe Crohn's disease, approval also requires:
- You are 6 years of age or older
- Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who specializes in digestive conditions)
- You will NOT use Cyltezo concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease

If you have moderate to severe ulcerative colitis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who specializes in digestive conditions)
- You will NOT use Cyltezo concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

If you have moderate to severe plaque psoriasis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
- You have psoriasis covering 3% or more of body surface area (BSA) or psoriatic lesions (rashes) affecting your hands, feet, face, scalp, or genital area
- You will NOT use Cyltezo concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis
- You meet ONE of the following:
  - You have had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy)
  - You have a contraindication (harmful for you to use) or intolerance (side effect) to both immunosuppressant (a type of drug that decreases the body's immune response) and PUVA (phototherapy)
  - You are switching from a different biologic (such as Remicade [infliximab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication

(Initial denial text continued on next page)

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ADALIMUMAB-ADBM (PART D)

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe hidradenitis suppurativa, approval also requires:
- You are 12 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
- You will NOT use Cyltezo concurrently (at the same time) with another systemic biologic (such as Cosentyx [secukinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of hidradenitis suppurativa

If you have non-infectious intermediate, posterior, or panuveitis, approval also requires:
- You are 2 years of age or older
- Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor)
- You do NOT have isolated anterior uveitis (a different type of eye inflammation)
- You will NOT use Cyltezo concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of uveitis

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ADALIMUMAB-ADBM (PART D)

RENEWAL CRITERIA

Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
The patient continues to benefit from the medication
Cyltezo will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)],PDE-4 inhibitor) for the treatment of RA

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #2.

Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (pJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
The patient continues to benefit from the medication
Cyltezo will NOT be used concurrently with another systemic biologic (e.g., Enbrel [etanercept]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of pJIA

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #3.

Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
The patient continues to benefit from the medication
Cyltezo will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)],PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #4.

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ADALIMUMAB-ADBM (PART D)

RENEWAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
The patient continues to benefit from the medication
Cyltezo will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)],PDE-4 inhibitor) for the treatment of AS

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #5.

Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
The patient continues to benefit from the medication
Cyltezo will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #6.

Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) **AND** meet the following criterion?
Cyltezo will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)],PDE-4 inhibitor) for the treatment of CD

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #7.

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ADALIMUMAB-ADBM (PART D)

RENEWAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51)
AND meet the following criterion?
Cyltezo will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)],PDE-4 inhibitor) for the treatment of UC

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.
If no, continue to #8.

Does the patient have a diagnosis of moderate to severe hidradenitis suppurativa (HS) (ICD-10 L73.2) and meet **ALL** of the following criteria?
The patient continues to benefit from the medication
Cyltezo will NOT be used concurrently with another systemic biologic (e.g., Cosentyx [secukinumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) forthe treatment of HS

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.
If no, continue to #9.

Does the patient have a diagnosis of non-infectious intermediate, posterior, or panuveitis (ICD-10 Group H44.11) and meet **ALL** of the following criteria?
The patient continues to benefit from the medication
Cyltezo will NOT be used concurrently with another systemic biologic or targetedsmall molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of uveitis

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.
If no, do not approve.
DENIAL TEXT: See the renewal denial text at the end of the guideline.

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ADALIMUMAB-ADBM (PART D)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ADALIMUMAB-ADBM (Cyltezo)** requires the following rule(s) be met for renewal:

You have ONE of the following:

- Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
- Moderate to severe polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition in children)
- Psoriatic arthritis (PsA: a type of skin and joint condition)
- Ankylosing spondylitis (AS: a type of joint condition) Moderate to severe Crohn's disease (CD: a type of bowel disorder)
- Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
- Moderate to severe plaque psoriasis (PsO: a type of skin condition)
- Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)
- Non-infectious intermediate, posterior, or panuveitis (a type of eye condition)

If you have moderate to severe rheumatoid arthritis, renewal also requires:

- You continue to benefit from the medication
- You will NOT use Cyltezo concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis

If you have moderate to severe polyarticular juvenile idiopathic arthritis, renewal also requires:

- You continue to benefit from the medication
- You will NOT use Cyltezo concurrently (at the same time) with another systemic biologic (such as Enbrel [etanercept]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis

If you have psoriatic arthritis, renewal also requires:

- You continue to benefit from the medication
- You will NOT use Cyltezo concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

(Renewal denial text continued on next page)

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ADALIMUMAB-ADBM (PART D)

RENEWAL CRITERIA (CONTINUED)

If you have ankylosing spondylitis, renewal also requires:
- You continue to benefit from the medication
- You will NOT use Cyltezo concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis

If you have moderate to severe plaque psoriasis, renewal also requires:
- You continue to benefit from the medication
- You will NOT use Cyltezo concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis

If you have moderate to severe Crohn's disease, renewal also requires:
- You will NOT use Cyltezo concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn’s disease

If you have moderate to severe ulcerative colitis, renewal also requires:
- You will NOT use Cyltezo concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

If you have moderate to severe hidradenitis suppurativa, renewal also requires:
- You continue to benefit from the medication
- You will NOT use Cyltezo concurrently (at the same time) with another systemic biologic (such as Cosentyx [secukinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of hidradenitis suppurativa

If you have non-infectious intermediate, posterior, or panuveitis, renewal also requires:
- You continue to benefit from the medication
- You will NOT use Cyltezo concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of uveitis

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ADALIMUMAB-ADBM (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cyltezo.

REFERENCES

Cyltezo [Prescribing Information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; October 2025.

For Part D use only:

ADALIMUMAB-ADBM (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	INITIAL: PLAQUE PSORIASIS (PSO): PSORIASIS COVERING 3 PERCENT OR MORE OF BODY SURFACE AREA OR PSORIATIC LESIONS AFFECTING THE HANDS, FEET, FACE, SCALP, OR GENITAL AREA.
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: RA, PJIA, ANKYLOSING SPONDYLITIS (AS): PRESCRIBED BY OR IN CONSULTATION WITH RHEUMATOLOGIST. PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH DERMATOLOGIST OR RHEUMATOLOGIST. PSO, HIDRADENITIS SUPPURATIVA (HS): PRESCRIBED BY OR IN CONSULTATION WITH DERMATOLOGIST. CROHNS DISEASE (CD), ULCERATIVE COLITIS (UC): PRESCRIBED BY OR IN CONSULTATION WITH GASTROENTEROLOGIST. UVEITIS: PRESCRIBED BY OR IN CONSULTATION WITH OPHTHALMOLOGIST
Coverage Duration	INITIAL: RA, PSO, PJIA, AS, PSA, CD, UC, UVEITIS: 6 MONTHS, HS: 12 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: RHEUMATOID ARTHRITIS (RA): TRIAL OF OR CONTRAINDICATION TO 3 MONTHS OF TREATMENT WITH ONE CONVENTIONAL SYNTHETIC DMARD (DISEASE-MODIFYING ANTIRHEUMATIC DRUG) - IF PATIENT TRIED METHOTREXATE, THEN TRIAL AT A DOSE OF AT LEAST 20 MG PER WEEK OR MAXIMALLY TOLERATED DOSE IS REQUIRED. AS: TRIAL OF OR CONTRAINDICATION TO AN NSAID. PSO: 1) AT LEAST A 3 MONTH TRIAL OF ONE ORAL IMMUNOSUPPRESSANT (CYCLOSPORINE, METHOTREXATE, TACROLIMUS) OR PUVA (PHOTOTHERAPY), 2) CONTRAINDICATION OR INTOLERANCE TO BOTH IMMUNOSUPPRESSANT AND PUVA, OR 3) PATIENT IS SWITCHING FROM A DIFFERENT BIOLOGIC, PDE-4 INHIBITOR, OR JAK INHIBITOR FOR THE SAME INDICATION. UVEITIS: DOES NOT HAVE ISOLATED

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	ANTERIOR UVEITIS. INITIAL/RENEWAL: ALL INDICATIONS: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION. RENEWAL: RA, POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA), PSA, AS, PSO, HS, UVEITIS: CONTINUES TO BENEFIT FROM THE MEDICATION.

Created: 03/25
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 01/26

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ADALIMUMAB-BWWD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ADALIMUMAB-BWWD	HADLIMA	45894		GPI-10 (6627001520)	BRAND ONLY

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist
- The patient had a trial of or contraindication to 3 months of treatment with ONE conventional synthetic DMARD (disease-modifying antirheumatic drug) (e.g., methotrexate at a dose of at least 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, sulfasalazine)
- Hadlima will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)],PDE-4 inhibitor) for the treatment of RA

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #2.

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ADALIMUMAB-BWWD (PART D)

INITIAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (pJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
The patient is 2 years of age or older
Therapy is prescribed by or in consultation with a rheumatologist
Hadlima will NOT be used concurrently with another systemic biologic (e.g., Enbrel [etanercept]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of pJIA

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #3.

Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
Hadlima will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)],PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #4.

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ADALIMUMAB-BWWD (PART D)

INITIAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist
- Hadlima will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)],PDE-4 inhibitor) for the treatment of AS
- The patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam)

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #5.

Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
- The patient is 6 years of age or older
- Therapy is prescribed by or in consultation with a gastroenterologist
- Hadlima will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)],PDE-4 inhibitor) for the treatment of CD

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #6.

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ADALIMUMAB-BWWD (PART D)

INITIAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a gastroenterologist
- Hadlima will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #7.

Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist
- The patient has psoriasis covering 3% or more of body surface area (BSA) OR psoriatic lesions affecting the hands, feet, face, scalp, or genital area
- Hadlima will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

If yes, continue to #8.
If no, continue to #9.

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ADALIMUMAB-BWWD (PART D)

INITIAL CRITERIA (CONTINUED)

Does the patient meet **ONE** of the following criteria?
- The patient has had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy)
- The patient has a contraindication or intolerance to both immunosuppressant and PUVA (phototherapy)
- The patient is switching from a different biologic (e.g., Remicade [infliximab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

Does the patient have a diagnosis of moderate to severe hidradenitis suppurativa (HS) (ICD-10 L73.2) and meet **ALL** of the following criteria?
- The patient is 12 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist
- Hadlima will NOT be used concurrently with another systemic biologic (e.g., Cosentyx [secukinumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of HS

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #10.

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ADALIMUMAB-BWWD (PART D)

INITIAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of non-infectious intermediate, posterior, or panuveitis (ICD-10 Group H44.11) and meet **ALL** of the following criteria?
- The patient is 2 years of age or older
- Therapy is prescribed by or in consultation with an ophthalmologist
- The patient does NOT have isolated anterior uveitis
- Hadlima will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of uveitis

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ADALIMUMAB-BWWD (Hadlima)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
- Moderate to severe polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition in children)
- Psoriatic arthritis (PsA: a type of skin and joint condition)
- Ankylosing spondylitis (AS: a type of joint condition)
- Moderate to severe Crohn's disease (CD: a type of bowel disorder)
- Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
- Moderate to severe plaque psoriasis (PsO: a type of skin condition)
- Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)
- Non-infectious intermediate, posterior, or panuveitis (a type of eye condition)

(Initial denial text continued on next page)

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ADALIMUMAB-BWWD (PART D)

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe rheumatoid arthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You have tried or have a contraindication to (harmful for you to use) 3 months of treatment with ONE conventional synthetic DMARD (disease-modifying antirheumatic drug, such as methotrexate at a dose of at least 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, sulfasalazine)
- You will NOT use Hadlima concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)

If you have moderate to severe polyarticular juvenile idiopathic arthritis, approval also requires:
- You are 2 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Hadlima concurrently (at the same time) with another systemic biologic (such as Enbrel [etanercept]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition in children)

If you have psoriatic arthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
- You will NOT use Hadlima concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)

If you have ankylosing spondylitis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Hadlima concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis (a type of joint condition)
- You have tried or have a contraindication to (harmful for you to use) an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)

(Initial denial text continued on next page)

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ADALIMUMAB-BWWD (PART D)

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe Crohn's disease, approval also requires:
- You are 6 years of age or older
- Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who specializes in digestive conditions)
- You will NOT use Hadlima concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)

If you have moderate to severe ulcerative colitis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who specializes in digestive conditions)
- You will NOT use Hadlima concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)

If you have moderate to severe plaque psoriasis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
- You have psoriasis covering 3% or more of body surface area (BSA) or psoriatic lesions (rashes) affecting your hands, feet, face, scalp, or genital area
- You will NOT use Hadlima concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)
- You meet ONE of the following:
  - You have had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy)
  - You have a contraindication (harmful for you to use) or intolerance (side effect) to both immunosuppressant (a type of drug that decreases the body's immune response) and PUVA (phototherapy)
  - You are switching from a different biologic (such as Remicade [infliximab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication

(Initial denial text continued on next page)

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ADALIMUMAB-BWWD (PART D)

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe hidradenitis suppurativa, approval also requires:
- You are 12 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
- You will NOT use Hadlima concurrently (at the same time) with another systemic biologic (such as Cosentyx [secukinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of hidradenitis suppurativa (a type of skin condition)

If you have non-infectious intermediate, posterior, or panuveitis, approval also requires:
- You are 2 years of age or older
- Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor)
- You do NOT have isolated anterior uveitis (a different type of eye inflammation)
- You will NOT use Hadlima concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of uveitis (a type of eye condition)

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ADALIMUMAB-BWWD (PART D)

RENEWAL CRITERIA

Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
The patient continues to benefit from the medication
Hadlima will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #2.

Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (pJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
The patient continues to benefit from the medication
Hadlima will NOT be used concurrently with another systemic biologic (e.g., Enbrel [etanercept]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of pJIA

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #3.

Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
The patient continues to benefit from the medication
Hadlima will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #4.

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ADALIMUMAB-BWWD (PART D)

RENEWAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
The patient continues to benefit from the medication
Hadlima will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #5.

Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
The patient continues to benefit from the medication
Hadlima will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #6.

Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) **AND** meet the following criterion?
Hadlima will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #7.

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ADALIMUMAB-BWWD (PART D)

RENEWAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51)
AND meet the following criterion?
Hadlima will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)],PDE-4 inhibitor) for the treatment of UC

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #8.

Does the patient have a diagnosis of moderate to severe hidradenitis suppurativa (HS) (ICD-10 L73.2) and meet **ALL** of the following criteria?
The patient continues to benefit from the medication
Hadlima will NOT be used concurrently with another systemic biologic (e.g., Cosentyx [secukinumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) forthe treatment of HS

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #9.

Does the patient have a diagnosis of non-infectious intermediate, posterior, or panuveitis (ICD-10 Group H44.11) and meet **ALL** of the following criteria?
The patient continues to benefit from the medication
Hadlima will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of uveitis

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the renewal denial text at the end of the guideline.

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ADALIMUMAB-BWWD (PART D)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ADALIMUMAB-BWWD (Hadlima)** requires the following rule(s) be met for renewal:
You have ONE of the following:
- Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
- Moderate to severe polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition in children)
- Psoriatic arthritis (PsA: a type of skin and joint condition)
- Ankylosing spondylitis (AS: a type of joint condition)
- Moderate to severe Crohn's disease (CD: a type of bowel disorder)
- Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
- Moderate to severe plaque psoriasis (PsO: a type of skin condition)
- Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)
- Non-infectious intermediate, posterior, or panuveitis (a type of eye condition)

If you have moderate to severe rheumatoid arthritis, renewal also requires:
- You continue to benefit from the medication
- You will NOT use Hadlima concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)

If you have moderate to severe polyarticular juvenile idiopathic arthritis, renewal also requires:
- You continue to benefit from the medication
- You will NOT use Hadlima concurrently (at the same time) with another systemic biologic (such as Enbrel [etanercept]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition in children)

If you have psoriatic arthritis, renewal also requires:
- You continue to benefit from the medication
- You will NOT use Hadlima concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)

(Renewal denial text continued on next page)

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ADALIMUMAB-BWWD (PART D)

RENEWAL CRITERIA (CONTINUED)

If you have ankylosing spondylitis, renewal also requires:
- You continue to benefit from the medication
- You will NOT use Hadlima concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis (a type of joint condition)

If you have moderate to severe plaque psoriasis, renewal also requires:
- You continue to benefit from the medication
- You will NOT use Hadlima concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)

If you have moderate to severe Crohn's disease, renewal also requires:
- You will NOT use Hadlima concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)

If you have moderate to severe ulcerative colitis, renewal also requires:
- You will NOT use Hadlima concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)

If you have moderate to severe hidradenitis suppurativa, renewal also requires:
- You continue to benefit from the medication
- You will NOT use Hadlima concurrently (at the same time) with another systemic biologic (such as Cosentyx [secukinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of hidradenitis suppurativa (a type of skin condition)

If you have non-infectious intermediate, posterior, or panuveitis, renewal also requires:
- You continue to benefit from the medication
- You will NOT use Hadlima concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of uveitis (a type of eye condition)

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ADALIMUMAB-BWWD (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Hadlima.

REFERENCES
Hadlima [Prescribing Information]. Jersey City, NJ: Organon LLC; April 2026.

For Part D use only:

ADALIMUMAB-BWWD (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	INITIAL: PLAQUE PSORIASIS (PSO): PSORIASIS COVERING 3 PERCENT OR MORE OF BODY SURFACE AREA OR PSORIATIC LESIONS AFFECTING THE HANDS, FEET, FACE, SCALP, OR GENITAL AREA.
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: RA, PJIA, ANKYLOSING SPONDYLITIS (AS): PRESCRIBED BY OR IN CONSULTATION WITH RHEUMATOLOGIST. PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH DERMATOLOGIST OR RHEUMATOLOGIST. PSO, HIDRADENITIS SUPPURATIVA (HS): PRESCRIBED BY OR IN CONSULTATION WITH DERMATOLOGIST. CROHNS DISEASE (CD), ULCERATIVE COLITIS (UC): PRESCRIBED BY OR IN CONSULTATION WITH GASTROENTEROLOGIST. UVEITIS: PRESCRIBED BY OR IN CONSULTATION WITH OPHTHALMOLOGIST.
Coverage Duration	INITIAL: RA, PSO, PJIA, AS, PSA, CD, UC, UVEITIS: 6 MONTHS, HS: 12 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: RHEUMATOID ARTHRITIS (RA): TRIAL OF OR CONTRAINDICATION TO 3 MONTHS OF TREATMENT WITH ONE CONVENTIONAL SYNTHETIC DMARD (DISEASE-MODIFYING ANTIRHEUMATIC DRUG) - IF PATIENT TRIED METHOTREXATE, THEN TRIAL OF AT LEAST 20 MG PER WEEK OR MAXIMALLY TOLERATED DOSE IS REQUIRED. AS: TRIAL OF OR CONTRAINDICATION TO AN NSAID. PSO: 1) AT LEAST A 3 MONTH TRIAL OF ONE ORAL IMMUNOSUPPRESSANT (CYCLOSPORINE, METHOTREXATE, TACROLIMUS) OR PUVA (PHOTOTHERAPY), 2) CONTRAINDICATION OR INTOLERANCE TO BOTH IMMUNOSUPPRESSANT AND PUVA, OR 3) PATIENT IS SWITCHING FROM A DIFFERENT BIOLOGIC, PDE-4 INHIBITOR, OR JAK INHIBITOR FOR THE SAME INDICATION. UVEITIS: DOES NOT HAVE ISOLATED ANTERIOR UVEITIS.

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	INITIAL/RENEWAL: ALL INDICATIONS: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION. RENEWAL: RA, POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA), PSA, AS, PSO, HS, UVEITIS: CONTINUES TO BENEFIT FROM THE MEDICATION.

Created: 03/26
Effective: 06/03/26 Client Approval: 06/26 P&T Approval: 07/26

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ADAMTS13 RECOMBINANT-KRHN BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ADAMTS13, RECOMBINANT-KRHN	ADZYNMA	49300		GPI-10 (8518200530)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	Yes	No	No	Yes	No	No	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

Is this a pharmacy call?

If yes, continue to #3.
If no, continue to #2.

Is the requested medication going to be filled at a pharmacy?

If yes, continue to #3.
If no, **Refer to plan. (This should be processed under the member's medical benefit)**

Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

If no, continue to #4.

Is the pharmacy dispensing the drug directly to the member or member's representative?

If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

If no, continue to #5.

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ADAMTS13 RECOMBINANT-KRHN BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

Is the internal HQ code ML500, SFC01, or SUM03?

If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).
For PAC's: Send an email to plan (reference UNSAD section of PACIP).

If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ADAMTS13 RECOMBINANT-KRHN BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

Does the patient have a diagnosis of congenital thrombotic thrombocytopenic purpura (cTTP) (ICD- 10 D69.42)?

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ADAMTS13 RECOMBINANT-KRHN (Adzynma)** requires the following rule(s) be met for approval:
You have congenital thrombotic thrombocytopenic purpura (cTTP: a type of blood disorder)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ADAMTS13 RECOMBINANT-KRHN BvD (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Adzynma.
The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Adzynma [Prescribing Information]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; November 2023.

Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed July 2, 2024].

For Part D use only:

ADAMTS13 RECOMBINANT-KRHN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 12/23
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 01/24

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ADAPALENE-BENZOYL-CLINDAMYCIN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ADAPALENE/BENZOYL/ CLINDAMYCIN	CABTREO	46076		GPI-10 (9005990302)	BRAND = CABTREO

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Is the request for a cosmetic indication (e.g., melasma, photoaging, or wrinkles) (ICD-10 L98.8, Group L81)?

If yes, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

If no, continue to #2.

Does the patient have a diagnosis of acne vulgaris (ICD-10 L70.0) and meet **ALL** of the following criteria?
The patient is 12 years of age or older
Cabtreo will NOT be used concurrently with other single source brand acne agents (e.g., Aklief, Winlevi)
The patient had a trial of or contraindication to **BOTH** of the following:
Adapalene/benzoyl peroxide (Epiduo, Epiduo Forte)
ONE topical antibiotic (e.g., clindamycin, erythromycin)

If yes, **approve for 12 weeks by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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ADAPALENE-BENZOYL-CLINDAMYCIN (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ADAPALENE-BENZOYL-CLINDAMYCIN (Cabtreo)** requires the following rule(s) be met for approval:
You have acne vulgaris (a type of skin condition usually called pimples)
You are 12 years of age or older
You will NOT use Cabtreo concurrently (at the same time) with other acne medications that are only available as brand (such as Aklief, Winlevi)
You have tried or have a contraindication to (harmful for you to use) BOTH of the following:
Adapalene/benzoyl peroxide (Epiduo, Epiduo Forte)
One topical antibiotic (such as clindamycin, erythromycin)
Your request is NOT for a cosmetic (not for appearance) diagnosis (such as melasma [freckle-like spots on the skin], photoaging [skin damage from the sun], wrinkles)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ADAPALENE-BENZOYL-CLINDAMYCIN (PART D)

RENEWAL CRITERIA

Does the patient have a diagnosis of acne vulgaris (ICD-10 L70.0) and meet **ALL** of the following criteria?
Cabtreo will NOT be used concurrently with other single source brand acne agents (e.g., Aklief, Winlevi)
The patient has shown improvement in acne symptoms

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ADAPALENE-BENZOYL-CLINDAMYCIN (Cabtreo)** requires the following rule(s) be met for renewal:
You have acne vulgaris (a type of skin condition usually called pimples)
You will NOT use Cabtreo concurrently (at the same time) with other acne medications that are only available as brand (such as Aklief, Winlevi)
You have shown improvement in acne symptoms (treatment is working)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cabtreo.

REFERENCES

Cabtreo [Prescribing Information]. Bridgewater, NJ: Bausch Health US, LLC; October 2023.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ADAPALENE-BENZOYL-CLINDAMYCIN (PART D)

For Part D use only:

ADAPALENE-BENZOYL-CLINDAMYCIN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	INITIAL: COSMETIC INDICATIONS SUCH AS MELASMA, PHOTOAGING, WRINKLES.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	INITIAL: 12 WEEKS. RENEWAL: 12 MONTHS.
Other Criteria	ACNE VULGARIS: INITIAL: 1) CABTREO WILL NOT BE USED CONCURRENTLY WITH OTHER SINGLE SOURCE BRAND ACNE AGENTS, AND 2) TRIAL OF OR CONTRAINDICATION TO ADAPALENE/BENZOYL PEROXIDE AND ONE TOPICAL ANTIBIOTIC. RENEWAL: 1) CABTREO WILL NOT BE USED CONCURRENTLY WITH OTHER SINGLE SOURCE BRAND ACNE AGENTS, AND 2) IMPROVEMENT IN ACNE SYMPTOMS.

Part D Effective: 01/01/25 Created: 11/23
Commercial Effective: N/A Client Approval: 06/24 P&T Approval: 10/23

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ADO-TRASTUZUMAB EMTANSINE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ADO-TRASTUZUMAB EMTANSINE	KADCYLA	40046		GPI-10 (2135507030)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

Does the patient have a diagnosis of breast cancer (ICD-10 Group C50)?

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

Is the patient's cancer metastatic and the patient meets **ALL** of the following criteria?
The patient's cancer is HER2-positive
The patient has previously received trastuzumab and a taxane (e.g., docetaxel, paclitaxel)
The patient has received prior therapy for metastatic disease OR has developed disease recurrence during or within 6 months of completing adjuvant therapy

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #3.

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ADO-TRASTUZUMAB EMTANSINE (PART D)

GUIDELINES FOR USE (CONTINUED)

Is the patient's cancer in early stage and the patient meets **ALL** of the following criteria?
- The patient's cancer is HER2-positive
- The patient has residual invasive disease after neoadjuvant taxane (e.g., docetaxel, paclitaxel) and trastuzumab-based treatment

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ADO-TRASTUZUMAB EMTANSINE (Kadcyla)** requires the following rule(s) be met for approval:
You have breast cancer
If you have metastatic breast cancer (cancer that has spread to other parts of the body), approval also requires:
- Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive
- You have previously received trastuzumab and a taxane (such as docetaxel, paclitaxel)
- You have received prior therapy for metastatic disease OR have developed disease recurrence (disease has returned) during or within 6 months of completing adjuvant (add-on) therapy

If you have early breast cancer (cancer has not spread to other parts of the body), approval also requires:
- Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive
- You have residual (remaining) invasive disease after neoadjuvant (given before main treatment) taxane (such as docetaxel, paclitaxel) and trastuzumab-based treatment (types of cancer treatment)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ADO-TRASTUZUMAB EMTANSINE (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Kadcyla.

REFERENCES
Kadcyla [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; February 2022.

For Part D use only:

ADO-TRASTUZUMAB EMTANSINE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 03/13
Effective: 07/01/25 Client Approval: 05/25 P&T Approval: 07/19

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AFATINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AFATINIB DIMALEATE	GILOTRIF	40478		GPI-10 (2136000610)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
- The patient's tumor has a non-resistant epidermal growth factor receptor (EGFR) mutation as detected by an FDA-approved test
- Gilotrif will NOT be used concurrently with an EGFR tyrosine kinase inhibitor (e.g., Tarceva [erlotinib], Iressa [gefitinib], Vizimpro [dacomitinib], Tagrisso [osimertinib])

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #2.

Does the patient have a diagnosis of metastatic squamous non-small cell lung cancer (NSCLC) (ICD-10 Group C34) **AND** meet the following criterion?
- The patient's disease has progressed after platinum-based chemotherapy (i.e., cisplatin, carboplatin, oxaliplatin)

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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AFATINIB (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AFATINIB (Gilotrif)** requires the following rule(s) be met for approval:
You have non-small cell lung cancer (NSCLC: a type of lung cancer)
If you have metastatic non-small cell lung cancer (cancer that has spread to other parts of the body), approval also requires:
Your tumor has a non-resistant epidermal growth factor receptor (EGFR: type of protein) mutation (abnormal change in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test
You will NOT use Gilotrif concurrently (at the same time) with an epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (such as Tarceva [erlotinib], Iressa [gefitinib], Vizimpro [dacomitinib], Tagrisso [osimertinib])
If you have metastatic squamous non-small cell lung cancer (cancer that begins in the squamous cells of the lung and has spread to other parts of the body), approval also requires:
Your disease has progressed (worsened) after using platinum-based chemotherapy (cisplatin, carboplatin, oxaliplatin)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Gilotrif.

REFERENCES
Gilotrif [Prescribing Information]. Ridgefield, CT; Boehringer Ingelheim Pharmaceuticals, Inc.; April 2022.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AFATINIB (PART D)

For Part D use only:

AFATINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Medical Required Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) WITH EGFR MUTATION: NOT ON CONCURRENT THERAPY WITH AN EGFR TYROSINE KINASE INHIBITOR.

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 10/13
Client Approval: 06/24
P&T Approval: 04/22

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STANDARD PART D
PRIOR AUTHORIZATION GUIDELINES

AFICAMTEN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AFICAMTEN	MYQORZO	51071		GPI-10 (4019000500)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of symptomatic obstructive hypertrophic cardiomyopathy (HCM) (ICD-10 I42.1) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a cardiologist
- The patient has New York Heart Association (NYHA) functional class II or III
- The patient has a peak left ventricular outflow tract (LVOT) gradient of at least 50 mmHg at rest or with provocation test
- Myqorzo will NOT be used concurrently with another myosin inhibitor (e.g., Camzyos [mavacamten]) for the treatment of hypertrophic cardiomyopathy
- The patient had a trial of, contraindication, or intolerance to ONE agent from any of the following clinical standard of care classes: a beta-blocker (e.g., metoprolol, carvedilol), a non-dihydropyridine calcium channel blocker (e.g., verapamil, diltiazem)

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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AFICAMTEN (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AFICAMTEN (Myqorzo)** requires the following rule(s) be met for approval:
You have symptomatic obstructive hypertrophic cardiomyopathy (HCM: a type of heart condition)
You are 18 years of age or older
Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor)
You have New York Heart Association (NYHA) functional class II or III (a way to classify the severity of symptoms)
You have a peak left ventricular outflow tract (LVOT) gradient (evaluates the severity of disease) of at least 50 mmHg at rest or with provocation test (a type of technique to evaluate how the heart performs under stress)
You will NOT use Myqorzo concurrently (at the same time) with another myosin inhibitor (such as Camzyos [mavacamten]) for the treatment of hypertrophic cardiomyopathy (a type of heart condition)
You have tried, have a contraindication (harmful for you to use), or intolerance to (side effect) ONE medication from any of the following clinical standard of care classes: beta- blocker (such as metoprolol, carvedilol), non-dihydropyridine calcium channel blocker (such as verapamil, diltiazem)

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AFICAMTEN (PART D)

RENEWAL CRITERIA

Does the patient have a diagnosis of symptomatic obstructive hypertrophic cardiomyopathy (HCM) (ICD-10 I42.1) and meet **ALL** of the following criteria?
- The patient has experienced continued clinical benefit (e.g., reduction of symptoms, NYHA classification improvement)
- Myqorzo will NOT be used concurrently with another myosin inhibitor (e.g., Camzyos [mavacamten]) for the treatment of hypertrophic cardiomyopathy

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AFICAMTEN (Myqorzo)** requires the following rule(s) be met for renewal:
- You have symptomatic obstructive hypertrophic cardiomyopathy (HCM: a type of heart condition)
- You have experienced continued clinical benefit (such as reduction of symptoms, New York Heart Association [NYHA] classification [a way to classify severity of symptoms] improvement)
- You will NOT use Myqorzo concurrently (at the same time) with another myosin inhibitor (such as Camzyos [mavacamten]) for the treatment of hypertrophic cardiomyopathy (a type of heart condition)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Myqorzo.

REFERENCES

Myqorzo [Prescribing Information]. South San Francisco, CA: Cytokinetics Incorpo; December 2025.

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STANDARD PART D
PRIOR AUTHORIZATION GUIDELINES

AFICAMTEN (PART D)

For Part D use only:

AFICAMTEN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	OBSTRUCTIVE HYPERTROPHIC CARDIOMYOPATHY (HCM): INITIAL: 1) NEW YORK HEART ASSOCIATION FUNCTIONAL CLASS II OR III, AND 2) PEAK LEFT VENTRICULAR OUTFLOW TRACT (LVOT) GRADIENT OF AT LEAST 50 MMHG AT REST OR WITH PROVOCATION TEST.
Age Restrictions	N/A
Prescriber Restrictions	OBSTRUCTIVE HCM: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	OBSTRUCTIVE HCM: INITIAL: TRIAL OF, CONTRAINDICATION, OR INTOLERANCE TO ONE AGENT FROM ANY OF THE FOLLOWING CLINICAL STANDARD OF CARE MEDICATION CLASSES: A BETA-BLOCKER, A NON-DIHYDROPYRIDINE CALCIUM CHANNEL BLOCKER. INITIAL/RENEWAL: NO CONCURRENT USE WITH ANOTHER MYOSIN INHIBITOR FOR THE TREATMENT OF HCM. RENEWAL: CONTINUED CLINICAL BENEFIT (E.G., REDUCTION OF SYMPTOMS, NYHA CLASSIFICATION IMPROVEMENT).

Created: 06/26
Effective: 07/01/26 DMC Approval: 06/16/26

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AGALSIDASE BETA (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AGALSIDASE BETA	FABRAZYME	24861		GPI-10 (3090361010)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of Fabry disease (ICD-10 E75.21) and meet **ALL** of the following criteria?
- The patient is 2 years of age or older
- Therapy is prescribed by or in consultation with a nephrologist, cardiologist, or specialist in genetics or inherited metabolic disorders
- Fabrazyme will NOT be used concurrently with another Fabry disease therapy (e.g., Elfabrio [pegunigalsidase alfa-iwxj], Galafold [migalastat])

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

Is the request for a female patient who meets the following criterion?
- The patient has a galactosidase alpha (GLA) gene mutation via genetic testing

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #3.

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AGALSIDASE BETA (PART D)

INITIAL CRITERIA (CONTINUED)

Is the request for a male patient who meets **ONE** of the following criteria?
The patient has an alpha galactosidase A (a-Gal-A) deficiency as indicated by an enzyme assay
The patient has a galactosidase alpha (GLA) gene mutation via genetic testing

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AGALSIDASE BETA (Fabrazyme)** requires the following rule(s) be met for approval:
You have Fabry disease (a rare genetic disease)
You are 2 years of age or older
Therapy is prescribed by or in consultation with a nephrologist (kidney doctor), cardiologist (heart doctor), or a doctor specializing in genetics or inherited metabolic disorders
You will NOT use Fabrazyme concurrently (at the same time) with another Fabry disease medication (such as Elfabrio [pegunigalsidase alfa-iwxj], Galafold [migalastat])
If you are a female, approval also requires:
You have a galactosidase alpha (GLA: a type of gene) gene mutation by genetic testing
If you are a male, approval also requires ONE of the following:
You do not have enough alpha galactosidase A (a-Gal-A: a type of protein) as indicated by an enzyme assay (a type of lab test)
You have a galactosidase alpha (GLA: a type of gene) gene mutation by genetic testing

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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AGALSIDASE BETA (PART D)

RENEWAL CRITERIA

Does the patient have a diagnosis of Fabry disease (ICD-10 E75.21) and meet **ALL** of the following criteria?
The patient has demonstrated improvement or stabilization
Fabrazyme will NOT be used concurrently with another Fabry disease therapy (e.g., Elfabrio [pegunigalsidase alfa-iwxj], Galafold [migalastat])

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AGALSIDASE BETA (Fabrazyme)** requires the following rule(s) be met for renewal:
You have Fabry disease (a rare genetic disease)
You have demonstrated improvement or stabilization
You will NOT use Fabrazyme concurrently (taking at the same time) with another Fabry disease medication (such as Elfabrio [pegunigalsidase alfa-iwxj], Galafold [migalastat])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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AGALSIDASE BETA (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Fabrazyme.

REFERENCES
Fabrazyme [Prescribing Information]. Cambridge, MA: Genzyme Corporation; February 2024.

For Part D use only:

AGALSIDASE BETA (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	FABRY DISEASE: INITIAL: ONE OF THE FOLLOWING: 1) FEMALES: GALACTOSIDASE ALPHA (GLA) GENE MUTATION VIA GENETIC TESTING, OR 2) MALES: ENZYME ASSAY INDICATING ALPHA GALACTOSIDASE A DEFICIENCY OR GLA GENE MUTATION VIA GENETIC TESTING.
Age Restrictions	N/A
Prescriber Restrictions	FABRY DISEASE: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH NEPHROLOGIST, CARDIOLOGIST, OR SPECIALIST IN GENETICS OR INHERITED METABOLIC DISORDERS.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	FABRY DISEASE: INITIAL: NO CONCURRENT USE WITH ANOTHER FABRY DISEASE THERAPY. RENEWAL: 1) DEMONSTRATED IMPROVEMENT OR STABILIZATION, AND 2) NO CONCURRENT USE WITH ANOTHER FABRY DISEASE THERAPY.

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 10/19
Client Approval: 11/24
P&T Approval: 07/23

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ALECTINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ALECTINIB HCL	ALECENSA	42895		GPI-10 (2153050710)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meets **ALL** of the following criteria?
- The patient is 18 years of age or older
- The patient's cancer is positive for anaplastic lymphoma kinase (ALK) fusion oncogene as detected by an FDA-approved test

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #2.

Does the patient have a diagnosis of non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meets **ALL** of the following criteria?
- The patient is 18 years of age or older
- The patient's cancer is node positive or the tumor is at least 4 cm
- The patient's cancer is anaplastic lymphoma kinase (ALK)-positive, as detected by an FDA-approved test
- Alecensa will be used as adjuvant treatment following tumor resection

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See denial text at the end of the guideline.

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ALECTINIB (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ALECTINIB (Alecensa)** requires the following rules be met for approval:
You have ONE of the following:
- Metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of the body)
- Non-small cell lung cancer (NSCLC: a type of lung cancer)

If you have metastatic non-small cell lung cancer, approval also requires:
- You are 18 years of age or older
- Your tumor is anaplastic lymphoma kinase (ALK)-positive (a type of abnormal gene change), as detected by a Food and Drug Administration (FDA)-approved test

If you have non-small cell lung cancer, approval also requires:
- You are 18 years of age or older
- You are node positive (cancer that has spread to the lymph nodes), or your tumor is at least 4 cm
- Your tumor is anaplastic lymphoma kinase (ALK)-positive (a type of abnormal gene change), as detected by a Food and Drug Administration (FDA)-approved test
- Alecensa will be used as adjuvant (additional) treatment following tumor resection (surgical removal of a tumor)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Alecensa.

REFERENCES

Alecensa [Prescribing Information]. South San Francisco, CA: Genentech, Inc. April 2024.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ALECTINIB (PART D)

For Part D use only:

ALECTINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25 Created: 12/15
Commercial Effective: N/A Client Approval: 08/24 P&T Approval: 07/24

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ALEMTUZUMAB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ALEMTUZUMAB	LEMTRADA	22112		GPI-10 (6240501000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), including relapsing-remitting disease or active secondary progressive disease, and meet **ALL** of the following criteria?
The patient is 18 years of age or older
The patient had a trial of TWO agents indicated for the treatment of relapsing form of MS (e.g., Mavenclad [cladribine], Copaxone [glatiramer])

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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ALEMTUZUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ALEMTUZUMAB (Lemtrada)** requires the following rules be met for approval:
You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes relapsing-remitting disease (symptoms or disease returns and goes away) or active secondary progressive disease (advanced disease)
You are 18 years of age or older
You have tried TWO medications indicated for the treatment of relapsing form of multiple sclerosis (such as Mavenclad [cladribine], Copaxone [glatiramer])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ALEMTUZUMAB (PART D)

RENEWAL CRITERIA

Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), including relapsing-remitting disease or active secondary progressive disease, **AND** meet the following criterion?
At least 12 months have elapsed since the patient received the most recent course of Lemtrada

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

RENEWAL DENIAL TEXT: Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ALEMTUZUMAB (Lemtrada)** requires the following rules be met for renewal:
You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes relapsing-remitting disease (symptoms or disease returns and goes away) or active secondary progressive disease (advanced disease)
At least 12 months have passed since you received the most recent course of Lemtrada

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Review for Lemtrada.

REFERENCES

Lemtrada [Prescribing Information]. Cambridge, MA: Genzyme Corporation; May 2024.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ALEMTUZUMAB (PART D)

For Part D use only:

ALEMTUZUMAB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	RELAPSING FORM OF MULTIPLE SCLEROSIS (MS): INITIAL: TRIAL OF TWO AGENTS INDICATED FOR THE TREATMENT OF RELAPSING FORMS OF MS. RENEWAL: AT LEAST 12 MONTHS HAVE ELAPSED SINCE RECEIVING THE MOST RECENT COURSE OF LEMTRADA.

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 01/15
Client Approval: 06/24
P&T Approval: 01/20

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ALLERGEN EXTRACT-HOUSE DUST MITE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MITE,D.FARINAE-D.PTERONYSSINUS	ODACTRA	34376		GPI-10 (2010990222)	ROUTE = SUBLINGUAL

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of house dust mite (HDM)-induced allergic rhinitis (ICD-10 J30.89) and meet **ALL** of the following criteria?

- The patient is 5 to 65 years of age
- The patient's diagnosis is confirmed by in vitro testing for IgE antibodies to *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites, OR by skin testing to licensed house dust mite allergen extracts
- Therapy is prescribed by or in consultation with an allergist, immunologist, or other physician experienced in the diagnosis and treatment of allergic diseases
- The patient has persistent symptoms of allergic rhinitis (defined as symptoms presenting for at least 4 days a week or for at least 4 weeks)
- The patient has moderate-to-severe symptoms of allergic rhinitis (including one or more of the following: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)
- The patient has a current claim or prescription for an auto-injectable epinephrine within the past 365 days

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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ALLERGEN EXTRACT-HOUSE DUST MITE (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ALLERGEN EXTRACT-HOUSE DUST MITE (Odactra)** requires the following rule(s) be met for approval:
You have allergic rhinitis (itchy, watery eyes, sneezing) caused by house dust mites
You are 5 to 65 years of age
Your diagnosis is confirmed by in vitro testing (testing outside of the body in a tube) for IgE (immunoglobulin E) antibodies to *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites, OR by skin testing to licensed house dust mite allergen extracts
Therapy is prescribed by or in consultation with an allergist (allergy doctor), immunologist (immune system doctor), or other physician experienced in the diagnosis and treatment of allergic diseases
You have persistent symptoms of allergic rhinitis (defined as symptoms presenting for at least 4 days a week or for at least 4 weeks)
You have moderate-to-severe symptoms of allergic rhinitis (including one or more of the following: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)
You have a current claim or prescription for an auto-injectable epinephrine within the past 365 days

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ALLERGEN EXTRACT-HOUSE DUST MITE (PART D)

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Has the patient experienced an improvement in signs and symptoms of allergic rhinitis from baseline?

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ALLERGEN EXTRACT-HOUSE DUST MITE (Odactra)** requires the following rule(s) be met for renewal:
You have experienced an improvement in signs and symptoms of allergic rhinitis (itchy, watery eyes, sneezing) from baseline (before treatment)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Odactra.

REFERENCES

Odactra [Prescribing Information]. Swindon, UK: Catalent Pharma Solutions Limited; February 2025.

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ALLERGEN EXTRACT-HOUSE DUST MITE (PART D)

For Part D use only:

ALLERGEN EXTRACT-HOUSE DUST MITE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	ALLERGIC RHINITIS: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH AN ALLERGIST, IMMUNOLOGIST, OR OTHER PHYSICIAN EXPERIENCED IN THE DIAGNOSIS AND TREATMENT OF ALLERGIC DISEASES.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS
Other Criteria	ALLERGIC RHINITIS: INITIAL: 1) PERSISTENT SYMPTOMS OF ALLERGIC RHINITIS (DEFINED AS SYMPTOMS PRESENTING FOR AT LEAST 4 DAYS A WEEK OR FOR AT LEAST 4 WEEKS), 2) MODERATE-TO-SEVERE SYMPTOMS OF ALLERGIC RHINITIS (INCLUDING ONE OR MORE OF THE FOLLOWING: TROUBLESOME SYMPTOMS, SLEEP DISTURBANCE, IMPAIRMENT OF DAILY ACTIVITIES, OR IMPAIRMENT OF SCHOOL OR WORK), AND 3) CURRENT CLAIM OR PRESCRIPTION FOR AN AUTO-INJECTABLE EPINEPHRINE WITHIN THE PAST 365 DAYS. RENEWAL: IMPROVEMENT IN SIGNS AND SYMPTOMS OF ALLERGIC RHINITIS FROM BASELINE.

Created: 12/19
Effective: 04/01/25 Client Approval: 03/25 P&T Approval: 04/25

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ALLERGEN EXTRACT-MIXED GRASS POLLEN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GR POL-ORC/SW VER/RYE/KENT/TIM	ORALAIR	39918		GPI-10 (2010990520)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of grass pollen-induced allergic rhinitis (ICD-10 J30.1) and meet **ALL** of the following criteria?

- The patient is 5 to 65 years of age
- The patient's diagnosis is confirmed by a positive skin test or in vitro testing for pollen-specific IgE antibodies for any of the five grass species contained in Oralair (sweet vernal, orchard, perennial rye, timothy, and Kentucky blue grass mixed pollens)
- Therapy is prescribed by or in consultation with an allergist, immunologist, or other physician experienced in the diagnosis and treatment of allergic diseases
- The patient has persistent symptoms of allergic rhinitis (defined as symptoms presenting for at least 4 days a week or for at least 4 weeks)
- The patient has moderate-to-severe symptoms of allergic rhinitis (including one or more of the following: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)
- The patient has a current claim or prescription for an auto-injectable epinephrine

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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ALLERGEN EXTRACT-MIXED GRASS POLLEN (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ALLERGEN EXTRACT-MIXED GRASS POLLEN (Oralair)** requires the following rule(s) be met for approval:
You have allergic rhinitis (itchy, watery eyes, sneezing) caused by grass pollen
You are 5 to 65 years of age
Your diagnosis is confirmed by a positive skin test or a positive titer (the amount of antibodies in the blood) to specific IgE (immunoglobulin E) antibodies for any of the five grass types included in Oralair (sweet vernal, orchard, perennial rye, timothy, and Kentucky blue grass mixed pollens)
Therapy is prescribed by or in consultation with an allergist (allergy doctor), immunologist (immune system doctor), or other physician experienced in the diagnosis and treatment of allergic diseases
You have persistent symptoms of allergic rhinitis (defined as symptoms presenting for at least 4 days a week or for at least 4 weeks)
You have moderate-to-severe symptoms of allergic rhinitis (including one or more of the following: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)
You have a current claim or prescription for an auto-injectable epinephrine

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ALLERGEN EXTRACT-MIXED GRASS POLLEN (PART D)

RENEWAL CRITERIA

Has the patient experienced an improvement in signs and symptoms of allergic rhinitis from baseline?

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ALLERGEN EXTRACT-MIXED GRASS POLLEN (Oralair)** requires the following rule(s) be met for renewal:
You have experienced an improvement in signs and symptoms of allergic rhinitis (itchy, watery eyes, sneezing) from baseline

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Oralair.

REFERENCES
Oralair [Prescribing Information]. Lenoir, NC: GREER Laboratories, Inc.; November 2023.

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ALLERGEN EXTRACT-MIXED GRASS POLLEN (PART D)

For Part D use only:

ALLERGEN EXTRACT-MIXED GRASS POLLEN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	ALLERGIC RHINITIS: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH AN ALLERGIST, IMMUNOLOGIST, OR OTHER PHYSICIAN EXPERIENCED IN THE DIAGNOSIS AND TREATMENT OF ALLERGIC DISEASES.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS
Other Criteria	ALLERGIC RHINITIS: INITIAL: 1) PERSISTENT SYMPTOMS OF ALLERGIC RHINITIS (DEFINED AS SYMPTOMS PRESENTING FOR AT LEAST 4 DAYS A WEEK OR FOR AT LEAST 4 WEEKS), 2) MODERATE-TO-SEVERE SYMPTOMS OF ALLERGIC RHINITIS (INCLUDING ONE OR MORE OF THE FOLLOWING: TROUBLESOME SYMPTOMS, SLEEP DISTURBANCE, IMPAIRMENT OF DAILY ACTIVITIES, OR IMPAIRMENT OF SCHOOL OR WORK), AND 3) CURRENT CLAIM OR PRESCRIPTION FOR AN AUTO-INJECTABLE EPINEPHRINE. RENEWAL: IMPROVEMENT IN SIGNS AND SYMPTOMS OF ALLERGIC RHINITIS FROM BASELINE.

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25 Created: 05/14
Commercial Effective: N/A Client Approval: 06/24 P&T Approval: 01/19

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ALLERGEN EXTRACT - SHORT RAGWEED POLLEN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
WEED POLLEN-SHORT RAGWEED	RAGWITEK	41079		GPI-10 (2010006020)	ROUTE = SUBLINGUAL

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of short ragweed pollen-induced allergic rhinitis (ICD-10 J30.1) and meet **ALL** of the following criteria?

- The patient is 5 to 65 years of age
- The patient's diagnosis is confirmed by a positive skin test or in vitro testing for pollen-specific IgE antibodies for short ragweed pollen
- Therapy is prescribed by or in consultation with an allergist, immunologist, or other physician experienced in the diagnosis and treatment of allergic diseases
- The patient has persistent symptoms of allergic rhinitis (defined as symptoms presenting for at least 4 days a week or for at least 4 weeks)
- The patient has moderate-to-severe symptoms of allergic rhinitis (including one or more of the following: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)
- The patient has a current claim or prescription for an auto-injectable epinephrine

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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ALLERGEN EXTRACT - SHORT RAGWEED POLLEN (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ALLERGEN EXTRACT - SHORT RAGWEED POLLEN (Ragwitek)** requires the following rule(s) be met for approval:
You have allergic rhinitis (itchy, watery eyes, sneezing) caused by short ragweed pollen
You are 5 to 65 years of age
Your diagnosis is confirmed by a positive skin test or in vitro testing (testing outside of the body in a tube) for pollen-specific IgE (immunoglobulin E) antibodies for short ragweed pollen
Therapy is prescribed by or in consultation with an allergist (allergy doctor), immunologist (immune system doctor), or other physician experienced in the diagnosis and treatment of allergic diseases
You have persistent symptoms of allergic rhinitis (defined as symptoms presenting for at least 4 days a week or for at least 4 weeks)
You have moderate-to-severe symptoms of allergic rhinitis (including one or more of the following: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)
You have a current claim or prescription for an auto-injectable epinephrine

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ALLERGEN EXTRACT - SHORT RAGWEED POLLEN (PART D)

RENEWAL CRITERIA

Has the patient experienced an improvement in signs and symptoms of allergic rhinitis from baseline?

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ALLERGEN EXTRACT - SHORT RAGWEED POLLEN (Ragwitek)** requires the following rule(s) be met for renewal:
You have experienced an improvement in signs and symptoms of allergic rhinitis (itchy, watery eyes, sneezing) from baseline

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ragwitek.

REFERENCES

Ragwitek [Prescribing Information]. Swindon, UK: Catalent Pharma Solutions Limited; September 2022.

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ALLERGEN EXTRACT - SHORT RAGWEED POLLEN (PART D)

For Part D use only:

ALLERGEN EXTRACT - SHORT RAGWEED POLLEN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	ALLERGIC RHINITIS: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH AN ALLERGIST, IMMUNOLOGIST, OR OTHER PHYSICIAN EXPERIENCED IN THE DIAGNOSIS AND TREATMENT OF ALLERGIC DISEASES.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS
Other Criteria	ALLERGIC RHINITIS: INITIAL: 1) PERSISTENT SYMPTOMS OF ALLERGIC RHINITIS (DEFINED AS SYMPTOMS PRESENTING FOR AT LEAST 4 DAYS A WEEK OR FOR AT LEAST 4 WEEKS), 2) MODERATE-TO-SEVERE SYMPTOMS OF ALLERGIC RHINITIS (INCLUDING ONE OR MORE OF THE FOLLOWING: TROUBLESOME SYMPTOMS, SLEEP DISTURBANCE, IMPAIRMENT OF DAILY ACTIVITIES, OR IMPAIRMENT OF SCHOOL OR WORK), AND 3) CURRENT CLAIM OR PRESCRIPTION FOR AN AUTO-INJECTABLE EPINEPHRINE. RENEWAL: IMPROVEMENT IN SIGNS AND SYMPTOMS OF ALLERGIC RHINITIS FROM BASELINE.

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25 Created: 05/14
Commercial Effective: N/A Client Approval: 06/24 P&T Approval: 07/21

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ALLERGEN EXTRACT-TIMOTHY GRASS POLLEN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GRASS POLLEN-TIMOTHY, STANDARD	GRASTEK	22138		GPI-10 (2010004800)	ROUTE = SUBLINGUAL

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of grass pollen-induced allergic rhinitis (ICD-10 J30.1) and meet **ALL** of the following criteria?

- The patient is 5 to 65 years of age
- The patient's diagnosis is confirmed by a positive skin test or in vitro testing for pollen-specific IgE antibodies for timothy grass or cross-reactive grass pollens
- Therapy is prescribed by or in consultation with an allergist, immunologist, or other physician experienced in the diagnosis and treatment of allergic diseases
- The patient has persistent symptoms of allergic rhinitis (defined as symptoms presenting for at least 4 days a week or for at least 4 weeks)
- The patient has moderate-to-severe symptoms of allergic rhinitis (including one or more of the following: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)
- The patient has a current claim or prescription for an auto-injectable epinephrine

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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ALLERGEN EXTRACT-TIMOTHY GRASS POLLEN (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ALLERGEN EXTRACT-TIMOTHY GRASS POLLEN (Grastek)** requires the following rule(s) be met for approval:
You have allergic rhinitis (itchy, watery eyes, sneezing) caused by grass pollen
You are 5 to 65 years of age
Your diagnosis is confirmed by a positive skin test or in vitro testing (testing outside of your body in a tube) for pollen-specific IgE (immunoglobulin E) antibodies for timothy grass or cross-reactive grass pollens
Therapy is prescribed by or in consultation with an allergist (allergy doctor), immunologist (immune system doctor), or other physician experienced in the diagnosis and treatment of allergic diseases
You have persistent symptoms of allergic rhinitis (defined as symptoms presenting for at least 4 days a week or for at least 4 weeks)
You have moderate-to-severe symptoms of allergic rhinitis (including one or more of the following: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)
You have a current claim or prescription for an auto-injectable epinephrine

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ALLERGEN EXTRACT-TIMOTHY GRASS POLLEN (PART D)

RENEWAL CRITERIA

Has the patient experienced an improvement in signs and symptoms of allergic rhinitis from baseline?

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ALLERGEN EXTRACT-TIMOTHY GRASS POLLEN (Grastek)** requires the following rule(s) be met for renewal:
You have experienced an improvement in signs and symptoms of allergic rhinitis (itchy, watery eyes, sneezing) from baseline

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Grastek.

REFERENCES

Grastek [Prescribing Information]. Swindon, UK: Catalent Pharma Solutions Limited; September 2022.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ALLERGEN EXTRACT-TIMOTHY GRASS POLLEN (PART D)

For Part D use only:

ALLERGEN EXTRACT - TIMOTHY GRASS POLLEN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	ALLERGIC RHINITIS: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH AN ALLERGIST, IMMUNOLOGIST, OR OTHER PHYSICIAN EXPERIENCED IN THE DIAGNOSIS AND TREATMENT OF ALLERGIC DISEASES.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS
Other Criteria	ALLERGIC RHINITIS: INITIAL: 1) PERSISTENT SYMPTOMS OF ALLERGIC RHINITIS (DEFINED AS SYMPTOMS PRESENTING FOR AT LEAST 4 DAYS A WEEK OR FOR AT LEAST 4 WEEKS), 2) MODERATE-TO-SEVERE SYMPTOMS OF ALLERGIC RHINITIS (INCLUDING ONE OR MORE OF THE FOLLOWING: TROUBLESOME SYMPTOMS, SLEEP DISTURBANCE, IMPAIRMENT OF DAILY ACTIVITIES, OR IMPAIRMENT OF SCHOOL OR WORK), AND 3) CURRENT CLAIM OR PRESCRIPTION FOR AN AUTO-INJECTABLE EPINEPHRINE. RENEWAL: IMPROVEMENT IN SIGNS AND SYMPTOMS OF ALLERGIC RHINITIS FROM BASELINE.

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25 Created: 05/14
Commercial Effective: N/A Client Approval: 06/24 P&T Approval: 01/18

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ALPELISIB-PIQRAY (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ALPELISIB	PIQRAY		46362 46359 46358	GPI-10 (2153801000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

Does the patient have a diagnosis of advanced or metastatic breast cancer (ICD-10 Group C50) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Piqray will be used in combination with fulvestrant (Faslodex)
- The patient's breast cancer is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative
- The patient's tumor is PIK3CA-mutated, as detected by an FDA-approved test
- The patient has disease progression on or after an endocrine-based regimen (e.g., letrozole, anastrozole, tamoxifen)

If yes, **approve for 12 months by GPID or GPI-10 for all strengths.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ALPELISIB-PIQRAY** requires the following rule(s) be met for approval:
- You have advanced or metastatic breast cancer (breast cancer that has spread to other parts of the body)
- You are 18 years of age or older
- Piqray will be used in combination with fulvestrant (Faslodex)
- Your breast cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative

(Denial text continued on next page)

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ALPELISIB-PIQRAY (PART D)

GUIDELINES FOR USE (CONTINUED)

Your tumor has a PIK3CA mutation (abnormal change in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test
You have disease progression (condition has worsened) on or after an endocrine (hormone)-based regimen (such as letrozole, anastrozole, tamoxifen)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Piqray.

REFERENCES

Piqray [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; January 2024.

For Part D use only:

ALPELISIB-PIQRAY (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 06/19
Effective: 07/01/25 Client Approval: 05/25 P&T Approval: 04/24

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ALPELISIB - VIJOICE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ALPELISIB	VIJOICE	45761		GPI-10 (9948601000)	BRAND ≠ PIQRAY

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

Does the patient have a diagnosis of PIK3CA-related overgrowth spectrum (PROS) and meet **ALL** of the following criteria?
The patient is 2 years of age or older
The patient has severe manifestations of PROS that require systemic therapy

If yes, **approve for 12 months by GPID or GPI-10 for all strengths.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ALPELISIB - VIJOICE** requires the following rule(s) be met for approval:
You have PIK3CA-related overgrowth spectrum (PROS: group of disorders that cause overgrowth of parts of the body due to mutations in a type of gene)
You are 2 years of age or older
You have severe manifestations (symptoms) of PROS that require systemic therapy (treatment that targets the entire body)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ALPELISIB - VIJOICE (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Vijoice.

REFERENCES
Vijoice [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals, Corporation; April 2024.

For Part D use only:

ALPELISIB - VIJOICE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 04/22
Client Approval: 06/24
P&T Approval: 07/22

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AMANTADINE EXTENDED RELEASE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AMANTADINE HCL	GOCOVRI		43787 43788	GPI-14 (73200010107020) (73200010107040)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE.

Does the patient have a diagnosis of Parkinson's disease (ICD-10 Group G20)?

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

Is the patient experiencing dyskinesia **AND** receiving levodopa-based therapy?

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #3.

Is the patient experiencing 'OFF' episodes **AND** meets the following criterion?
Gocovri will be used as an adjunctive treatment to levodopa/carbidopa therapy

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AMANTADINE EXTENDED RELEASE (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AMANTADINE EXTENDED RELEASE (Gocovri)** requires the following rule(s) be met for approval:
You have Parkinson's disease (a type of movement disorder)
If you are experiencing dyskinesia (uncontrolled involuntary muscle movements), approval also requires:
You are receiving levodopa-based therapy
If you are experiencing 'OFF' episodes (period of symptoms in between doses), approval also requires:
Gocovri will be used as adjunctive (add-on) treatment to levodopa-carbidopa therapy

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Gocovri.

REFERENCES

Gocovri [Prescribing Information]. Emeryville, CA: Adamas Pharma, LLC.; January 2021.

For Part D use only:

AMANTADINE EXTENDED RELEASE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Medical Required Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25
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Created: 10/17
Client Approval: 06/24
P&T Approval: 04/21

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AMBRISENTAN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AMBRISENTAN	LETAIRIS, AMBRISENTAN	34849		GPI-10 (4016000700)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (World Health Organization Group 1) (ICD-10 I27.0, Group I27.2) and meet **ALL** of the following criteria?
Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
The patient does NOT have idiopathic pulmonary fibrosis (IPF)

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

Is the PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
Mean pulmonary artery pressure (PAP) greater than 20 mmHg
Pulmonary capillary wedge pressure (PCWP) of 15 mmHg or less
Pulmonary vascular resistance (PVR) greater than 2 Wood units

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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AMBRISENTAN (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AMBRISENTAN (Letairis)** requires the following rule(s) be met for approval:

- You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization Group 1: a way to classify the severity of disease)
- Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
- Your pulmonary arterial hypertension diagnosis is confirmed by right heart catheterization (a test used to measure how well the heart is pumping) with ALL of the following lab values:
  - Mean pulmonary artery pressure (PAP: a type of measurement for pulmonary arterial hypertension) greater than 20 mmHg
  - Pulmonary capillary wedge pressure (PCWP: a type of measurement for pulmonary arterial hypertension) of 15 mmHg or less
  - Pulmonary vascular resistance (PVR: a type of measurement for pulmonary arterial hypertension) greater than 2 Wood units
- You do NOT have idiopathic pulmonary fibrosis (lung disease that causes scarring for unknown reason)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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AMBRISENTAN (PART D)

RENEWAL CRITERIA

Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (World Health Organization Group 1) (ICD-10 I27.0, Group I27.2)?

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AMBRISENTAN (Letairis)** requires the following rule(s) be met for renewal:
You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization Group 1: a way to classify the severity of disease)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph(s) for Letairis.

REFERENCES

Letairis [Prescribing Information]. Foster City, CA: Gilead Sciences, Inc; August 2019.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AMBRISENTAN (PART D)

For Part D use only:

AMBRISENTAN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	PULMONARY ARTERIAL HYPERTENSION (PAH): INITIAL: DIAGNOSIS CONFIRMED BY RIGHT HEART CATHETERIZATION WITH THE FOLLOWING PARAMETERS: 1) MEAN PULMONARY ARTERY PRESSURE (PAP) GREATER THAN 20 MMHG, 2) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF 15 MMHG OR LESS, AND 3) PULMONARY VASCULAR RESISTANCE (PVR) GREATER THAN 2 WOOD UNITS.
Age Restrictions	N/A
Prescriber Restrictions	PAH: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	PAH: INITIAL: DOES NOT HAVE IDIOPATHIC PULMONARY FIBROSIS.

Created: 10/22
Effective: 01/01/26 Client Approval: 01/26 P&T Approval: 01/24

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AMIFAMPRIDINE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AMIFAMPRIDINE PHOSPHATE	FIRDAPSE	36930		GPI-10 (7600001210)	
AMIFAMPRIDINE	RUZURGI	34158		GPI-10 (7600001200)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of Lambert-Eaton myasthenic syndrome (LEMS) (ICD-10 G70.80) and meet **ALL** of the following criteria?
Therapy is prescribed by or in consultation with a neurologist, hematologist, or oncologist
Diagnosis is confirmed by electrodiagnostic studies (e.g., reduced compound muscle action potential (CMAP)) and/or voltage-gated calcium channel (VGCC) antibody testing AND clinical triad of muscle weakness, autonomic dysfunction, and decreased tendon reflexes

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

Is the request for Firdapse **AND** the patient meets the following criterion?
The patient is 6 years of age or older

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #3.

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AMIFAMPRIDINE (PART D)

INITIAL CRITERIA (CONTINUED)

Is the request for Ruzurgi?

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AMIFAMPRIDINE (Firdapse, Ruzurgi)** requires the following rule(s) be met for approval:
You have Lambert-Eaton myasthenic syndrome (a type of muscle disorder)
Therapy is prescribed by or in consultation with a neurologist (type of brain doctor), hematologist (a type of blood doctor), or oncologist (a type of cancer doctor)
Your diagnosis is confirmed by ALL of the following:
- Electrodiagnostic studies and/or voltage-gated calcium channel (type of lab tests) antibody testing
- Three clinical symptoms of muscle weakness, autonomic dysfunction (nerve dysfunction), and decreased tendon reflexes

If you are requesting Firdapse, approval also requires:
- You are 6 years of age or older

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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AMIFAMPRIDINE (PART D)

RENEWAL CRITERIA

Does the patient have a diagnosis of Lambert-Eaton myasthenic syndrome (LEMS) (ICD-10 G70.80) **AND** meet the following criterion?
The patient has shown improvement or stabilization in muscle weakness compared to baseline

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AMIFAMPRIDINE (Firdapse, Ruzurgi)** requires the following rule(s) be met for renewal:
You have Lambert-Eaton myasthenic syndrome (a type of muscle disorder)
You have shown improvement or stabilization in muscle weakness compared to baseline

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Firdapse and Ruzurgi.

REFERENCES

Firdapse [Prescribing Information]. Coral Gables, FL: Catalyst Pharmaceuticals, Inc: September 2022.
Ruzurgi [Prescribing Information]. Princeton, NJ: Jacobus Pharmaceutical Company, Inc.; April 2020.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AMIFAMPRIDINE (PART D)

For Part D use only:

AMIFAMPRIDINE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	LAMBERT-EATON MYASTHENIC SYNDROME (LEMS): INITIAL: DIAGNOSIS CONFIRMED BY 1) ELECTRODIAGNOSTIC STUDIES AND/OR VOLTAGE-GATED CALCIUM CHANNEL (VGCC) ANTIBODY TESTING, AND 2) CLINICAL TRIAD OF MUSCLE WEAKNESS, AUTONOMIC DYSFUNCTION, AND DECREASED TENDON REFLEXES.
Age Restrictions	N/A
Prescriber Restrictions	LEMS: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST, HEMATOLOGIST, OR ONCOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS
Other Criteria	LEMS: RENEWAL: IMPROVEMENT OR STABILIZATION IN MUSCLE WEAKNESS COMPARED TO BASELINE.

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25 Created: 12/18
Commercial Effective: N/A Client Approval: 08/24 P&T Approval: 10/22

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AMIKACIN LIPOSOMAL INH (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AMIKACIN LIPOSOMAL/ NEB. ACCESSR	ARIKAYCE	45298		GPI-10 (0700001012)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

Does the patient have a diagnosis of *Mycobacterium avium complex* (MAC) lung disease (ICD-10 A31.0) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a pulmonologist or infectious disease specialist
- The patient has NOT achieved negative sputum cultures after a minimum of 6 consecutive months of multidrug background regimen therapy
- Arikayce will be used as part of a combination antibacterial drug regimen

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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AMIKACIN LIPOSOMAL INH (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AMIKACIN LIPOSOMAL INH (Arikayce)** requires the following rules be met for approval:
You have *Mycobacterium avium complex* (MAC: a type of bacteria) lung disease
You are 18 years of age or older
Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or infectious disease specialist (a doctor who specializes in the treatment of infections)
You do not have negative sputum cultures (lab tests of mucus in your lungs) after a minimum of 6 consecutive months of multidrug background regimen therapy
Arikayce will be used as part of a combination antibacterial drug regimen

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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AMIKACIN LIPOSOMAL INH (PART D)

RENEWAL CRITERIA

Is the request for the first renewal of Arikayce for treatment of *Mycobacterium avium complex* (MAC) lung disease (ICD-10 A31.0) and the patient meets **ALL** of the following criteria?
The patient has had at least ONE negative sputum culture for MAC by 6 months of Arikayce treatment
The patient has NOT had a positive MAC sputum culture after consecutive negative cultures
The patient has improvement in symptoms

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #2.

Is the request for the second or subsequent renewal of Arikayce for treatment of *Mycobacterium avium complex* (MAC) lung disease (ICD-10 A31.0) and the patient meets **ALL** of the following criteria?
The patient has had at least THREE negative sputum cultures for MAC by 12 months of Arikayce treatment
The patient has NOT had a positive MAC sputum culture after consecutive negative cultures
The patient has improvement in symptoms

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AMIKACIN LIPOSOMAL INH (Arikayce)** requires the following rules be met for renewal:
You have *Mycobacterium avium complex* (MAC: a type of bacteria) lung disease
You have NOT had a positive MAC sputum culture after consecutive negative cultures (lab tests of mucus in your lungs)
You have improvement in symptoms
(Renewal denial text continued on next page)

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AMIKACIN LIPOSOMAL INH (PART D)

RENEWAL CRITERIA (CONTINUED)

You meet ONE of the following:
- For the first renewal request, approval requires at least ONE negative sputum culture (lab test of mucus in your lungs) for MAC by 6 months of Arikayce treatment
- For second or subsequent renewal requests, approval requires at least THREE negative sputum cultures for MAC by 12 months of Arikayce treatment

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Arikayce.

REFERENCES
Arikayce [Prescribing information]. Bridgewater, NJ. Insmed Incorporated; March 2020.

For Part D use only:

AMIKACIN LIPOSOMAL INH (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	MYCOBACTERIUM AVIUM COMPLEX (MAC) LUNG DISEASE: RENEWAL: 1) NO POSITIVE MAC SPUTUM CULTURE AFTER CONSECUTIVE NEGATIVE CULTURES, AND 2) IMPROVEMENT IN SYMPTOMS. ADDITIONALLY, FOR FIRST RENEWAL, APPROVAL REQUIRES AT LEAST ONE NEGATIVE SPUTUM CULTURE FOR MAC BY SIX MONTHS OF ARIKAYCE TREATMENT. FOR SECOND AND SUBSEQUENT RENEWALS, APPROVAL REQUIRES AT LEAST THREE NEGATIVE SPUTUM CULTURES FOR MAC BY 12 MONTHS OF ARIKAYCE TREATMENT.
Age Restrictions	N/A
Prescriber Restrictions	MAC LUNG DISEASE: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A PULMONOLOGIST OR INFECTIOUS DISEASE SPECIALIST.
Coverage Duration	INITIAL/RENEWAL: 6 MONTHS
Other Criteria	N/A

Created: 10/18
Effective: 01/01/26 Client Approval: 01/26 P&T Approval: 10/18

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AMIVANTAMAB-HYALURONIDASE-LPUJ BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AMIVANTAMAB-HYALURONIDASE-LPUJ	RYBREVANT FASPRO	51068		GPI-10 (2199000203)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	Yes	No	Yes	Yes	No	Yes	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

Is this a pharmacy call?

If yes, continue to #3.
If no, continue to #2.

Is the requested medication going to be filled at a pharmacy?

If yes, continue to #3.
If no, **Refer to plan. (This should be processed under the member's medical benefit).**

Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

If no, continue to #4.

Is the pharmacy dispensing the drug directly to the member or member's representative?

If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

If no, continue to #5.

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AMIVANTAMAB-HYALURONIDASE-LPUJ BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

Is the internal HQ code ML500, SFC01, or SUM03?

If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).
For PAC's: Send an email to plan (reference UNSAD section of PACIP).

If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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AMIVANTAMAB-HYALURONIDASE-LPUJ BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

Does the patient have a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) **AND** meet the following criterion?
The patient is 18 years of age or older

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

Does the patient have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations?

If yes, continue to #3.
If no, continue to #5.

Does the patient meet **ALL** of the following criteria?
The patient's mutation is detected by an FDA-approved test
Rybrevant Faspro will be used in combination with lazertinib (Lazcluze)

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #4.

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AMIVANTAMAB-HYALURONIDASE-LPUJ BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

Does the patient meet **ALL** of the following criteria?
- Rybrevant Faspro will be used in combination with carboplatin and pemetrexed
- The patient's disease has progressed while on or after epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor therapy (e.g., Tagrisso [osimertinib], Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib])

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

Does the patient have epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test, and meet **ONE** of the following criteria?
- Rybrevant Faspro will be used in combination with carboplatin and pemetrexed
- Rybrevant Faspro will be used as a single agent and the patient's disease has progressed on or after platinum-based chemotherapy (e.g., cisplatin, carboplatin)

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AMIVANTAMAB-HYALURONIDASE-LPUJ (Rybrevant Faspro)** requires the following rule(s) be met for approval:
- You have locally advanced or metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to nearby tissue, lymph nodes, or other parts of the body)
- You are 18 years of age or older

(Denial text continued on next page)

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AMIVANTAMAB-HYALURONIDASE-LPUJ BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

If you have epidermal growth factor receptor (EGFR: a type of protein) exon 19 deletions or exon 21 L858R substitution mutations (abnormal changes in a type of gene), approval also requires ONE of the following:

Your mutation is detected by a Food and Drug Administration (FDA)-approved test AND Rybrevant Faspro will be used in combination with lazertinib (Lazcluze)

Rybrevant Faspro will be used in combination with carboplatin and pemetrexed AND your disease has progressed while on or after epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor therapy (such as Tagrisso [osimertinib], Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib])

If you have epidermal growth factor receptor (EGFR: a type of protein) exon 20 insertion mutations (abnormal changes in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test, approval also requires you meet ONE of the following:

Rybrevant Faspro will be used in combination with carboplatin and pemetrexed

Rybrevant Faspro will be used as a single agent AND your disease has progressed on or after platinum-based chemotherapy (such as cisplatin, carboplatin)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rybrevant Faspro.

The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Rybrevant Faspro [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; December 2025.

Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed December 29, 2025].

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AMIVANTAMAB-HYALURONIDASE-LPUJ BvD (PART D)

For Part D use only:

AMIVANTAMAB-HYALURONIDASE-LPUJ (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 12/25
Effective: 01/12/26 Client Approval: 12/25 P&T Approval: 01/26

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AMIVANTAMAB-VMJW BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AMIVANTAMAB-VMJW	RYBREVANT	47385		GPI-10 (2135971080)	

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

Is this a pharmacy call?

If yes, continue to #3.
If no, continue to #2.

Is the requested medication going to be filled at a pharmacy?

If yes, continue to #3.
If no, **Refer to plan. (This should be processed under the member's medical benefit)**

Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

If yes, continue to #6.
If no, continue to #4.

Is the pharmacy dispensing the drug directly to the member or member's representative?

If yes, continue to #6.
If no, continue to #5.

Is the internal HQ code ML500, SFC01, or SUM03?

If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).
For PAC's: Send an email to plan (reference UNSAD section of PACIP).

If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

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AMIVANTAMAB-VMJW BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

Is the drug administered via an implantable pump?

If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field.).**

If no, continue to #7.

Is the drug administered using an external pump?

If yes, continue to #8.
If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

Is the drug specifically infused through an external infusion pump covered by Medicare?

If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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AMIVANTAMAB-VMJW BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

Does the patient have a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) **AND** meet the following criterion?
The patient is 18 years of age or older

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

Does the patient have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations?

If yes, continue to #3.
If no, continue to #5.

Does the patient meet **ALL** of the following criteria?
The patient's mutation is detected by an FDA-approved test
Rybrevant will be used in combination with lazertinib (Lazcluze)

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #4.

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AMIVANTAMAB-VMJW BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

Does the patient meet **ALL** of the following criteria?
- Rybrevant will be used in combination with carboplatin and pemetrexed
- The patient's disease has progressed while on or after epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor therapy (e.g., Tagrisso [osimertinib], Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib])

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

Does the patient have epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test, and meet **ONE** of the following criteria?
- Rybrevant will be used in combination with carboplatin and pemetrexed
- Rybrevant will be used as a single agent for a patient whose disease has progressed on or after platinum-based chemotherapy (e.g., cisplatin, carboplatin)

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AMIVANTAMAB-VMJW (Rybrevant)** requires the following rule(s) be met for approval:
- You have locally advanced or metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to nearby tissue, lymph nodes, or other parts of the body)
- You are 18 years of age or older

(Denial text continued on next page)

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AMIVANTAMAB-VMJW BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

If you have epidermal growth factor receptor (EGFR: a type of protein) exon 19 deletions or exon 21 L858R substitution mutations (abnormal changes in a type of gene), approval also requires ONE of the following:

Your mutation is detected by a Food and Drug Administration (FDA)-approved test AND Rybrevant will be used in combination with lazertinib (Lazcluze)

Rybrevant will be used in combination with carboplatin and pemetrexed AND your disease has progressed while on or after epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor therapy (such as Tagrisso [osimertinib], Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib])

If you have epidermal growth factor receptor (EGFR: a type of protein) exon 20 insertion mutations (abnormal changes in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test, approval also requires you meet ONE of the following:

Rybrevant will be used in combination with carboplatin and pemetrexed

Rybrevant will be used as a single agent AND your disease has progressed on or after platinum-based chemotherapy (such as cisplatin, carboplatin)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rybrevant.

The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B. Drugs administered by an implantable pump are covered under Part B. Drugs administered via an external pump are covered under Part B if they are included under the local coverage policy of the applicable Medicare coverage policies (National and/or Local Coverage Policies). Drugs administered via an external pump that are not included under the applicable Medicare coverage policies are covered under Part D. A CMS website to assist with National and Local Coverage Determination for BvD review is http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx

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AMIVANTAMAB-VMJW BvD (PART D)

REFERENCES

Rybrevant [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; February 2025.
Medicare Prescription Drug Benefit Manual Chapter 6 – Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed May 21, 2025].

For Part D use only:

AMIVANTAMAB-VMJW (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 06/21
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 10/24

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AMLODIPINE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AMLODIPINE BESYLATE	SDMALO	06494		GPI-10 (3400000310)	BRAND = SDMALO

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

Does the patient have a diagnosis of hypertension (ICD-10 I10) and meet **ALL** of the following criteria?
The patient is 6 years of age or older
The patient has a contraindication to or is unable to swallow amlodipine tablets

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #2.

Does the patient have a diagnosis of chronic stable angina (ICD-10 I20.9, I20.89) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
The patient has a contraindication to or is unable to swallow amlodipine tablets

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #3.

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AMLODIPINE (PART D)

GUIDELINES FOR USE (CONTINUED)

Does the patient have a diagnosis of confirmed or suspected vasospastic angina (Prinzmetal's or variant angina) (ICD-10 I20.1) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
The patient has a contraindication to or is unable to swallow amlodipine tablets

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #4.

Does the patient have a diagnosis of angiographically documented coronary artery disease (CAD) (ICD-10 Group I25) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
The patient does not have heart failure OR an ejection fraction of less than 40%
The patient has a contraindication to or is unable to swallow amlodipine tablets

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AMLODIPINE (Sdmalo)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Hypertension (high blood pressure)
- Chronic stable angina (a type of heart condition)
- Confirmed or suspected vasospastic angina (Prinzmetal's or variant angina) (a type of heart condition)
- Angiographically documented coronary artery disease (a type of heart condition that has been confirmed by a type of imaging test)

If you have hypertension, approval also requires:
- You are 6 years of age or older
- You have a contraindication to (harmful for you to use) or are unable to swallow amlodipine tablets

If you have chronic stable angina, approval also requires:
- You are 18 years of age or older
- You have a contraindication to (harmful for you to use) or are unable to swallow amlodipine tablets

(Denial text continued on next page)
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AMLODIPINE (PART D)

GUIDELINES FOR USE (CONTINUED)

If you have confirmed or suspected vasospastic angina (Prinzmetal's or variant angina), approval also requires:
You are 18 years of age or older
You have a contraindication to (harmful for you to use) or are unable to swallow amlodipine tablets

If you have angiographically documented coronary artery disease (CAD), approval also requires:
You are 18 years of age or older
You do not have heart failure (a type of heart condition) OR an ejection fraction (evaluates heart function) of less than 40 percent
You have a contraindication to (harmful for you to use) or are unable to swallow amlodipine tablets

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Sdmalo.

REFERENCES
Sdmalo [Prescribing Information]. Edison, NJ: Brillian Pharma Inc.; July 2025.

For Part D use only:

AMLODIPINE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	HYPERTENSION, CORONARY ARTERY DISEASE: CONTRAINDICATION TO OR UNABLE TO SWALLOW AMLODIPINE TABLETS.

Created: 01/26
Effective: 02/09/26 Client Approval: 01/26 P&T Approval: 04/26

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AMPHETAMINE SULFATE DvE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AMPHETAMINE SULFATE	EVEKEO, AMPHETAMINE SULFATE		19821 19822	GPI-14 (61100010100320, 61100010100310)	

These are DvE drugs requiring a payment determination for "Part D" or "Non-Part D".

PAYMENT DETERMINATION CRITERIA

Does the patient have a diagnosis of exogenous obesity (ICD-10 Group E66.0)?

If yes, **set CMS_DVE_OVR to 'E' and approve for 12 months by GPID or GPI-14. Document in the PA comments: Payment Determination Override. This is not a Part D indication.**

If no, continue to #2.

Does the patient have **ONE** of the following diagnoses and associated criteria?
Narcolepsy (ICD-10 Group G47.41) AND the patient is 6 years of age or older
Attention deficit disorder with hyperactivity (ICD-10 Group F90) AND the patient is 3 years of age or older

If yes, **set CMS_DVE_OVR to 'D' and approve for 12 months by HICL or GPI-10. Document in the PA comments: Part D Determination Override.**

If no, **set CMS_DVE_OVR to 'E' and approve for 12 months by GPID or GPI-14. Document in the PA comments: Payment Determination Override. This is not a Part D indication.**

NOTE: If the claim rejects after analyzing, then follow the clinical authorization process within HQ notes.

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AMPHETAMINE SULFATE DvE (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AMPHETAMINE SULFATE (Evekeo)** requires the following rule(s) be met for approval:
You have ONE of the following:
Narcolepsy (a type of sleep condition)
Attention deficit disorder with hyperactivity (a type of mental health disorder)
If you have narcolepsy, approval also requires:
You are 6 years of age or older
If you have attention deficit disorder with hyperactivity, approval also requires:
You are 3 years of age or older

Note: The requested medication will NOT be approved if the request is for exogenous obesity (a condition of higher than normal body fat)

RATIONALE

To limit the coverage of Evekeo to the Medicare Part D covered indication of attention deficit disorder with hyperactivity and narcolepsy, and exclude coverage for the treatment of obesity. For further information, please refer to the Prescribing Information and/or Drug Monograph for Evekeo.

REFERENCES

Evekeo [Prescribing Information]. Atlanta, GA: Arbor Pharmaceuticals LLC; October 2025.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements. Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf. [Accessed March 2, 2026].

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AMPHETAMINE SULFATE DvE (PART D)

For Part D use only:

AMPHETAMINE SULFATE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	TREATMENT OF EXOGENOUS OBESITY
Required Medical Information	N/A
Age Restrictions	NARCOLEPSY: 6 YEARS OF AGE AND OLDER. ATTENTION DEFICIT DISORDER WITH HYPERACTIVITY (ADHD): 3 YEARS OF AGE AND OLDER.
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 10/19
Effective: 03/09/26 Client Approval: 03/26 P&T Approval: 05/19

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ANAKINRA (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ANAKINRA	KINERET	22953		GPI-10 (6626001000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Is the request for the treatment of coronavirus disease 2019 (COVID-19) in a hospitalized adult?

If yes, **do not approve**. [NOTE: This indication is for hospital use only.]
DENIAL TEXT: See initial denial text at the end of the guideline.

If no, continue to #2.

Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist
- The patient had a trial of or contraindication to TWO of the following preferred agents:
  - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
  - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
  - Orencia (abatacept)
- Kineret will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.
If no, continue to #3.

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ANAKINRA (PART D)

INITIAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of cryopyrin-associated periodic syndrome (CAPS), including neonatal-onset multisystem inflammatory disease (NOMID) (ICD-10 M04.2) and meet **ALL** of the following criteria?
- The patient had genetic testing for gain-of-function mutations in the NLRP3 gene OR has inflammatory markers (i.e., elevated CRP, ESR, serum amyloid A protein (SAA) or S100 proteins)
- The patient has TWO of the following: urticarial-like rash (neutrophilic dermatitis), cold-triggered episodes, sensorineural hearing loss, musculoskeletal symptoms, chronic aseptic meningitis, skeletal abnormalities
- Kineret will NOT be used concurrently with another systemic biologic (e.g., Arcalyst [rilonacept]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CAPS, including NOMID

If yes, **approve for lifetime by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #4.

Does the patient have a diagnosis of deficiency of interleukin-1 receptor antagonist (DIRA) (ICD-10 M04.8) and meet **ALL** of the following criteria?
- The patient had genetic testing for gain-of-function mutations in the IL1RN gene OR has inflammatory markers (i.e., elevated CRP, ESR)
- The patient has ONE of the following: pustular psoriasis-like rashes, osteomyelitis, absence of bacterial osteomyelitis, nail changes (i.e., onychomadesis)
- Kineret will NOT be used concurrently with another systemic biologic (e.g., Arcalyst [rilonacept]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of DIRA

If yes, **approve for lifetime by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See initial denial text at the end of the guideline.

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ANAKINRA (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ANAKINRA (Kineret)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Moderate to severe rheumatoid arthritis (a type of joint condition)
- Cryopyrin-associated periodic syndromes (CAPS) including neonatal-onset multisystem inflammatory disease (NOMID) (types of immune system disorders)
- Deficiency of interleukin-1 receptor antagonist (DIRA: a type of immune system disorder)

If you have moderate to severe rheumatoid arthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
  - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
  - Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/ Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as Humira (adalimumab)/ Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
  - Orencia (abatacept)
- You will NOT use Kineret concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis

(Initial denial text continued on next page)

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ANAKINRA (PART D)

INITIAL CRITERIA (CONTINUED)

If you have cryopyrin-associated periodic syndromes, including neonatal-onset multisystem inflammatory disease, approval also requires:

- You had genetic testing for gain-of-function mutations (abnormal change in gene) in the *NLRP3* gene (a type of gene), OR you have inflammatory markers (elevated C-reactive protein [CRP: sign of inflammation], erythrocyte sedimentation rate [ESR: a type of blood test], serum amyloid A protein [SAA: a type of protein] or S100 proteins [a type of protein])
- You have TWO of the following: urticarial-like rash (neutrophilic dermatitis: a type of skin condition), cold-triggered episodes, sensorineural hearing loss (SNHL: a type of hearing loss), musculoskeletal symptoms (symptoms related to the muscles and bones), chronic aseptic meningitis (inflammation of the brain and spinal cord), skeletal (bone) abnormalities
- You will NOT use Kineret concurrently (at the same time) with another systemic biologic (such as Arcalyst [rilonacept]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of cryopyrin-associated periodic syndromes, including neonatal-onset multisystem inflammatory disease

If you have deficiency of interleukin-1 receptor antagonist, approval also requires:

- You had genetic testing for gain-of-function mutations (abnormal change in gene) in the *IL1RN gene* (a type of gene), OR you have inflammatory markers (elevated C-reactive protein [CRP: sign of inflammation], erythrocyte sedimentation rate [ESR: a type of blood test])
- You have ONE of the following: pustular psoriasis-like rashes (a type of skin condition), osteomyelitis (bone infection), absence of bacterial osteomyelitis, nail changes (onychomadesis: nail shedding)
- You will NOT use Kineret concurrently (at the same time) with another systemic biologic (such as Arcalyst [rilonacept]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of deficiency of interleukin-1 receptor antagonist

NOTE: Kineret will not be approved for the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults

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ANAKINRA (PART D)

RENEWAL CRITERIA

NOTE: For neonatal-onset multisystem inflammatory disease (NOMID) cryopyrin-associated periodic syndromes (CAPS) or deficiency of interleukin-1 receptor antagonist (DIRA), please refer to the Initial Criteria section.

Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
The patient continues to benefit from the medication
Kineret will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ANAKINRA (Kineret)** requires the following rule(s) be met for renewal:
You have moderate to severe rheumatoid arthritis (a type of joint condition)
You continue to benefit from the medication
You will NOT use Kineret concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis

RATIONALE
For further information, please refer to the prescribing information and/or Drug Monograph for Kineret.

REFERENCES
Kineret [Prescribing Information]. Stockholm, Sweden: Swedish Orphan Biovitrum; October 2025.

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ANAKINRA (PART D)

For Part D use only:

ANAKINRA (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	CORONAVIRUS DISEASE 2019 (COVID-19) IN HOSPITALIZED ADULTS.
Required Medical Information	INITIAL: CRYOPYRIN-ASSOCIATED PERIODIC SYNDROMES (CAPS): 1) ONE OF THE FOLLOWING: (A) GENETIC TEST FOR GAIN-OF-FUNCTION MUTATIONS IN THE NLRP3 GENE, OR (B) HAS INFLAMMATORY MARKERS (I.E., ELEVATED CRP, ESR, SERUM AMYLOID A PROTEIN (SAA) OR S100 PROTEINS), AND 2) TWO OF THE FOLLOWING: URTICARIAL-LIKE RASH (NEUTROPHILIC DERMATITIS), COLD-TRIGGERED EPISODES, SENSORINEURAL HEARING LOSS, MUSCULOSKELETAL SYMPTOMS, CHRONIC ASEPTIC MENINGITIS, SKELETAL ABNORMALITIES. DEFICIENCY OF INTERLEUKIN-1 RECEPTOR ANTAGONIST (DIRA): 1) ONE OF THE FOLLOWING: (A) GENETIC TEST FOR GAIN-OF-FUNCTION MUTATIONS IN THE IL1RN GENE, OR (B) HAS INFLAMMATORY MARKERS (I.E., ELEVATED CRP, ESR), AND 2) ONE OF THE FOLLOWING: PUSTULAR PSORIASIS-LIKE RASHES, OSTEOMYELITIS, ABSENCE OF BACTERIAL OSTEOMYELITIS, ONYCHOMADESIS.
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: RHEUMATOID ARTHRITIS (RA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST.
Coverage Duration	RA: INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS. CAPS, DIRA: LIFETIME.
Other Criteria	INITIAL: ALL INDICATIONS: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION. RA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, XELJANZ, RINVOQ, ORENCIA. RENEWAL: RA: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR THE SAME INDICATION.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ANIFROLUMAB-FNIA (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ANIFROLUMAB-FNIA	SAPHNELO	47512		GPI-10 (9942701025)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of moderate to severe systemic lupus erythematosus (SLE) (ICD-10 Group M32) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist
- The patient is receiving standard SLE therapy (e.g., oral corticosteroids, antimalarials, immunosuppressants)
- Saphnelo will NOT be used concurrently with another systemic biologic (e.g., Benlysta [belimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of SLE

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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ANIFROLUMAB-FNIA (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ANIFROLUMAB-FNIA (Saphnelo)** requires the following rule(s) be met for approval:

You have moderate to severe systemic lupus erythematosus (SLE: a type of immune condition)
You are 18 years of age or older
Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
You are receiving standard SLE therapy (such as oral corticosteroids, antimalarials, immunosuppressants)
You will NOT use Saphnelo concurrently (at the same time) with another systemic biologic (such as Benlysta [belimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of SLE

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ANIFROLUMAB-FNIA (PART D)

RENEWAL CRITERIA

Does the patient have a diagnosis of moderate to severe systemic lupus erythematosus (SLE) (ICD-10 Group M32) and meet **ALL** of the following criteria?
The patient has had clinical improvement while on therapy
Saphnelo will NOT be used concurrently with another systemic biologic (e.g., Benlysta [belimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of SLE

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ANIFROLUMAB-FNIA (Saphnelo)** requires the following rule(s) be met for renewal:
You have moderate to severe systemic lupus erythematosus (SLE: a type of immune condition)
You have had clinical improvement while on therapy
You will NOT use Saphnelo concurrently (at the same time) with another systemic biologic (such as Benlysta [belimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of SLE

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Saphnelo.

REFERENCES

Saphnelo [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals, LP., August 2024.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ANIFROLUMAB-FNIA (PART D)

For Part D use only:

ANIFROLUMAB-FNIA (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	SYSTEMIC LUPUS ERYTHEMATOSUS (SLE): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	SLE: INITIAL: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR SLE. RENEWAL: 1) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR SLE, 2) CLINICAL IMPROVEMENT WHILE ON THERAPY.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ANTI-NAUSEA AGENT BVD DETERMINATION (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ONDANSETRON HCL	ONDANSETRON HCL	06055		GPI-14 (50250065050310), (50250065052070), (50250065050320)	ROUTE = ORAL, GENERIC ONLY
ONDANSETRON	ONDANSETRON ODT	19058		GPI-10 (5025006500)	
GRANISETRON HCL	GRANISETRON HCL, GRANISOL	07611		GPI-10 (5025003510)	ROUTE = ORAL
APREPITANT	EMEND, APREPITANT	25058		GPI-10 (5028002000)	ROUTE = ORAL
NETUPITANT/ PALONOSETRON HCL	AKYNZEO	41467		GPI-10 (5030990229)	
ROLAPITANT HCL	VARUBI	42468		GPI-10 (5028005020)	ROUTE = ORAL
DOLASETRON MESYLATE	ANZEMET	16576		GPI-10 (5025002520)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

NOTE: This PA is for administrative purposes to determine Medicare Part B versus Medicare Part D funding and applies to ORAL forms of these agents only.

GUIDELINES FOR USE

Is the request for Emend (aprepitant)?

If yes, continue to #3.
If no, continue to #2.

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ANTI-NAUSEA AGENT BVD DETERMINATION (PART D)

GUIDELINES FOR USE (CONTINUED)

Is the prescription written for a full therapeutic replacement for an intravenous anti-emetic drug as part of a cancer chemotherapeutic regimen for use within 48 hours of the patient receiving cancer treatment?

If yes, **approve for 12 months under Part B by HICL or GPI-10 (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, **approve for 12 months under Part D by HICL or GPI-10 (Populate the B vs. D field with a 'D' in the PA override field).**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

Does the patient meet **ALL** of the following criteria?

The patient is receiving the oral anti-emetic drug as full therapeutic replacement for an intravenous anti-emetic drug as part of a cancer chemotherapeutic regimen, for use within 48 hours of the patient receiving cancer treatment

Emend (aprepitant) will be used as part of the three-drug regimen which includes ALL of the following drugs:
Emend (aprepitant)
5-HT3 antagonist (e.g., granisetron, ondansetron, dolasetron)
Dexamethasone (a corticosteroid)
[**NOTE**: Recent claims for a 5-HT3 antagonist and Dexamethasone can be assumed as being used in combination with Emend (aprepitant)].

If yes, **approve for 12 months under Part B by HICL or GPI-10 (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, **approve for 12 months under Part D by HICL or GPI-10 (Populate the B vs. D field with a 'D' in the PA override field).**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

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ANTI-NAUSEA AGENT BVD DETERMINATION (PART D)

RATIONALE

This drug may be covered under Medicare part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination.

Ensure that any use as a full therapeutic replacement for an intravenous anti-emetic drug as part of a cancer chemotherapeutic regimen within 48 hours of the patient receiving cancer treatment is billed under Part B.

Aprepitant (Emend) will be covered under Part B when used as part of a 3-drug combination regimen: Days 1- 3 of the oral anti-emetic 3-drug combination of Emend, a 5-HT3 antagonist, and dexamethasone. This regimen acts as a full replacement for IV anti-emetic therapy for patients receiving one or more anti-cancer chemotherapeutic agents.

REFERENCES

Medicare Prescription Drug Benefit Manual Chapter 6 – Part D Drugs and Formulary Requirements, Appendix C- Summary of Coverage Policy Medicare Part B Versus Part DCoverage Issues. Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed July 10, 2024].

Clarification for Billing Part B versus Part D for the Anti-emetic Aprepitant (Emend®), MLNMatters Number SE0910, Centers for Medicare and Medicaid Services, January 25, 2013. Available at: https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/SE0910.pdf. [Accessed July 10, 2024].

For Part D use only:

ANTI-NAUSEA AGENT BVD DETERMINATION (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	PART D DOES NOT COVER THIS DRUG WHEN USED FOR FULL THERAPEUTIC REPLACEMENT FOR AN INTRAVENOUS ANTI-EMETIC DRUG AS PART OF A CANCER CHEMOTHERAPEUTIC REGIMEN FOR USE WITHIN 48 HOURS OF THE PATIENT RECEIVING CANCER TREATMENT
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

APALUTAMIDE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
APALUTAMIDE	ERLEADA	44773		GPI-10 (2140241000)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

Does the patient have **ONE** of the following diagnoses?
- Metastatic castration-sensitive prostate cancer (mCSPC) (ICD-10 Z19.1, C61)
- Non-metastatic castration-resistant prostate cancer (nmCRPC) (ICD-10 Z19.2, C61)

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

Does the patient meet **ONE** of the following criteria?
- The patient has received a bilateral orchiectomy
- The patient has a castrate level of testosterone (i.e., less than 50 ng/dL)
- Erleada will be used concurrently with a gonadotropin releasing hormone (GnRH) analog (e.g., Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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APALUTAMIDE (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **APALUTAMIDE (Erleada)** requires the following rule(s) be met for approval:

You have ONE of the following:
- Metastatic castration-sensitive prostate cancer (mCSPC: prostate cancer that has spread to other parts of the body and responds to hormone therapy)
- Non-metastatic castration-resistant prostate cancer (nmCRPC: prostate cancer that has not spread to other parts of the body and does not respond to hormone therapy)

You meet ONE of the following:
- You have received a bilateral orchiectomy (surgical removal of both testicles)
- You have a castrate level of testosterone (blood testosterone levels are less than 50 ng/dL)
- Erleada will be used concurrently (at the same time) with a gonadotropin releasing hormone analog (such as Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the prescribing information and/or drug monograph for Erleada.

REFERENCES

Erleada [Prescribing Information]. Horsham, PA: Janssen; August 2024.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

APALUTAMIDE (PART D)

For Part D use only:

APALUTAMIDE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	NON-METASTATIC CASTRATION-RESISTANT PROSTATE CANCER (NMCRPC), METASTATIC CASTRATION-SENSITIVE PROSTATE CANCER (MCSPC): 1) RECEIVED A BILATERAL ORCHIECTOMY, 2) CASTRATE LEVEL OF TESTOSTERONE (I.E., LESS THAN 50 NG/DL), OR 3) CONCURRENT USE WITH A GONADOTROPIN RELEASING HORMONE (GNRH) ANALOG.

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ADVANTAGE AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

APOMORPHINE - SL (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
APOMORPHINE HCL	KYNMOBI	01934		GPI-10 (7320301010)	BRAND = KYNMOBI

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of Parkinson's disease (ICD-10 Group G20) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
Therapy is prescribed by or in consultation with a neurologist
Kynmobi will be used for the acute, intermittent treatment of 'OFF' episodes

If yes, **approve for 6 months for all strengths by GPID or GPI-14.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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APOMORPHINE - SL (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **APOMORPHINE - SL (Kynmobi)** requires the following rule(s) be met for approval:
You have Parkinson's disease (a type of movement disorder)
You are 18 years of age or older
Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
Kynmobi will be used for acute, intermittent treatment (sudden and periodic treatment) of 'OFF' episodes (when symptoms return due to your medication for Parkinson's disease wearing off)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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APOMORPHINE - SL (PART D)

RENEWAL CRITERIA

Does the patient have a diagnosis of Parkinson's disease (ICD-10 Group G20) **AND** meet the following criterion?

The patient has had improvement with motor fluctuations during 'OFF' episodes with the use of Kynmobi (e.g., improvement in speech, facial expression, tremor at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair)

If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **APOMORPHINE - SL (Kynmobi)** requires the following rule(s) be met for renewal:
You have Parkinson's disease (a type of movement disorder)
You have had improvement with motor fluctuations during 'OFF' episodes (when symptoms return due to your medications for Parkinson's disease wearing off) with the use of Kynmobi (such as improvement in speech, facial expression, tremor at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kynmobi.

REFERENCES

Kynmobi [Prescribing Information]. Marlborough, MA: Sunovion Pharmaceuticals Inc., September 2022.

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ADVANTAGE AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

APOMORPHINE - SL (PART D)

For Part D use only:

APOMORPHINE - SL (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	PARKINSONS DISEASE (PD): INITIAL: 18 YEARS OF AGE OR OLDER.
Prescriber Restrictions	PD: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS
Other Criteria	PD: RENEWAL: IMPROVEMENT WITH MOTOR FLUCTUATIONS DURING OFF EPISODES WITH THE USE OF THERAPY.

Core	Advantage	Plus
No	Yes	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 06/20
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P&T Approval: 07/20

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

APOMORPHINE - APOKYN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
APOMORPHINE HCL	APOKYN, APOMORPHINE HCL		42078	GPI-14 (7320301010E220)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of advanced Parkinson's disease (PD) (ICD-10 Group G20) and meet **ALL** of the following criteria?
- Apokyn (apomorphine) will be used for the acute, intermittent treatment of hypomobility,'OFF' episodes
- Therapy is prescribed by or in consultation with a neurologist

If yes, **approve for 6 months by GPID or GPI-14.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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APOMORPHINE - APOKYN (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **APOMORPHINE - APOKYN** requires the following rule(s) be met for approval:
You have advanced Parkinson's disease (PD: a type of movement disorder)
Apokyn (apomorphine) will be used for the acute (short-term), intermittent treatment of hypomobility (short and sudden episodes of decreased ability to move), OFF episodes (period of symptoms in between doses)
Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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APOMORPHINE - APOKYN (PART D)

RENEWAL CRITERIA

Does the patient have a diagnosis of advanced Parkinson's disease (PD) (ICD-10 Group G20) **AND** meet the following criterion?

The patient has experienced improvement with motor fluctuations during 'OFF' episodes with the use of Apokyn (apomorphine) (e.g., improvement in speech, facial expression, tremor at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair)

If yes, **approve for 12 months by GPID or GPI-14.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **APOMORPHINE - APOKYN** requires the following rule(s) be met for renewal:
You have advanced Parkinson's disease (PD: a type of movement disorder)
You have experienced improvement with motor fluctuations during OFF episodes (period of symptoms in between doses) with the use of Apokyn (apomorphine) (such as improvement in speech, facial expression, tremor at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Apokyn.

REFERENCES

Apokyn [Prescribing Information]. Rockville, MD: MDD US Operations, LLC; June 2022.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

APOMORPHINE - APOKYN (PART D)

For Part D use only:

APOMORPHINE - APOKYN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	PARKINSONS DISEASE (PD): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST.
Coverage Duration	INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS.
Other Criteria	PD: RENEWAL: IMPROVEMENT WITH MOTOR FLUCTUATIONS DURING OFF EPISODES WHILE ON THERAPY.

Created: 10/19
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 04/19

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

APOMORPHINE - ONAPGO (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
APOMORPHINE HCL	ONAPGO	01934		GPI-10 (7320301010)	BRAND = ONAPGO

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of advanced Parkinson's disease (PD) (ICD-10 Group G20) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
Onapgo will be used for the treatment of motor fluctuations associated with Parkinson's disease
Therapy is prescribed by or in consultation with a neurologist

If yes, **approve for 12 months by GPID or GPI-14.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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APOMORPHINE - ONAPGO (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **APOMORPHINE - ONAPGO** requires the following rule(s) be met for approval:
You have advanced Parkinson's disease (PD: a type of movement disorder)
You are 18 years of age or older
Onapgo will be used for the treatment of motor fluctuations (changes in the ability to move) associated with Parkinson's disease
Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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APOMORPHINE - ONAPGO (PART D)

RENEWAL CRITERIA

Does the patient have a diagnosis of advanced Parkinson's disease (PD) (ICD-10 Group G20) **AND** meet the following criterion?
The patient has experienced improvement in motor symptoms while on Onapgo

If yes, **approve for 12 months by GPID or GPI-14.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **APOMORPHINE - ONAPGO** requires the following rule(s) be met for renewal:
You have advanced Parkinson's disease (PD: a type of movement disorder)
You have experienced improvement in motor symptoms while on Onapgo

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Onapgo.

REFERENCES

Onapgo [Prescribing Information]. Rockville, MD: Supernus Pharmaceuticals, Inc.; February 2025.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

APOMORPHINE - ONAPGO (PART D)

For Part D use only:

APOMORPHINE - ONAPGO (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	PARKINSONS DISEASE (PD): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	PD: RENEWAL: IMPROVEMENT IN MOTOR SYMPTOMS WHILE ON THERAPY.

Created: 02/25
Effective: 08/04/25 Client Approval: 07/25 P&T Approval: 04/25

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

APREMILAST (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
APREMILAST	OTEZLA, OTEZLA XR	40967		GPI-10 (6670001500)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
The patient is 6 years of age or older
Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of PsA

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #2.

Does the patient have a diagnosis of plaque psoriasis (PsO) (ICD-10 L40.0)?

If yes, continue to #3.
If no, continue to #7.

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APREMILAST (PART D)

INITIAL CRITERIA (CONTINUED)

Is the patient's disease mild and the patient meets **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist
- The patient had a trial of or contraindication to one conventional systemic agent (e.g., methotrexate, acitretin, cyclosporine) OR one conventional topical therapy (e.g., topical corticosteroids [e.g., clobetasol, betamethasone])
- The requested medication will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Zoryve (roflumilast)]) for the treatment of mild PsO

If yes, continue to #4.
If no, continue to #5.

Does the patient meet **ONE** of the following criteria?
- The patient has psoriasis covering less than 3% of body surface area (BSA)
- The patient has a static Physician Global Assessment (sPGA) score of 2
- The patient has a Psoriasis Area and Severity Index (PASI) score of 2 to 9

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

Is the patient's disease moderate to severe and the patient meets **ALL** of the following criteria?
- The patient is 6 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist
- The patient has psoriasis covering 3% or more of body surface area (BSA) OR psoriatic lesions affecting the hands, feet, face, scalp, or genital area
- The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Zoryve (roflumilast)]) for the treatment of moderate to severe PsO

If yes, continue to #6.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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APREMILAST (PART D)

INITIAL CRITERIA (CONTINUED)

Does the patient meet **ONE** of the following criteria?
- The patient has had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy)
- The patient has a contraindication or intolerance to both immunosuppressant and PUVA (phototherapy)
- The patient is switching from a different biologic (e.g., Humira [adalimumab]), PDE-4 inhibitor, or JAK inhibitor for the same indication

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

Does the patient have a diagnosis of Behcet's disease (ICD-10 M35.2) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist
- The patient has oral ulcers or a history of recurrent oral ulcers based on clinical symptoms
- The patient had a trial of or contraindication to one or more conservative treatments (e.g., colchicine, topical corticosteroid [e.g., triamcinolone acetonide], oral corticosteroid [e.g., prednisone, methylprednisolone])
- The requested medication will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of Behcet's disease

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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APREMILAST (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **APREMILAST (Otezla, Otezla XR)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Psoriatic arthritis (PsA: a type of skin and joint condition)
- Plaque psoriasis (PsO: a type of skin condition)
- Behcet's disease (a type of inflammation disorder)

If you have psoriatic arthritis, approval also requires:
- You are 6 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of PsA

If you have mild plaque psoriasis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
- You have tried or have a contraindication to (harmful for you to use) one conventional (standard) systemic (treatment that targets the entire body) medication (such as methotrexate, acitretin, cyclosporine) OR one conventional topical treatment (such as topical corticosteroids [such as clobetasol, betamethasone])
- You will NOT use Otezla concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Zoryve (roflumilast)] for the treatment of mild plaque psoriasis
- You meet ONE of the following:
  - You have psoriasis covering less than 3% of your body surface area (BSA)
  - You have a static Physician Global Assessment (sPGA: a measure used to evaluate severity of the disease) score of 2
  - You have a Psoriasis Area and Severity Index (PASI: a measure used to evaluate severity of the disease) score of 2 to 9

(Initial denial text continued on next page)

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APREMILAST (PART D)

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe plaque psoriasis, approval also requires:
- You are 6 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
- You have psoriasis covering 3% or more of your body surface area (BSA) or psoriatic lesions (rashes) affecting your hands, feet, face, scalp, or genital area
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Zoryve (roflumilast)]) for the treatment of moderate to severe plaque psoriasis
- You meet ONE of the following:
  - You have had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy)
  - You have a contraindication (harmful for you to use) or intolerance (side effect) to both immunosuppressant (a type of drug that decreases the body's immune response) and PUVA (phototherapy)
  - You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor, or JAK (Janus kinase) inhibitor for the same indication

If you have Behcet's disease, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You have oral ulcers or a history of repeated oral ulcers based on your symptoms
- You have tried or have a contraindication to (harmful for you to use) one or more conservative treatments (such as colchicine, topical corticosteroid [such as triamcinolone acetonide], oral corticosteroid [such as prednisone, methylprednisolone])
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Behcet's disease

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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APREMILAST (PART D)

RENEWAL CRITERIA

Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
- The patient continues to benefit from the medication
- The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of PsA

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #2.

Does the patient have a diagnosis of plaque psoriasis (PsO) (ICD-10 L40.0)?

If yes, continue to #3.
If no, continue to #5.

Is the patient's disease mild and the patient meets **ALL** of the following criteria?
- The patient continues to benefit from the medication
- The requested medication will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Zoryve (roflumilast)]) for the treatment of mild PsO

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days

If no, continue to #4.

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APREMILAST (PART D)

RENEWAL CRITERIA (CONTINUED)

Is the patient's disease moderate to severe and the patient meets **ALL** of the following criteria?
- The patient continues to benefit from the medication
- The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Zoryve (roflumilast)]) for the treatment of moderate to severe PsO

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the renewal denial text at the end of the guideline.

Does the patient have a diagnosis of Behcet's disease (ICD-10 M35.2) and meet **ALL** of the following criteria?
- The patient continues to benefit from the medication
- The requested medication will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of Behcet's disease

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **APREMILAST (Otezla, Otezla XR)** requires the following rule(s) be met for renewal:
You have ONE of the following:
- Psoriatic arthritis (PsA: a type of skin and joint condition)
- Plaque psoriasis (PsO: a type of skin condition)
- Behcet's disease (a type of inflammation disorder)

(Renewal denial text continued on next page)

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APREMILAST (PART D)

RENEWAL CRITERIA (CONTINUED)

If you have psoriatic arthritis, renewal also requires:
- You continue to benefit from the medication
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of psoriatic arthritis

If you have mild plaque psoriasis, renewal also requires:
- You continue to benefit from the medication
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Zoryve (roflumilast) for the treatment of mild plaque psoriasis

If you have moderate to severe plaque psoriasis, renewal also requires:
- You continue to benefit from the medication
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Zoryve (roflumilast) for the treatment of moderate to severe plaque psoriasis

If you have Behcet's disease, renewal also requires:
- You continue to benefit from the medication
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Behcet's disease

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Otezla/Otezla XR.

REFERENCE
Otezla/Otezla XR [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; August 2025.

For Part D use only:

APREMILAST (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	INITIAL: MILD PLAQUE PSORIASIS (PSO): 1) PSORIASIS COVERING LESS THAN 3 PERCENT OF BODY SURFACE

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	AREA (BSA), 2) STATIC PHYSICIAN GLOBAL ASSESSMENT (SPGA) SCORE OF 2, OR 3) PSORIASIS AREA AND SEVERITY INDEX (PASI) SCORE OF 2 TO 9. MODERATE TO SEVERE PSO: PSORIASIS COVERING 3 PERCENT OR MORE OF BSA, OR PSORIATIC LESIONS AFFECTING THE HANDS, FEET, FACE, SCALP, OR GENITAL AREA.
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST. PSO: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST. BEHCETS DISEASE: PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: MILD PSO: TRIAL OF OR CONTRAINDICATION TO ONE CONVENTIONAL SYSTEMIC THERAPY (E.G., METHOTREXATE, ACITRETIN, CYCLOSPORINE) OR ONE CONVENTIONAL TOPICAL THERAPY (E.G., TOPICAL CORTICOSTEROIDS). MODERATE TO SEVERE PSO: 1) AT LEAST A 3 MONTH TRIAL OF ONE ORAL IMMUNOSUPPRESSANT (CYCLOSPORINE, METHOTREXATE, TACROLIMUS) OR PUVA (PHOTOTHERAPY), 2) CONTRAINDICATION OR INTOLERANCE TO BOTH IMMUNOSUPPRESSANT AND PUVA, OR 3) PATIENT IS SWITCHING FROM A DIFFERENT BIOLOGIC, PDE-4 INHIBITOR, OR JAK INHIBITOR FOR THE SAME INDICATION. BEHCETS DISEASE: 1) HAS ORAL ULCERS OR A HISTORY OF RECURRENT ORAL ULCERS BASED ON CLINICAL SYMPTOMS, AND 2) TRIAL OF OR CONTRAINDICATION TO ONE OR MORE CONSERVATIVE TREATMENTS (E.G., COLCHICINE, TOPICAL CORTICOSTEROID, ORAL CORTICOSTEROID). INITIAL/RENEWAL: ALL INDICATIONS: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION. RENEWAL: ALL INDICATIONS: CONTINUES TO BENEFIT FROM THE MEDICATION.

Created: 04/14
Effective: 02/04/26 Client Approval: 02/26 P&T Approval: 10/25

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

APROCITENTAN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
APROCITENTAN	TRYVIO	49465		GPI-10 (3618001000)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of hypertension (ICD-10 I10) and meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a cardiologist, nephrologist, or endocrinologist
- The patient's blood pressure is NOT controlled on at least three anti-hypertensive agents of different pharmacologic classes (e.g., an angiotensin receptor blocker [e.g., valsartan], a calcium channel blocker [e.g., amlodipine], a diuretic [e.g., hydrochlorothiazide]) at a maximally tolerated dose for at least 4 weeks
- The patient does NOT have resistant hypertension due to white coat effect, medical inertia, poor therapeutic adherence, or secondary causes of hypertension (except sleep apnea)
- Tryvio will be used concurrently with at least three other anti-hypertensive agents (e.g., valsartan, amlodipine, hydrochlorothiazide) at maximally tolerated doses
- The patient had a trial of or contraindication to a potent diuretic (i.e., chlorthalidone or indapamide) AND a mineralocorticoid receptor antagonist (i.e., spironolactone or eplerenone)

If yes, **approve for 2 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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APROCITENTAN (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **APROCITENTAN (Tryvio)** requires the following rule(s) be met for approval:
You have hypertension (high blood pressure)
You are 18 years of age or older
Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor), nephrologist (a type of kidney doctor), or endocrinologist (a type of hormone doctor)
Your blood pressure is NOT controlled on at least three anti-hypertensive medications (drugs used to treat high blood pressure) with different mechanisms of action (such as an angiotensin receptor blocker [such as valsartan], a calcium channel blocker [such as amlodipine], a diuretic [such as hydrochlorothiazide]) at a maximally tolerated dose for at least 4 weeks
You do NOT have resistant hypertension (a type of high blood pressure) due to white coat effect (a condition where blood pressure is higher in a medical setting), medical inertia (when healthcare providers do not make changes to treatment even if the medical condition is poorly controlled), poor therapeutic adherence (not keeping up with therapy), or secondary causes of hypertension (high blood pressure that is caused by another medical condition) (except sleep apnea [a type of sleep condition with difficulty breathing])
You will use Tryvio concurrently (at the same time) with at least three other anti-hypertensive medications (drugs used to treat high blood pressure such as valsartan, amlodipine, hydrochlorothiazide) at maximally tolerated doses
You have tried or have a contraindication to (harmful for you to use) a potent diuretic (chlorthalidone or indapamide) AND a mineralocorticoid receptor antagonist (spironolactone or eplerenone)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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APROCITENTAN (PART D)

RENEWAL CRITERIA

Does the patient have a diagnosis of hypertension (ICD-10 I10) and meet **ALL** of the following criteria?
The patient continues to benefit from the medication
Tryvio will be used concurrently with at least three other anti-hypertensive agents (e.g., valsartan, amlodipine, hydrochlorothiazide) at maximally tolerated doses

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **APROCITENTAN (Tryvio)** requires the following rule(s) be met for renewal:
You have hypertension (high blood pressure)
You continue to benefit from Tryvio
You will use Tryvio concurrently (at the same time) with at least three other anti-hypertensive medications (drugs used to treat high blood pressure such as valsartan, amlodipine, hydrochlorothiazide) at maximally tolerated doses

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tryvio.

REFERENCES

Tryvio [Prescribing Information]. Radnor, PA: Idorsia Pharmaceuticals US Inc.; March 2024.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

APROCITENTAN (PART D)

For Part D use only:

APROCITENTAN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	HYPERTENSION: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST, NEPHROLOGIST, OR ENDOCRINOLOGIST.
Coverage Duration	INITIAL: 2 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	HYPERTENSION: INITIAL: 1) BLOOD PRESSURE IS NOT CONTROLLED ON AT LEAST THREE ANTIHYPERTENSIVE AGENTS FROM DIFFERENT PHARMACOLOGIC CLASSES AT A MAXIMALLY TOLERATED DOSE FOR AT LEAST 4 WEEKS, 2) DOES NOT HAVE RESISTANT HYPERTENSION DUE TO WHITE COAT EFFECT, MEDICAL INERTIA, POOR THERAPEUTIC ADHERENCE, OR SECONDARY CAUSES OF HYPERTENSION (EXCEPT SLEEP APNEA), 3) CONCURRENT TREATMENT WITH AT LEAST THREE OTHER ANTIHYPERTENSIVE AGENTS AT MAXIMALLY TOLERATED DOSES, AND 4) TRIAL OF OR CONTRAINDICATION TO A POTENT DIURETIC (CHLORTHALIDONE OR INDAPAMIDE) AND A MINERALOCORTICOID RECEPTOR ANTAGONIST (SPIRONOLACTONE OR EPLERENONE). RENEWAL: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) CONCURRENT TREATMENT WITH AT LEAST THREE OTHER ANTIHYPERTENSIVE AGENTS AT MAXIMALLY TOLERATED DOSES.

Part D Effective: 09/23/24 Created: 09/24
Commercial Effective: N/A Client Approval: 09/24 P&T Approval: 07/24

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ARIMOCLOMOL (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ARIMOCLOMOL CITRATE	MIPLYFFA	49879		GPI-10 (6200000320)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of Niemann-Pick disease type C (NPC) (ICD-10 E75.242) and meet **ALL** of the following criteria?
The patient is 2 years of age or older
Therapy is prescribed by or in consultation with a neurologist or geneticist
Miplyffa will be used in combination with miglustat (Zavesca)

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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ARIMOCLOMOL (PART D)

INITIAL CRITERA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ARIMOCLOMOL (Miplyffa)** requires the following rule(s) be met for approval:
You have Niemann-Pick disease type C (NPC: a type of genetic condition)
You are 2 years of age or older
Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor) or geneticist (a doctor who treats gene disorders)
Miplyffa will used in combination with miglustat (Zavesca)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ARIMOCLOMOL (PART D)

RENEWAL CRITERA

Does the patient have a diagnosis of Niemann-Pick disease type C (NPC) (ICD-10 E75.242) **AND** meet the following criterion?
The patient has experienced improvement or a slowing of disease progression

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ARIMOCLOMOL (Miplyffa)** requires the following rule(s) be met for renewal:
You have Niemann-Pick disease type C (NPC: a type of genetic condition)
You have shown improvement or a slowing of disease progression

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Miplyffa.

REFERENCES

Miplyffa [Prescribing Information]. Celebration, FL: Zevra Therapeutics, Inc.; September 2024.

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ARIMOCLOMOL (PART D)

For Part D use only:

ARIMOCLOMOL (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	NIEMANN-PICK DISEASE TYPE C (NPC): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH NEUROLOGIST OR GENETICIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	NPC: RENEWAL: IMPROVEMENT OR SLOWING OF DISEASE PROGRESSION.

Part D Effective: 10/14/24 Created: 10/24
Commercial Effective: N/A Client Approval: 10/24 P&T Approval: 07/24

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ASCIMINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ASCIMINIB HYDROCHLORIDE	SCEMBLIX	47647		GPI-10 (2153180610)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

Does the patient have a diagnosis of Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP) (ICD-10 Group C92.1) **AND** meets the following criterion?
The patient is 18 years of age or older

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

Does the patient meet **ONE** of the following criteria?
The patient's cancer is newly diagnosed
The patient's cancer has a T315I mutation AND the patient had a mutational analysis prior to initiation and Scemblix is appropriate based on the NCCN guideline table for treatment recommendations based on BCR-ABL1 mutation profile *(Please see header CML-5 of the current NCCN guidelines)*
The patient has been previously treated AND the patient had a mutational analysis prior to initiation and Scemblix is appropriate based on the NCCN guideline table for treatment recommendations based on BCR-ABL1 mutation profile *(Please see header CML-5 of the current NCCN guidelines)*

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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ASCIMINIB (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ASCIMINIB (Scemblix)** requires the following rule(s) be met for approval:
You have Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML: a type of blood cell cancer) in chronic phase
You are 18 years of age or older
You meet ONE of the following:
- Your cancer is newly diagnosed
- Your cancer has a T315I mutation (abnormal change in a type of gene) AND you had a mutational analysis (a type of lab test) prior to the start of therapy and Scemblix is appropriate based on the National Comprehensive Cancer Network (NCCN) guideline table for treatment recommendations based on the profile for the breakpoint cluster region-Abelson murine leukemia 1 (BCR-ABL1: a type of gene) mutation
- You have been previously treated AND you had a mutational analysis prior to the start of therapy and Scemblix is appropriate based on the NCCN guideline table for treatment recommendations based on the profile for the BCR-ABL1 mutation

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Scemblix.

REFERENCES

Scemblix [Prescribing Information]. East Hanover, New Jersey: Novartis Pharmaceuticals Co.; October 2024.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ASCIMINIB (PART D)

For Part D use only:

ASCIMINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	PREVIOUSLY TREATED OR T315I MUTATION PHILADELPHIA CHROMOSOME-POSITIVE CHRONIC MYELOID LEUKEMIA (Ph+ CML): MUTATIONAL ANALYSIS PRIOR TO INITIATION AND SCEMBLIX IS APPROPRIATE PER NCCN GUIDELINE TABLE FOR TREATMENT RECOMMENDATIONS BASED ON BCR-ABL1 MUTATION PROFILE.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 11/21
Client Approval: 11/24
P&T Approval: 01/22

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ADVANTAGE AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ASFOTASE ALFA (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ASFOTASE ALFA	STRENSIQ	42649		GPI-10 (3090561000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of perinatal/infantile-onset hypophosphatasia (HPP) (ICD-10 E83.39) and meet **ALL** of the following criteria?
Therapy is prescribed by or in consultation with an endocrinologist, geneticist, or a metabolic specialist
The patient was 6 months of age or younger at onset of hypophosphatasia

If yes, continue to #2.
If no, continue to #4.

Does the patient have a positive tissue non-specific alkaline phosphatase (TNSALP) (ALPL) gene mutation as confirmed by genetic testing?

If yes, continue to #7.
If no, continue to #3.

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ASFOTASE ALFA (PART D)

INITIAL CRITERIA (CONTINUED)

Does the patient meet TWO of the following criteria?
- The patient has a serum alkaline phosphatase (ALP) level below the normal range for patient age
- The patient has an elevated serum pyridoxal-5'-phosphate (PLP) level AND has not received vitamin B6 supplementation in the previous week
- The patient has a urine phosphoethanolamine (PEA) level above the normal range for patient age
- The patient has radiographic evidence of hypophosphatasia (HPP) (e.g., flared and frayed metaphyses, osteopenia, widened growth plates, areas of radiolucency or sclerosis)
- The patient has at least TWO of the following:
  - Rachitic chest deformity
  - Craniosynostosis (premature closure of skull bones)
  - Delay in skeletal growth resulting in delay of motor development
  - History of vitamin B6 dependent seizures
  - Nephrocalcinosis or history of elevated serum calcium
  - History or presence of non-traumatic postnatal fracture and delayed fracture healing

  If yes, continue to #7.
  If no, do not approve.
  DENIAL TEXT: See the initial denial text at the end of the guideline.

Does the patient have a diagnosis of juvenile-onset hypophosphatasia (HPP) (ICD-10 E83.39) and meet **ALL** of the following criteria?
- Therapy is prescribed by or in consultation with an endocrinologist, geneticist, or a metabolic specialist
- The patient was 18 years of age or younger at onset of hypophosphatasia

  If yes, continue to #5.
  If no, do not approve.
  DENIAL TEXT: See the initial denial text at the end of the guideline.

Does the patient have a positive tissue non-specific alkaline phosphatase (TNSALP) (ALPL) gene mutation as confirmed by genetic testing?

  If yes, continue to #7.
  If no, continue to #6.

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ASFOTASE ALFA (PART D)

INITIAL CRITERIA (CONTINUED)

Does the patient meet **TWO** of the following criteria?
- The patient has a serum alkaline phosphatase (ALP) level below the normal range for patient age
- The patient has an elevated serum pyridoxal-5'-phosphate (PLP) level AND has not received vitamin B6 supplementation in the previous week
- The patient has a urine phosphoethanolamine (PEA) level above the normal range for patient age
- The patient has radiographic evidence of hypophosphatasia (HPP) (e.g., flared and frayed metaphyses, osteopenia, osteomalacia, widened growth plates, areas of radiolucency or sclerosis)
- The patient has TWO of the following:
  - Rachitic deformities (rachitic chest, bowed legs, knock-knees)
  - Premature loss of primary teeth prior to 5 years of age
  - Delay in skeletal growth resulting in delay of motor development
  - History or presence of non-traumatic fractures or delayed fracture healing

  If yes, continue to #7.
  If no, do not approve.
  DENIAL TEXT: See the initial denial text at the end of the guideline.

Does the patient meet **ALL** of the following criteria?
- The patient is NOT currently receiving treatment with a bisphosphonate (e.g., Boniva [ibandronate], Fosamax [alendronate], Actonel [risedronate])
- The patient does NOT have serum calcium or phosphate levels below the normal range
- The patient does NOT have a treatable form of rickets

  If yes, **approve for 6 months by HICL or GPI-10.**
  APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

  If no, do not approve.
  DENIAL TEXT: See the initial denial text at the end of the guideline.

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ASFOTASE ALFA (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ASFOTASE ALFA (Strensiq)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Perinatal/infantile hypophosphatasia (HPP: a type of genetic condition)
- Juvenile-onset hypophosphatasia (HPP: a type of genetic condition)

If you have perinatal/infantile-onset hypophosphatasia, approval also requires:
- You were 6 months of age or younger at the onset of hypophosphatasia
- Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor), geneticist (a doctor who treats gene disorders), or a metabolic specialist
- You will NOT use Strensiq together with a bisphosphonate (such as Boniva [ibandronate], Fosamax [alendronate], Actonel [risedronate])
- Your serum (blood) calcium or phosphate levels are NOT below the normal range
- You do NOT have a treatable form of rickets (a type of bone condition in children)
- You meet ONE of the following:
  - You are positive for a tissue non-specific alkaline phosphatase (TNSALP: a type of enzyme) gene mutation (abnormal change) as confirmed by genetic testing
  - You meet TWO of the following:
    - Your serum alkaline phosphatase (type of lab test) level is below the normal range for your age
    - Your serum pyridoxal-5'-phosphate (PLP: type of lab test) level is elevated AND you have NOT received vitamin B6 supplementation in the previous week
    - Your urine phosphoethanolamine (PEA: type of lab test) level is above the normal range for your age
    - You have radiographic (X-ray) evidence of hypophosphatasia (such as flared and frayed metaphyses [a part of the long bone], osteopenia [bone loss], widened growth plates, areas of radiolucency [ability to see through with X-rays/ radiation] or sclerosis [hardening of an area])
    - You have TWO of the following:
      - Rachitic chest deformity (chest bones are abnormal)
      - Craniosynostosis (premature closure of skull bones)
      - Delay in skeletal growth leading to motor development delay
      - History of vitamin B6 dependent seizures
      - Nephrocalcinosis (high calcium levels in kidney) or history of elevated serum calcium
      - History or presence of fracture after birth not due to injury and delayed fracture healing

(Initial denial text continued on next page)

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ASFOTASE ALFA (PART D)

INITIAL CRITERIA (CONTINUED)

If you have juvenile-onset hypophosphatasia, approval also requires:
- You were 18 years of age or younger at the onset of hypophosphatasia
- Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor), geneticist (a doctor who treats gene disorders), or a metabolic specialist
- You will NOT use Strensiq together with a bisphosphonate (such as Boniva [ibandronate], Fosamax [alendronate], Actonel [risedronate])
- Your serum (blood) calcium or phosphate levels are NOT below the normal range
- You do NOT have a treatable form of rickets (a type of bone condition in children)
- You meet ONE of the following:
  - You are positive for a tissue non-specific alkaline phosphatase (TNSALP: a type of enzyme) gene mutation (abnormal change) as confirmed by genetic testing
  - You meet TWO of the following:
    - Your serum alkaline phosphatase (type of lab test) level is below the normal range for your age
    - Your serum pyridoxal-5'-phosphate (PLP: type of lab test) level is elevated AND you have NOT received vitamin B6 supplementation in the previous week
    - Your urine phosphoethanolamine (PEA: type of lab test) level is above the normal range for your age
    - You have radiographic (X-ray) evidence of hypophosphatasia (such as flared and frayed metaphyses [a part of the long bone], osteopenia [bone loss], osteomalacia [bone softening], widened growth plates, areas of radiolucency [ability to see through with X-rays/radiation] or sclerosis [hardening of an area])
    - You have TWO of the following:
      - Rachitic deformities (rachitic chest, bowed legs, knock-knees)
      - Premature loss of primary teeth prior to 5 years of age
      - Delay in skeletal growth leading to motor development delay
      - History or presence of fracture after birth not due to injury or delayed fracture healing

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ASFOTASE ALFA (PART D)

RENEWAL CRITERIA

Has the patient experienced an improvement in the skeletal characteristics of hypophosphatasia (HPP) (e.g., improvement of the irregularity of the provisional zone of calcification, physeal widening, metaphyseal flaring, radiolucencies, patchy osteosclerosis, ratio of mid-diaphyseal cortex to bone thickness, gracile bones, bone formation and fractures)?

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the renewal denial text at the end of the guideline.

Is the patient currently receiving treatment with a bisphosphonate (e.g., Boniva [ibandronate], Fosamax [alendronate], Actonel [risedronate])?

If yes, do not approve.
If no, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ASFOTASE ALFA (Strensiq)** requires the following rule(s) be met for renewal:
You have experienced an improvement in skeletal characteristics (bones, teeth) of hypophosphatasia (HPP: a type of genetic condition)
You will NOT use Strensiq together with a bisphosphonate (such as Boniva [ibandronate], Fosamax [alendronate], Actonel [risedronate])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Strensiq.

REFERENCES

Strensiq [Prescribing Information]. Boston, MA: Alexion Pharmaceuticals, Inc.; March 2023.

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ASFOTASE ALFA (PART D)

For Part D use only:

ASFOTASE ALFA (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	HYPOPHOSPHATASIA (HPP): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST, GENETICIST, OR METABOLIC SPECIALIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: PERINATAL/INFANTILE-ONSET HPP: 1) 6 MONTHS OF AGE OR YOUNGER AT ONSET OF HPP, AND 2) POSITIVE FOR A TISSUE NON-SPECIFIC ALKALINE PHOSPHATASE (TNSALP) (ALPL) GENE MUTATION AS CONFIRMED BY GENETIC TESTING OR TWO OF THE FOLLOWING: (A) SERUM ALKALINE PHOSPHATASE (ALP) LEVEL BELOW THAT OF NORMAL RANGE FOR PATIENT AGE, (B) ELEVATED SERUM PYRIDOXAL-5'-PHOSPHATE (PLP) LEVELS AND NO VITAMIN B6 SUPPLEMENTATION IN THE PREVIOUS WEEK, (C) URINE PHOSPHOETHANOLAMINE (PEA) LEVEL ABOVE THAT OF NORMAL RANGE FOR PATIENT AGE, (D) RADIOGRAPHIC EVIDENCE OF HPP, (E) AT LEAST TWO OF THE FOLLOWING: (I) RACHITIC CHEST DEFORMITY, (II) CRANIOSYNOSTOSIS, (III) DELAY IN SKELETAL GROWTH RESULTING IN DELAY OF MOTOR DEVELOPMENT, (IV) HISTORY OF VITAMIN B6 DEPENDENT SEIZURES, (V) NEPHROCALCINOSIS OR HISTORY OF ELEVATED SERUM CALCIUM, (VI) HISTORY OR PRESENCE OF NON-TRAUMATIC POSTNATAL FRACTURE AND DELAYED FRACTURE HEALING. JUVENILE-ONSET HPP: 1) 18 YEARS OF AGE OR YOUNGER AT ONSET OF HPP, AND 2) POSITIVE FOR A TNSALP ALPL GENE MUTATION AS CONFIRMED BY GENETIC TESTING OR TWO OF THE FOLLOWING: (A) SERUM ALP LEVEL BELOW THAT OF NORMAL RANGE FOR PATIENT AGE, (B) ELEVATED SERUM PLP LEVELS AND NO VITAMIN B6 SUPPLEMENTATION IN THE PREVIOUS WEEK, (C) URINE PEA LEVEL ABOVE THAT OF NORMAL RANGE FOR PATIENT AGE, (D) RADIOGRAPHIC EVIDENCE OF HPP, (E) AT LEAST TWO OF THE FOLLOWING: (I) RACHITIC DEFORMITIES, (II) PREMATURE LOSS OF PRIMARY TEETH PRIOR TO 5 YEARS OF AGE, (III) DELAY IN SKELETAL GROWTH RESULTING IN DELAY OF MOTOR DEVELOPMENT, (IV) HISTORY OR PRESENCE OF NON-TRAUMATIC

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	FRACTURES OR DELAYED FRACTURE HEALING. ALL INDICATIONS: 1) NOT CURRENTLY RECEIVING TREATMENT WITH A BISPHOSPHONATE, 2) CALCIUM OR PHOSPHATE LEVELS ARE NOT BELOW THE NORMAL RANGE, 3) NOT HAVE A TREATABLE FORM OF RICKETS. RENEWAL: ALL INDICATIONS: 1) IMPROVEMENT IN THE SKELETAL CHARACTERISTICS OF HPP, AND 2) NOT CURRENTLY RECEIVING TREATMENT WITH A BISPHOSPHONATE.

Core	Advantage	Plus
No	Yes	Yes

Part D Effective: 01/01/25 Created: 11/15
Commercial Effective: N/A Client Approval: 06/24 P&T Approval: 11/16

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ASPARAGINASE ERWINIA-RYWN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ASPARAGINASE ERWINIA-RYWN	RYLAZE	47474		GPI-10 (2125001060)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

Does the patient have a diagnosis of acute lymphoblastic leukemia (ALL) (ICD-10 Group C91.0) or lymphoblastic lymphoma (LBL) (ICD-10 C83.5) and meet **ALL** of the following criteria?
The patient is 1 month of age or older
The patient has developed hypersensitivity to E. coli-derived asparaginase
Rylaze will be used as a component of a multi-agent chemotherapeutic regimen

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ASPARAGINASE ERWINIA-RYWN (RYLAZE)** requires the following rule(s) be met for approval:
You have acute lymphoblastic leukemia (ALL: type of blood cancer) or lymphoblastic lymphoma (LBL: type of cancer affecting the immune system)
You are 1 month of age or older
You have developed hypersensitivity to E. coli-derived asparaginase (you are allergic to an enzyme/protein that is from a type of bacteria)
Rylaze will be used as a component of a multi-agent chemotherapeutic regimen (treatment using multiple drugs)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ASPARAGINASE ERWINIA-RYWN (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Rylaze.

REFERENCES
Rylaze [Prescribing Information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc., June 2021.

For Part D use only:

ASPARAGINASE ERWINIA-RYWN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A
Quantity Limit (from Formulary ASCII file)	N/A

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 07/21
Client Approval: 08/24
P&T Approval: 10/21

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ATEZOLIZUMAB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ATEZOLIZUMAB	TECENTRIQ	43408		GPI-10 (2135821500)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

Does the patient have a diagnosis of non-small cell lung cancer (NSCLC) (ICD-10 Group C34) **AND** meet the following criterion?
The patient is 18 years of age or older

If yes, continue to #2.
If no, continue to #6.

Is the patient's cancer stage II to IIIA and the patient meets **ALL** of the following criteria?
Tecentriq will be used as adjuvant treatment following resection and platinum-based chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
The patient has tumor(s) that express PD-L1 on at least 1% of tumor cells, as determined by an FDA-authorized test

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #3.

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ATEZOLIZUMAB (PART D)

GUIDELINES FOR USE (CONTINUED)

Is the patient's cancer metastatic without an EGFR or ALK mutation and the patient meets **ONE** of the following criteria?
- The patient has experienced disease progression during or following treatment with platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
- The patient has tumor(s) that have high PD-L1 expression (PD-L1 stained at least 50% of tumor cells [TC at least 50%] or PD-L1 stained tumor-infiltrating immune cells [IC] covering at least 10% of the tumor area [IC at least 10%]), as determined by an FDA-authorized test

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #4.

Is the patient's cancer metastatic with an ALK mutation **AND** the patient meets the following criterion?
- The patient has experienced disease progression during or following treatment with platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin) AND ALK-directed therapy (e.g., Xalkori [crizotinib], Zykadia [ceritinib])

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #5.

Is the patient's cancer metastatic with an EGFR mutation **AND** the patient meets the following criterion?
- The patient has experienced disease progression during or following treatment with platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin) AND EGFR-directed therapy (e.g., Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib])

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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ATEZOLIZUMAB (PART D)

GUIDELINES FOR USE (CONTINUED)

Does the patient have a diagnosis of metastatic non-squamous non-small cell lung cancer (NSq NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
The patient's cancer does NOT have EGFR or ALK genomic tumor aberrations
Tecentriq will be used in combination with bevacizumab, paclitaxel, and carboplatin, OR in combination with paclitaxel protein-bound and carboplatin

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #7.

Does the patient have a diagnosis of extensive-stage small cell lung cancer (ES-SCLC) (ICD-10 Group C34) **AND** meet the following criterion?
The patient is 18 years of age or older

If yes, continue to #8.
If no, continue to #9.

Does the patient meet **ONE** of the following criteria?
Tecentriq will be used in combination with carboplatin and etoposide
Tecentriq will be used in combination with Zepzelca (lurbinectedin) AND the patient's disease has not progressed after first-line induction therapy with Tecentriq or Tecentriq Hybreza (atezolizumab and hyaluronidase-tqjs), carboplatin, and etoposide

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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ATEZOLIZUMAB (PART D)

GUIDELINES FOR USE (CONTINUED)

Does the patient have a diagnosis of unresectable or metastatic hepatocellular carcinoma (HCC) (ICD-10 C22.0) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
The patient has not received prior systemic therapy
Tecentriq will be used in combination with bevacizumab

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #10.

Does the patient have a diagnosis of unresectable or metastatic melanoma (ICD-10 Group C43) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
Tecentriq will be used in combination with cobimetinib (Cotellic) and vemurafenib (Zelboraf)
The patient's cancer is BRAF V600 mutation-positive

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #11.

Does the patient have a diagnosis of unresectable or metastatic alveolar soft part sarcoma (ASPS) (ICD-10 C49.9) **AND** meet the following criterion?
The patient is 2 years of age or older

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #12.

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ATEZOLIZUMAB (PART D)

GUIDELINES FOR USE (CONTINUED)

Does the patient have a diagnosis of muscle invasive bladder cancer (MIBC) (ICD-10 Group C67) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Tecentriq will be used as adjuvant treatment after a cystectomy
- The patient has circulating tumor DNA molecular residual disease (ctDNA MRD), as determined by an FDA-authorized test

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ATEZOLIZUMAB (Tecentriq)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Non-small cell lung cancer (NSCLC: a type of lung cancer)
- Metastatic non-squamous non-small cell lung cancer (NSq NSCLC: a type of lung cancer that has spread to other parts of the body)
- Extensive-stage small cell lung cancer (ES-SCLC: a type of lung cancer)
- Unresectable or metastatic hepatocellular carcinoma (HCC: a type of liver cancer that cannot be removed by surgery or has spread to other parts of the body)
- Unresectable or metastatic melanoma (a type of skin cancer that cannot be removed by surgery or has spread to other parts of the body)
- Unresectable or metastatic alveolar soft part sarcoma (ASPS: a type of soft tissue cancer that cannot be removed by surgery or has spread to other parts of the body)
- Muscle invasive bladder cancer (MIBC: a type of bladder cancer that has spread to the muscle)

(Denial text continued on next page)

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ATEZOLIZUMAB (PART D)

GUIDELINES FOR USE (CONTINUED)

If you have non-small cell lung cancer, approval also requires:

- You are 18 years of age or older
- You meet ONE of the following:
  - Your cancer is stage II to IIIA, Tecentriq will be used as adjuvant (add-on) treatment following resection (removal of tissue or organ) and platinum-based chemotherapy (a type of therapy to treat cancer such as cisplatin, carboplatin, oxaliplatin), AND your tumor(s) express programmed death-ligand 1 (PD-L1: type of protein) on at least 1% of tumor cells, as determined by a Food and Drug Administration (FDA)-authorized test
  - Your cancer is metastatic (has spread to other parts of the body) and you meet ONE of the following:
    - Your cancer does NOT have an epidermal growth factor receptor (EGFR: a type of protein) or anaplastic lymphoma kinase (ALK: a type of protein) mutation (abnormal change in a type of gene); AND your disease has gotten worse during or after treatment with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
    - Your cancer does NOT have an epidermal growth factor receptor (EGFR: a type of protein) or anaplastic lymphoma kinase (ALK: a type of protein) mutation (abnormal change in a type of gene); AND you have tumor(s) that have high programmed death-ligand 1 (PD-L1: type of protein) expression (PD-L1 stained at least 50% of tumor cells OR PD-L1 stained tumor-infiltrating immune cells covering at least 10% of the tumor area), as determined by a Food and Drug Administration (FDA)-authorized test
    - Your cancer has an anaplastic lymphoma kinase (ALK: a type of protein) mutation (abnormal change in a type of gene); your disease has gotten worse during or after treatment with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin) AND ALK-directed therapy (such as Xalkori [crizotinib], Zykadia [ceritinib])
    - Your cancer has an epidermal growth factor receptor (EGFR: a type of protein) mutation (abnormal change in a type of gene); your disease has gotten worse during or after treatment with a platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin) AND EGFR-directed therapy [such as Tarceva (erlotinib), Iressa (gefitinib), Gilotrif (afatinib)]

(Denial text continued on next page)

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ATEZOLIZUMAB (PART D)

GUIDELINES FOR USE (CONTINUED)

If you have metastatic non-squamous non-small cell lung cancer, approval also requires:
- You are 18 years of age or older
- Your cancer does NOT have epidermal growth factor receptor (EGFR: a type of protein) or anaplastic lymphoma kinase (ALK: a type of protein) genomic tumor abnormalities (type of abnormal gene)
- Tecentriq will be used in combination with bevacizumab, paclitaxel, and carboplatin, OR in combination with paclitaxel protein-bound and carboplatin

If you have extensive-stage small cell lung cancer, approval also requires:
- You are 18 years of age or older
- You meet ONE of the following:
  - Tecentriq will be used in combination with carboplatin and etoposide
  - Tecentriq will be used in combination with Zepzelca (lurbinectedin) AND your disease has not progressed (worsened) after first-line induction therapy (start of treatment) with Tecentriq or Tecentriq Hybreza (atezolizumab and hyaluronidase-tqjs), carboplatin, and etoposide

If you have unresectable or metastatic hepatocellular carcinoma, approval also requires:
- You are 18 years of age or older
- You have NOT previously been treated with systemic therapy (treatment that targets the entire body)
- Tecentriq will be used in combination with bevacizumab

If you have unresectable or metastatic melanoma, approval also requires:
- You are 18 years of age or older
- Tecentriq will be used in combination with cobimetinib (Cotellic) and vemurafenib (Zelboraf)
- Your cancer is BRAF V600 mutation (abnormal change in a type of gene) positive

If you have unresectable or metastatic alveolar soft part sarcoma, approval also requires:
- You are 2 years of age or older

If you have muscle invasive bladder cancer, approval also requires:
- You are 18 years of age or older
- Tecentriq will be used as adjuvant (add-on) treatment after a cystectomy (bladder removal surgery)
- You have circulating tumor DNA molecular residual disease (ctDNA MRD: traces of cancer DNA in your body), as determined by a Food and Drug Administration (FDA)-authorized test

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ATEZOLIZUMAB (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tecentriq.

REFERENCES

Tecentriq [Prescribing Information]. South San Francisco, CA: Genentech Inc.; May 2026.

For Part D use only:

ATEZOLIZUMAB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 05/16
Effective: 06/10/26 Client Approval: 06/26 DMC Approval: 05/27/26

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ATEZOLIZUMAB-HYALURONIDASE-TQJS BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ATEZOLIZUMAB-HYALURONIDASE-TQJS	TECENTRIQ HYBREZA	49873		GPI-10 (2199000205)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	Yes	No	No	Yes	No	Yes	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

Is this a pharmacy call?

If yes, continue to #3.
If no, continue to #2.

Is the requested medication going to be filled at a pharmacy?

If yes, continue to #3.
If no, **Refer to plan. (This should be processed under the member's medical benefit)**

Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

If no, continue to #4.

Is the pharmacy dispensing the drug directly to the member or member's representative?

If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

If no, continue to #5.

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ATEZOLIZUMAB-HYALURONIDASE-TQJS BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

Is the internal HQ code ML500, SFC01, or SUM03?

If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).
For PAC's: Send an email to plan (reference UNSAD section of PACIP).

If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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ATEZOLIZUMAB-HYALURONIDASE-TQJS BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

Does the patient have a diagnosis of non-small cell lung cancer (NSCLC) (ICD-10 Group C34) **AND** meet the following criterion?
The patient is 18 years of age or older

If yes, continue to #2.
If no, continue to #6.

Is the patient's cancer stage II to IIIA and the patient meets **ALL** of the following criteria?
Tecentriq Hybreza will be used as adjuvant treatment following resection and platinum-based chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
The patient has tumor(s) that express PD-L1 on at least 1% of tumor cells, as determined by an FDA-authorized test

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #3.

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ATEZOLIZUMAB-HYALURONIDASE-TQJS BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

Is the patient's cancer metastatic without an EGFR or ALK mutation and the patient meets **ONE** of the following criteria?
- The patient has experienced disease progression during or following treatment with platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
- The patient has tumor(s) that have high PD-L1 expression (PD-L1 stained at least 50% of tumor cells [TC at least 50%] or PD-L1 stained tumor-infiltrating immune cells [IC] covering at least 10% of the tumor area [IC at least 10%]), as determined by an FDA-authorized test

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #4.

Is the patient's cancer metastatic with an ALK mutation **AND** the patient meets the following criterion?
- The patient has experienced disease progression during or following treatment with platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin) AND ALK-directed therapy (e.g., Xalkori [crizotinib], Zykadia [ceritinib])

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #5.

Is the patient's cancer metastatic with an EGFR mutation **AND** the patient meets the following criterion?
- The patient has experienced disease progression during or following treatment with platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin) AND EGFR-directed therapy (e.g., Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib])

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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ATEZOLIZUMAB-HYALURONIDASE-TQJS BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

Does the patient have a diagnosis of metastatic non-squamous non-small cell lung cancer (NSq NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- The patient's cancer does NOT have EGFR or ALK genomic tumor aberrations
- Tecentriq Hybreza will be used in combination with bevacizumab, paclitaxel, and carboplatin, OR in combination with paclitaxel protein-bound and carboplatin

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #7.

Does the patient have a diagnosis of extensive-stage small cell lung cancer (ES-SCLC) (ICD-10 Group C34) **AND** meet the following criterion?
- The patient is 18 years of age or older

If yes, continue to #8.
If no, continue to #9.

Does the patient meet **ONE** of the following criteria?
- Tecentriq Hybreza will be used in combination with carboplatin and etoposide
- Tecentriq Hybreza will be used in combination with Zepzelca (lurbinectedin) AND the patient's disease has not progressed after first-line induction therapy with Tecentriq Hybreza or intravenous Tecentriq (atezolizumab), carboplatin, and etoposide

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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ATEZOLIZUMAB-HYALURONIDASE-TQJS BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

Does the patient have a diagnosis of unresectable or metastatic hepatocellular carcinoma (HCC) (ICD-10 C22.0) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- The patient has NOT received prior systemic therapy
- Tecentriq Hybreza will be used in combination with bevacizumab

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #10.

Does the patient have a diagnosis of unresectable or metastatic melanoma (ICD-10 Group C43) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Tecentriq Hybreza will be used in combination with cobimetinib (Cotellic) and vemurafenib (Zelboraf)
- The patient's cancer is BRAF V600 mutation-positive, as determined by an FDA-approved test

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #11.

Does the patient have a diagnosis of unresectable or metastatic alveolar soft part sarcoma (ASPS) (ICD-10 C49.9) **AND** meet the following criterion?
- The patient is 18 years of age or older

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #12.

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ATEZOLIZUMAB-HYALURONIDASE-TQJS BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

Does the patient have a diagnosis of muscle invasive bladder cancer (MIBC) (ICD-10 Group C67) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
Tecentriq Hybreza will be used as adjuvant treatment after a cystectomy
The patient has circulating tumor DNA molecular residual disease (ctDNA MRD), as determined by an FDA-authorized test

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ATEZOLIZUMAB-HYALURONIDASE-TQJS (Tecentriq Hybreza)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Non-small cell lung cancer (NSCLC: a type of lung cancer)
- Metastatic non-squamous non-small cell lung cancer (NSq NSCLC: a type of lung cancer that has spread to other parts of the body)
- Extensive-stage small cell lung cancer (ES-SCLC: a type of lung cancer)
- Unresectable or metastatic hepatocellular carcinoma (HCC: a type of liver cancer that cannot be removed by surgery or has spread to other parts of the body)
- Unresectable or metastatic melanoma (a type of skin cancer that cannot be removed by surgery or has spread to other parts of the body)
- Unresectable or metastatic alveolar soft part sarcoma (ASPS: a type of soft tissue cancer that cannot be removed by surgery or has spread to other parts of the body)
- Muscle invasive bladder cancer (MIBC: a type of bladder cancer that has spread to the muscle)

(Denial text continued on next page)

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ATEZOLIZUMAB-HYALURONIDASE-TQJS BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

If you have non-small cell lung cancer, approval also requires:

- You are 18 years of age or older
- You meet ONE of the following:
  - Your cancer is stage II or IIIA; Tecentriq Hybreza will be used as adjuvant treatment (additional treatment) following resection (removal of tissue or organ) and platinum-based chemotherapy (such as cisplatin, carboplatin, oxaliplatin); AND your tumor(s) express programmed death-ligand 1 (PD-L1: type of protein) on at least 1% of tumor cells, as determined by a Food and Drug Administration (FDA)-authorized test
  - Your cancer is metastatic (has spread to other parts of the body) and you meet ONE of the following:
    - Your cancer does NOT have an epidermal growth factor receptor (EGFR: a type of protein) or anaplastic lymphoma kinase (ALK: a type of protein) mutation (abnormal change in a type of gene); AND you have experienced disease progression (worsening) during or after treatment with a platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
    - Your cancer does NOT have an epidermal growth factor receptor (EGFR: a type of protein) or anaplastic lymphoma kinase (ALK: a type of protein) mutation (abnormal change in a type of gene); AND you have tumors that have high programmed death-ligand 1 (PD-L1: type of protein) expression (PD-L1 stained at least 50% of tumor cells OR PD-L1 stained tumor-infiltrating immune cells covering at least 10% of the tumor area), as determined by a Food and Drug Administration (FDA)-authorized test
    - Your cancer has an anaplastic lymphoma kinase (ALK: a type of protein) mutation (abnormal change in a type of gene); your disease has gotten worse during or after treatment with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin) AND ALK-directed therapy (such as Xalkori [crizotinib], Zykadia [ceritinib])
    - Your cancer has an epidermal growth factor receptor (EGFR: a type of protein) mutation (abnormal change in a type of gene); your disease has gotten worse during or after treatment with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin) AND EGFR-directed therapy (such as Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib])

(Denial text continued on next page)

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ATEZOLIZUMAB-HYALURONIDASE-TQJS BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

- **If you have metastatic non-squamous non-small cell lung cancer, approval also requires:**
  - You are 18 years of age or older
  - You do NOT have epidermal growth factor receptor (EGFR: a type of protein) or anaplastic lymphoma kinase (ALK: a type of protein) genomic tumor abnormalities (type of abnormal gene)
  - Tecentriq Hybreza will be used in combination with bevacizumab, paclitaxel, and carboplatin, OR in combination with paclitaxel protein-bound and carboplatin
- **If you have extensive-stage small cell lung cancer, approval also requires:**
  - You are 18 years of age or older
  - You meet ONE of the following:
    - Tecentriq Hybreza will be used in combination with carboplatin and etoposide
    - Tecentriq Hybreza will be used in combination with Zepzelca (lurbinectedin) AND your disease has not progressed (worsened) after first-line induction therapy (start of treatment) with Tecentriq Hybreza or intravenous (injection into the vein) Tecentriq (atezolizumab), carboplatin, and etoposide
- **If you have unresectable or metastatic hepatocellular carcinoma, approval also requires:**
  - You are 18 years of age or older
  - You have NOT previously been treated with systemic therapy (treatment that targets the entire body)
  - Tecentriq Hybreza will be used in combination with bevacizumab
- **If you have unresectable or metastatic melanoma, approval also requires:**
  - You are 18 years of age or older
  - Tecentriq Hybreza will be used in combination with cobimetinib (Cotellic) and vemurafenib (Zelboraf)
  - Your cancer is BRAF V600 mutation (abnormal change in a type of gene)-positive as determined by a Food and Drug Administration (FDA)-approved test
- **If you have unresectable or metastatic alveolar soft part sarcoma, approval also requires:**
  - You are 18 years of age or older
- **If you have muscle invasive bladder cancer, approval also requires:**
  - You are 18 years of age or older
  - Tecentriq Hybreza will be used as adjuvant (add-on) treatment after a cystectomy (bladder removal surgery)
  - You have circulating tumor DNA molecular residual disease (ctDNA MRD: traces of cancer DNA in your body), as determined by a Food and Drug Administration (FDA)-authorized test

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ATEZOLIZUMAB-HYALURONIDASE-TQJS BvD (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tecentriq Hybreza.
The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Tecentriq Hybreza [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; May 2026.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed May 29, 2026].

For Part D use only:

ATEZOLIZUMAB-HYALURONIDASE-TQJS (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 09/24
Effective: 06/10/26 Client Approval: 06/26 DMC Approval: 05/27/26

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ATOGEPANT (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ATOGEPANT	QULIPTA	47599		GPI-10 (6770101000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Is the request for the preventive treatment of migraines (ICD Group G43) and the patient meets **ALL** of the following criteria?
The patient is 18 years of age or older
Qulipta will NOT be used concurrently with other CGRP inhibitors (e.g., Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm]) for migraine prevention

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ATOGEPANT (Qulipta)** requires the following rule(s) be met for approval:
The request is for the preventive treatment of migraines (a type of headache)
You are 18 years of age or older
You will NOT use Qulipta concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm]) for migraine prevention

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ATOGEPANT (PART D)

RENEWAL CRITERIA

Is the request for the preventive treatment of migraines (ICD Group G43) **AND** the patient meets the following criterion?
Qulipta will NOT be used concurrently with other CGRP inhibitors (e.g., Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm]) for migraine prevention

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the renewal denial text at the end of the guideline.

Does the patient meet **ONE** of the following criteria?
The patient has experienced a reduction in migraine or headache frequency with therapy
The patient has experienced a reduction in migraine severity with therapy
The patient has experienced a reduction in migraine duration with therapy

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ATOGEPANT (Qulipta)** requires the following rule(s) be met for renewal:
The request is for the preventive treatment of migraines (a type of headache)
You will NOT use Qulipta concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm]) for migraine prevention
You meet ONE of the following:
You have experienced a reduction in migraine or headache frequency with therapy
You have experienced a reduction in migraine severity with therapy
You have experienced a reduction in migraine duration with therapy

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ATOGEPANT (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Qulipta.

REFERENCES
Qulipta [Prescribing Information]. North Chicago, IL: AbbVie, Inc., March 2025.

For Part D use only:

ATOGEPANT (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	MIGRAINE PREVENTION: INITIAL/RENEWAL: NO CONCURRENT USE WITH OTHER CGRP INHIBITORS FOR MIGRAINE PREVENTION. RENEWAL: REDUCTION IN MIGRAINE OR HEADACHE FREQUENCY, MIGRAINE SEVERITY, OR MIGRAINE DURATION WITH THERAPY.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ATRASENTAN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ATRASENTAN HYDROCHLORIDE	VANRAFIA	50412		GPI-10 (5648250720)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of primary immunoglobulin A nephropathy (IgAN) (ICD-10 Group N02.B) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- The patient is at risk of rapid disease progression (e.g., urine protein-to-creatinine ratio [UPCR] of at least 1.5 g/g)
- Therapy is prescribed by or in consultation with a nephrologist
- The patient's IgAN diagnosis is confirmed by a biopsy
- The patient has proteinuria of at least 0.5 g/day
- The patient has an eGFR of at least 30 mL/min/1.73 m(2)
- The patient has tried an ACE inhibitor (e.g., benazepril, lisinopril) or an ARB (e.g., losartan, valsartan) for at least 3 months at a maximum tolerated dose and will continue use, OR has a contraindication to both drug classes

If yes, **approve for 9 months by HICL or GPI-10.**

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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ATRASENTAN (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ATRASENTAN (Vanrafia)** requires the following rule(s) be met for approval:
You have primary immunoglobulin A nephropathy (IgAN: a type of kidney disease)
You are 18 years of age or older
You are at risk of rapid disease progression (such as a urine protein-to-creatinine ratio [UPCR: a test that measures the amount of protein in urine] of at least 1.5 g/g)
Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor)
Your diagnosis is confirmed by a biopsy (removal of cells or tissue for examination)
You have proteinuria (increased levels of protein in the urine) of at least 0.5 g/day
You have an estimated glomerular filtration rate (eGFR: a tool for evaluating kidney function) of at least 30 mL/min/1.73 m(2)
You have tried an angiotensin converting enzyme inhibitor (ACE-I: a type of medication used to protect kidneys, such as benazepril, lisinopril) or an angiotensin receptor blocker (ARB: a type of medication used to protect kidneys, such as losartan, valsartan) for at least 3 months at a maximum tolerated dose and will continue use, OR you have a contraindication to (harmful for you to use) both of these medication classes

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ATRASENTAN (PART D)

RENEWAL CRITERIA

Does the patient have a diagnosis of primary immunoglobulin A nephropathy (IgAN) (ICD-10 Group N02.B) **AND** meet the following criterion?
The patient has improved or stable kidney function compared to baseline OR has a reduction in proteinuria

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ATRASENTAN (Vanrafia)** requires the following rule(s) be met for renewal:
You have primary immunoglobulin A nephropathy (IgAN: a type of kidney disease)
You have improved or stable kidney function compared to baseline (before starting Vanrafia) OR you have a reduction (decrease) in proteinuria (a condition with high levels of protein in the urine)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vanrafia.

REFERENCES

Vanrafia [PrescribingInformation]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2025.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ATRASENTAN (PART D)

For Part D use only:

ATRASENTAN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	PRIMARY IMMUNOGLOBULIN A NEPHROPATHY (IGAN): INITIAL: 1) DIAGNOSIS CONFIRMED BY A BIOPSY, 2) PROTEINURIA OF AT LEAST 0.5 G/DAY, AND 3) EGFR OF AT LEAST 30 ML/MIN/1.73 M2.
Age Restrictions	N/A
Prescriber Restrictions	PRIMARY IGAN: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEPHROLOGIST.
Coverage Duration	INITIAL: 9 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	PRIMARY IGAN: INITIAL: TRIAL AND CONTINUATION OF AN ACE INHIBITOR OR ARB AT MAXIMUM TOLERATED DOSE FOR AT LEAST 3 MONTHS OR CONTRAINDICATION TO BOTH CLASSES. RENEWAL: IMPROVED OR STABLE KIDNEY FUNCTION COMPARED TO BASELINE OR REDUCTION IN PROTEINURIA.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AVACOPAN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AVACOPAN	TAVNEOS	47626		GPI-10 (8580551000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] ormicroscopic polyangiitis [MPA]) (ICD-10 I77.82) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
Therapy is prescribed by or in consultation with a rheumatologist or nephrologist
The patient is ANCA seropositive (anti-PR3 or anti-MPO)
Tavneos will be used as adjunctive therapy in combination with standardtherapy including glucocorticoids (e.g., methylprednisolone, prednisone)

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See initial denial text at the end of the guideline.

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AVACOPAN (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AVACOPAN (Tavneos)** requires the following rule(s) be met for approval:
You have severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (inflammation of blood vessels) (granulomatosis with polyangiitis [GPA] or microscopic polyangiitis [MPA]: conditions that affect the blood vessels)
You are 18 years of age or older
Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or nephrologist (a type of kidney doctor)
You are ANCA seropositive for anti-PR3 or anti-MPO (a type of lab test)
Tavneos will be used as adjunctive (add-on) therapy in combination with standard therapy including glucocorticoids (such as methylprednisolone, prednisone)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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AVACOPAN (PART D)

RENEWAL CRITERIA

Does the patient have a diagnosis of severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] ormicroscopic polyangiitis [MPA]) (ICD-10 I77.82) **AND** meet the following criterion?
The patient continues to benefit from therapy (e.g., improvement of clinical manifestations, if renal vasculitis - improvement in eGFR and proteinuria values, reduction of corticosteroid dose without disease flares)

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AVACOPAN (Tavneos)** requires the following rule(s) be met for renewal:
You have severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (inflammation of blood vessels) (granulomatosis with polyangiitis [GPA] or microscopic polyangiitis [MPA]: conditions that affect the blood vessels)
You continue to benefit from the medication (such as improvement of clinical symptoms, if renal vasculitis [inflammation of blood vessels] - improvement in estimated glomerular filtration rate [eGFR: a tool for evaluating kidney function] and proteinuria [increased levels of protein in the urine] values, reduction of corticosteroid [a type of drug used to treat inflammation] dose without disease flares)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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AVACOPAN (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Tavneos.

REFERENCES
Tavneos [Prescribing Information]. Cincinnati, OH: ChemoCentryx Inc., October 2021.

For Part D use only:

AVACOPAN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	ANTI-NEUTROPHIL CYTOPLASMIC AUTOANTIBODY (ANCA)-ASSOCIATED VASCULITIS: INITIAL: ANCA SEROPOSITIVE (ANTI-PR3 OR ANTI-MPO).
Age Restrictions	N/A
Prescriber Restrictions	ANCA-ASSOCIATED VASCULITIS: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST OR NEPHROLOGIST.
Coverage Duration	INITIAL/RENEWAL: 6 MONTHS.
Other Criteria	ANCA-ASSOCIATED VASCULITIS: RENEWAL: CONTINUES TO BENEFIT FROM THERAPY.

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Effective: 01/01/26 Client Approval: 01/26 P&T Approval: 01/22

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AVALGLUCOSIDASE ALFA-NGPT BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AVALGLUCOSIDASE ALFA-NGPT	NEXVIAZYME	47521		GPI-10 (3090772255)	

PAYMENT DETERMINATION CRITERIA

NOTE: This PA is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

Is this a pharmacy call?

If yes, continue to #3.
If no, continue to #2.

Is the requested medication going to be filled at a pharmacy?

If yes, continue to #3.
If no, **Refer to plan. (This should be processed under the member's medical benefit)**

Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

If yes, continue to #6.
If no, continue to #4.

Is the pharmacy dispensing the drug directly to the member or member's representative?

If yes, continue to #6.
If no, continue to #5.

Is the internal HQ code ML500, SFC01, or SUM03?

If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).
For PAC's: Send an email to plan (reference UNSAD section of PACIP).

If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

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AVALGLUCOSIDASE ALFA-NGPT BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

Is the drug administered via an implantable pump?

If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field.).**
If no, continue to #7.

Is the drug administered using an external pump?

If yes, continue to #8.
If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field.).**

Is the drug specifically covered under the applicable Medicare Part B coverage policies (National and/or Local Coverage Policies)?

If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field.).**

If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field.).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AVALGLUCOSIDASE ALFA-NGPT BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

Does the patient have a diagnosis of late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) (ICD-10 E74.02) **AND** meet the following criterion?
The patient is 1 year of age or older

If yes, **approve for lifetime by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AVALGLUCOSIDASE ALFA-NGPT (Nexviazyme)** requires the following rule(s) be met for approval:
You have late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) (a type of gene disorder)
You are 1 year of age or older

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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AVALGLUCOSIDASE ALFA-NGPT BvD (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nexviazyme.

The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B. Drugs administered by an implantable pump are covered under Part B. Drugs administered via an external pump are covered under Part B if they are included under the local coverage policy of the applicable Medicare coverage policies (National and/or Local Coverage Policies). Drugs administered via an external pump that are not included under the applicable Medicare coverage policies are covered under Part D. A CMS website to assist with National and Local Coverage Determination for BvD review is http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx

REFERENCES

Nexviazyme [Prescribing Information]. Cambridge, MA: Genzyme Corporation, September 2023.
Medicare Prescription Drug Benefit Manual Chapter 6 – Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed July 2, 2024].

For Part D use only:

AVALGLUCOSIDASE ALFA-NGPT (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	LIFETIME
Other Criteria	N/A

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AVAPRITINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AVAPRITINIB	AYVAKIT	46291		GPI-10 (2149000900)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

Does the patient have a diagnosis of unresectable or metastatic gastrointestinal stromal tumor (GIST) (ICD-10 Group C49.A) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
The patient has a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #2.

Does the patient have a diagnosis of advanced systemic mastocytosis (AdvSM), including aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL) (ICD-10 D47.02, C96.21; Group C94.3), **AND** meet the following criterion?
The patient is 18 years of age or older

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #3.

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AVAPRITINIB (PART D)

GUIDELINES FOR USE (CONTINUED)

Does the patient have a diagnosis of indolent systemic mastocytosis (ISM) (ICD-10 D47.02) **AND** meet the following criterion?
The patient is 18 years of age or older

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AVAPRITINIB (Ayvakit)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Unresectable or metastatic gastrointestinal stromal tumor (GIST: a type of digestive tumor that cannot be removed through surgery or has spread to other parts of the body)
- Advanced systemic mastocytosis (AdvSM: a type of blood disorder), including aggressive systemic mastocytosis (ASM: a type of blood disorder), systemic mastocytosis with an associated hematological neoplasm (SM-AHN: a type of blood disorder), or mast cell leukemia (MCL: a type of blood cancer)
- Indolent systemic mastocytosis (ISM: a type of blood disorder)

If you have unresectable or metastatic gastrointestinal stromal tumor, approval also requires:
- You are 18 years of age or older
- You have a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations (abnormal change in a type of genes)

If you have advanced systemic mastocytosis, approval also requires:
- You are 18 years of age or older

If you have indolent systemic mastocytosis, approval also requires:
- You are 18 years of age or older

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Ayvakit.

REFERENCES
Ayvakit [Prescribing Information]. Cambridge, MA: Blueprint Medicines Corporation; May 2023.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AVAPRITINIB (PART D)

For Part D use only:

AVAPRITINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25 Created: 01/20
Commercial Effective: N/A Client Approval: 06/24 P&T Approval: 07/23

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AVATROMBOPAG (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AVATROMBOPAG MALEATE	DOPTELET, DOPTELET SPRINKLE	44942		GPI-10 (8240501020)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of thrombocytopenia in chronic liver disease and meet **ALL** of the following criteria?

The patient is 18 years of age or older

Therapy is prescribed by or in consultation with a hematologist, gastroenterologist, hepatologist, immunologist, endocrinologist, or surgeon

The patient is scheduled to undergo a procedure 10 to 13 days following the initiation of Doptelet therapy

Doptelet will NOT be used concurrently with other thrombopoietin receptor agonists (TPO-RAs) (e.g., Nplate [romiplostim], Promacta [eltrombopag])

If yes, **approve for 1 month by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #2.

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AVATROMBOPAG (PART D)

INITIAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of persistent or chronic immune thrombocytopenia (ITP) (ICD-10 D69.3) and meet **ALL** of the following criteria?

- The patient is 1 year of age or older
- Therapy is prescribed by or in consultation with a hematologist or immunologist
- The patient had a trial of or contraindication to one corticosteroid (e.g., prednisone) or immunoglobulin (e.g., Panzyga [immune globulin]), OR had an insufficient response to a splenectomy
- The patient has a platelet count of less than 30 x10^9/L, OR a platelet count of less than 50 x 10^9/L and a prior bleeding event
- The requested medication will NOT be used concurrently with other thrombopoietin receptor agonists (TPO-RAs) (e.g., Nplate [romiplostim], Promacta [eltrombopag])

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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AVATROMBOPAG (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AVATROMBOPAG (Doptelet, Doptelet Sprinkle)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Thrombocytopenia (a type of blood disorder) in chronic (long-term) liver disease
- Persistent or chronic immune thrombocytopenia (TIP: a type of blood disorder)

If you have thrombocytopenia in chronic liver disease, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor), gastroenterologist (doctor who treats digestive conditions), hepatologist (a type of liver doctor), immunologist (a type of immune system doctor), endocrinologist (hormone doctor), or surgeon
- You are scheduled to undergo a procedure 10 to 13 days after starting Doptelet (avatrombopag) therapy
- You will NOT use Doptelet concurrently (at the same time) with other thrombopoietin receptor agonists (TPO-RAs, such as Nplate [romiplostim], Promacta [eltrombopag])

If you have persistent or chronic immune thrombocytopenia, approval also requires:
- You are 1 year of age or older
- Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or immunologist (a type of immune system doctor)
- You have tried or have a contraindication to (harmful for you to use) one corticosteroid (such as prednisone) or immunoglobulin (such as Panzyga [immune globulin]), OR you had an insufficient response to a splenectomy (surgical removal of spleen did not work)
- You have a platelet (a type of blood cell) count of less than 30 x10^9/L, OR you have a platelet count of less than 50 x 10^9/L and had a prior bleeding event
- You will NOT use the requested medication concurrently (at the same time) with other thrombopoietin receptor agonists (TPO-Ras, such as Nplate [romiplostim], Promacta [eltrombopag])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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AVATROMBOPAG (PART D)

RENEWAL CRITERIA

NOTE: For the diagnosis of thrombocytopenia in chronic liver disease, please refer to the Initial Criteria section.

Does the patient have a diagnosis of persistent or chronic immune thrombocytopenia (ITP) (ICD-10 D69.3) and meet **ALL** of the following criteria?
The patient has improvement in platelet counts from baseline or reduction in bleeding events
The requested medication will NOT be used concurrently with other thrombopoietin receptor agonists (TPO-RAs) (e.g., Nplate [romiplostim], Promacta [eltrombopag])

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AVATROMBOPAG (Doptelet, Doptelet Sprinkle)** requires the following rule(s) be met for renewal:
You have persistent or chronic immune thrombocytopenia (ITP: a type of blood disorder)
You have improvement in platelet (a type of blood cell) counts from baseline or reduction in bleeding events
You will NOT use the requested medication concurrently (at the same time) with other thrombopoietin receptor agonists (TPO-Ras, such as Nplate [romiplostim], Promacta [eltrombopag])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Doptelet/Doptelet Sprinkle.

REFERENCES

Doptelet/Doptelet Sprinkle [Prescribing Information]. Durham, NC: Dova Pharmaceuticals, Inc.; July 2025.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AVATROMBOPAG (PART D)

For Part D use only:

AVATROMBOPAG (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	PERSISTENT OR CHRONIC IMMUNE THROMBOCYTOPENIA (ITP): INITIAL: 1) PLATELET COUNT OF LESS THAN 30 X 10^9/L, OR 2) PLATELET COUNT OF LESS THAN 50 X 10^9/L AND A PRIOR BLEEDING EVENT.
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: CHRONIC LIVER DISEASE (CLD): PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST, GASTROENTEROLOGIST, HEPATOLOGIST, IMMUNOLOGIST, ENDOCRINOLOGIST, OR SURGEON. ITP: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR IMMUNOLOGIST.
Coverage Duration	CLD: 1 MONTH. ITP: INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: CLD: 1) PLANNED PROCEDURE 10 TO 13 DAYS AFTER INITIATION OF DOPTELET, AND 2) NO CONCURRENT USE WITH OTHER THROMBOPOIETIN RECEPTOR AGONISTS (TPO-RAS). ITP: 1) TRIAL OF OR CONTRAINDICATION TO ONE CORTICOSTEROID OR IMMUNOGLOBULIN, OR HAD INSUFFICIENT RESPONSE TO SPLENECTOMY, AND 2) NO CONCURRENT USE WITH OTHER TPO-RAS. RENEWAL: ITP: 1) IMPROVEMENT IN PLATELET COUNTS FROM BASELINE OR REDUCTION IN BLEEDING EVENTS, AND 2) NO CONCURRENT USE WITH OTHER TPO-RAS.

Created: 06/18
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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AVELUMAB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AVELUMAB	BAVENCIO	44170		GPI-10 (2135822000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

Does the patient have a diagnosis of metastatic Merkel cell carcinoma (MCC) (ICD-10 C7B.1; Group C4A) **AND** meet the following criterion?
The patient is 12 years of age or older

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #2.

Does the patient have a diagnosis of locally advanced or metastatic urothelial carcinoma (UC) (ICD- 10 Groups C66, C67, C68) and meet **ONE** of the following criteria?
The patient has disease progression during or following platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
The patient has disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
The patient does not have disease progression with first-line platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin), AND Bavencio will be used as first-line maintenance treatment

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #3.

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AVELUMAB (PART D)

GUIDELINES FOR USE (CONTINUED)

Does the patient have a diagnosis of advanced renal cell carcinoma (RCC) (ICD-10 Groups C64, C65) **AND** meet the following criterion?
Bavencio will be used in combination with Inlyta (axitinib)

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it

Our guideline named **AVELUMAB (Bavencio)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Metastatic Merkel cell carcinoma (MCC: a type of skin cancer)
- Locally advanced or metastatic urothelial carcinoma (UC: a type of bladder cancer that has spread from where it started to nearby tissue/lymph nodes or to other parts of the body)
- Advanced renal cell carcinoma (RCC: a type of kidney cancer)

If you have metastatic Merkel cell carcinoma, approval also requires:
- You are 12 years of age or older

If you have locally advanced or metastatic urothelial carcinoma, approval also requires ONE of the following:
- Your disease has worsened during or after platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
- Your disease has worsened within 12 months of neoadjuvant (treatment given before a main treatment) or adjuvant treatment (add-on to a main treatment) with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
- Your disease has not worsened with first-line platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin), AND Bavencio will be used as first-line maintenance treatment

If you have advanced renal cell carcinoma, approval also requires:
- Bavencio will be used in combination with Inlyta (axitinib)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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AVELUMAB (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Bavencio.

REFERENCES
Bavencio [Prescribing Information]. Rockland, MA: EMD Serono, Inc.; November 2020.

For Part D use only:

AVELUMAB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AVUTOMETINIB-DEFACTINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AVUTOMETINIB-DEFACTINIB	AVMAPKI-FAKZYNJA	50549		GPI-10 (2199000207)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

Does the patient have a diagnosis of recurrent low-grade serous ovarian cancer (LGSOC) (ICD-10 Group C56) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
The patient's cancer has a KRAS mutation
The patient has received prior systemic therapy (e.g., platinum-based chemotherapy)

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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AVUTOMETINIB-DEFACTINIB (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AVUTOMETINIB-DEFACTINIB (Avmapki-Fakzynja)** requires the following rule(s) be met for approval:
You have recurrent low-grade serous ovarian cancer (LGSOC: a type of reproductive system cancer that has returned)
You are 18 years of age or older
Your cancer has a KRAS mutation (a type of abnormal gene)
You have received prior systemic therapy (such as platinum-based chemotherapy [a type of therapy to treat cancer])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Avmapki-Fakzynja.

REFERENCES

Avmapki-Fakzynja [Prescribing Information]. Needham, MA: Verastem, Inc.; May 2025.

For Part D use only:

AVUTOMETINIB-DEFACTINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AXATILIMAB-CSFR (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AXATILIMAB-CSFR	NIKTIMVO	49817		GPI-10 (9939261010)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

Does the patient have a diagnosis of chronic graft-versus-host disease (cGVHD) (ICD-10 D89.811, D89.812) and meet **ALL** of the following criteria?
- The patient weighs at least 40 kg (88 lbs)
- The patient has failed at least TWO lines of systemic therapy (e.g., prednisone, methotrexate, mycophenolate mofetil), one of which must be a trial of or contraindication to Jakafi (ruxolitinib)
- Niktimvo will NOT be used concurrently with Jakafi (ruxolitinib), Rezurock (belumosudil), or Imbruvica (ibrutinib)

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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AXATILIMAB-CSFR (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AXATILIMAB-CSFR (Niktimvo)** requires the following rule(s) be met for approval:
You have chronic graft-versus-host disease (cGVHD: a type of long-term immune disorder)
You weigh at least 40 kilograms (88 pounds)
You have failed at least TWO lines of systemic therapy (treatment that targets the entire body, such as prednisone, methotrexate, mycophenolate mofetil), one of which must be a trial of or contraindication to (harmful for you to use) Jakafi (ruxolitinib)
You will NOT use Niktimvo concurrently (at the same time) with Jakafi (ruxolitinib), Rezurock (belumosudil), or Imbruvica (ibrutinib)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Niktimvo.

REFERENCES

Niktimvo [Prescribing Information]. Wilmington, DE: Incyte Corporation; January 2025.

For Part D use only:

AXATILIMAB-CSFR (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	CHRONIC GRAFT VS HOST DISEASE (CGVHD): 1) FAILURE OF AT LEAST TWO LINES OF SYSTEMIC THERAPY, ONE OF WHICH MUST BE A TRIAL OF OR CONTRAINDICATION TO JAKAFI, AND 2) NO CONCURRENT USE WITH JAKAFI, REZUROCK, OR IMBRUVICA.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AXITINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AXITINIB	INLYTA	38446		GPI-10 (2133501300)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

Does the patient have a diagnosis of advanced renal cell carcinoma (RCC) (ICD-10 Groups C64, C65) and meet **ONE** of the following criteria?
Inlyta will be used in combination with avelumab (Bavencio)
Inlyta will be used in combination with pembrolizumab (Keytruda)
The patient has tried at least one systemic therapy for RCC (e.g., temsirolimus [Torisel], sunitinib [Sutent], bevacizumab [Avastin] in combination with interferon)

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AXITINIB (Inlyta)** requires the following rule(s) be met for approval:
You have advanced renal cell carcinoma (RCC: a type of kidney cancer)
You meet ONE of the following:
Inlyta will be used in combination with avelumab (Bavencio)
Inlyta will be used in combination with pembrolizumab (Keytruda)
You have tried at least one systemic therapy (treatment that targets the entire body) for RCC (such as temsirolimus [Torisel], sunitinib [Sutent], bevacizumab [Avastin] in combination with interferon)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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AXITINIB (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Inlyta.

REFERENCES
Inlyta [Prescribing Information]. New York, NY: Pfizer; September 2022.

For Part D use only:

AXITINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25 Created: 02/12
Commercial Effective: N/A Client Approval: 08/24 P&T Approval: 07/20

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AZACITIDINE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AZACITIDINE	ONUREG		48545 48540	GPI-14 (21300003000320, 21300003000330)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

Does the patient have a diagnosis of acute myeloid leukemia (ICD-10 Group C92.0) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
The patient achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy
The patient is not able to complete intensive curative therapy

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AZACITIDINE (Onureg)** requires the following rule(s) be met for approval:
You have acute myeloid leukemia (AML: type of blood and bone marrow cancer)
You are 18 years of age or older
You have achieved first complete remission (CR: signs or symptoms of cancer have disappeared) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy (medications for cancer)
You are not able to complete intensive curative therapy (treatment to cure the disease)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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AZACITIDINE (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Onureg.

REFERENCES

Onureg [Prescribing Information]. Summit, NJ: Celgene Corporation; September 2020.

For Part D use only:

AZACITIDINE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25 Created: 09/20
Commercial Effective: N/A Client Approval: 08/24 P&T Approval: 10/20

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AZTREONAM INHALED (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AZTREONAM LYSINE	CAYSTON	36792		GPI-10 (1614001040)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

Does the patient have a diagnosis of cystic fibrosis (CF) (ICD-10 Group E84) and meet **ALL** of the following criteria?
The patient is 7 years of age or older
The patient has a lung infection with *Pseudomonas aeruginosa*

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AZTREONAM INHALED (Cayston)** requires the following rule(s) be met for approval:
You have cystic fibrosis (a type of lung disorder)
You are 7 years of age or older
You have a lung infection with *Pseudomonas aeruginosa* (a type of bacteria)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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AZTREONAM INHALED (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Cayston.

REFERENCES
Cayston [Prescribing Information]. Foster City, CA: Gilead Sciences, Inc.; November 2019.

For Part D use only:

AZTREONAM INHALED (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	7 YEARS OF AGE OR OLDER
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25 Created: 10/19
Commercial Effective: N/A Client Approval: 08/24 P&T Approval: 05/12

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STANDARD PART D
PRIOR AUTHORIZATION GUIDELINES

BAXDROSTAT (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BAXDROSTAT	BAXFENDY	51327		GPI-10 (3613002000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of hypertension (ICD-10 I10) and meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a cardiologist, nephrologist, or endocrinologist
- The patient's blood pressure is NOT controlled on at least three anti-hypertensive agents of different pharmacologic classes (e.g., an angiotensin receptor blocker [e.g., valsartan], a calcium channel blocker [e.g., amlodipine]), with at least one being a diuretic (e.g., hydrochlorothiazide), at maximally tolerated doses for at least 4 weeks
- The patient does NOT have resistant hypertension due to white coat effect, medical inertia, poor therapeutic adherence, or secondary causes of hypertension (except primary aldosteronism and sleep apnea)
- The patient had a trial of or contraindication to ONE of the following clinical standard of care agents: spironolactone, eplerenone

If yes, **approve for 6 months by HICL or GPI-10.**
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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BAXDROSTAT (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: Our guideline named **BAXDROSTAT (Baxfendy)** requires the following rule(s) be met for approval:

You have hypertension (high blood pressure)

You are 18 years of age or older

Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor), nephrologist (a type of kidney doctor), or endocrinologist (a type of hormone doctor)

Your blood pressure is NOT controlled on at least three anti-hypertensive medications (medications used to treat high blood pressure) with different mechanisms of action (such as an angiotensin receptor blocker [such as valsartan], a calcium channel blocker [such as amlodipine]), with at least one being a diuretic (such as hydrochlorothiazide), at maximally tolerated doses for at least 4 weeks

You do NOT have resistant hypertension (a type of high blood pressure) due to white coat effect (a condition where blood pressure is higher in a medical setting), medical inertia (when healthcare providers do not make changes to treatment even if the medical condition is poorly controlled), poor therapeutic adherence (not keeping up with therapy), or secondary causes of hypertension (except primary aldosteronism [a type of hormone disorder] and sleep apnea [a type of sleep condition with difficulty breathing])

You have tried or have a contraindication to (harmful for you to use) ONE of the following clinical standard of care medications: spironolactone, eplerenone

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STANDARD PART D
PRIOR AUTHORIZATION GUIDELINES

BAXDROSTAT (PART D)

RENEWAL CRITERIA

Does the patient have a diagnosis of hypertension (ICD-10 I10) **AND** meet the following criterion?
The patient has had blood pressure reduction or achieved blood pressure goal

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.

RENEWAL DENIAL TEXT: Our guideline named **BAXDROSTAT (Baxfendy)** requires the following rule(s) be met for renewal:
You have hypertension (high blood pressure)
You have had blood pressure reduction (decrease) or achieved blood pressure goal

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Baxfendy.

REFERENCES

Baxfendy [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; May 2026.

Created: 05/26
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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BECAPLERMIN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BECAPLERMIN	REGRANEX	17028		GPI-10 (9094502000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

Does the patient have a diagnosis of lower extremity diabetic neuropathic ulcers (ICD-10 Group E11.62) and meet **ALL** of the following criteria?
The ulcers extend into the subcutaneous tissue or beyond AND have an adequate blood supply
Therapy is prescribed by or in consultation with a vascular surgeon, podiatrist, endocrinologist, a physician practicing in a specialty wound clinic, or an infectious disease specialist

If yes, **approve for 3 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BECAPLERMIN (Regranex)** requires the following rule(s) bet met for approval:
You have lower extremity diabetic neuropathic ulcers (wounds associated with diabetes)
The ulcers go into the subcutaneous tissue (under the skin) or deeper and have enough blood supply
Therapy is prescribed by or in consultation with a vascular surgeon (specialist in veins and arteries), podiatrist (foot doctor), endocrinologist (a type of hormone doctor), a physician practicing in a specialty wound clinic, or an infectious disease specialist (a doctor who specializes in the treatment of infections)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BECAPLERMIN (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Regranex

REFERENCES
Regranex [Prescribing Information]. Fort Worth, TX: Smith & Nephew, Inc.; August 2019.

For Part D use only:

BECAPLERMIN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	DIABETIC NEUROPATHIC ULCERS: PRESCRIBED BY OR IN CONSULTATION WITH A VASCULAR SURGEON, PODIATRIST, ENDOCRINOLOGIST, PHYSICIAN PRACTICING IN A SPECIALTY WOUND CLINIC OR INFECTIOUS DISEASE SPECIALIST.
Coverage Duration	3 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25 Created: 11/00
Commercial Effective: N/A Client Approval: 06/24 P&T Approval: 11/16

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BEDAQUILINE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BEDAQUILINE FUMARATE	SIRTURO	39895		GPI-10 (0900001510)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

Does the patient have a diagnosis of pulmonary tuberculosis (TB) (ICD-10 Group A15) and meet **ALL** of the following criteria?
The patient is 2 years of age or older
The patient has an isolate of Mycobacterium tuberculosis that is resistant to rifampin and isoniazid

If yes, **approve for 24 weeks by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BEDAQUILINE (Sirturo)** requires the following rule(s) be met for approval:
You have pulmonary tuberculosis (TB:a type of lung infection)
You are 2 years of age or older
You have an isolate of *Mycobacterium tuberculosis* (a type of bacterium) that is resistant to rifampin and isoniazid

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BEDAQUILINE (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Sirturo.

REFERENCES
Sirturo [Prescribing Information]. Titusville, NJ: Janssen Therapeutics; July 2025.

For Part D use only:

BEDAQUILINE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	24 WEEKS
Other Criteria	N/A

Created: 05/13
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 10/25

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BELANTAMAB MAFODOTIN-BLMF BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BELANTAMAB MAFODOTIN-BLMF	BLENREP	46762		GPI-10 (2135051520)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	Yes	No	No	Yes	No	No	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

Is this a pharmacy call?

If yes, continue to #3.
If no, continue to #2.

Is the requested medication going to be filled at a pharmacy?

If yes, continue to #3.
If no, **Refer to plan. (This should be processed under the member's medical benefit)**

Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

If no, continue to #4.

Is the pharmacy dispensing the drug directly to the member or member's representative?

If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

If no, continue to #5.

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BELANTAMAB MAFODOTIN-BLMF BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

Is the internal HQ code ML500, SFC01, or SUM03?

If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).
For PAC's: Send an email to plan (reference UNSAD section of PACIP).

If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BELANTAMAB MAFODOTIN-BLMF BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

Does the patient have a diagnosis of relapsed or refractory multiple myeloma (ICD-10 Group C90.0) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
Blenrep will be used in combination with bortezomib and dexamethasone
The patient has received at least two prior lines of therapy, including a proteasome inhibitor (e.g., Ninlaro [ixazomib], Kyprolis [carfilzomib]) and an immunomodulatory agent (e.g., Revlimid [lenalidomide], Pomalyst [pomalidomide])

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BELANTAMAB MAFODOTIN-BLMF (Blenrep)** requires the following rule(s) be met for approval:
You have relapsed or refractory multiple myeloma (a type of blood cancer that has returned or did not respond to treatment)
You are 18 years of age or older
Blenrep will be used in combination with bortezomib and dexamethasone
You have received at least two prior lines of therapy, including a proteasome inhibitor (such as Ninlaro [ixazomib], Kyprolis [carfilzomib]) and an immunomodulatory agent (such as Revlimid [lenalidomide], Pomalyst [pomalidomide])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BELANTAMAB MAFODOTIN-BLMF BvD (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Blenrep. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Blenrep [Prescribing Information]. Durham, NC: GlaxoSmithKline; October 2025.
Medicare Prescription Drug Benefit Manual Chapter 6 – Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Availableat: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed November 5, 2025].

For Part D use only:

BELANTAMAB MAFODOTIN-BLMF (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 11/25
Effective: 01/01/26 Client Approval: 11/25 P&T Approval: 01/26

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BELIMUMAB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BELIMUMAB	BENLYSTA	37462		GPI-10 (9942201500)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of systemic lupus erythematosus (SLE) (ICD-10 Group M32) and meet **ALL** of the following criteria?
The patient is 5 years of age or older
Therapy is prescribed by or in consultation with a rheumatologist
The patient is currently taking corticosteroids, antimalarials, NSAIDs or immunosuppressive agents)

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #2.

Does the patient have a diagnosis of lupus nephritis (ICD-10 M32.14) and meet **ALL** of the following criteria?
The patient is 5 years of age or older
Therapy is prescribed by or in consultation with a rheumatologist or nephrologist
The patient is receiving standard therapy (e.g., steroids, antimalarials, NSAIDs, immunosuppressives)

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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BELIMUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BELIMUMAB (Benlysta)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Systemic lupus erythematosus (SLE: a type of immune condition)
- Lupus nephritis (a type of immune condition that affects the kidneys)

If you have systemic lupus erythematosus, approval also requires:
- You are 5 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You are currently taking corticosteroids, antimalarials, non-steroidal anti-inflammatory drugs (NSAIDs), or immunosuppressives

If you have lupus nephritis, approval also requires:
- You are 5 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or nephrologist (a type of kidney doctor)
- You are receiving standard treatment (such as steroids, antimalarials, nonsteroidal anti-inflammatory drugs [NSAIDs], immunosuppressives)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BELIMUMAB (PART D)

RENEWAL CRITERIA

Does the patient have a diagnosis of systemic lupus erythematosus (SLE) (ICD-10 Group M32) **AND** meet the following criterion?
The patient has shown clinical improvement

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #2.

Does the patient have a diagnosis of lupus nephritis (ICD-10 M32.14) **AND** meet the following criterion?
The patient has shown improvement in renal response from baseline laboratory values (i.e., eGFR or proteinuria) and/or clinical parameters (e.g., fluid retention, use of rescue drugs, glucocorticoid dose)

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BELIMUMAB (Benlysta)** requires the following rule(s) be met for renewal:
You have ONE of the following:
- Systemic lupus erythematosus (SLE: a type of immune condition)
- Lupus nephritis (a type of immune condition that affects the kidneys)

If you have systemic lupus erythematosus, renewal also requires:
- You have shown clinical improvement while on Benlysta

If you have lupus nephritis, renewal also requires:
- You have shown improvement in kidney response as compared to baseline laboratory values (estimated glomerular filtration rate [eGFR: a tool for evaluating kidney function] or proteinuria [level of protein in the urine]) and/or clinical parameters (such as fluid retention, use of rescue drugs, steroid dose)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BELIMUMAB (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Benlysta.

REFERENCES
Benlysta [Prescribing Information]. Philadelphia, PA: GlaxoSmithKline LLC; May 2024.

For Part D use only:

BELIMUMAB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: SYSTEMIC LUPUS ERYTHEMATOSUS (SLE): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. LUPUS NEPHRITIS (LN): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST OR NEPHROLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS
Other Criteria	INITIAL: SLE: CURRENTLY TAKING CORTICOSTEROIDS, ANTIMALARIALS, NSAIDS, OR IMMUNOSUPPRESSIVE AGENTS. RENEWAL: SLE: PATIENT HAD CLINICAL IMPROVEMENT. LN: IMPROVEMENT IN RENAL RESPONSE FROM BASELINE LABORATORY VALUES (I.E., EGFR OR PROTEINURIA) AND/OR CLINICAL PARAMETERS.

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 03/11
Client Approval: 11/24
P&T Approval: 10/24

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BELINOSTAT (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BELINOSTAT	BELEODAQ	41264		GPI-10 (2153152000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

Does the patient have a diagnosis of relapsed or refractory peripheral T-cell lymphoma (PTCL) (ICD-10 Group C84.4) **AND** meet the following criterion?
The patient is 18 years of age or older

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BELINOSTAT (Beleodaq)** requires that the following rule(s) be met for approval:
You have relapsed or refractory (disease that has returned or did not respond to treatment) peripheral T-cell lymphoma (PTCL: a type of blood cancer)
You are 18 years of age or older

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BELINOSTAT (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Beleodaq.

REFERENCES

Beleodaq [Prescribing Information]. Irvine, CA: Spectrum Pharmaceuticals; January 2020.

For Part D use only:

BELINOSTAT (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 07/14
Effective: 01/01/26 Client Approval: 01/26 P&T Approval: 08/16

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BELUMOSUDIL (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BELUMOSUDIL MESYLATE	REZUROCK	47503		GPI-10 (9939851050)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

Does the patient have a diagnosis of chronic graft-versus-host-disease (cGVHD) (ICD-10 D89.811, D89.812) and meet **ALL** of the following criteria?
- The patient is 12 years of age or older
- The patient has failed at least TWO lines of systemic therapy (e.g., prednisone, methotrexate, mycophenolate mofetil), one of which must be a trial of or contraindication to Jakafi (ruxolitinib)
- Rezurock will NOT be used concurrently with Jakafi (ruxolitinib), Niktimvo (axatilimab-csfr), or Imbruvica (ibrutinib)

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BELUMOSUDIL (Rezurock)** requires the following rule(s) be met for approval:
- You have chronic graft-versus-host-disease (cGVHD: a type of long-term immune disorder)
- You are 12 years of age or older
- You have failed at least TWO lines of systemic therapy (treatment that targets the entire body such as prednisone, methotrexate, mycophenolate mofetil), one of which must be a trial of or contraindication to (harmful for you to use) Jakafi (ruxolitinib)
- You will NOT use Rezurock concurrently (at the same time) with Jakafi (ruxolitinib), Niktimvo (axatilimab-csfr), or Imbruvica (ibrutinib)

(Denial text continued on the next page)

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BELUMOSUDIL (PART D)

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rezurock.

REFERENCES

Rezurock [Prescribing Information]. Bridgewater, NJ: Kadmon Pharmaceuticals, LLC; December 2024.

For Part D use only:

BELUMOSUDIL (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	CHRONIC GRAFT VS HOST DISEASE (CGVHD): 1) FAILURE OF AT LEAST TWO LINES OF SYSTEMIC THERAPY, ONE OF WHICH MUST BE A TRIAL OF OR CONTRAINDICATION TO JAKAFI, AND 2) NO CONCURRENT USE WITH JAKAFI, NIKTIMVO, OR IMBRUVICA.

Created: 08/21
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 07/24

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BELZUTIFAN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BELZUTIFAN	WELIREG	47546		GPI-10 (2142102000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

Does the patient have a diagnosis of von Hippel-Lindau (VHL) disease (ICD-10 Q85.83) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- The patient requires therapy for associated renal cell carcinoma (RCC), central nervous system (CNS) hemangioblastomas, or pancreatic neuroendocrine tumors (pNET)
- The patient does NOT require immediate surgery

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #2.

Does the patient have a diagnosis of renal cell carcinoma (RCC) (ICD-10 Groups C64, C65) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Welireg will be used for adjuvant treatment
- Welireg will be used in combination with Keytruda (pembrolizumab) or Keytruda Qlex (pembrolizumab and berahyaluronidase alfa-pmph)
- The patient has renal cell carcinoma with a clear cell component (ccRCC)
- The patient is at intermediate-high or high risk of recurrence following a nephrectomy, or following a nephrectomy and resection of metastatic lesions

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #3.

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BELZUTIFAN (PART D)

GUIDELINES FOR USE (CONTINUED)

Does the patient have a diagnosis of advanced renal cell carcinoma (RCC) (ICD-10 Groups C64, C65) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- The patient has renal cell carcinoma with a clear cell component (ccRCC)
- The patient was previously treated with a programmed death receptor-1 (PD-1) inhibitor (e.g., Keytruda [pembrolizumab]) OR a programmed death-ligand 1 (PD-L1) inhibitor (e.g., Bavencio [avelumab])
- The patient was previously treated with a vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI) (e.g., Nexavar [sorafenib])

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #4.

Does the patient have a diagnosis of pheochromocytoma (ICD-10 Groups D35.0, C74.1) or paraganglioma (PPGL) (ICD-10 D44.7, C75.5) and meet **ALL** the following criteria?
- The patient is 12 years of age or older
- The patient's tumor is locally advanced, unresectable, or metastatic

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.

DENIAL TEXT: Our guideline named **BELZUTIFAN (Welireg)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Von Hippel-Lindau (VHL) disease (a genetic disorder that causes tumors to grow in the body)
- Renal cell carcinoma (RCC: a type of kidney cancer)
- Pheochromocytoma (a type of rare tumor) or paraganglioma (a type of nerve condition)

If you have von Hippel-Lindau disease, approval also requires:
- You are 18 years of age or older
- You require therapy for associated renal cell carcinoma (RCC: a type of kidney cancer), central nervous system (CNS) hemangioblastomas (tumor in the brain or spinal cord), or pancreatic neuroendocrine tumors (pNET: tumor in the pancreas)
- You do NOT require immediate surgery

(Denial text continued on next page)

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BELZUTIFAN (PART D)

GUIDELINES FOR USE (CONTINUED)

If you have renal cell carcinoma, approval also requires ONE of the following:

- You are 18 years of age or older; AND Welireg will be used in combination with Keytruda (pembrolizumab) or Keytruda Qlex (pembrolizumab and berahyaluronidase alfa-pmph); AND Welireg will be used for adjuvant (add-on) treatment; AND you have renal cell carcinoma with a clear cell component (ccRCC: a type of kidney cancer); AND your cancer is at intermediate-high or high risk of recurrence (returning) following a nephrectomy (surgical removal of the kidney), or following a nephrectomy and resection (surgical removal) of metastatic lesions (abnormal area of tissue)
- You are 18 years of age or older; AND your cancer is advanced; AND you have renal cell carcinoma with a clear cell component (ccRCC: a type of kidney cancer); AND you were previously treated with a programmed death receptor-1 (PD-1) inhibitor (such as Keytruda [pembrolizumab]) OR a programmed death-ligand 1 (PD-L1) inhibitor (such as Bavencio [avelumab]); AND you were previously treated with a vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI, such as Nexavar [sorafenib])

If you have pheochromocytoma or paraganglioma, approval also requires:

- You are 12 years of age or older
- Your tumor is locally advanced (spread from where it started to nearby tissue or lymph nodes), unresectable (cannot be removed by surgery), or metastatic (has spread to other parts of the body)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Welireg.

REFERENCES

Welireg [Prescribing Information]. Rahway, NJ: Merck Sharp & Dohme LLC, June 2026.

For Part D use only:

BELZUTIFAN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 09/21
Effective: 07/01/26 Client Approval: 06/26 DMC Approval: 07/26

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BENDAMUSTINE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BENDAMUSTINE HCL	BENDEKA, TREANDA, BENDAMUSTINE HCL	16785		GPI-10 (2110000910)	BRAND ≠ BELRAPZO, VIVIMUSTA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

Does the patient have a diagnosis of chronic lymphocytic leukemia (CLL) (ICD-10 Group C91.1)?

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #2.

Does the patient have a diagnosis of indolent B-cell non-Hodgkin lymphoma (NHL) (ICD-10 Group C85) **AND** meet the following criterion?
The disease has progressed during or within 6 months of treatment with rituximab or a rituximab-containing regimen

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guidelin.

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GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BENDAMUSTINE (Bendeka, Treanda)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Chronic lymphocytic leukemia (CLL: a type of blood cancer)
- Indolent B-cell non-Hodgkin lymphoma (NHL: type of blood cancer)

If you have indolent B-cell non-Hodgkin lymphoma, approval also requires:
- Your disease has progressed (gotten worse) during or within 6 months of treatment with rituximab or a rituximab-containing regimen

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Bendeka or Treanda (bendamustine HCL).

REFERENCES

Bendeka [Prescribing Information]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; October 2021.
Treanda [Prescribing Information]. North Wales, PA: Cephalon, Inc.; June 2021.

For Part D use only:

BENDAMUSTINE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 12/15
Client Approval: 08/24
P&T Approval: 10/19

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BENRALIZUMAB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BENRALIZUMAB	FASENRA	44635		GPI-10 (4460402000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of severe asthma with an eosinophilic phenotype (ICD-10 J82.83) and meet **ALL** of the following criteria?

- The patient is 6 years of age or older
- Therapy is prescribed by or in consultation with a physician specializing in pulmonary or allergy medicine
- The patient has a blood eosinophil level of at least 150 cells/mcL within the past 12 months
- Fasenra will be used in combination with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (e.g., triamcinolone acetonide, beclomethasone, mometasone) AND at least ONE other maintenance medication (e.g., a long-acting inhaled beta2-agonist [e.g., salmeterol, formoterol], a long-acting muscarinic antagonist [e.g., Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [e.g., montelukast, zafirlukast, zileuton], theophylline, an oral corticosteroid [e.g., prednisone])
- Fasenra will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of eosinophilic phenotype asthma

If yes, continue to #2.
If no, continue to #4.

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BENRALIZUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

Does the patient meet **ONE** of the following criteria?
- The patient has experienced at least ONE asthma exacerbation requiring systemic corticosteroid (e.g., prednisone) burst lasting at least 3 days within the past 12 months
- The patient has experienced at least ONE serious asthma exacerbation requiring hospitalization or an emergency room visit within the past 12 months

If yes, **approve for 12 months by HICL or GPI-10.**

If no, continue to #3.

Does the patient have poor symptom control despite current therapy as evidenced by at least **THREE** of the following within the past 4 weeks?
- Daytime asthma symptoms more than twice per week
- Any night waking due to asthma
- Use of a short-acting inhaled beta2-agonist (SABA) reliever (e.g., albuterol) for symptoms more than twice per week
- Any activity limitation due to asthma

If yes, **approve for 12 months by HICL or GPI-10.**

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

Does the patient have a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA) (ICD-10 M30.1), also known as Churg-Strauss syndrome, and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Fasenra will NOT be used concurrently with another systemic biologic (e.g., Nucala [mepolizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of EGPA

If yes, **approve for 12 months by HICL or GPI-10.**

If no, continue to #5.

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BENRALIZUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of hypereosinophilic syndrome (HES) (ICD-10 Group D72.11) and meet **ALL** of the following criteria?
The patient is 12 years of age or older
The patient has HES without an identifiable non-hematologic secondary cause
Fasenra will NOT be used concurrently with another systemic biologic (e.g., Nucala [mepolizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) forthe treatment of HES

If yes, **approve for 12 months by HICL or GPI-10.**

If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BENRALIZUMAB (Fasenra)** requires the following rule(s) be met for approval:
You have ONE of the following:
Severe asthma with an eosinophilic phenotype (a type of lung condition with inflammation)
Eosinophilic granulomatosis with polyangiitis (EGPA), also known as Churg-Strauss syndrome (a type of immune system disorder with inflammation of blood vessels)
Hypereosinophilic syndrome (HES: a type of blood disorder)
(Initial denial text continued on next page)

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BENRALIZUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

If you have severe asthma with an eosinophilic phenotype, approval also requires:

- You are 6 years of age or older
- Therapy is prescribed by or in consultation with a physician specializing in pulmonary (relating to lungs/breathing) medicine or allergy medicine
- You have a blood eosinophil level (a type of lab test) of at least 150 cells/mcL within the past 12 months
- Fasenra will be used in combination with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (such as triamcinolone acetonide, beclomethasone, mometasone) AND at least ONE other maintenance medication (taken on a regular basis) (such as a long-acting inhaled beta-2-agonist [such as salmeterol, formoterol], a long-acting muscarinic antagonist [such as Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [such as montelukast, zafirlukast, zileuton], theophylline, an oral corticosteroid [such as prednisone])
- You will NOT use Fasenra concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor for the treatment of eosinophilic phenotype asthma
- You meet ONE of the following:
  - You have experienced at least ONE asthma exacerbation (worsening of symptoms) requiring systemic corticosteroid (such as prednisone) burst lasting at least 3 days within the past 12 months
  - You have experienced at least ONE serious asthma exacerbation requiring hospitalization or an emergency room visit within the past 12 months
  - You have poor symptom control despite current therapy as evidenced by at least THREE of the following within the past 4 weeks:
    - Daytime asthma symptoms more than twice per week
    - Any night waking due to asthma
    - Use of a short-acting beta2-agonist reliever (such as albuterol) for symptoms more than twice per week
    - Any activity limitation due to asthma

If you have eosinophilic granulomatosis with polyangiitis, approval also requires:

- You are 18 years of age or older
- You will NOT use Fasenra concurrently (at the same time) with another systemic biologic (such as Nucala [mepolizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic granulomatosis with polyangiitis

(Initial denial text continued on next page)

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BENRALIZUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

If you have hypereosinophilic syndrome, approval also requires:

- You are 12 years of age or older
- You have hypereosinophilic syndrome (HES: a type of blood disorder) without an identifiable non-hematologic (not present in the blood) secondary cause (HES is not caused by another condition)
- You will NOT use Fasenra concurrently (at the same time) with another systemic biologic (such as Nucala [mepolizumab]) or targeted small molecules (such as JAK inhibitor, PDE-4 inhibitor) for the treatment of hypereosinophilic syndrome (a type of blood disorder)

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BENRALIZUMAB (PART D)

RENEWAL CRITERIA

NOTE: For the diagnosis of hypereosinophilic syndrome (HES), please refer to the Initial Criteria section.

Does the patient have a diagnosis of severe asthma with an eosinophilic phenotype (ICD-10 J82.83) and meet **ALL** of the following criteria?
- The patient will continue to use an inhaled corticosteroid (e.g., beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (e.g., a long-acting inhaled beta2-agonist [e.g., formoterol, salmeterol], a long-acting muscarinic antagonist [e.g., Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [e.g., montelukast, zafirlukast, zileuton], theophylline, an oral corticosteroid [e.g., prednisone])
- Fasenra will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of eosinophilic phenotype asthma

If yes, continue to #2.
If no, continue to #3.

Has the patient shown a clinical response as evidenced by **ONE** of the following criteria?
- Reduction in asthma exacerbations from baseline
- Decreased utilization of rescue medications (e.g., albuterol)
- Increase in percent predicted FEV1 from pretreatment baseline
- Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing)

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.
DENIAL TEXT: See the renewal denial text at the end of the guideline.

Does the patient have a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA) (ICD-10 M30.1), also known as Churg-Strauss syndrome, and meet **ALL** of the following criteria?
- The patient has a reduction in EGPA symptoms compared to baseline OR has been able to reduce/eliminate corticosteroid (e.g., prednisone) use
- Fasenra will NOT be used concurrently with another systemic biologic (e.g., Nucala [mepolizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of EGPA

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.

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BENRALIZUMAB (PART D)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BENRALIZUMAB (Fasenra)** requires the following rule(s) be met for renewal:

You have ONE of the following:
- Severe asthma with an eosinophilic phenotype (a type of lung condition with inflammation)
- Eosinophilic granulomatosis with polyangiitis (EGPA), also known as Churg-Strauss syndrome (a type of immune system disorder with inflammation of blood vessels)

If you have severe asthma with an eosinophilic phenotype, renewal also requires:
- You will continue to use an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis), such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast, zileuton), theophylline, or an oral corticosteroid (such as prednisone)
- You will NOT use Fasenra concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic phenotype asthma
- You have shown a clinical response as evidenced by ONE the following:
  - You have experienced a decrease in asthma exacerbations (worsening of symptoms) from baseline
  - You have decreased your use of rescue medications (such as albuterol)
  - Your percent predicted FEV1 (amount of air exhaled in one second) has increased from pretreatment baseline (before starting Fasenra)
  - You have experienced a reduction in severity or frequency of asthma-related symptoms (such as wheezing, shortness of breath, coughing)

If you have eosinophilic granulomatosis with polyangiitis, renewal also requires:
- You have a reduction in EGPA symptoms compared to baseline (before starting Fasenra), OR you have been able to decrease or eliminate (stop) corticosteroid (such as prednisone) use
- You will NOT use Fasenra concurrently (at the same time) with another systemic biologic (such as Nucala [mepolizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic granulomatosis with polyangiitis

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BENRALIZUMAB (PART D)

RATIONALE
For further information, please refer to the prescribing information and/or drug monograph for Fasenra.

REFERENCES
Fasenra [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceutical LP.; May 2026.

For Part D use only:

BENRALIZUMAB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	INITIAL: ASTHMA: BLOOD EOSINOPHIL LEVEL OF AT LEAST 150 CELLS/MCL WITHIN THE PAST 12 MONTHS.
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: ASTHMA: PRESCRIBED BY OR IN CONSULTATION WITH A PHYSICIAN SPECIALIZING IN ALLERGY OR PULMONARY MEDICINE.
Coverage Duration	ASTHMA, EGPA: INITIAL/RENEWAL: 12 MO. HYPEREOSINOPHILIC SYNDROME (HES): 12 MO.
Other Criteria	INITIAL: ASTHMA: 1) CONCURRENT THERAPY WITH A MEDIUM, HIGH-DOSE, OR MAXIMALLY TOLERATED DOSE OF AN INHALED CORTICOSTEROID (ICS) AND ONE OTHER MAINTENANCE MEDICATION, AND 2) ONE ASTHMA EXACERBATION REQUIRING SYSTEMIC CORTICOSTEROID BURST LASTING AT LEAST 3 DAYS WITHIN THE PAST 12 MONTHS, OR AT LEAST ONE SERIOUS EXACERBATION REQUIRING HOSPITALIZATION OR ER VISIT WITHIN THE PAST 12 MONTHS, OR POOR SYMPTOM CONTROL DESPITE CURRENT THERAPY AS EVIDENCED BY AT LEAST THREE OF THE FOLLOWING WITHIN THE PAST 4 WEEKS: (A) DAYTIME ASTHMA SYMPTOMS MORE THAN TWICE/WEEK, (B) ANY NIGHT WAKING DUE TO ASTHMA, (C) SABA RELIEVER FOR SYMPTOMS MORE THAN TWICE/WEEK, (D) ANY ACTIVITY LIMITATION DUE TO ASTHMA. INITIAL/RENEWAL: ALL INDICATIONS: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION. RENEWAL: ASTHMA: 1) CONTINUED USE OF ICS AND ONE OTHER MAINTENANCE MEDICATION, AND 2) CLINICAL RESPONSE AS EVIDENCED BY: (A) REDUCTION IN ASTHMA EXACERBATIONS FROM BASELINE, (B) DECREASED UTILIZATION OF RESCUE MEDICATIONS, (C) INCREASE IN PERCENT PREDICTED FEV1 FROM PRETREATMENT BASELINE, OR (D) REDUCTION IN SEVERITY OR FREQUENCY OF ASTHMA-RELATED SYMPTOMS. EOSINOPHILIC GRANULOMATOSIS WITH POLYANGIITIS (EGPA): REDUCTION IN EGPA SYMPTOMS COMPARED TO BASELINE OR ABILITY TO REDUCE/ELIMINATE CORTICOSTEROID USE.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BERDAZIMER (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BERDAZIMER SODIUM	ZELSUVMI	49364		GPI-10 (9035001450)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

Does the patient have a diagnosis of molluscum contagiosum (MC) (ICD-10 B08.1) and meet **ALL** of the following criteria?

The patient is 1 year of age or older

Zelsuvmi will NOT be used concurrently with another topical agent for the treatment of molluscum contagiosum (e.g., Ycanth [cantharidin])

If yes, **approve for 12 weeks by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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BERDAZIMER (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BERDAZIMER (Zelsuvmi)** requires the following rule(s) be met for approval:
You have molluscum contagiosum (MC: a viral skin infection)
You are 1 year of age or older
You will NOT use Zelsuvmi concurrently (at the same time) with another topical medication for the treatment of molluscum contagiosum (a viral skin infection) (such as Ycanth [cantharidin])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Zelsuvmi.

REFERENCES
Zelsuvmi [Prescribing Information]. Wilmington, DE: EPIH SPV, LLC.; January 2024.

For Part D use only:

BERDAZIMER (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 WEEKS
Other Criteria	MOLLUSCUM CONTAGIOSUM: NO CONCURRENT USE WITH ANOTHER TOPICAL AGENT FOR TREATMENT OF MOLLUSCUM CONTAGIOSUM.

Created: 08/25
Effective: 09/01/25 Client Approval: 08/25 P&T Approval: 07/25

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BEREMAGENE GEPERPAVEC-SVDT (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BEREMAGENE GEPERPAVEC-SVDT	VYJUVEK	48966		GPI-10 (9094452020)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

Does the patient have a diagnosis of dystrophic epidermolysis bullosa (DEB) (ICD-10 Q81.2) **AND** meet the following criterion?
The patient has mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BEREMAGENE GEPERPAVEC-SVDT (Vyjuvek)** requires the following rule(s) be met for approval:

You have dystrophic epidermolysis bullosa (DEB: a type of genetic skin disorder)
You have mutation(s) (abnormal change) in the collagen type VII alpha 1 chain (COL7A1) gene

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BEREMAGENE GEPERPAVEC-SVDT (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Vyjuvek.

REFERENCES
Vyjuvek [Prescribing Information]. Pittsburgh, PA: Krystal Biotech, Inc.; September 2025.

For Part D use only:

BEREMAGENE GEPERPAVEC-SVDT (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 06/23
Effective: 10/20/25 Client Approval: 10/25 P&T Approval: 10/25

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BEROTRALSTAT (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BEROTRALSTAT HYDROCHLORIDE	ORLADEYO	47016		GPI-10 (8584001020)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of hereditary angioedema (HAE) (ICD-10 D84.1) and meet **ALL** of the following criteria?

The patient is 2 years of age or older

Orladeyo will be used for prophylaxis against HAE attacks

Therapy is prescribed by or in consultation with an allergist, immunologist, hematologist, or pulmonologist

Orladeyo will NOT be used concurrently with an alternative prophylactic agent for HAE attacks (e.g., Takhzyro [lanadelumab-flyo], Haegarda [C1 esterase inhibitor], Cinryze [C1 esterase inhibitor], danazol, Andembry [garadacimab-gxii])

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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BEROTRALSTAT (PART D)

INITIAL CRITERIA (CONTINUED)

Does the patient meet **ONE** of the following criteria?
- The patient has Type I or II HAE, as confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q
- The patient has Type III HAE

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BEROTRALSTAT (Orladeyo)** requires the following rule(s) be met for approval:
- You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
- You are 2 years of age or older
- Orladeyo will be used for the prevention of hereditary angioedema attacks
- Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), immunologist (a type of immune system doctor), hematologist (a type of blood doctor), or pulmonologist (lung/breathing doctor)
- You will NOT use Orladeyo concurrently (at the same time) with an alternative preventive medication for hereditary angioedema attacks (such as Takhzyro [lanadelumab-flyo], Haegarda [C1 esterase inhibitor], Cinryze [C1 esterase inhibitor], danazol, Andembry [garadacimab-gxii])
- You meet ONE of the following:
  - You have Type I or II hereditary angioedema (a type of gene condition with severe body swelling), as confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q (types of lab tests)
  - You have Type III hereditary angioedema (a type of gene condition with severe body swelling)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BEROTRALSTAT (PART D)

RENEWAL CRITERIA

Does the patient have a diagnosis of hereditary angioedema (HAE) (ICD-10 D84.1) **AND** meet the following criterion?

Orladeyo will NOT be used concurrently with an alternative prophylactic agent for HAE attacks (e.g., Takhzyro [lanadelumab-flyo], Haegarda [C1 esterase inhibitor], Cinryze [C1 esterase inhibitor], danazol, Andembry [garadacimab-gxii])

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BEROTRALSTAT (Orladeyo)** requires the following rule(s) be met for renewal:
You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
You will NOT use Orladeyo concurrently (at the same time) with an alternative preventive medication for HAE attacks (such as Takhzyro [lanadelumab-flyo], Haegarda [C1 esterase inhibitor], Cinryze [C1 esterase inhibitor], danazol, Andembry [garadacimab-gxii])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Orladeyo.

REFERENCES

Orladeyo [Prescribing Information]. Durham, NC: BioCryst Pharmaceuticals, Inc.; December 2025.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BEROTRALSTAT (PART D)

For Part D use only:

BEROTRALSTAT (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	HEREDITARY ANGIOEDEMA (HAE): INITIAL: 1) TYPE III HAE, OR 2) TYPE I OR II HAE CONFIRMED BY ONE OF THE FOLLOWING COMPLEMENT TESTS: C1-INH PROTEIN LEVELS, C4 PROTEIN LEVELS, C1-INH FUNCTIONAL LEVELS, C1Q.
Age Restrictions	N/A
Prescriber Restrictions	HAE: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH AN ALLERGIST, IMMUNOLOGIST, HEMATOLOGIST, OR PULMONOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	HAE: INITIAL/RENEWAL: NOT ON CONCURRENT TREATMENT WITH ALTERNATIVE PROPHYLACTIC AGENT FOR HAE ATTACKS.

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ADVANTAGE AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BETAINE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BETAINE	CYSTADANE, BETAINE ANHYDROUS	12233		GPI-10 (3090452000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

Does the patient have a diagnosis of homocystinuria (ICD-10 E72.11) (including cystathionine beta-synthase [CBS] deficiency [ICD-10 E72.11], 5,10-methylenetetrahydrofolate reductase [MTHFR] deficiency [ICD-10 E72.12], cobalamin cofactor metabolism [cbl] defect)?

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BETAINE (Cystadane)** requires the following rule(s) be met for approval:
You have homocystinuria (a type of genetic metabolic disorder), including cystathionine beta-synthase (CBS: a type of enzyme) deficiency, 5,10-methylenetetrahydrofolate reductase (MTHFR: a type of enzyme) deficiency, cobalamin cofactor metabolism (cbl: vitamin B12 that is required for enzyme activity) defect

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BETAINE (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cystadane.

REFERENCES

Cystadane [Prescribing Information]. Lebanon, NJ. Recordati Rare Disease Inc.; October 2018.

For Part D use only:

BETAINE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BEVACIZUMAB BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BEVACIZUMAB	AVASTIN	25963		GPI-10 (2133502000)	

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

Is this a pharmacy call?

If yes, continue to #3.
If no, continue to #2.

Is the requested medication going to be filled at a pharmacy?

If yes, continue to #3.
If no, **Refer to plan. (This should be processed under the member's medical benefit)**

Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**
If no, continue to #4.

Is the pharmacy dispensing the drug directly to the member or member's representative?

If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**
If no, continue to #5.

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BEVACIZUMAB BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

Is the internal HQ code ML500, SFC01, or SUM03?

If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override)
For PAC's: Send an email to plan (reference UNSAD section of PACIP).

If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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BEVACIZUMAB BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

Does the patient have a diagnosis of metastatic colorectal cancer (mCRC) (ICD-10 C19) **AND** meet the following criterion?
The patient had a trial of or contraindication to the following preferred agent: Zirabev (bevacizumab-bvzr)

If yes, continue to #2.
If no, continue to #4.

Will Avastin be used in combination with intravenous 5-fluorouracil based chemotherapy?

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #3.

Does the patient meet **ALL** of the following criteria?
Avastin will be used in combination with fluoropyrimidine-irinotecan- (e.g., FOLFIRI) or fluoropyrimidine-oxaliplatin- (e.g., FOLFOX, CapeOx) based chemotherapy
The patient's disease has progressed on a first-line bevacizumab product-containing regimen

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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BEVACIZUMAB BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

Does the patient have a diagnosis of unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
Avastin will be used in combination with carboplatin and paclitaxel
The patient had a trial of or contraindication to the following preferred agent: Zirabev (bevacizumab-bvzr)

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #5.

Does the patient have a diagnosis of recurrent glioblastoma (GBM) (ICD-10 C72.9; Group C71) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
The patient had a trial of or contraindication to the following preferred agent: Zirabev (bevacizumab-bvzr)

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #6.

Does the patient have a diagnosis of metastatic renal cell carcinoma (mRCC) (ICD-10 Groups C64, C65) and meet **ALL** of the following criteria?
Avastin will be used in combination with interferon alfa
The patient had a trial of or contraindication to the following preferred agent: Zirabev (bevacizumab-bvzr)

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #7.

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BEVACIZUMAB BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

Does the patient have a diagnosis of persistent, recurrent, or metastatic cervical cancer (ICD-10 Group C53) and meet **ALL** of the following criteria?
Avastin will be used in combination with paclitaxel and cisplatin OR paclitaxel and topotecan
The patient had a trial of or contraindication to the following preferred agent: Zirabev (bevacizumab-bvzr)

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #8.

Does the patient have a diagnosis of epithelial ovarian, fallopian tube, or primary peritoneal cancer (ICD-10 Groups C56, C57.0, C48, C79.6) **AND** meet the following criterion?
The patient had a trial of or contraindication to the following preferred agent: Zirabev (bevacizumab-bvzr)

If yes, continue to #9.
If no, continue to #12.

Is the patient's cancer stage III or IV, and the patient meets **ALL** of the following criteria?
Avastin will be used following initial surgical resection
Avastin will be used in combination with carboplatin and paclitaxel, OR as a single agent after prior use in combination with carboplatin and paclitaxel

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #10.

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BEVACIZUMAB BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

Is the patient's cancer platinum-resistant and recurrent, and the patient meets **ALL** of the following criteria?
Avastin will be used in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan
The patient has received no more than two prior chemotherapy regimens

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #11.

Is the patient's cancer platinum-sensitive and recurrent, and the patient meets **ONE** of the following criteria?
Avastin will be used in combination with carboplatin and paclitaxel
Avastin will be used in combination with carboplatin and gemcitabine
Avastin will be used as a single agent after prior use in combination with one of the carboplatin-containing chemotherapy regimens listed above

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

Does the patient have a diagnosis of unresectable or metastatic hepatocellular carcinoma (HCC) (ICD-10 C22.0) and meet **ALL** of the following criteria?
Avastin will be used in combination with Tecentriq (atezolizumab)
The patient has not received prior systemic therapy

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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BEVACIZUMAB BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BEVACIZUMAB (Avastin)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Metastatic colorectal cancer (mCRC: colon cancer that has spread to other parts of the body)
- Unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer (NSCLC: a type of lung cancer that cannot be completely removed with surgery or has spread/returned)
- Recurrent glioblastoma (GBM: type of brain cancer that has returned)
- Metastatic renal cell carcinoma (mRCC: type of kidney cancer that has spread to other parts of the body)
- Persistent, recurrent, or metastatic cervical cancer (type of uterus cancer that continues to exist, returns, or has spread to other parts of the body)
- Epithelial ovarian, fallopian tube, or primary peritoneal cancer (types of reproductive system or abdomen cancers)
- Unresectable or metastatic hepatocellular carcinoma (HCC: type of liver cancer that cannot be completely removed with surgery or has spread to other parts of the body)

If you have metastatic colorectal cancer, approval also requires:
- You have tried or have a contraindication to (harmful for you to use) the following preferred medication: Zirabev (bevacizumab-bvzr)
- You meet ONE of the following:
  - Avastin will be used in combination with intravenous (given into the vein) 5-fluorouracil based chemotherapy
  - Avastin will be used in combination with fluoropyrimidine-irinotecan- (such as FOLFIRI) or fluoropyrimidine-oxaliplatin- (such as FOLFOX, CapeOx) based chemotherapy AND your disease has worsened on a first-line bevacizumab product-containing regimen

(Denial text continued on next page)

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BEVACIZUMAB BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

If you have unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer, approval also requires:
- Avastin will be used in combination with carboplatin and paclitaxel
- You have tried or have a contraindication to (harmful for you to use) the following preferred medication: Zirabev (bevacizumab-bvzr)

If you have recurrent glioblastoma, approval also requires:
- You are 18 years of age or older
- You have tried or have a contraindication to (harmful for you to use) the following preferred medication: Zirabev (bevacizumab-bvzr)

If you have metastatic renal cell carcinoma, approval also requires:
- Avastin will be used in combination with interferon alfa
- You have tried or have a contraindication to (harmful for you to use) the following preferred medication: Zirabev (bevacizumab-bvzr)

If you have persistent, recurrent, or metastatic cervical cancer, approval also requires:
- Avastin will be used in combination with paclitaxel and cisplatin OR paclitaxel and topotecan
- You have tried or have a contraindication to (harmful for you to use) the following preferred medication: Zirabev (bevacizumab-bvzr)

If you have epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:
- You have tried or have a contraindication to (harmful for you to use) the following preferred medication: Zirabev (bevacizumab-bvzr)
- You meet ONE of the following:
  - You have stage III or IV epithelial ovarian, fallopian tube or primary peritoneal cancer; Avastin will be used following initial surgical resection (removal); AND Avastin will be used in combination with carboplatin and paclitaxel, OR as a single medication after previous use in combination with carboplatin and paclitaxel
  - You have platinum-resistant, recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer (cancer that no longer responds to a type of treatment and has returned); Avastin will be used in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan; AND you have received no more than two prior chemotherapy regimens
  - You have platinum-sensitive, recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer (cancer that responds to a type of treatment and has returned); AND Avastin will be used in combination with carboplatin and paclitaxel, OR with carboplatin and gemcitabine, OR as a single medication after previous use in combination with one of these carboplatin-containing chemotherapy regimens

(Denial text continued on next page)

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BEVACIZUMAB BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

If you have unresectable or metastatic hepatocellular carcinoma, approval also requires:
Avastin will be used in combination with Tecentriq (atezolizumab)
You have not received prior systemic therapy (treatment that targets the entire body)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Avastin. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Avastin [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; September 2022.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed April 7, 2025].

For Part D use only:

BEVACIZUMAB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT: ZIRABEV, WHERE INDICATIONS ALIGN.

Created: 02/13
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 07/20

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BEVACIZUMAB-ADCD BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BEVACIZUMAB-ADCD	VEGZELMA	48357		GPI-10 (2133502010)	

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

Is this a pharmacy call?

If yes, continue to #3.
If no, continue to #2.

Is the requested medication going to be filled at a pharmacy?

If yes, continue to #3.
If no, **Refer to plan. (This should be processed under the member's medical benefit)**

Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

If no, continue to #4.

Is the pharmacy dispensing the drug directly to the member or member's representative?

If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

If no, continue to #5.

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BEVACIZUMAB-ADCD BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

Is the internal HQ code ML500, SFC01, or SUM03?

If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override)
For PAC's: Send an email to plan (reference UNSAD section of PACIP).

If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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BEVACIZUMAB-ADCD BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

Does the patient have a diagnosis of metastatic colorectal cancer (mCRC) (ICD-10 C19) **AND** meet the following criterion?
The patient had a trial of or contraindication to the following preferred agent: Zirabev (bevacizumab-bvzr)

If yes, continue to #2.
If no, continue to #3.

Does the patient meet **ONE** of the following criteria?
Vegzelma will be used in combination with intravenous 5-fluorouracil based chemotherapy
Vegzelma will be used in combination with fluoropyrimidine-irinotecan- (e.g., FOLFIRI) or fluoropyrimidine-oxaliplatin- (e.g., FOLFOX, CapeOx) based chemotherapy AND the patient has progressed on a first-line bevacizumab product-containing regimen

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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BEVACIZUMAB-ADCD BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

Does the patient have a diagnosis of unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
Vegzelma will be used in combination with carboplatin and paclitaxel
The patient had a trial of or contraindication to the following preferred agent: Zirabev (bevacizumab-bvzr)

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #4.

Does the patient have a diagnosis of recurrent glioblastoma (GBM) (ICD-10 C72.9, Group C71) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
The patient had a trial of or contraindication to the following preferred agent: Zirabev (bevacizumab-bvzr)

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #5.

Does the patient have a diagnosis of metastatic renal cell carcinoma (mRCC) (ICD-10 Groups C64, C65) and meet **ALL** of the following criteria?
Vegzelma will be used in combination with interferon alfa
The patient had a trial of or contraindication to the following preferred agent: Zirabev (bevacizumab-bvzr)

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #6.

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BEVACIZUMAB-ADCD BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

Does the patient have a diagnosis of persistent, recurrent, or metastatic cervical cancer (ICD-10 Group C53) and meet **ALL** of the following criteria?
Vegzelma will be used in combination with paclitaxel and cisplatin OR paclitaxel and topotecan
The patient had a trial of or contraindication to the following preferred agent: Zirabev (bevacizumab-bvzr)

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #7.

Does the patient have a diagnosis of epithelial ovarian, fallopian tube, or primary peritoneal cancer (ICD-10 Groups C56, C57.0, C48, C79.6) **AND** meet the following criterion?
The patient had a trial of or contraindication to the following preferred agent: Zirabev (bevacizumab-bvzr)

If yes, continue to #8.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

Is the patient's cancer stage III or IV, and the patient meets **ALL** of the following criteria?
Vegzelma will be used following initial surgical resection
Vegzelma will be used in combination with carboplatin and paclitaxel OR as a single agent after prior use in combination with carboplatin and paclitaxel

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.
If no, continue to #9.

Is the patient's cancer platinum-resistant and recurrent, and the patient meets **ALL** of the following criteria?
Vegzelma will be used in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan
The patient has received no more than two prior chemotherapy regimens

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.
If no, continue to #10.

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BEVACIZUMAB-ADCD BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

Is the patient's cancer platinum-sensitive and recurrent, and the patient meets **ONE** of the following criteria?
- Vegzelma will be used in combination with carboplatin and paclitaxel
- Vegzelma will be used in combination with carboplatin and gemcitabine
- Vegzelma will be used as a single agent after prior use in combination with one ofthe carboplatin-containing chemotherapy regimens listed above

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BEVACIZUMAB-ADCD (Vegzelma)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Metastatic colorectal cancer (mCRC: colon cancer that has spread to other parts of the body)
- Unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer (NSCLC: type of lung cancer that cannot be completely removed with surgery or has spread/returned)
- Recurrent glioblastoma (GBM: type of brain cancer that has returned)
- Metastatic renal cell carcinoma (mRCC: type of kidney cancer that has spread to other parts of the body)
- Persistent, recurrent, or metastatic cervical cancer (type of uterus cancer that continues to exist, returns, or has spread to other parts of the body)
- Epithelial ovarian, fallopian tube, or primary peritoneal cancer (types of reproductive system or abdomen cancers)

(Denial text continued on next page)

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BEVACIZUMAB-ADCD BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

If you have metastatic colorectal cancer, approval also requires:
- You have tried or have a contraindication to (harmful for you to use) the following preferred medication: Zirabev (bevacizumab-bvzr)
- You meet ONE of the following:
  - Vegzelma will be used in combination with intravenous (given into the vein) 5-fluorouracil based chemotherapy
  - Vegzelma will be used in combination with fluoropyrimidine-irinotecan- (such as FOLFIRI) or fluoropyrimidine-oxaliplatin- (such as FOLFOX, CapeOx) based chemotherapy AND your disease has worsened on a first-line bevacizumab product-containing regimen

If you have unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer, approval also requires:
- Vegzelma will be used in combination with carboplatin and paclitaxel
- You have tried or have a contraindication to (harmful for you to use) the following preferred medication: Zirabev (bevacizumab-bvzr)

If you have recurrent glioblastoma, approval also requires:
- You are 18 years of age or older
- You have tried or have a contraindication to (harmful for you to use) the following preferred medication: Zirabev (bevacizumab-bvzr)

If you have metastatic renal cell carcinoma, approval also requires:
- Vegzelma will be used in combination with interferon alfa
- You have tried or have a contraindication to (harmful for you to use) the following preferred medication: Zirabev (bevacizumab-bvzr)

If you have persistent, recurrent, or metastatic cervical cancer, approval also requires:
- Vegzelma will be used in combination with paclitaxel and cisplatin OR paclitaxel and topotecan
- You have tried or have a contraindication to (harmful for you to use) the following preferred medication: Zirabev (bevacizumab-bvzr)

(Denial text continued on next page)

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BEVACIZUMAB-ADCD BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

If you have epithelial ovarian, fallopian tube or primary peritoneal cancer, approval also requires:

You have tried or have a contraindication to (harmful for you to use) the following preferred medication: Zirabev (bevacizumab-bvzr)

You meet ONE of the following:

- You have stage III or IV epithelial ovarian, fallopian tube, or primary peritoneal cancer; Vegzelma will be used following initial surgical resection (removal); AND Vegzelma will be used in combination with carboplatin and paclitaxel, OR as a single agent after previous use in combination with carboplatin and paclitaxel
- You have platinum-resistant recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer (cancer that no longer responds to a type of treatment and has returned); Vegzelma will be used in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan; AND you have received no more than two prior chemotherapy regimens
- You have platinum-sensitive recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer (cancer that responds to a type of treatment and has returned); AND Vegzelma will be used in combination with carboplatin and paclitaxel, OR with carboplatin and gemcitabine, OR as a single medication after previous use in combination with one of the carboplatin-containing chemotherapy regimens listed above

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vegzelma.

The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Vegzelma [Prescribing Information]. Incheon, Republic of Korea: Celltrion, Inc.; February 2023.

Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed June 26, 2025].

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BEVACIZUMAB-ADCD BvD (PART D)

For Part D use only:

BEVACIZUMAB-ADCD (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT: ZIRABEV, WHERE INDICATIONS ALIGN.

Created: 02/23
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 07/19

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BEVACIZUMAB-AWWB BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BEVACIZUMAB-AWWB	MVASI	44500		GPI-10 (2133502020)	

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

Is this a pharmacy call?

If yes, continue to #3.
If no, continue to #2.

Is the requested medication going to be filled at a pharmacy?

If yes, continue to #3.
If no, **Refer to plan. (This should be processed under the member's medical benefit)**

Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

If no, continue to #4.

Is the pharmacy dispensing the drug directly to the member or member's representative?

If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

If no, continue to #5.

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BEVACIZUMAB-AWWB BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

Is the internal HQ code ML500, SFC01, or SUM03?

If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override)
For PAC's: Send an email to plan (reference UNSAD section of PACIP).

If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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BEVACIZUMAB-AWWB BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

Does the patient have a diagnosis of metastatic colorectal cancer (mCRC) (ICD-10 C19) **AND** meet the following criterion?
The patient had a trial of or contraindication to the following preferred agent: Zirabev (bevacizumab-bvzr)

If yes, continue to #2.
If no, continue to #3.

Does the patient meet **ONE** of the following criteria?
Mvasi will be used in combination with intravenous 5-fluorouracil based chemotherapy
Mvasi will be used in combination with fluoropyrimidine-irinotecan- (e.g., FOLFIRI) or fluoropyrimidine-oxaliplatin- (e.g., FOLFOX, CapeOx) based chemotherapy AND the patient's disease has progressed on a first-line bevacizumab product-containing regimen

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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BEVACIZUMAB-AWWB BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

Does the patient have a diagnosis of unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
Mvasi will be used in combination with carboplatin and paclitaxel
The patient had a trial of or contraindication to the following preferred agent: Zirabev (bevacizumab-bvzr)

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #4.

Does the patient have a diagnosis of recurrent glioblastoma (GBM) (ICD-10 C72.9, Group C71) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
The patient had a trial of or contraindication to the following preferred agent: Zirabev (bevacizumab-bvzr)

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #5.

Does the patient have a diagnosis of metastatic renal cell carcinoma (mRCC) (ICD-10 Groups C64, C65) and meet **ALL** of the following criteria?
Mvasi will be used in combination with interferon-alfa
The patient had a trial of or contraindication to the following preferred agent: Zirabev (bevacizumab-bvzr)

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #6.

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BEVACIZUMAB-AWWB BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

Does the patient have a diagnosis of persistent, recurrent, or metastatic cervical cancer (ICD-10 Group C53) and meet **ALL** of the following criteria?
Mvasi will be used in combination with paclitaxel and cisplatin OR paclitaxel and topotecan
The patient had a trial of or contraindication to the following preferred agent: Zirabev (bevacizumab-bvzr)

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #7.

Does the patient have a diagnosis of epithelial ovarian, fallopian tube, or primary peritoneal cancer (ICD-10 Groups C56, C57.0, C48, C79.6) **AND** meet the following criterion?
The patient had a trial of or contraindication to the following preferred agent: Zirabev (bevacizumab-bvzr)

If yes, continue to #8.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

Is the patient's cancer stage III or IV, and the patient meets **ALL** of the following criteria?
Mvasi will be used following initial surgical resection
Mvasi will be used in combination with carboplatin and paclitaxel, OR as a single agent after prior use in combination with carboplatin and paclitaxel

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #9.

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BEVACIZUMAB-AWWB BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

Is the patient's cancer platinum-resistant and recurrent, and the patient meets **ALL** of the following criteria?
Mvasi will be used in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan
The patient has received no more than two prior chemotherapy regimens

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #10.

Is the patient's cancer platinum-sensitive and recurrent, and the patient meets **ONE** of the following criteria?
Mvasi will be used in combination with carboplatin and paclitaxel
Mvasi will be used in combination with carboplatin and gemcitabine
Mvasi will be used as a single agent after prior use in combination with one of the carboplatin-containing chemotherapy regimens listed above

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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BEVACIZUMAB-AWWB BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BEVACIZUMAB-AWWB (Mvasi)** requires the following rule(s) be met for approval:

You have ONE of the following:
- Metastatic colorectal cancer (mCRC: colon cancer that has spread to other parts of the body)
- Unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer (NSCLC: type of lung cancer that cannot be completely removed with surgery or has spread/returned)
- Recurrent glioblastoma (GBM: type of brain cancer that has returned)
- Metastatic renal cell carcinoma (mRCC: type of kidney cancer that has spread to other parts of the body)
- Persistent, recurrent, or metastatic cervical cancer (type of uterus cancer that continues to exist, returns, or has spread to other parts of the body)
- Epithelial ovarian, fallopian tube, or primary peritoneal cancer (types of reproductive system or abdomen cancers)

If you have metastatic colorectal cancer, approval also requires:
- You have tried or have a contraindication to (harmful for you to use) the following preferred medication: Zirabev (bevacizumab-bvzr)
- You meet ONE of the following:
  - Mvasi will be used in combination with intravenous (given into the vein) 5-fluorouracil based chemotherapy
  - Mvasi will be used in combination with fluoropyrimidine-irinotecan- (such as FOLFIRI) or fluoropyrimidine-oxaliplatin- (such as FOLFOX, CapeOx) based chemotherapy AND your disease has worsened on a first-line bevacizumab product-containing regimen

If you have unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer, approval also requires:
- Mvasi will be used in combination with carboplatin and paclitaxel
- You have tried or have a contraindication to (harmful for you to use) the following preferred medication: Zirabev (bevacizumab-bvzr)

If you have recurrent glioblastoma, approval also requires:
- You are 18 years of age or older
- You have tried or have a contraindication to (harmful for you to use) the following preferred medication: Zirabev (bevacizumab-bvzr)

(Denial text continued on next page)

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BEVACIZUMAB-AWWB BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

If you have metastatic renal cell carcinoma, approval also requires:
- Mvasi will be used in combination with interferon alfa
- You have tried or have a contraindication to (harmful for you to use) the following preferred medication: Zirabev (bevacizumab-bvzr)

If you have persistent, recurrent, or metastatic cervical cancer, approval also requires:
- Mvasi will be used in combination with paclitaxel and cisplatin OR paclitaxel and topotecan
- You have tried or have a contraindication to (harmful for you to use) the following preferred medication: Zirabev (bevacizumab-bvzr)

If you have epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:
- You have tried or have a contraindication to (harmful for you to use) the following preferred medication: Zirabev (bevacizumab-bvzr)
- You meet ONE of the following:
  - You have stage III or IV epithelial ovarian, fallopian tube, or primary peritoneal cancer; Mvasi will be used following initial surgical resection (removal); AND Mvasi will be used in combination with carboplatin and paclitaxel, OR as a single medication after previous use in combination with carboplatin and paclitaxel
  - You have platinum-resistant, recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer (cancer that no longer responds to a type of treatment and has returned); Mvasi will be used in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan; AND you have received no more than two prior chemotherapy regimens
  - You have platinum-sensitive, recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer (cancer that responds to a type of treatment and has returned); AND Mvasi will be used in combination with carboplatin and paclitaxel, OR with carboplatin and gemcitabine, OR as a single medication after previous use in combination with one of the carboplatin-containing chemotherapy regimens listed above

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BEVACIZUMAB-AWWB BvD (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Mvasi. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Mvasi [Prescribing Information]. Thousand Oaks, CA: Amgen, Inc.; February 2023.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed April 7, 2025].

For Part D use only:

BEVACIZUMAB-AWWB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT: ZIRABEV, WHERE INDICATIONS ALIGN.

Created: 07/19
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 01/22

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BEVACIZUMAB-BVZR BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BEVACIZUMAB-BVZR	ZIRABEV	45849		GPI-10 (2133502030)	

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

Is this a pharmacy call?

If yes, continue to #3.
If no, continue to #2.

Is the requested medication going to be filled at a pharmacy?

If yes, continue to #3.
If no, **Refer to plan. (This should be processed under the member's medical benefit)**

Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**
If no, continue to #4.

Is the pharmacy dispensing the drug directly to the member or member's representative?

If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

If no, continue to #5.

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BEVACIZUMAB-BVZR BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

Is the internal HQ code ML500, SFC01, or SUM03?

If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override)
For PAC's: Send an email to plan (reference UNSAD section of PACIP).

If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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BEVACIZUMAB-BVZR BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

Does the patient have a diagnosis of metastatic colorectal cancer (mCRC) (ICD-10 C19) and meet **ONE** of the following criteria?
Zirabev will be used in combination with intravenous 5-fluorouracil based chemotherapy
Zirabev will be used in combination with fluoropyrimidine-irinotecan- (e.g., FOLFIRI) or fluoropyrimidine-oxaliplatin- (e.g., FOLFOX, CapeOx) based chemotherapy AND the patient's disease has progressed on a first-line bevacizumab product-containing regimen

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #2.

Does the patient have a diagnosis of unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer (NSCLC) (ICD-10 Group C34) **AND** meet the following criterion?
Zirabev will be used in combination with carboplatin and paclitaxel

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #3.

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BEVACIZUMAB-BVZR BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

Does the patient have a diagnosis of recurrent glioblastoma (GBM) (ICD-10 C72.9, Group C71) **AND** meet the following criterion?
The patient is 18 years of age or older

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #4.

Does the patient have a diagnosis of metastatic renal cell carcinoma (mRCC) (ICD-10 Groups C64, C65) **AND** meet the following criterion?
Zirabev will be used in combination with interferon-alfa

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #5.

Does the patient have a diagnosis of persistent, recurrent, or metastatic cervical cancer (ICD-10 Group C53) **AND** meet the following criterion?
Zirabev will be used in combination with paclitaxel and cisplatin OR paclitaxel and topotecan

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #6.

Does the patient have a diagnosis of epithelial ovarian, fallopian tube, or primary peritoneal cancer (ICD-10 Groups C56, C57.0, C48, C79.6)?

If yes, continue to #7.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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BEVACIZUMAB-BVZR BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

Is the patient's cancer stage III or IV, and the patient meets **ALL** of the following criteria?
- Zirabev will be used following initial surgical resection
- Zirabev will be used in combination with carboplatin and paclitaxel, OR as a single agent after prior use in combination with carboplatin and paclitaxel

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #8.

Is the patient's cancer platinum-resistant and recurrent, and the patient meets **ALL** of the following criteria?
- Zirabev will be used in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan
- The patient has received no more than two prior chemotherapy regimens

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #9.

Is the patient's cancer platinum-sensitive and recurrent, and the patient meets **ONE** of the following criteria?
- Zirabev will be used in combination with carboplatin and paclitaxel
- Zirabev will be used in combination with carboplatin and gemcitabine
- Zirabev will be used as a single agent after prior use in combination with one of the carboplatin-containing chemotherapy regimens listed above

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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BEVACIZUMAB-BVZR BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BEVACIZUMAB-BVZR (Zirabev)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Metastatic colorectal cancer (mCRC: colon cancer that has spread to other parts of the body)
- Unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer (NSCLC: a type of lung cancer that cannot be completely removed with surgery or has spread/returned)
- Recurrent glioblastoma (GBM: type of brain cancer that has returned)
- Metastatic renal cell carcinoma (mRCC: type of kidney cancer that has spread to other parts of the body)
- Persistent, recurrent, or metastatic cervical cancer (type of uterus cancer that continues to exist, returns, or has spread to other parts of the body)
- Epithelial ovarian, fallopian tube, or primary peritoneal cancer (types of reproductive system or abdomen cancers)

If you have metastatic colorectal cancer, approval also requires ONE of the following:
- Zirabev will be used in combination with intravenous (given into the vein) 5-fluorouracil based chemotherapy
- Zirabev will be used in combination with fluoropyrimidine-irinotecan- (such as FOLFIRI) or fluoropyrimidine-oxaliplatin- (such as FOLFOX, CapeOX) based chemotherapy AND your disease has progressed (gotten worse) on a first-line bevacizumab product-containing regimen

If you have unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer, approval also requires:
- Zirabev will be used in combination with carboplatin and paclitaxel

If you have recurrent glioblastoma, approval also requires:
- You are 18 years of age or older

If you have metastatic renal cell carcinoma, approval also requires:
- Zirabev will be used in combination with interferon-alfa

(Denial text continued on the next page)

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BEVACIZUMAB-BVZR BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

If you have persistent, recurrent, or metastatic cervical cancer, approval also requires:
Zirabev will be used in combination with paclitaxel and cisplatin OR paclitaxel and topotecan

If you have epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires ONE of the following:
You have stage III or IV epithelial ovarian, fallopian tube, or primary peritoneal cancer; Zirabev will be used following initial surgical resection (removal); AND Zirabev will be used in combination with carboplatin and paclitaxel, OR as a single medication after previous use in combination with carboplatin and paclitaxel

You have platinum-resistant, recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer (cancer that no longer responds to a type of treatment and has returned); Zirabev will be used in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan; AND you have received no more than two prior chemotherapy regimens

You have platinum-sensitive, recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer (cancer that responds to a type of treatment and has returned); AND Zirabev will be used in combination with carboplatin and paclitaxel, OR with carboplatin and gemcitabine, OR as a single medication after previous use in combination with one of these carboplatin-containing chemotherapy regimens

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zirabev. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Zirabev [Prescribing Information]. New York, New York: Pfizer Inc.; August 2024.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed April 7, 2025].

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BEVACIZUMAB-BVZR BvD (PART D)

For Part D use only:

BEVACIZUMAB-BVZR (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 01/20
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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BEVACIZUMAB-MALY BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BEVACIZUMAB-MALY	ALYMSYS	47950		GPI-10 (2133502050)	

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

Is this a pharmacy call?

If yes, continue to #3.
If no, continue to #2.

Is the requested medication going to be filled at a pharmacy?

If yes, continue to #3.
If no, **Refer to plan. (This should be processed under the member's medical benefit)**

Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

If no, continue to #4.

Is the pharmacy dispensing the drug directly to the member or member's representative?

If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

If no, continue to #5.

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BEVACIZUMAB-MALY BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

Is the internal HQ code ML500, SFC01, or SUM03?

If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override)
For PAC's: Send an email to plan (reference UNSAD section of PACIP).

If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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BEVACIZUMAB-MALY BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

Does the patient have a diagnosis of metastatic colorectal cancer (mCRC) (ICD-10 C19) **AND** meet the following criterion?
The patient had a trial of or contraindication to the following preferred agent: Zirabev (bevacizumab-bvzr)

If yes, continue to #2.
If no, continue to #4.

Will Alymsys be used in combination with intravenous 5-fluorouracil based chemotherapy?

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #3.

Does the patient meet **ALL** of the following criteria?
Alymsys will be used in combination with fluoropyrimidine-irinotecan- (e.g., FOLFIRI) or fluoropyrimidine-oxaliplatin- (e.g., FOLFOX, CapeOx) based chemotherapy
The patient's disease has progressed on a first-line bevacizumab product-containing regimen

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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BEVACIZUMAB-MALY BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

Does the patient have a diagnosis of unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
Alymsys will be used in combination with carboplatin and paclitaxel
The patient had a trial of or contraindication to the following preferred agent: Zirabev (bevacizumab-bvzr)

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #5.

Does the patient have a diagnosis of recurrent glioblastoma (GBM) (ICD-10 C72.9, Group C71) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
The patient had a trial of or contraindication to the following preferred agent: Zirabev (bevacizumab-bvzr)

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #6.

Does the patient have a diagnosis of metastatic renal cell carcinoma (mRCC) (ICD-10 Groups C64, C65) and meet **ALL** of the following criteria?
Alymsys will be used in combination with interferon alfa
The patient had a trial of or contraindication to the following preferred agent: Zirabev (bevacizumab-bvzr)

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #7.

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BEVACIZUMAB-MALY BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

Does the patient have a diagnosis of persistent, recurrent, or metastatic cervical cancer (ICD-10 Group C53) and meet **ALL** of the following criteria?
Alymsys will be used in combination with paclitaxel and cisplatin OR paclitaxel and topotecan
The patient had a trial of or contraindication to the following preferred agent: Zirabev (bevacizumab-bvzr)

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #8.

Does the patient have a diagnosis of platinum-resistant, recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer (ICD-10 Groups C56, C57.0, C48, C79.6) and meet **ALL** of the following criteria?
Alymsys will be used in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan
The patient has received no more than two prior chemotherapy regimens
The patient had a trial of or contraindication to the following preferred agent: Zirabev (bevacizumab-bvzr)

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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BEVACIZUMAB-MALY BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BEVACIZUMAB-MALY (Alymsys)** requires the following rule(s) be met for approval:

You have ONE of the following:
- Metastatic colorectal cancer (mCRC: colon cancer that has spread to other parts of the body)
- Unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer (NSCLC: type of lung cancer that cannot be completely removed with surgery or has spread/returned)
- Recurrent glioblastoma (GBM: type of brain cancer that has returned)
- Metastatic renal cell carcinoma (mRCC: type of kidney cancer that has spread to other parts of the body)
- Persistent, recurrent, or metastatic cervical cancer (type of uterus cancer that continues to exist, returns, or has spread to other parts of the body)
- Platinum-resistant, recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer (types of reproductive system or abdomen cancers that no longer respond to a type of treatment and have returned)

If you have metastatic colorectal cancer, approval also requires:

You meet ONE of the following:
- Alymsys will be used in combination with intravenous (given into the vein) 5-fluorouracil based chemotherapy
- Alymsys will be used in combination with fluoropyrimidine-irinotecan- (for example FOLFIRI) or fluoropyrimidine-oxaliplatin- (for example FOLFOX, CapeOx) based chemotherapy AND your disease has worsened on a first-line bevacizumab product-containing regimen

You have tried or have a contraindication to (harmful for you to use) the following preferred medication: Zirabev (bevacizumab-bvzr)

If you have unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer, approval also requires:

Alymsys will be used in combination with carboplatin and paclitaxel

You have tried or have a contraindication to (harmful for you to use) the following preferred medication: Zirabev (bevacizumab-bvzr)

If you have recurrent glioblastoma, approval also requires:

You are 18 years of age or older

You have tried or have a contraindication to (harmful for you to use) the following preferred medication: Zirabev (bevacizumab-bvzr)

(Denial text continued on next page)

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BEVACIZUMAB-MALY BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

If you have metastatic renal cell carcinoma, approval also requires:
Alymsys will be used in combination with interferon-alfa
You have tried or have a contraindication to (harmful for you to use) the following preferred medication: Zirabev (bevacizumab-bvzr)

If you have persistent, recurrent, or metastatic cervical cancer, approval also requires:
Alymsys will be used in combination with paclitaxel and cisplatin OR paclitaxel and topotecan
You have tried or have a contraindication to (harmful for you to use) the following preferred medication: Zirabev (bevacizumab-bvzr)

If you have platinum-resistant, recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, approval also requires:
Alymsys will be used in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan
You have received no more than two prior chemotherapy regimens
You have tried or have a contraindication to (harmful for you to use) the following preferred medication: Zirabev (bevacizumab-bvzr)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Alymsys. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Alymsys [Prescribing Information]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; April 2022.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed June 26, 2025].

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BEVACIZUMAB-MALY BvD (PART D)

For Part D use only:

BEVACIZUMAB-MALY (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT: ZIRABEV, WHERE INDICATIONS ALIGN.

Created: 06/22
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 04/21

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BEVACIZUMAB-NWGD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BEVACIZUMAB-NWGD	JOBEVNE	50512		GPI-10 (2133502055)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	Yes	No	No	Yes	No	No	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

Is this a pharmacy call?

If yes, continue to #3.
If no, continue to #2.

Is the requested medication going to be filled at a pharmacy?

If yes, continue to #3.
If no, **Refer to plan. (This should be processed under the member's medical benefit)**

Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

If no, continue to #4.

Is the pharmacy dispensing the drug directly to the member or member's representative?

If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

If no, continue to #5.

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BEVACIZUMAB-NWGD BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

Is the internal HQ code ML500, SFC01, or SUM03?

If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override)
For PAC's: Send an email to plan (reference UNSAD section of PACIP).

If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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BEVACIZUMAB-NWGD BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

Does the patient have a diagnosis of metastatic colorectal cancer (mCRC) (ICD-10 C19) **AND** meet the following criterion?
The patient had a trial of or contraindication to the following preferred agent: Zirabev (bevacizumab-bvzr)

If yes, continue to #2.
If no, continue to #3.

Does the patient meet **ONE** of the following criteria?
Jobevne will be used in combination with intravenous 5-fluorouracil based chemotherapy
Jobevne will be used in combination with fluoropyrimidine- irinotecan- (e.g., FOLFIRI) or fluoropyrimidine-oxaliplatin- (e.g., FOLFOX, CapeOx) based chemotherapy AND the patient has progressed on a first-line bevacizumab product-containing regimen

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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BEVACIZUMAB-NWGD BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

Does the patient have a diagnosis of unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
Jobevne will be used in combination with carboplatin and paclitaxel
The patient had a trial of or contraindication to the following preferred agent: Zirabev (bevacizumab-bvzr)

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #4.

Does the patient have a diagnosis of recurrent glioblastoma (GBM) (ICD-10 C72.9; Group C71) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
The patient had a trial of or contraindication to the following preferred agent: Zirabev (bevacizumab-bvzr)

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #5.

Does the patient have a diagnosis of metastatic renal cell carcinoma (mRCC) (ICD-10 Groups C64, C65) and meet **ALL** of the following criteria?
Jobevne will be used in combination with interferon alfa
The patient had a trial of or contraindication to the following preferred agent: Zirabev (bevacizumab-bvzr)

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #6.

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BEVACIZUMAB-NWGD BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

Does the patient have a diagnosis of persistent, recurrent, or metastatic cervical cancer (ICD-10 Group C53) and meet **ALL** of the following criteria?
- Jobevne will be used in combination with paclitaxel and cisplatin OR paclitaxel and topotecan
- The patient had a trial of or contraindication to the following preferred agent: Zirabev (bevacizumab-bvzr)

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #7.

Does the patient have a diagnosis of epithelial ovarian, fallopian tube, or primary peritoneal cancer (ICD-10 Groups C56, C57.0, C48, C79.6) **AND** meet the following criterion?
- The patient had a trial of or contraindication to the following preferred agent: Zirabev (bevacizumab-bvzr)

If yes, continue to #8.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

Is the cancer stage III or IV and the patient meets **ALL** of the following criteria?
- Jobevne will be used following initial surgical resection
- Jobevne will be used in combination with carboplatin and paclitaxel, OR as a single agent after prior use in combination with carboplatin and paclitaxel

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #9.

Is the cancer platinum-resistant recurrent and the patient meets **ALL** of the following criteria?
- Jobevne will be used in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan
- The patient has received no more than two prior chemotherapy regimens

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #10.

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BEVACIZUMAB-NWGD BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

Is the cancer platinum-sensitive recurrent and the patient meets **ONE** of the following criteria?
- Jobevne will be used in combination with carboplatin and paclitaxel
- Jobevne will be used in combination with carboplatin and gemcitabine
- Jobevne will be used as a single agent after prior use in combination with one of the carboplatin-containing chemotherapy regimens listed above

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BEVACIZUMAB-NWGD (Jobevne)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Metastatic colorectal cancer (mCRC: colon cancer that has spread to other parts of the body)
- Unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer (NSCLC: a type of lung cancer that cannot be completely removed with surgery or has spread/returned)
- Recurrent glioblastoma (GBM: type of brain cancer)
- Metastatic renal cell carcinoma (mRCC: type of kidney cancer that has spread to other parts of the body)
- Persistent, recurrent, or metastatic cervical cancer (type of uterus cancer that continues to exist, returns, or has spread to other parts of the body)
- Epithelial ovarian, fallopian tube, or primary peritoneal cancer (types of reproductive system or abdomen cancers)

(Denial text continued on next page)

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BEVACIZUMAB-NWGD BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

If you have metastatic colorectal cancer, approval also requires:
- You meet ONE of the following:
  - Jobevne will be used in combination with intravenous (given into the vein) 5-fluorouracil based chemotherapy
  - Jobevne will be used in combination with fluoropyrimidine- irinotecan- (such as FOLFIRI) or fluoropyrimidine-oxaliplatin- (such as FOLFOX, CapeOx) based chemotherapy AND your disease has worsened on a first-line bevacizumab product-containing regimen
- You have tried or have a contraindication to (harmful for you to use) the following preferred medication: Zirabev (bevacizumab-bvzr)

If you have unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer, approval also requires:
- Jobevne will be used in combination with carboplatin and paclitaxel
- You have tried or have a contraindication to (harmful for you to use) the following preferred medication: Zirabev (bevacizumab-bvzr)

If you have recurrent glioblastoma, approval also requires:
- You are 18 years of age or older
- You have tried or have a contraindication to (harmful for you to use) the following preferred medication: Zirabev (bevacizumab-bvzr)

If you have metastatic renal cell carcinoma, approval also requires:
- Jobevne will be used in combination with interferon alfa
- You have tried or have a contraindication to (harmful for you to use) the following preferred medication: Zirabev (bevacizumab-bvzr)

If you have persistent, recurrent, or metastatic cervical cancer, approval also requires:
- Jobevne will be used in combination with paclitaxel and cisplatin OR paclitaxel and topotecan
- You have tried or have a contraindication to (harmful for you to use) the following preferred medication: Zirabev (bevacizumab-bvzr)

(Denial text continued on next page)

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BEVACIZUMAB-NWGD BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

If you have epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:

You meet ONE of the following:

- Your cancer is stage III or IV; Jobevne will be used following initial surgical resection (removal); AND Jobevne will be used in combination with carboplatin and paclitaxel, or as a single agent after previous use in combination with carboplatin and paclitaxel
- Your cancer is platinum-resistant recurrent; Jobevne will be used in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan; AND you have received no more than two prior chemotherapy regimens
- Your cancer is platinum-sensitive recurrent; AND Jobevne will be used in combination with carboplatin and paclitaxel, OR with carboplatin and gemcitabine, OR as a single agent after previous use in combination with one of these carboplatin- containing chemotherapy regimens

You have tried or have a contraindication to (harmful for you to use) the following preferred medication: Zirabev (bevacizumab-bvzr)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Jobevne. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Jobevne [Prescribing Information]. Cambridge, MA: Biosimilars Newco, Ltd.; April 2025.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed August 26, 2025].

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BEVACIZUMAB-NWGD BvD (PART D)

For Part D use only:

BEVACIZUMAB-NWGD (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT: ZIRABEV, WHERE INDICATIONS ALIGN.

Created: 08/25
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 07/20

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BEXAROTENE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BEXAROTENE CAPSULE, BEXAROTENE 1% TOPICAL GEL	TARGRETIN, BEXAROTENE	20832		GPI-10 (9037622000), (2170822000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

****Please use the criteria for the specific drug requested****

GUIDELINES FOR USE

TARGRETIN (BEXAROTENE) CAPSULE

Does the patient have a diagnosis of cutaneous T-cell lymphoma (CTCL) (ICD-10 Group C84.A)
AND meet the following criterion?
The patient is refractory to at least one prior systemic therapy (e.g., gemcitabine, methotrexate, liposomal doxorubicin, bortezomib)

If yes, **approve for 12 months by GPID or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **BEXAROTENE (Targretin capsule)** requires the following rule(s) be met for approval:
You have cutaneous T-cell lymphoma (CTCL: a type of blood cancer)
You are refractory (resistant) to at least one prior systemic therapy (therapy that spreads through the blood, such as gemcitabine, methotrexate, liposomal doxorubicin, bortezomib)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BEXAROTENE (PART D)

GUIDELINES FOR USE (CONTINUED)

TARGRETIN (BEXAROTENE) GEL

Does the patient have a diagnosis of cutaneous T-cell lymphoma (CTCL) (stage IA or IB) (ICD-10 Group C84.A) and meet **ONE** of the following criteria?
The patient has refractory or persistent disease after other therapies
The patient has not tolerated other therapies

If yes, **approve for 12 months by GPID or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BEXAROTENE (Targretin gel)** requires the following rule(s) be met for approval:
You have cutaneous T-cell lymphoma (CTCL: a type of blood cancer) (stage IA or IB)
You meet ONE of the following:
- You have refractory (resistant) or persistent disease after other therapies
- You have not tolerated other therapies

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Targretin.

REFERENCES

Targretin Capsule [Prescribing Information]. Bridgewater, NJ: Baush Health US LLC; April 2020.
Targretin Gel [Prescribing Information]. Bridgewater, NJ: Baush Health US LLC; February 2020.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BEXAROTENE (PART D)

For Part D use only:

BEXAROTENE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25 Created: 05/12
Commercial Effective: N/A Client Approval: 08/24 P&T Approval: 04/20

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BIMEKIZUMAB-BKZX (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BIMEKIZUMAB-BKZX	BIMZELX	47629		GPI-10 (9025051800)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist
- The patient has psoriasis covering 3% or more of body surface area (BSA) OR psoriatic lesions affecting the hands, feet, genital area, scalp, or face
- Bimzelx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO
- The patient had a trial of or contraindication to TWO of the following preferred agents: Cosentyx (secukinumab), Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima, Selarsdi/Yesintek/ustekinumab-aauz, Skyrizi (risankizumab-rzaa), Tremfya (guselkumab), Otezla (apremilast)

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #2.

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BIMEKIZUMAB-BKZX (PART D)

INITIAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
- Bimzelx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA
- The patient had a trial of or contraindication to TWO of the following preferred agents:
  - Cosentyx (secukinumab)
  - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
  - Selarsdi/Yesintek/ustekinumab-aauz
  - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
  - Tremfya (guselkumab)
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
  - Skyrizi (risankizumab-rzaa)
  - Orencia (abatacept)
  - Otezla (apremilast)

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #3.

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BIMEKIZUMAB-BKZX (PART D)

INITIAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of non-radiographic axial spondyloarthritis (nr-axSpA) (ICD-10 Group M45.A) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist
- The patient has C-reactive protein (CRP) levels above the upper limit of normal, OR has sacroiliitis on magnetic resonance imaging (MRI)
- Bimzelx will NOT be used concurrently with another systemic biologic (e.g., Taltz [ixekizumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of nr-axSpA
- The patient had a trial of or contraindication to TWO of the following preferred agents:
  - Cosentyx (secukinumab)
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Cimzia (certolizumab pegol)])
  - Cimzia (certolizumab pegol)

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #4.

Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist
- Bimzelx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor] for the treatment of AS
- The patient had a trial of or contraindication to TWO of the following preferred agents:
  - Cosentyx (secukinumab)
  - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
  - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.
If no, continue to #5.

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BIMEKIZUMAB-BKZX (PART D)

INITIAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of moderate to severe hidradenitis suppurativa (HS) (ICD-10 L73.2) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist
- Bimzelx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of HS
- The patient had a trial of or contraindication to ONE of the following preferred agents: Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima, Cosentyx (secukinumab)

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BIMEKIZUMAB-BKZX (Bimzelx)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Moderate to severe plaque psoriasis (PsO: a type of skin condition)
- Psoriatic arthritis (PsA: a type of skin and joint condition)
- Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)
- Ankylosing spondylitis (AS: a type of joint condition)
- Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)

(Initial denial text continued on next page)

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BIMEKIZUMAB-BKZX (PART D)

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe plaque psoriasis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
- You have psoriasis covering 3% or more of body surface area (BSA) OR psoriatic lesions (patches) affecting the hands, feet, face, scalp, or genital area
- You will NOT use Bimzelx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Cosentyx (secukinumab), Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima, Selarsdi/Yesintek/ustekinumab-aauz, Skyrizi (risankizumab-rzaa), Tremfya (guselkumab), Otezla (apremilast)

If you have psoriatic arthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
- You will NOT use Bimzelx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
  - Cosentyx (secukinumab)
  - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
  - Selarsdi/Yesintek/ustekinumab-aauz
  - Xeljanz (tofacitinib immediate release or extended release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/ Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
  - Tremfya (guselkumab)
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as Humira (adalimumab)/Cyltezo/ Yuflyma (adalimumab-aaty)/Hadlima])
  - Skyrizi (risankizumab-rzaa)
  - Orencia (abatacept)
  - Otezla (apremilast)

(Initial denial text continued on next page)

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BIMEKIZUMAB-BKZX (PART D)

INITIAL CRITERIA (CONTINUED)

If you have non-radiographic axial spondyloarthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- Your C-reactive protein (CRP: indicator of inflammation) levels are above the upper limit of normal, OR you have sacroiliitis (inflammation where lower spine and pelvis connect) on magnetic resonance imaging (MRI: type of imaging lab)
- You will NOT use Bimzelx concurrently (at the same time) with another systemic biologic (such as Taltz [ixekizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-radiographic axial spondyloarthritis
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
  - Cosentyx (secukinumab)
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Cimzia (certolizumab pegol)])
  - Cimzia (certolizumab pegol)

If you have ankylosing spondylitis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Bimzelx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred agents:
  - Cosentyx (secukinumab)
  - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
  - Xeljanz (tofacitinib immediate release or extended release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as Humira (adalimumab)/Cyltezo/ Yuflyma (adalimumab-aaty)/Hadlima])

(Initial denial text continued on next page)

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BIMEKIZUMAB-BKZX (PART D)

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe hidradenitis suppurativa, approval also requires:

- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
- You will NOT use Bimzelx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of hidradenitis suppurativa
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima, Cosentyx (secukinumab)

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BIMEKIZUMAB-BKZX (PART D)

RENEWAL CRITERIA

Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
- The patient continues to benefit from the medication
- Bimzelx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #2.

Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
- The patient continues to benefit from the medication
- Bimzelx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #3.

Does the patient have a diagnosis of non-radiographic axial spondyloarthritis (nr-axSpA) (ICD-10 Group M45.A) and meet **ALL** of the following criteria?
- The patient continues to benefit from the medication
- Bimzelx will NOT be used concurrently with another systemic biologic (e.g., Taltz [ixekizumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of nr-axSpA

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #4.

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BIMEKIZUMAB-BKZX (PART D)

RENEWAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
The patient continues to benefit from the medication
Bimzelx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor] for the treatment of AS

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #5.

Does the patient have a diagnosis of moderate to severe hidradenitis suppurativa (HS) (ICD-10 L73.2) and meet **ALL** of the following criteria?
The patient continues to benefit from the medication
Bimzelx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of HS

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BIMEKIZUMAB-BKZX (Bimzelx)** requires the following rule(s) be met for renewal:
You have ONE of the following:
Moderate to severe plaque psoriasis (PsO: a type of skin condition)
Psoriatic arthritis (PsA: a type of skin and joint condition)
Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)
Ankylosing spondylitis (AS: a type of joint condition)
Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)
(Renewal denial text continued on next page)

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BIMEKIZUMAB-BKZX (PART D)

RENEWAL CRITERIA (CONTINUED)

If you have moderate to severe plaque psoriasis, renewal also requires:
- You continue to benefit from the medication
- You will NOT use Bimzelx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis

If you have psoriatic arthritis, renewal also requires:
- You continue to benefit from the medication
- You will NOT use Bimzelx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

If you have non-radiographic axial spondyloarthritis, renewal also requires:
- You continue to benefit from the medication
- You will NOT use Bimzelx concurrently (at the same time) with another systemic biologic (such as Taltz [ixekizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-radiographic axial spondyloarthritis

If you have ankylosing spondylitis, renewal also requires:
- You continue to benefit from the medication
- You will not use Bimzelx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis

If you have moderate to severe hidradenitis suppurativa, renewal also requires:
- You continue to benefit from the medication
- You will NOT use Bimzelx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of hidradenitis suppurativa

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BIMEKIZUMAB-BKZX (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Bimzelx.

REFERENCES

Bimzelx [Prescribing Information]. Smyrna, GA: UCB, Inc.; November 2024.

For Part D use only:

BIMEKIZUMAB-BKZX (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	INITIAL: PLAQUE PSORIASIS (PSO): PSORIASIS COVERING 3 PERCENT OR MORE OF BODY SURFACE AREA OR PSORIATIC LESIONS AFFECTING THE HANDS, FEET, GENITAL AREA, SCALP, OR FACE. NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS (NR-AXSPA): 1) C-REACTIVE PROTEIN (CRP) LEVELS ABOVE THE UPPER LIMIT OF NORMAL, OR 2) SACROILIITIS ON MAGNETIC RESONANCE IMAGING (MRI).
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: PSO, HIDRADENITIS SUPPURATIVA (HS): PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST. PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST OR DERMATOLOGIST. ANKYLOSING SPONDYLITIS (AS), NR-AXSPA: PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST.
Coverage Duration	INITIAL: HS: 12 MONTHS, ALL OTHER INDICATIONS: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: PSO: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: COSENTYX, HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, SELARSDI/YESINTEK/USTEKINUMAB-AAUZ, SKYRIZI, TREMFYA, OTEZLA. PSA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: COSENTYX, HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, SELARSDI/YESINTEK/USTEKINUMAB-AAUZ, XELJANZ, TREMFYA, RINVOQ, SKYRIZI, ORENCIA, OTEZLA. NR-AXSPA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: COSENTYX, RINVOQ, CIMZIA. AS: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: COSENTYX, HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, XELJANZ, RINVOQ. HS: TRIAL OF OR CONTRAINDICATION TO ONE OF THE FOLLOWING PREFERRED AGENTS:

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	HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, COSENTYX. INITIAL/RENEWAL: ALL INDICATIONS: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION. RENEWAL: ALL INDICATIONS: CONTINUES TO BENEFIT FROM THE MEDICATION.

Created: 11/23
Effective: 05/01/26 Client Approval: 04/26 P&T Approval: 10/24

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BINIMETINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BINIMETINIB	MEKTOVI	45040		GPI-10 (21533520000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

Does the patient have a diagnosis of unresectable or metastatic melanoma (ICD-10 Group C43) and meet **ALL** of the following criteria?
The patient has a BRAF V600E or V600K mutation, as detected by an FDA-approved test
Mektovi will be used in combination with Braftovi (encorafenib)

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #2.

Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
The patient has a BRAF V600E mutation, as detected by an FDA-approved test
Mektovi will be used in combination with Braftovi (encorafenib)

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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BINIMETINIB (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BINIMETINIB (Mektovi)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Unresectable or metastatic melanoma (a type of skin cancer that cannot be removed by surgery or has spread to other parts of the body)
- Metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of the body)

If you have unresectable or metastatic melanoma, approval also requires:
- You have a BRAF V600E or V600K mutation (types of gene mutations), as detected by a Food and Drug Administration (FDA)-approved test
- Mektovi will be used in combination with Braftovi (encorafenib)

If you have metastatic non-small cell lung cancer, approval also requires:
- You are 18 years of age or older
- You have a BRAF V600E mutation (a type of gene mutation), as detected by a Food and Drug Administration (FDA)-approved test
- Mektovi will be used in combination with Braftovi (encorafenib)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Mektovi.

REFERENCES

Mektovi [Prescribing Information]. Boulder, CO: Array BioPharma Inc.; October 2023.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BINIMETINIB (PART D)

For Part D use only:

BINIMETINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25 Created: 07/18
Commercial Effective: N/A Client Approval: 08/24 P&T Approval: 01/24

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BIRCH BARK EXTRACT (PART D)

Generic	Brand	HICL	GCN	Medi-Span		Exception/Other
BIRCH BARK EXTRACT	FILSUVEZ	48746		GPI-10 (9094402000)		

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

Does the patient have a diagnosis of epidermolysis bullosa (EB) (ICD-10 Q81.9) and meet **ALL** of the following criteria?
The patient is 6 months of age or older
Filsuvez will be used for the treatment of wounds associated with dystrophic or junctional epidermolysis bullosa

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BIRCH BARK EXTRACT (Filsuvez)** requires the following rule(s) be met for approval:
You have epidermolysis bullosa (EB: a type of genetic skin disorder)
You are 6 months of age or older
Filsuvez will be used for the treatment of wounds associated with dystrophic or junctional epidermolysis bullosa (types of genetic skin disorders)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BIRCH BARK EXTRACT

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Filsuvez.

REFERENCES

Filsuvez [Prescribing Information]. Wahlstedt, Germany: Lichtenheldt GmbH Pharmazeutische Fabrik; January 2024.

For Part D use only:

BIRCH BARK EXTRACT (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 03/24
Client Approval: 08/24
P&T Approval: 04/24

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BLINATUMOMAB BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BLINATUMOMAB	BLINCYTO	41612		GPI-10 (2135202000)	

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

Is this a pharmacy call?

If yes, continue to #3.
If no, continue to #2.

Is the requested medication going to be filled at a pharmacy?

If yes, continue to #3.
If no, **Refer to plan. (This should be processed under the member's medical benefit)**

Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

If yes, continue to #6.
If no, continue to #4.

Is the pharmacy dispensing the drug directly to the member or member's representative?

If yes, continue to #6.
If no, continue to #5.

Is the internal HQ code ML500, SFC01, or SUM03?

If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).
For PAC's: Send an email to plan (reference UNSAD section of PACIP).

If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

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BLINATUMOMAB BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

Is the drug administered via an implantable pump?

> If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**
> If no, continue to #7.

Is the drug administered via an external pump?

> If yes, continue to #8.
> If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

Is the drug specifically infused through an external infusion pump covered by Medicare?

> If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**
>
> If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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BLINATUMOMAB BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

Does the patient have a diagnosis of CD19-positive B-cell precursor acute lymphoblastic leukemia (ALL) (ICD-10 Group C91.0) **AND** meet the following criterion?
The patient is 1 month of age or older

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

Is the cancer minimal residual disease (MRD)-positive and the patient meets **ALL** of the following criteria?
The patient is in first or second complete remission
The patient has minimal residual disease (MRD) of at least 0.1%

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #3.

Is the cancer relapsed or refractory?

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #4.

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BLINATUMOMAB BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

Is the cancer Philadelphia chromosome-negative **AND** the patient meets the following criterion?
The patient is in the consolidation phase of multiphase chemotherapy

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BLINATUMOMAB (Blincyto)** requires the following rule(s) be met for approval:
You have CD19 (a type of protein)-positive B-cell precursor acute lymphoblastic leukemia (ALL: a type of blood cancer)
You are 1 month of age and older
You meet ONE of the following:
- You have minimal residual disease (MRD)-positive acute lymphoblastic leukemia (a small number of cancer cells remain after treatment), you are in first or second complete remission (no symptoms or signs of disease), AND you have minimal residual disease of at least 0.1%
- You have relapsed or refractory acute lymphoblastic leukemia (a type of blood cancer that has returned or did not respond to treatment)
- You have Philadelphia chromosome-negative acute lymphoblastic leukemia (a type of blood cancer) AND you are in the consolidation phase (treatment following initial therapy) of multiphase chemotherapy (cancer treatment that involves multiple courses of therapy)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BLINATUMOMAB BvD (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Blincyto.

The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B. Drugs administered by an implantable pump are covered under Part B. Drugs administered via an external pump are covered under Part B if they are included under the local coverage policy of the applicable Medicare coverage policies (National and/or Local Coverage Policies). Drugs administered via an external pump that are not included under the applicable Medicare coverage policies are covered under Part D. A CMS website to assist with National and Local Coverage Determination for B versus D review is http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx.

REFERENCES

Blincyto [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; December 2024.
Medicare Prescription Drug Benefit Manual Chapter 6 – Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed April 1, 2025].

For Part D use only:

BLINATUMOMAB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 02/15
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 07/24

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BORTEZOMIB BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BORTEZOMIB	VELCADE, BORUZU, BORTEZOMIB	25202		GPI-10 (2153601500)	

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

Is this a pharmacy call?

If yes, continue to #3.
If no, continue to #2.

Is the requested medication going to be filled at a pharmacy?

If yes, continue to #3.
If no, **Refer to plan. (This should be processed under the member's medical benefit)**

Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

If no, continue to #4.

Is the pharmacy dispensing the drug directly to the member or member's representative?

If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

If no, continue to #5.

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BORTEZOMIB BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

Is the internal HQ code ML500, SFC01, or SUM03?

If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).
For PAC's: Send an email to plan (reference UNSAD section of PACIP).

If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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BORTEZOMIB BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

Does the patient have a diagnosis of multiple myeloma (ICD-10 Group C90.0) **AND** meet the following criterion?
The patient is 18 years of age or older

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #2.

Does the patient have a diagnosis of mantle cell lymphoma (ICD-10 Group C83.1) **AND** meet the following criterion?
The patient is 18 years of age or older

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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BORTEZOMIB BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BORTEZOMIB (Velcade, Boruzu)** requires the following rule(s) be met for approval:
You have ONE of the following:
Multiple myeloma (a type of blood cancer)
Mantle cell lymphoma (a type of blood cancer)
You are 18 years of age or older

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Velcade or Boruzu.
The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Velcade [Prescribing Information]. Lexington, MA: Takeda Pharmaceuticals America Inc.; August 2022.
Boruzu [Prescribing Information]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; September 2024.
Medicare Prescription Drug Benefit Manual Chapter 6 – Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Availableat: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed April 1, 2025].

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BORTEZOMIB BvD (PART D)

For Part D use only:

BORTEZOMIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 12/21
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 01/25

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BOSENTAN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BOSENTAN	TRACLEER, BOSENTAN	22990		GPI-10 (4016001500)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD- 10 I27.0, Group I27.2) and meet **ALL** of the following criteria?
The patient is 3 years of age or older
Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
The patient does NOT have elevated liver enzymes (ALT, AST) greater than 3 times the upper limit of normal (ULN) or increases in bilirubin two or more times ULN
The requested medication will NOT be used concurrently with cyclosporine A or glyburide

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

Is the PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
Mean pulmonary artery pressure (PAP) greater than 20 mmHg
Pulmonary capillary wedge pressure (PCWP) of 15 mmHg or less
Pulmonary vascular resistance (PVR) greater than 2 Wood units

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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BOSENTAN (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BOSENTAN (Tracleer)** requires the following rule(s) be met for approval:
- You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1: a way to classify the severity of disease)
- You are 3 years of age or older
- Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
- Your pulmonary arterial hypertension diagnosis is confirmed by right heart catheterization (a test used to measure how well the heart is pumping) with ALL of the following lab values:
  - Mean pulmonary artery pressure (PAP: a type of measurement for pulmonary arterial hypertension) greater than 20 mmHg
  - Pulmonary capillary wedge pressure (PCWP: a type of measurement for pulmonary arterial hypertension) of 15 mmHg or less
  - Pulmonary vascular resistance (PVR: a type of measurement for pulmonary arterial hypertension) greater than 2 Wood units
- You do not have elevated liver enzymes (ALT [alanine transaminase], AST [aspartate transaminase]) greater than 3 times the upper limit of normal or increases in bilirubin two or more times the upper limit of normal
- You will NOT use the requested medication concurrently (at the same time) with cyclosporine A or glyburide

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BOSENTAN (PART D)

RENEWAL CRITERIA

Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD- 10 I27.0, Group I27.2) **AND** meet the following criterion?
The requested medication will NOT be used concurrently with cyclosporine A or glyburide

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BOSENTAN (Tracleer)** requires the following rule(s) be met for renewal:
You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
You will NOT use the requested medication concurrently (at the same time) with cyclosporine A or glyburide

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph(s) for Tracleer.

REFERENCES

Tracleer [Prescribing Information]. Titusville, NJ: Actelion Pharmaceuticals US, Inc; February 2024.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BOSENTAN (PART D)

For Part D use only:

BOSENTAN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	PULMONARY ARTERIAL HYPERTENSION (PAH): INITIAL: DIAGNOSIS CONFIRMED BY RIGHT HEART CATHETERIZATION WITH THE FOLLOWING PARAMETERS: 1) MEAN PULMONARY ARTERY PRESSURE (PAP) GREATER THAN 20 MMHG, 2) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF 15 MMHG OR LESS, AND 3) PULMONARY VASCULAR RESISTANCE (PVR) GREATER THAN 2 WOOD UNITS.
Age Restrictions	N/A
Prescriber Restrictions	PAH: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	PAH: INITIAL: 1) DOES NOT HAVE ELEVATED LIVER ENZYMES (ALT, AST) MORE THAN 3 TIMES UPPER LIMIT OF NORMAL (ULN) OR INCREASE IN BILIRUBIN BY 2 OR MORE TIMES ULN, AND 2) NO CONCURRENT USE WITH CYCLOSPORINE A OR GLYBURIDE. RENEWAL: NO CONCURRENT USE WITH CYCLOSPORINE A OR GLYBURIDE.

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25 Created: 10/22
Commercial Effective: N/A Client Approval: 06/24 P&T Approval: 01/24

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BOSUTINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BOSUTINIB	BOSULIF, BOSUTINIB	39590		GPI-10 (2153181200)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

Does the patient have a diagnosis of Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML) (ICD-10 Group C92.1)?

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

Is the Ph+ CML in chronic phase (CP) **AND** the patient meets the following criterion?
The patient is 1 year of age or older

If yes, continue to #3.
If no, continue to #5.

Is the patient newly diagnosed (e.g., starting or previously started Bosulif treatment at the time of diagnosis)?

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #4.

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BOSUTINIB (PART D)

GUIDELINES FOR USE (CONTINUED)

Does the patient have a resistance or intolerance to a prior therapy (e.g., Gleevec [imatinib], Sprycel [dasatinib], Tasigna [nilotinib]) **AND** meet the following criterion?
The patient had a mutational analysis prior to initiation of therapy AND therapy is appropriate based on the NCCN guideline table for treatment recommendations based on BCR-ABL1 mutation profile *(Please see header CML-5 of the current NCCN guidelines)*

If yes, **approve for 12 months by HICL or GPI-10.**

If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

Is the Ph+ CML in accelerated phase (AP) or blast phase (BP), and the patient meets **ALL** of the following criteria?
The patient is 18 years of age or older
The patient has a resistance or intolerance to prior therapy (e.g., Gleevec [imatinib], Sprycel [dasatinib], Tasigna [nilotinib])
The patient had a mutational analysis prior to initiation of therapy AND therapy is appropriate based on the NCCN guideline table for treatment recommendations based on BCR-ABL1 mutation profile *(Please see header CML-5 of the current NCCN guidelines)*

If yes, **approve for 12 months by HICL or GPI-10.**

If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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BOSUTINIB (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT:

Our guideline named **BOSUTINIB (Bosulif)** requires the following rule(s) be met for approval:
You have Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML: a type of blood cell cancer)
If you have Philadelphia chromosome-positive chronic myelogenous leukemia in chronic phase (CP), approval also requires:
You are 1 year of age or older
You meet ONE of the following:
You are newly diagnosed (such as you are starting or previously started Bosulif treatment at the time your condition was identified)
You have a resistance (medication no longer works as well) or intolerance (side effect) to prior therapy (such as Gleevec [imatinib], Sprycel [dasatinib], Tasigna [nilotinib]); you had a mutational analysis (a type of lab test) prior to the start of therapy; AND therapy is appropriate based on the National Comprehensive Cancer Network (NCCN) guideline table for treatment recommendations based on BCR- ABL1 mutation (breakpoint cluster region-Abelson murine leukemia 1: a type of abnormal gene) profile
If you have Philadelphia chromosome-positive chronic myelogenous leukemia in accelerated phase (AP) or blast phase (BP), approval also requires:
You are 18 years of age or older
You have a resistance (medication no longer works as well) or intolerance (side effect) to prior therapy (such as Gleevec [imatinib], Sprycel [dasatinib], Tasigna [nilotinib])
You had a mutational analysis (a type of lab test) prior to the start of therapy; AND therapy is appropriate based on the National Comprehensive Cancer Network (NCCN) guideline table for treatment recommendations based on BCR-ABL1 mutation (breakpoint cluster region-Abelson murine leukemia 1: a type of abnormal gene) profile

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Bosulif.

REFERENCES

Bosulif [Prescribing Information]. New York, NY: Pfizer; March 2026.

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BOSUTINIB (PART D)

For Part D use only:

BOSUTINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	PREVIOUSLY TREATED PHILADELPHIA CHROMOSOME-POSITIVE CHRONIC MYELOID LEUKEMIA (Ph+ CML): MUTATIONAL ANALYSIS PRIOR TO INITIATION AND THERAPY IS APPROPRIATE PER NCCN GUIDELINE TABLE FOR TREATMENT RECOMMENDATIONS BASED ON BCR-ABL1 MUTATION PROFILE.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 09/12
Effective: 09/01/26 Client Approval: 08/26 P&T Approval: 10/23

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BRENSOCATIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BRENSOCATIB	BRINSUPRI	50812		GPI-10 (4500150800)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

Does the patient have a diagnosis of non-cystic fibrosis bronchiectasis (NCFB) **AND** meet the following criterion?
The patient is 12 years of age or older

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BRENSOCATIB (Brinsupri)** requires the following rule(s) be met for approval:
You have non-cystic fibrosis bronchiectasis (NCFB: a condition where your lungs' airway becomes damaged, widened, and thickened)
You are 12 years of age or older

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BRENSOCATIB (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Brinsupri.

REFERENCES

Brinsupri [Prescribing Information]. Bridgewater, NJ: f Insmed Incorporated; August 2025.

For Part D use only:

BRENSOCATIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 08/25
Effective: 09/08/25 Client Approval: 08/25 P&T Approval: 10/25

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BRENTUXIMAB BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BRENTUXIMAB VEDOTIN	ADCETRIS	37879		GPI-10 (2135322020)	

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

Is this a pharmacy call?

If yes, continue to #3.
If no, continue to #2.

Is the requested medication going to be filled at a pharmacy?

If yes, continue to #3.
If no, **Refer to plan. (This should be processed under the member's medical benefit)**

Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

If no, continue to #4.

Is the pharmacy dispensing the drug directly to the member or member's representative?

If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

If no, continue to #5.

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BRENTUXIMAB BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

Is the internal HQ code ML500, SFC01, or SUM03?

If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).
For PAC's: Send an email to plan (reference UNSAD section of PACIP).

If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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BRENTUXIMAB BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

Does the patient have a diagnosis of classical Hodgkin lymphoma (cHL) (ICD-10 Group C81)?

If yes, continue to #2.
If no, continue to #7.

Is the patient's cancer at stage III or IV and the patient meets **ALL** of the following criteria?
The patient is 18 years of age or older
The patient has not been previously treated
Adcetris will be used in combination with doxorubicin, vinblastine, and dacarbazine

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #3.

Is the patient's cancer considered high-risk and the patient meets **ALL** of the following criteria?
The patient is 2 years of age or older
The patient has not been previously treated
Adcetris will be used in combination with doxorubicin, vincristine, etoposide, prednisone, and cyclophosphamide

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #4.

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BRENTUXIMAB BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

Is the patient at high risk of relapse or disease progression post-autologous hematopoietic stem cell transplant (auto-HSCT) **AND** the patient meets the following criterion?
The patient is 18 years of age or older

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #5.

Has the patient's cancer relapsed **AND** the patient meets the following criterion?
The patient is 18 years of age or older

If yes, continue to #6.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

Does the patient meet **ONE** of the following criteria?
The patient has failed an autologous hematopoietic stem cell transplant (auto-HSCT)
The patient is not an auto-HSCT candidate AND has failed at least two prior multi-agent chemotherapy regimens (e.g., ABVD [doxorubicin, bleomycin, vinblastine, dacarbazine], Stanford V [doxorubicin, vinblastine, mechlorethamine, etoposide, vincristine, bleomycin, prednisone], BEACOPP [bleomycin, etoposide, doxorubicin, cyclophosphamide, vincristine, procarbazine, prednisone])

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

Does the patient have a diagnosis of systemic anaplastic large cell lymphoma (sALCL) (ICD-10 Groups C84.6, C84.7) **AND** meet the following criterion?
The patient is 18 years of age or older

If yes, continue to #8.
If no, continue to #10.

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BRENTUXIMAB BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

Is the patient previously untreated **AND** Adcetris will be used in combination with cyclophosphamide, doxorubicin, and prednisone?

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #9.

Has the patient relapsed **AND** failed at least one multi-agent chemotherapy regimen (e.g., CHOP [cyclophosphamide, doxorubicin, vincristine, prednisone], CHOEP [cyclophosphamide, doxorubicin, vincristine, etoposide, prednisone])?

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

Does the patient have a diagnosis of CD30-expressing peripheral T-cell lymphomas (PTCL), including angioimmunoblastic T-cell lymphoma (ICD-10 C86.5) or PTCL not otherwise specified (ICD-10 Group C84.4), and meet **ALL** of the following criteria?
The patient is 18 years of age or older
The patient has not been previously treated
Adcetris will be used in combination with cyclophosphamide, doxorubicin, and prednisone

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #11.

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BRENTUXIMAB BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

Does the patient have a diagnosis of primary cutaneous anaplastic large cell lymphoma (pcALCL) (ICD-10 C86.6) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
The patient has received prior systemic therapy (e.g., CHOP [cyclophosphamide, doxorubicin, vincristine, prednisone], methotrexate)

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #12.

Does the patient have a diagnosis of mycosis fungoides (MF) (ICD-10 Group C84.0) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
The patient's cancer is CD30-positive
The patient has received prior systemic therapy (e.g., Istodax [romidepsin], methotrexate)

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #13.

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BRENTUXIMAB BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

Does the patient have a diagnosis of large B-cell lymphoma (LBCL) (ICD-10 Groups C83.3, C85.2), including diffuse large B-cell lymphoma (DLBCL) not other specified (ICD-10 Group C83.3), DLBCL arising from indolent lymphoma (ICD-10 Group C83.3), or high-grade B-cell lymphoma (HGBL), and meet **ALL** of the following criteria?
The patient is 18 years of age or older
The patient's cancer is relapsed or refractory
Adcetris will be used in combination with Revlimid (lenalidomide) AND a rituximab product (e.g., Rituxan [rituximab], Truxima [rituximab-abbs])
The patient has tried at least two lines of systemic therapy (e.g., R-CHOP [rituximab, cyclophosphamide, doxorubicin, vincristine and prednisone], GemOx [gemcitabine, oxaliplatin])
The patient is not eligible for auto-HSCT or chimeric antigen receptor (CAR) T-cell therapy (e.g., Yescarta [axicabtagene ciloleucel], Kymriah [tisagenlecleucel])

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BRENTUXIMAB (Adcetris)** requires the following rule(s) be met for approval:
You have ONE of the following:
Classical Hodgkin lymphoma (a type of blood cancer)
Systemic anaplastic large cell lymphoma (a type of blood cancer)
CD30-expressing peripheral T-cell lymphomas (a type of blood cancer)
Primary cutaneous anaplastic large cell lymphoma (a type of blood cancer)
Mycosis fungoides (a type of blood cancer affecting the skin)
Large B-cell lymphoma (LBCL), which includes diffuse large B-cell lymphoma (DLBCL) not other specified, DLBCL arising from indolent lymphoma, or high-grade B-cell lymphoma (HGBL) (types of blood cancer)

(Denial text continued on next page)

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GUIDELINES FOR USE (CONTINUED)

If you have classical Hodgkin lymphoma, approval also requires ONE of the following:
- Your cancer is stage III or IV; you are 18 years of age or older; you have not been previously treated; AND Adcetris will be used in combination with doxorubicin, vinblastine, and dacarbazine
- Your cancer is considered high-risk; you are 2 years of age or older; you have not been previously treated; AND Adcetris will be used in combination with doxorubicin, vincristine, etoposide, prednisone, and cyclophosphamide
- You are at high risk of relapse (disease comes back) or disease progression (disease gets worse) after having autologous hematopoietic stem cell transplant (auto-HSCT: transplant cells are from your own body) AND you are 18 years of age or older
- Your cancer has relapsed; you are 18 years of age or older; AND you have failed auto-HSCT
- Your cancer has relapsed; you are 18 years of age or older; you are not a candidate for auto-HSCT; AND you have failed at least two multi-agent chemotherapy regimens (such as ABVD [doxorubicin, bleomycin, vinblastine, dacarbazine], Stanford V [doxorubicin, vinblastine, mechlorethamine, etoposide, vincristine, bleomycin, prednisone], BEACOPP [bleomycin, etoposide, doxorubicin, cyclophosphamide, vincristine, procarbazine, prednisone])

If you have systemic anaplastic large cell lymphoma, approval also requires:
- You are 18 years of age or older
- You meet ONE of the following:
  - You have not been previously treated AND Adcetris will be used in combination with cyclophosphamide, doxorubicin, and prednisone
  - Your cancer has relapsed (disease that has returned) AND you have failed at least one multi-agent chemotherapy regimen (such as CHOP [cyclophosphamide, doxorubicin, vincristine, prednisone], CHOEP [cyclophosphamide, doxorubicin, vincristine, etoposide, prednisone])

If you have CD30-expressing peripheral T-cell lymphomas, including angioimmunoblastic T-cell lymphoma or peripheral T-cell lymphoma not otherwise specified, approval also requires:
- You are 18 years of age or older
- You have not been previously treated
- Adcetris will be used in combination with cyclophosphamide, doxorubicin, and prednisone

(Denial text continued on next page)

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BRENTUXIMAB BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

If you have primary cutaneous anaplastic large cell lymphoma, approval also requires:
- You are 18 years of age or older
- You have received prior systemic therapy (treatment that targets the entire body such as CHOP [cyclophosphamide, doxorubicin, vincristine, prednisone], methotrexate)

If you have mycosis fungoides, approval also requires:
- You are 18 years of age or older
- Your cancer is CD30 (a type of protein)-positive
- You have received prior systemic therapy (treatment that targets the entire body such as Istodax [romidepsin], methotrexate)

If you have large B-cell lymphoma, which includes diffuse large B-cell lymphoma not other specified, diffuse large B-cell lymphoma arising from indolent lymphoma, or high-grade B-cell lymphoma, approval also requires:
- You are 18 years of age or older
- Your cancer is relapsed (disease that has returned) or refractory (did not respond to treatment)
- Adcetris will be used in combination with Revlimid (lenalidomide) AND a rituximab product (such as Rituxan [rituximab], Truxima [rituximab-abbs])
- You have has tried at least two lines of systemic therapy (such as R-CHOP [rituximab, cyclophosphamide, doxorubicin, vincristine and prednisone], GemOx [gemcitabine, oxaliplatin])
- You are not eligible for autologous hematopoietic stem cell transplantation (auto-HSCT: a type of procedure to replace damaged bone marrow with your own healthy blood-forming cells) or chimeric antigen receptor (CAR) T-cell therapy (such as Yescarta [axicabtagene ciloleucel], Kymriah [tisagenlecleucel])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Adcetris.

The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

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BRENTUXIMAB BvD (PART D)

REFERENCES

Adcetris [Prescribing Information]. Bothell, WA: Seagen Inc.; February 2025.
Medicare Prescription Drug Benefit Manual Chapter 6 – Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Availableat: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed March 28, 2024].

For Part D use only:

BRENTUXIMAB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 12/19
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 04/25

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BRIGATINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BRIGATINIB	ALUNBRIG	44226		GPI-10 (2153051000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
The patient's tumor is positive for anaplastic lymphoma kinase (ALK) fusion oncogene, as detected by an FDA-approved test

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BRIGATINIB (Alunbrig)** requires the following rule(s) be met for approval:
You have metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body)
You are 18 years of age or older
Your tumors are positive for anaplastic lymphoma kinase (ALK) fusion oncogene (mutated gene), as detected by a Food and Drug Administration (FDA)-approved test

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BRIGATINIB (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Alunbrig.

REFERENCES
Alunbrig [Prescribing Information]. Cambridge, MA: Ariad Pharmaceuticals, Inc.; February 2022.

For Part D use only:

BRIGATINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Medical Required Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25 Created: 05/17
Commercial Effective: N/A Client Approval: 08/24 P&T Approval: 07/20

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BRODALUMAB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BRODALUMAB	SILIQ	44102		GPI-10 (9025052000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- The patient is a candidate for phototherapy or systemic therapy
- Therapy is prescribed by or in consultation with a dermatologist
- The patient has psoriasis covering 3% or more of body surface area (BSA) OR psoriatic lesions affecting the hands, feet, face, scalp, or genital area
- The patient has been counseled on and expresses understanding of the risk of suicidal ideation and behavior
- Siliq will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of plaque psoriasis
- The patient had a trial of or contraindication to TWO of the following preferred agents: Cosentyx (secukinumab), Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima, Selarsdi /Yesintek /ustekinumab-aauz, Skyrizi (risankizumab-rzaa), Tremfya (guselkumab), Otezla (apremilast)

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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BRODALUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BRODALUMAB (Siliq)** requires the following rule(s) be met for approval:
You have moderate to severe plaque psoriasis (PsO: a type of skin condition)
You are 18 years of age or older
You are a candidate for phototherapy (light therapy) or systemic therapy (therapy that travels through the entire body)
Therapy is prescribed by or in consultation with a dermatologist (skin doctor)
You have psoriasis covering 3% or more of body surface area (BSA) OR psoriatic lesions (patches) affecting the hands, feet, face, scalp, or genital area
You have been counseled on and express an understanding of the risk of suicidal thoughts and behavior
You will NOT use Siliq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis
You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Cosentyx (secukinumab), Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima, Selarsdi /Yesintek/ustekinumab-aauz, Skyrizi (risankizumab-rzaa), Tremfya (guselkumab), Otezla (apremilast)

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BRODALUMAB (PART D)

RENEWAL CRITERIA

Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
- The patient continues to benefit from the medication
- The patient has not developed or reported worsening depressive symptoms or suicidal ideation and behaviors while on treatment with Siliq
- Siliq will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BRODALUMAB (Siliq)** requires the following rule(s) be met for renewal:
- You have moderate to severe plaque psoriasis (PsO: a type of skin condition)
- You continue to benefit from the medication
- You have not developed or reported worsening depressive symptoms or suicidal thoughts and behaviors while on treatment with Siliq
- You will NOT use Siliq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis

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BRODALUMAB (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Siliq.

REFERENCES

Siliq [Prescribing Information]. Bridgewater: NJ: Bausch Health US, LLC; February 2026.

For Part D use only:

BRODALUMAB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	PLAQUE PSORIASIS (PSO): INITIAL: PSORIASIS COVERING 3 PERCENT OR MORE OF BODY SURFACE AREA OR PSORIATIC LESIONS AFFECTING THE HANDS, FEET, FACE, SCALP, OR GENITAL AREA.
Age Restrictions	N/A
Prescriber Restrictions	PSO: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST.
Coverage Duration	INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS.
Other Criteria	PSO: INITIAL: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: COSENTYX, HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, SELARSDI/YESINTEK/USTEKINUMAB-AAUZ, SKYRIZI, TREMFYA, OTEZLA, AND 2) HAS BEEN COUNSELED ON AND EXPRESSES UNDERSTANDING OF THE RISK OF SUICIDAL IDEATION AND BEHAVIOR. INITIAL/RENEWAL: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION. RENEWAL: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) HAS NOT DEVELOPED OR REPORTED WORSENING DEPRESSIVE SYMPTOMS OR SUICIDAL IDEATION AND BEHAVIORS WHILE ON TREATMENT WITH SILIQ.

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Effective: 05/01/26 Client Approval: 04/26 P&T Approval: 10/24

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BUDESONIDE - EOHILIA (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BUDESONIDE	EOHILIA		55273	GPI-14 (22100012001820)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of eosinophilic esophagitis (EoE) (ICD-10 K20.0) and meet **ALL** of the following criteria?
The patient is 11 years of age or older
Therapy is prescribed by or in consultation with a gastroenterologist or allergist
The patient has at least 15 eosinophils/hpf in the esophagus as confirmed by a biopsy

If yes, **approve for 3 months by GPID or GPI-14.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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BUDESONIDE – EOHILIA (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BUDESONIDE - EOHILIA** requires the following rule(s) be met for approval:
You have eosinophilic esophagitis (a type of immune system disorder)
You are 11 years of age or older
Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions) or allergist (a type of allergy doctor)
You have at least 15 eosinophils/high powered field (a type of lab test) in the esophagus as confirmed by a biopsy (removal of cells or tissue from the body for examination)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BUDESONIDE - EOHILIA (PART D)

RENEWAL CRITERIA

Does the patient have a diagnosis of eosinophilic esophagitis (EoE) (ICD-10 K20.0) **AND** meet the following criterion?
The patient has experienced improvement in dysphagia compared to baseline

If yes, **approve for 12 months by GPID or GPI-14.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BUDESONIDE - EOHILIA** requires the following rule(s) be met for renewal:
You have eosinophilic esophagitis (a type of immune system disorder)
You have experienced improvement in dysphagia (difficulty swallowing) compared to baseline

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Eohilia.

REFERENCES

Eohilia [Prescribing Information]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; February 2024.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BUDESONIDE - EOHILIA (PART D)

For Part D use only:

BUDESONIDE - EOHILIA (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	EOSINOPHILIC ESOPHAGITIS (EOE): INITIAL: HAS AT LEAST 15 EOSINOPHILS/HIGH POWERED FIELD IN THE ESOPHAGUS AS CONFIRMED BY A BIOPSY.
Age Restrictions	N/A
Prescriber Restrictions	EOE: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST OR ALLERGIST.
Coverage Duration	INITIAL: 3 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	EOE: RENEWAL: IMPROVEMENT IN DYSPHAGIA COMPARED TO BASELINE.

Part D Effective: 01/01/25 Created: 02/24
Commercial Effective: N/A Client Approval: 08/24 P&T Approval: 07/21

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BUDESONIDE - TARPEYO (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BUDESONIDE	TARPEYO		51745	GPI-14 (22100012006520)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of primary immunoglobulin A nephropathy (IgAN) (ICD-10 Group N02.B) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a nephrologist
- The patient's diagnosis is confirmed by a renal biopsy
- The patient has tried an ACE inhibitor (e.g., benazepril, lisinopril) or an ARB (e.g., losartan, valsartan) for at least three months at a maximum tolerated dose and will continue use, OR has a contraindication to both drug classes
- The patient has an eGFR of at least 35 mL/min/1.73 m(2)
- The patient has a progressively declining glomerular filtration rate (GFR) and/or worsening proteinuria (e.g., greater than 1 gram protein/24-hour urine collection or UPCR [urine protein to creatinine ratio] of at least 1 g/g)

If yes, **approve for 9 months by GPID or GPI-14.**
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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BUDESONIDE - TARPEYO (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT:*Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BUDESONIDE - TARPEYO** requires the following rule(s) be met for approval:
You have primary immunoglobulin A nephropathy (IgAN: a type of kidney disease)
You are 18 years of age or older
Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor)
Your diagnosis is confirmed by a renal biopsy (removal of cells or tissue from the kidney for examination)
You have tried an angiotensin converting enzyme inhibitor (ACE-I: a type of medication used to protect kidneys such as benazepril, lisinopril) or an angiotensin receptor blocker (ARB: a type of medication used to protect kidneys such as losartan, valsartan) for at least 3 months at a maximum tolerated dose and will continue use OR you have a contraindication to (harmful for you to use) both of these medication classes
You have an estimated glomerular filtration rate (eGFR: a tool for evaluating kidney function) of at least 35 mL/min/1.73m(2)
You have a progressively declining glomerular filtration rate (GFR: a tool for evaluating kidney function) and/or worsening proteinuria (high level of protein in the urine, such as greater than 1 gram of protein in a 24-hour urine collection, or at least 1 g/g urine protein to creatinine ratio [UPCR: test that measures the amount of protein in urine])

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BUDESONIDE - TARPEYO (PART D)

RENEWAL CRITERIA

Does the patient have a diagnosis of primary immunoglobulin A nephropathy (IgAN) (ICD-10 Group N02.B) and meet **ONE** of the following criteria?
The patient has improved or stable kidney function compared to baseline
The patient has had a reduction in proteinuria

If yes, **approve for 9 months by GPID or GPI-14.**
If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BUDESONIDE - TARPEYO** requires the following rule(s) be met for renewal:
You have primary immunoglobulin A nephropathy (IgAN: a type of kidney disease)
You have improved or stable kidney function compared to baseline (before starting Tarpeyo)
OR you have a reduction in proteinuria (increased levels of protein in the urine)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tarpeyo.

REFERENCES

Tarpeyo [Prescribing Information]. Stockholm, Sweden: Calliditas Therapeutics, Inc.; June 2024.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BUDESONIDE - TARPEYO (PART D)

For Part D use only:

BUDESONIDE-TARPEYO (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	PRIMARY IMMUNOGLOBULIN A NEPHROPATHY (IGAN): INITIAL: 1) DIAGNOSIS IS CONFIRMED BY A RENAL BIOPSY, 2) EGFR OF AT LEAST 35 ML/MIN/1.73 M2, AND 3) PROGRESSIVELY DECLINING GLOMERULAR FILTRATION RATE AND/OR WORSENING PROTEINURIA.
Age Restrictions	N/A
Prescriber Restrictions	PRIMARY IGAN: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEPHROLOGIST.
Coverage Duration	INITIAL/RENEWAL: 9 MONTHS.
Other Criteria	PRIMARY IGAN: INITIAL: TRIAL AND CONTINUATION OF AN ACE INHIBITOR OR AN ARB AT MAXIMUM TOLERATED DOSE FOR AT LEAST 3 MONTHS OR CONTRAINDICATION TO BOTH CLASSES. RENEWAL: 1) IMPROVED OR STABLE KIDNEY FUNCTION COMPARED TO BASELINE, OR 2) REDUCTION IN PROTEINURIA.

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Effective: 08/01/26 Client Approval: 07/26 P&T Approval: 10/24

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STANDARD PART D
PRIOR AUTHORIZATION GUIDELINES

BULEVIRTIDE-GMOD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BULEVIRTIDE ACETATE-GMOD	HEPCLUDEX	48141		GPI-10 (1235402001)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of chronic hepatitis delta virus (HDV) (ICD-10 B18.0) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- The patient has compensated cirrhosis OR does not have cirrhosis
- Therapy is prescribed by or in consultation with a gastroenterologist, infectious disease specialist, physician specializing in treatment of hepatitis (e.g., hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes)
- The patient has a positive serum anti-HDV antibody test OR a positive serum/plasma HDV RNA PCR

If yes, **approve for 6 months by HICL or GPI-10**.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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BULEVIRTIDE-GMOD (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: Our guideline named **BULEVIRTIDE-GMOD (Hepcludex)** requires the following rule(s) be met for approval:

- You have chronic (long-term) hepatitis delta virus (HDV: liver inflammation caused by a type of virus)
- You are 18 years of age or older
- You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) OR you do not have cirrhosis (liver damage or scarring)
- Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions), infectious disease specialist (a doctor who specializes in the treatment of infections), physician specializing in treatment of hepatitis (liver inflammation) (such as a hepatologist [a type of liver doctor]), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes)
- You have a positive serum anti-HDV (hepatitis delta virus) antibody test (a type of blood test) OR a positive serum/plasma HDV RNA PCR (a type of blood test)

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STANDARD PART D
PRIOR AUTHORIZATION GUIDELINES

BULEVIRTIDE-GMOD (PART D)

RENEWAL CRITERIA

Does the patient have a diagnosis of chronic hepatitis delta virus (HDV) (ICD-10 B18.0) and meet **ALL** of the following criteria?

The patient has compensated cirrhosis OR does not have cirrhosis

The patient had a virological or biochemical response (e.g., undetectable HDV RNA or a decrease by 2 log10 IU/mL from baseline or ALT normalization or a trend towards these items)

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.

RENEWAL DENIAL TEXT: Our guideline named **BULEVIRTIDE-GMOD (Hepcludex)** requires the following rule(s) be met for renewal:

You have chronic (long-term) hepatitis delta virus (HDV: liver inflammation caused by a type of virus)

You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) OR you do not have cirrhosis (liver damage or scarring)

You had a virological or biochemical response (measures that show Hepcludex therapy is effective, such as an undetectable HDV RNA or a decrease by 2 log10 IU/mL from baseline [a type of lab test that shows a suppressed or reduced viral load from before start of treatment] or alanine transaminase [ALT: a type of liver enzyme test] normalization or a trend towards these items)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Hepcludex.

REFERENCES

Hepcludex [Prescribing Information]. Foster City, CA: Gilead Sciences, Inc.; May 2026.

Created: 06/26
Effective: 08/01/26 DMC Approval: 07/21/26

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BUMETANIDE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BUMETANIDE	ENBUMYST	03664		GPI-10 (3720001000)	ROUTE = NASAL

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

Does the patient have a diagnosis of edema (ICD-10 Group R60) associated with congestive heart failure, hepatic disease or renal disease (including nephrotic syndrome) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
Therapy is prescribed by or in consultation with a cardiologist, nephrologist, hepatologist, or gastroenterologist
The patient has a contraindication to or is unable to swallow bumetanide tablets

If yes, **approve for 30 days by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BUMETANIDE (Enbumyst)** requires the following rule(s) be met for approval:
You have edema (swelling caused by fluid build-up in the body) associated with congestive heart failure (a type of heart condition), hepatic (liver) disease or renal (kidney) disease (including nephrotic syndrome [a type of kidney disorder])
You are 18 years of age or older
(Denial text continued on the next page)

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BUMETANIDE (PART D)

GUIDELINES FOR USE (CONTINUED)

Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor), nephrologist (a type of kidney doctor), hepatologist (a type of liver doctor), or gastroenterologist (doctor who treats digestive conditions)
You have a contraindication to (harmful for you to use) or are unable to swallow bumetanide tablets

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Enbumyst.

REFERENCES

Enbumyst [Prescribing Information]. Henderson, NV: Corstasis Therapeutics; September 2025.

For Part D use only:

BUMETANIDE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	EDEMA ASSOCIATED WITH CONGESTIVE HEART FAILURE, HEPATIC DISEASE, OR RENAL DISEASE (INCLUDING NEPHROTIC SYNDROME): PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST, NEPHROLOGIST, HEPATOLOGIST, OR GASTROENTEROLOGIST.
Coverage Duration	30 DAYS
Other Criteria	EDEMA ASSOCIATED WITH CONGESTIVE HEART FAILURE, HEPATIC DISEASE, OR RENAL DISEASE (INCLUDING NEPHROTIC SYNDROME): CONTRAINDICATION TO OR UNABLE TO SWALLOW BUMETANIDE TABLETS.

Created: 12/25
Effective: 12/15/25 Client Approval: 12/25 P&T Approval: 10/25

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BUPRENORPHINE BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BUPRENORPHINE	SUBLOCADE		44187 44186	GPI-14 (6520001000E520), (6520001000E530)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	Yes	No	No	Yes	No	No	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

Is this a pharmacy call?

If yes, continue to #3.
If no, continue to #2.

Is the requested medication going to be filled at a pharmacy?

If yes, continue to #3.
If no, **Refer to plan. (This should be processed under the member's medical benefit)**

Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

If no, continue to #4.

Is the pharmacy dispensing the drug directly to the member or member's representative?

If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

If no, continue to #5.

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BUPRENORPHINE BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

Is the internal HQ code ML500, SFC01, or SUM03?

If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override)
For PAC's: Send an email to plan (reference UNSAD section of PACIP).

If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BUPRENORPHINE BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

Does the patient have a diagnosis of moderate to severe opioid use disorder (ICD-10 Group F11)
AND meet the following criterion?
The patient has initiated treatment with a single dose of a transmucosal buprenorphine product (e.g., Suboxone [buprenorphine/naloxone], Zubsolv [buprenorphine/naloxone]) OR is already being treated with buprenorphine

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BUPRENORPHINE (Sublocade)** requires the following rule(s) be met for approval:
You have moderate to severe opioid use disorder (misuse of a type of pain medication)
You started treatment with a single dose of a transmucosal (medication that enters the body through a mucous layer like those in the mouth) buprenorphine product (such as Suboxone [buprenorphine/naloxone], Zubsolv [buprenorphine/naloxone]), OR you are already being treated with buprenorphine

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BUPRENORPHINE BvD (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sublocade. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Sublocade [Prescribing Information]. North Chesterfield, VA: Indivior, Inc.; February 2025.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed April 5, 2025].

For Part D use only:

BUPRENORPHINE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 07/24
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 04/25

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

C1 ESTERASE INHIBITOR - BERINERT BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
C1 ESTERASE INHIBITOR	BERINERT	18568		GPI-10 (8580202200)	BRAND = BERINERT

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	Yes	No	No	Yes	No	No	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

Is this a pharmacy call?

If yes, continue to #3.
If no, continue to #2.

Is the requested medication going to be filled at a pharmacy?

If yes, continue to #3.
If no, **Refer to plan. (This should be processed under the member's medical benefit)**

Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

If yes, continue to #6.
If no, continue to #4.

Is the pharmacy dispensing the drug directly to the member or member's representative?

If yes, continue to #6.
If no, continue to #5.

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C1 ESTERASE INHIBITOR - BERINERT BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

Is the internal HQ code ML500, SFC01, or SUM03?

If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override)
For PAC's: Send an email to plan (reference UNSAD section of PACIP).

If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Is the drug administered via an implantable pump?

If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**
If no, continue to #7.

Is the drug administered using an external pump?

If yes, continue to #8.
If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

Is the drug specifically infused through an external infusion pump covered by Medicare?

If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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C1 ESTERASE INHIBITOR - BERINERT BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of hereditary angioedema (HAE) (ICD-10 D84.1) and meet **ALL** of the following criteria?
- Berinert will be used for the treatment of acute HAE attacks
- Therapy is prescribed by or in consultation with an allergist, immunologist, hematologist or pulmonologist
- Berinert will NOT be used concurrently with other agents used for the treatment of acute HAE attacks (e.g., Ruconest [C1 esterase inhibitor], Firazyr [icatibant], Kalbitor [ecallantide])

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

Does the patient meet **ONE** of the following criteria?
- The patient has Type I or II HAE, as confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q
- The patient has Type III HAE

If yes, **approve for 12 months by NDC.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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C1 ESTERASE INHIBITOR - BERINERT BvD (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **C1 ESTERASE INHIBITOR - BERINERT** requires the following rule(s) be met for approval:
You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
Berinert will be used for the treatment of acute (sudden and severe) hereditary angioedema attacks
Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), immunologist (a type of immune system doctor), hematologist (a type of blood doctor) or pulmonologist (lung/breathing doctor)
You will NOT use Berinert concurrently (at the same time) with other medications used for the treatment of acute (sudden and severe) hereditary angioedema attacks (such as Ruconest [C1 esterase inhibitor], Firazyr [icatibant], Kalbitor [ecallantide])
You meet ONE of the following:
- You have Type I or II hereditary angioedema (a type of gene condition with severe body swelling), as confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q (types of lab tests)
- You have Type III hereditary angioedema (a type of gene condition with severe body swelling)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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C1 ESTERASE INHIBITOR - BERINERT BvD (PART D)

RENEWAL CRITERIA

Does the patient have a diagnosis of hereditary angioedema (HAE) (ICD-10 D84.1) **AND** meet the following criterion?
Berinert will NOT be used concurrently with other agents used for the treatment of acute HAE attacks (e.g., Ruconest [C1 esterase inhibitor], Firazyr [icatibant], Kalbitor [ecallantide])

If yes, **approve for 12 months by NDC.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **C1 ESTERASE INHIBITOR - BERINERT** requires the following rule(s) be met for renewal:
You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
You will NOT use Berinert concurrently (at the same time) with other medications used for the treatment of acute (sudden and severe) hereditary angioedema attacks (such as Ruconest [C1 esterase inhibitor], Firazyr [icatibant], Kalbitor [ecallantide])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Berinert.

The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B. Drugs administered by an implantable pump are covered under Part B. Drugs administered via an external pump are covered under Part B if they are included under the local coverage policy of the applicable Medicare coverage policies (National and/or Local Coverage Policies). Drugs administered via an external pump that are not included under the applicable Medicare coverage policies are covered under Part D. A CMS website to assist with National and Local Coverage Determination for B versus D review is http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx.

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C1 ESTERASE INHIBITOR - BERINERT BvD (PART D)

REFERENCES

Berinert [Prescribing Information]. Kankakee, IL: CSL Behring LLC.; September 2021.
Medicare Prescription Drug Benefit Manual Chapter 6 – Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed February 2, 2026].

For Part D use only:

C1 ESTERASE INHIBITOR-BERINERT (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	HEREDITARY ANGIOEDEMA (HAE): INITIAL: 1) TYPE III HAE, OR 2) TYPE I OR II HAE CONFIRMED BY ONE OF THE FOLLOWING COMPLEMENT TESTS: C1-INH PROTEIN LEVELS, C4 PROTEIN LEVELS, C1-INH FUNCTIONAL LEVELS, C1Q.
Age Restrictions	N/A
Prescriber Restrictions	HAE: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH AN ALLERGIST, IMMUNOLOGIST, HEMATOLOGIST OR PULMONOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	HAE: INITIAL/RENEWAL: NO CONCURRENT USE WITH OTHER MEDICATIONS FOR THE TREATMENT OF ACUTE HAE ATTACKS.

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Effective: 03/01/26 Client Approval: 02/26 P&T Approval: 04/25

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

C1 ESTERASE INHIBITOR - CINRYZE BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
C1 ESTERASE INHIBITOR	CINRYZE	18568		GPI-10 (8580202200)	BRAND = CINRYZE

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	Yes	No	No	Yes	No	No	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

Is this a pharmacy call?

If yes, continue to #3.
If no, continue to #2.

Is the requested medication going to be filled at a pharmacy?

If yes, continue to #3.
If no, **Refer to plan. (This should be processed under the member's medical benefit).**

Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

If yes, continue to #6.
If no, continue to #4.

Is the pharmacy dispensing the drug directly to the member or member's representative?

If yes, continue to #6.
If no, continue to #5.

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C1 ESTERASE INHIBITOR - CINRYZE BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

Is the internal HQ code ML500, SFC01, or SUM03?

If yes, **Refer to plan. (The health plan makes the final payment determination decision).**
For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).
For PAC's: Send an email to plan (reference UNSAD section of PACIP).

If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Is the drug administered via an implantable pump?

If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**
If no, continue to #7.

Is the drug administered using an external pump?

If yes, continue to #8.
If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

Is the drug specifically infused through an external infusion pump covered by Medicare?

If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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C1 ESTERASE INHIBITOR - CINRYZE BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of hereditary angioedema (HAE) (ICD-10 D84.1) and meet **ALL** of the following criteria?
- The patient is 6 years of age or older
- Cinryze will be used for routine prophylaxis against HAE attacks
- Therapy is prescribed by or in consultation with a hematologist, immunologist, allergist, or pulmonologist
- Cinryze will NOT be used concurrently with an alternative prophylactic agent for HAE attacks (e.g., Takhzyro [lanadelumab-flyo], Haegarda [C1 esterase inhibitor], danazol, Orladeyo [berotralstat], Andembry [garadacimab-gxii])

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

Does the patient meet **ONE** of the following criteria?
- The patient has Type I or II HAE, as confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q
- The patient has Type III HAE

If yes, **approve for 12 months for all NDCs.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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C1 ESTERASE INHIBITOR - CINRYZE BvD (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **C1 ESTERASE INHIBITOR - CINRYZE** requires the following rule(s) be met for approval:
You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
You are 6 years of age or older
Cinryze will be used for the routine prevention of hereditary angioedema attacks
Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor), immunologist (a type of immune system doctor), allergist (a type of allergy doctor), or pulmonologist (lung/breathing doctor)
You will NOT use Cinryze concurrently (at the same time) with an alternative preventive medication for HAE attacks (such as Takhzyro [lanadelumab-flyo], Haegarda [C1 esterase inhibitor], danazol, Orladeyo [berotralstat], Andembry [garadacimab-gxii])
You meet ONE of the following:
- You have Type I or II hereditary angioedema (a type of gene condition with severe body swelling), as confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q (types of lab tests)
- You have Type III hereditary angioedema (a type of gene condition with severe body swelling)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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C1 ESTERASE INHIBITOR - CINRYZE BvD (PART D)

RENEWAL CRITERIA

Does the patient have a diagnosis of hereditary angioedema (HAE) (ICD-10 D84.1) **AND** meet the following criterion?

Cinryze will NOT be used concurrently with an alternative prophylactic agent for HAE attacks (e.g., Takhzyro [lanadelumab-flyo], Haegarda [C1 esterase inhibitor], danazol, Orladeyo [berotralstat], Andembry [garadacimab-gxii])

If yes, **approve for 12 months for all NDCs.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **C1 ESTERASE INHIBITOR - CINRYZE** requires the following rule(s) be met for renewal:
You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
You will NOT use Cinryze concurrently (at the same time) with an alternative preventive medication for HAE attacks (such as Takhzyro [lanadelumab-flyo], Haegarda [C1 esterase inhibitor], danazol, Orladeyo [berotralstat], Andembry [garadacimab-gxii])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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C1 ESTERASE INHIBITOR - CINRYZE BvD (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cinryze.

The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B. Drugs administered by an implantable pump are covered under Part B. Drugs administered via an external pump are covered under Part B if they are included under the local coverage policy of the applicable Medicare coverage policies (National and/or Local Coverage Policies). Drugs administered via an external pump that are not included under the applicable Medicare coverage policies are covered under Part D. A CMS website to assist with National and Local Coverage Determination for B versus D review is http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx.

REFERENCES

Cinryze [Prescribing Information]. Lexington, MA: Takeda Pharmaceuticals USA; November 2024.

Medicare Prescription Drug Benefit Manual Chapter 6 – Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed February 2, 2026].

For Part D use only:

C1 ESTERASE INHIBITOR-CINRYZE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	HEREDITARY ANGIOEDEMA (HAE): INITIAL: 1) TYPE III HAE, OR 2) TYPE I OR II HAE CONFIRMED BY ONE OF THE FOLLOWING COMPLEMENT TESTS: C1-INH PROTEIN LEVELS, C4 PROTEIN LEVELS, C1-INH FUNCTIONAL LEVELS, C1Q.
Age Restrictions	N/A
Prescriber Restrictions	HAE: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST, IMMUNOLOGIST, ALLERGIST, OR PULMONOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	HAE: INITIAL/RENEWAL: NOT ON CONCURRENT TREATMENT WITH ALTERNATIVE PROPHYLACTIC AGENT FOR HAE ATTACKS.

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Effective: 03/01/26 Client Approval: 02/26 P&T Approval: 07/24

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

C1 ESTERASE INHIBITOR - HAEGARDA (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
C1 ESTERASE INHIBITOR	HAEGARDA		39478 43356	GPI-14 (85802022002130, 85802022002140)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of hereditary angioedema (HAE) (ICD-10 D84.1) and meet **ALL** of the following criteria?
- The patient is 6 years of age or older
- Haegarda will be used for routine prophylaxis against HAE attacks
- Therapy is prescribed by or in consultation with a hematologist, immunologist, allergist, or pulmonologist
- Haegarda will NOT be used concurrently with an alternative prophylactic agent for HAE attacks (e.g., Takhzyro [lanadelumab-flyo], Cinryze [C1 esterase inhibitor], danazol, Orladeyo [berotralstat], Andembry [garadacimab-gxii])

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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C1 ESTERASE INHIBITOR - HAEGARDA (PART D)

INITIAL CRITERIA (CONTINUED)

Does the patient meet **ONE** of the following criteria?

The patient has Type I or II HAE, as confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q

The patient has Type III HAE

If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **C1 ESTERASE INHIBITOR - HAEGARDA** requires the following rule(s) be met for approval:
You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
You are 6 years of age or older
Haegarda will be used for the routine prevention of hereditary angioedema attacks
Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor), immunologist (a type of immune system doctor), allergist (a type of allergy doctor), or pulmonologist (lung/breathing doctor)
You will NOT use Haegarda concurrently (at the same time) with an alternative preventive medication for HAE attacks (such as Takhzyro [lanadelumab-flyo], Cinryze [C1 esterase inhibitor], danazol, Orladeyo [berotralstat], Andembry [garadacimab-gxii])
You meet ONE of the following:
- You have Type I or II hereditary angioedema (a type of gene condition with severe body swelling), as confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q (types of lab tests)
- You have Type III hereditary angioedema (a type of gene condition with severe body swelling)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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C1 ESTERASE INHIBITOR - HAEGARDA (PART D)

RENEWAL CRITERIA

Does the patient have a diagnosis of hereditary angioedema (HAE) (ICD-10 D84.1) **AND** meet the following criterion?

Haegarda will NOT be used concurrently with an alternative prophylactic agent for HAE attacks (e.g., Takhzyro [lanadelumab-flyo], Cinryze [C1 esterase inhibitor], danazol, Orladeyo [berotralstat], Andembry [garadacimab-gxii])

If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **C1 ESTERASE INHIBITOR - HAEGARDA** requires the following rule(s) be met for renewal:
You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
You will NOT use Haegarda concurrently (at the same time) with an alternative preventive medication for HAE attacks (such as Takhzyro [lanadelumab-flyo], Cinryze [C1 esterase inhibitor], danazol, Orladeyo [berotralstat], Andembry [garadacimab-gxii])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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C1 ESTERASE INHIBITOR - HAEGARDA (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monographs for Haegarda.

REFERENCES

Haegarda [Prescribing Information]. Kankakee, IL: CSL Behring LLC.; January 2022.

For Part D use only:

C1 ESTERASE INHIBITOR-HAEGARDA (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	HEREDITARY ANGIOEDEMA (HAE): INITIAL: 1) TYPE III HAE, OR 2) TYPE I OR II HAE CONFIRMED BY ONE OF THE FOLLOWING COMPLEMENT TESTS: C1-INH PROTEIN LEVELS, C4 PROTEIN LEVELS, C1-INH FUNCTIONAL LEVELS, C1Q.
Age Restrictions	N/A
Prescriber Restrictions	HAE: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST, IMMUNOLOGIST, ALLERGIST OR PULMONOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	HAE: INITIAL/RENEWAL: NOT ON CONCURRENT TREATMENT WITH ALTERNATIVE PROPHYLACTIC AGENT FOR HAE ATTACKS.

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Effective: 03/01/26 Client Approval: 02/26 P&T Approval: 07/24

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

C1 ESTERASE INHIBITOR - RUCONEST (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
C1 ESTERASE INHIBITOR, RECOMB	RUCONEST	37766		GPI-10 (8580202210)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of hereditary angioedema (HAE) (ICD-10 D84.1) and meet **ALL** of the following criteria?
- Ruconest will be used for the treatment of acute HAE attacks
- Therapy is prescribed by or in consultation with an allergist, immunologist, hematologist or pulmonologist
- Ruconest will NOT be used concurrently with other agents used for the treatment of acute HAE attacks (e.g., Berinert [C1 esterase inhibitor], Firazyr [icatibant], Kalbitor [ecallantide])

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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C1 ESTERASE INHIBITOR - RUCONEST (PART D)

INITIAL CRITERIA (CONTINUED)

Does the patient meet **ONE** of the following criteria?

The patient has Type I or II HAE, as confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q

The patient has Type III HAE

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **C1 ESTERASE INHIBITOR - RUCONEST** requires the following rule(s) be met for approval:

You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)

Ruconest will be used for the treatment of acute (sudden) hereditary angioedema attacks

Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), immunologist (a type of immune system doctor), hematologist (a type of blood doctor) or pulmonologist (lung/breathing doctor)

You will NOT use Ruconest concurrently (at the same time) with other medications for the treatment of acute (sudden) hereditary angioedema attacks (such as Berinert [C1 esterase inhibitor], Firazyr [icatibant], Kalbitor [ecallantide])

You meet ONE of the following:

- You have Type I or II hereditary angioedema (a type of gene condition with severe body swelling), as confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q (types of lab tests)
- You have Type III hereditary angioedema (a type of gene condition with severe body swelling)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

C1 ESTERASE INHIBITOR - RUCONEST (PART D)

RENEWAL CRITERIA

Does the patient have a diagnosis of hereditary angioedema (HAE) (ICD-10 D84.1) **AND** meet the following criterion?
Ruconest will NOT be used concurrently with other agents used for the treatment of acute HAE attacks (e.g., Berinert [C1 esterase inhibitor], Firazyr [icatibant], Kalbitor [ecallantide])

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **C1 ESTERASE INHIBITOR - RUCONEST** requires the following rule(s) be met for renewal:
You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
You will NOT use Ruconest concurrently (at the same time) with other medications used for the treatment of acute (sudden) hereditary angioedema attacks (such as Berinert [C1 esterase inhibitor], Firazyr [icatibant], Kalbitor [ecallantide])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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C1 ESTERASE INHIBITOR - RUCONEST (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monographs for Ruconest.

REFERENCES

Ruconest [Prescribing Information]. Warren, NJ: Pharming Healthcare Inc.; April 2020.

For Part D use only:

C1 ESTERASE INHIBITOR - RUCONEST (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	HEREDITARY ANGIOEDEMA (HAE): INITIAL: 1) TYPE III HAE, OR 2) TYPE I OR II HAE CONFIRMED BY ONE OF THE FOLLOWING COMPLEMENT TESTS: C1-INH PROTEIN LEVELS, C4 PROTEIN LEVELS, C1-INH FUNCTIONAL LEVELS, C1Q.
Age Restrictions	N/A
Prescriber Restrictions	HAE: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH AN ALLERGIST, IMMUNOLOGIST, HEMATOLOGIST OR PULMONOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	HAE: INITIAL/RENEWAL: NO CONCURRENT USE WITH OTHER MEDICATIONS FOR THE TREATMENT OF ACUTE HAE ATTACKS.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CABOZANTINIB CAPSULE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CABOZANTINIB S-MALATE	COMETRIQ		33903 33904 33905	GPI-14 (21533010106460, 21533010106470, 21533010106480)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

**** Please use the criteria for the specific drug requested ****

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of progressive, metastatic medullary thyroid cancer (MTC) (ICD-10 C73)?

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CABOZANTINIB CAPSULE (Cometriq)** requires the following rule be met for approval:
   A. You have progressive, metastatic medullary thyroid cancer (a type of thyroid cancer that has spread to other parts of the body)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CABOZANTINIB CAPSULE (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cometriq or Cabometyx.

REFERENCES

Cometriq [Prescribing Information]. South San Francisco, CA: Exelixis, Inc.; October 2020.

For Part D use only:

CABOZANTINIB CAPSULE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 07/23
Client Approval: 08/24
P&T Approval: 10/21

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CABOZANTINIB TABLET (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CABOZANTINIB S-MALATE	CABOMETYX		41146 41147 41148	GPI-14 (21533010100320, 21533010100330, 21533010100340)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

**** Please use the criteria for the specific drug requested ****

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC) (ICD-10 Groups C64, C65) and meet **ONE** of the following criteria?
   - Cabometyx will be used as a single agent
   - Cabometyx will be used in combination with Opdivo (nivolumab) as first-line treatment (no prior treatment for advanced RCC)

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of hepatocellular carcinoma (HCC) (ICD-10 C22.0) **AND** meet the following criterion?
   - The patient has been previously treated with Nexavar (sorafenib)

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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CABOZANTINIB TABLET (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of locally advanced or metastatic differentiated thyroid cancer (DTC) (ICD-10 C73) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient has disease progression following prior vascular endothelial growth factor receptor (VEGFR)-targeted therapy (e.g., Lenvima [lenvatinib])
   - The patient is radioactive iodine-refractory or ineligible

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

4. Does the patient have a diagnosis of pancreatic or extra-pancreatic neuroendocrine tumor (pNET or epNET) (ICD-10 C25.4, Group C7A) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The tumor is unresectable, locally advanced or metastatic, and well-differentiated
   - The tumor has been previously treated

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CABOZANTINIB TABLET (Cabometyx)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Advanced renal cell carcinoma (RCC: a type of kidney cancer)
      2. Hepatocellular carcinoma (HCC: a type of liver cancer)
      3. Locally advanced or metastatic differentiated thyroid cancer (DTC: a type of thyroid cancer that has spread to nearby tissue/lymph nodes or to other parts of the body)
      4. Pancreatic neuroendocrine tumor (pNET: tumor that began in the pancreas)
      5. Extra-pancreatic neuroendocrine tumor (epNET: tumor that began outside of the pancreas)

   (Denial text continued on next page)

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CABOZANTINIB TABLET (PART D)

GUIDELINES FOR USE (CONTINUED)

B. If you have advanced renal cell carcinoma, approval also requires ONE of the following:
1. Cabometyx will be used as a single agent (used alone)
2. Cabometyx will be used in combination with Opdivo (nivolumab) as first-line treatment (you have NOT received prior treatment for advanced renal cell carcinoma)

C. If you have hepatocellular carcinoma, approval also requires:
1. You have been previously treated with Nexavar (sorafenib)

D. If you have locally advanced or metastatic differentiated thyroid cancer, approval also requires:
1. You are 12 years of age or older
2. You have disease progression (worsening) following prior vascular endothelial growth factor receptor (VEGFR)-targeted therapy (such as Lenvima [lenvatinib])
3. You are radioactive iodine-refractory (resistant to) or ineligible

E. If you have a pancreatic or extra-pancreatic neuroendocrine tumor, approval also requires:
1. You are 12 years of age or older
2. Your tumor is unresectable (unable to remove by surgery), locally advanced or metastatic (cancer that has spread to nearby tissue/lymph nodes or to other parts of the body), and well-differentiated
3. Your tumor has been previously treated

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cabometyx.

REFERENCES

Cabometyx [Prescribing Information]. Alameda, CA: Exelixis, Inc.; March 2025.

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CABOZANTINIB TABLET (PART D)

For Part D use only:

CABOZANTINIB TABLET (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 05/23
Effective: 05/05/25 Client Approval: 04/25 P&T Approval: 10/21

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CALASPARGASE PEGOL-MKNL (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CALASPARGASE PEGOL-MKNL	ASPARLAS	45566		GPI-10 (2125003050)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of acute lymphoblastic leukemia (ALL) (ICD-10 Group C91.0) and meet **ALL** of the following criteria?
   - The patient is 1 month to 21 years of age
   - Asparlas will be used as a component of a multi-agent chemotherapeutic regimen

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CALASPARGASE PEGOL-MKNL (Asparlas)** requires the following rule(s) be met for approval:
   A. You have acute lymphoblastic leukemia (a type of blood and bone marrow cancer)
   B. You are 1 month to 21 years of age
   C. Asparlas will be used as a part of a chemotherapeutic plan that contains multiple drugs

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CALASPARGASE PEGOL-MKNL (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Asparlas.

REFERENCES

Asparlas [Prescribing Information]. Boston, MA: Servier Pharmaceuticals LLC; June 2020.

For Part D use only:

CALASPARGASE PEGOL-MKNL (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A
Quantity Limit (from Formulary ASCII file)	N/A

Created: 11/20
Effective: 01/01/26 Client Approval: 01/26 P&T Approval: 04/19

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CANAKINUMAB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CANAKINUMAB/PF	ILARIS	36497		GPI-10 (6646002000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of cryopyrin-associated periodic syndromes (CAPS), including familial cold autoinflammatory syndrome (FCAS) or Muckle-Wells syndrome (MWS) (ICD-10 M04.2), and meet **ALL** of the following criteria?
   - The patient is 4 years of age or older
   - The patient had genetic testing for gain-of-function mutations in the NLRP3 gene OR has inflammatory markers (i.e., elevated CRP, ESR, serum amyloid A protein (SAA) or S100 proteins)
   - The patient has TWO of the following: urticarial-like rash (neutrophilic dermatitis), cold-triggered episodes, sensorineural hearing loss, musculoskeletal symptoms, chronic aseptic meningitis, skeletal abnormalities
   - Ilaris will NOT be used concurrently with other IL-1 inhibitors (e.g., Arcalyst [rilonacept], Kineret [anakinra])

   If yes, **approve for lifetime by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

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CANAKINUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of **ONE** of the following periodic fever syndromes?
   - Tumor necrosis factor receptor associated periodic syndrome (TRAPS) (ICD-10 M04.1)
   - Hyperimmunoglobulin D syndrome (HIDS)/mevalonate kinase deficiency (MKD) (ICD-10 M04.1)
   - Familial Mediterranean fever (FMF) (ICD-10 M04.1)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Does the patient have a diagnosis of systemic juvenile idiopathic arthritis (SJIA) (ICD-10 Group M08.2) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist, dermatologist, or immunologist
   - Ilaris will NOT be used concurrently with another systemic biologic (e.g., Actemra [tocilizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of SJIA

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

4. Does the patient have a diagnosis of adult-onset Still's disease (AOSD) (ICD-10 M06.1) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a rheumatologist, dermatologist, or immunologist
   - Ilaris will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of AOSD

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

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CANAKINUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of gout (ICD-10 Group M10) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Ilaris will be used for the symptomatic treatment of gout flares (e.g., episodes of pain, swelling)
   - The patient had an inadequate response, intolerance, or contraindication to NSAIDs (non-steroidal anti-inflammatory drugs) (e.g., ibuprofen, naproxen, indomethacin)
   - The patient had an inadequate response, intolerance, or contraindication to colchicine
   - The patient is not able to receive repeated courses of corticosteroids (e.g., triamcinolone acetonide)
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Ilaris will NOT be used concurrently with other IL-1 inhibitors (e.g., Arcalyst [rilonacept], Kineret [anakinra])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CANAKINUMAB (Ilaris)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Cryopyrin-associated periodic syndromes (CAPS), including familial cold auto-inflammatory syndrome (FCAS: inherited inflammatory disorder that is triggered with cold) or Muckle-Wells syndrome (MWS: disorder characterized by periodic episodes of skin rash, fever, and joint pain)
      2. Tumor necrosis factor receptor associated periodic syndrome (TRAPS: a type of genetic disease)
      3. Hyperimmunoglobulin D syndrome (HIDS)/mevalonate kinase deficiency (MKD) (types of genetic disorders)
      4. Familial Mediterranean fever (FMF: a type of genetic disorder)
      5. Systemic juvenile idiopathic arthritis (SJIA: a type of joint condition)
      6. Adult-onset Still's disease (AOSD: an autoinflammatory disease)
      7. Gout (a type of joint condition)

   (Initial denial text continued on next page)

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CANAKINUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

B. If you have cryopyrin-associated periodic syndromes, including familial cold autoinflammatory syndrome or Muckle-Wells syndrome, approval also requires:
1. You are 4 years of age or older
2. You had genetic testing for gain-of-function mutations (abnormal change in gene) in the NLRP3 gene (a type of gene) OR you have inflammatory markers (elevated C-reactive protein [CRP: sign of inflammation], erythrocyte sedimentation rate [ESR: a type of blood test], serum amyloid A protein [SAA: a type of protein] or S100 proteins [a type of protein])
3. You have TWO of the following: urticarial-like rash (neutrophilic dermatitis: a type of skin condition), cold-triggered episodes, sensorineural hearing loss (SNHL: a type of hearing loss), musculoskeletal symptoms (symptoms related to muscles and bones), chronic aseptic meningitis (inflammation of the brain and spinal cord), skeletal (bone) abnormalities
4. Ilaris will NOT be used concurrently (at the same time) with other IL-1 inhibitors (such as Arcalyst [rilonacept], Kineret [anakinra])

C. If you have systemic juvenile idiopathic arthritis, approval also requires:
1. You are 2 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
3. You will NOT use Ilaris concurrently (at the same time) with another systemic biologic (such as Actemra [tocilizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic juvenile idiopathic arthritis

D. If you have adult-onset Still's disease, approval also requires:
1. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
2. You will NOT use Ilaris concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of adult-onset Still's disease

(Initial denial text continued on next page)

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CANAKINUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

E. If you have gout, approval also requires:

1. You are 18 years of age or older
2. Ilaris will be used for the symptomatic treatment of gout flares (such as episodes of pain or swelling)
3. You had an inadequate response (drug did not work), intolerance (side effect) of, or contraindication to (harmful for you to use) NSAIDs (non-steroidal anti-inflammatory drugs, such as ibuprofen, naproxen, indomethacin)
4. You had an inadequate response, intolerance of, or contraindication to colchicine
5. You are not able to receive repeated treatments of corticosteroids (such as triamcinolone acetonide)
6. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
7. You will NOT use Ilaris concurrently (at the same time) with other IL-1 inhibitors (such as Arcalyst [rilonacept], Kineret [anakinra])

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CANAKINUMAB (PART D)

RENEWAL CRITERIA

NOTE: For the diagnosis of cryopyrin-associated periodic syndromes (CAPS), including familial cold autoinflammatory syndrome (FCAS), Muckle-Wells syndrome (MWS), tumor necrosis factor receptor associated periodic syndrome (TRAPS), hyperimmunoglobulin D syndrome (HIDS)/mevalonate kinase deficiency (MKD) or familial Mediterranean fever (FMF), please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of systemic juvenile idiopathic arthritis (SJIA) (ICD-10 Group M08.2) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Ilaris will NOT be used concurrently with another systemic biologic (e.g., Actemra [tocilizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of SJIA

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of adult-onset Still's disease (AOSD) (ICD-10 M06.1) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Ilaris will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of AOSD

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Does the patient have a diagnosis of gout (ICD-10 Group M10) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Ilaris will NOT be used concurrently with other IL-1 inhibitors (e.g., Arcalyst [rilonacept], Kineret [anakinra])
   - The patient has improvement in gout flares (e.g., episodes of pain, swelling)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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CANAKINUMAB (PART D)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CANAKINUMAB (Ilaris)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Systemic juvenile idiopathic arthritis (SJIA: a type of joint condition)
   2. Adult-onset Still's disease (AOSD: an autoinflammatory disorder)
   3. Gout (a type of joint condition)

B. If you have systemic juvenile idiopathic arthritis, renewal also requires:
   1. You continue to benefit from the medication
   2. You will NOT use Ilaris concurrently (at the same time) with another systemic biologic (such as Actemra [tocilizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic juvenile idiopathic arthritis

C. If you have adult-onset Still's disease, renewal also requires:
   1. You continue to benefit from the medication
   2. You will NOT use Ilaris concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of adult-onset Still's disease

D. If you have gout, renewal also requires:
   1. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   2. You will NOT use Ilaris concurrently (at the same time) with other IL-1 inhibitors (such as Arcalyst [rilonacept], Kineret [anakinra])
   3. You have improvement in gout flares (such as episodes of pain, swelling)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ilaris.

REFERENCES

Ilaris [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; November 2024.

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CANAKINUMAB (PART D)

For Part D use only:

CANAKINUMAB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	INITIAL: CRYOPYRIN-ASSOCIATED PERIODIC SYNDROMES (CAPS): 1) ONE OF THE FOLLOWING: (A) GENETIC TEST FOR GAIN-OF-FUNCTION MUTATIONS IN THE NLRP3 GENE, OR (B) HAS INFLAMMATORY MARKERS (I.E., ELEVATED CRP, ESR, SERUM AMYLOID A PROTEIN (SAA) OR S100 PROTEINS), AND 2) TWO OF THE FOLLOWING: URTICARIAL-LIKE RASH (NEUTROPHILIC DERMATITIS), COLD-TRIGGERED EPISODES, SENSORINEURAL HEARING LOSS, MUSCULOSKELETAL SYMPTOMS, CHRONIC ASEPTIC MENINGITIS, SKELETAL ABNORMALITIES.
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS (SJIA), ADULT-ONSET STILLS DISEASE (AOSD): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST, DERMATOLOGIST, OR IMMUNOLOGIST. GOUT: PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. RENEWAL: GOUT: PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST.
Coverage Duration	INITIAL: AOSD/SJIA: 6 MO, CAPS: LIFETIME, ALL OTHER DIAGNOSES: 12 MO. RENEWAL: AOSD/SJIA/GOUT: 12 MO
Other Criteria	INITIAL: CAPS: NO CONCURRENT USE WITH OTHER IL-1 INHIBITORS. AOSD: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AOSD. SJIA: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR SJIA. GOUT: NO CONCURRENT USE WITH OTHER IL-1 INHIBITORS. RENEWAL: AOSD: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR AOSD. SJIA: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR SJIA. GOUT: 1) NO CONCURRENT USE WITH OTHER IL-1 INHIBITORS, AND 2) IMPROVEMENT IN GOUT FLARES.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CANNABIDIOL (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CANNABIDIOL (CBD)	EPIDIOLEX	45006		GPI-10 (7260001700)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of seizures associated with Dravet syndrome (DS) (ICD-10 G40.833) and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - Therapy is prescribed by or in consultation with a neurologist

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of seizures associated with Lennox-Gastaut syndrome (LGS) (ICD-10 Group G40.81) and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient had a trial of or contraindication to TWO of the following antiepileptic medications: rufinamide, felbamate, clobazam, topiramate, lamotrigine, clonazepam

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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CANNABIDIOL (PART D)

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of seizures associated with tuberous sclerosis complex (TSC) (ICD-10 Q85.1) and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - Therapy is prescribed by or in consultation with a neurologist

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CANNABIDIOL (Epidiolex)** requires the following rule(s) be met for approval:
   A. You have seizures associated with ONE of the following:
      1. Dravet syndrome (DS: a rare type of seizure)
      2. Lennox-Gastaut syndrome (LGS: a type of seizure disorder in young children)
      3. Tuberous sclerosis complex (TSC: a rare type of tumor disorder)
   B. If you have seizures associated with Dravet syndrome, approval also requires:
      1. You are 1 year of age or older
      2. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor)
   C. If you have seizures associated with Lennox-Gastaut syndrome, approval also requires:
      1. You are 1 year of age or older
      2. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor)
      3. You had a trial of or contraindication to (harmful for you to use) TWO of the following antiepileptic medications (drugs used to treat seizures): rufinamide, felbamate, clobazam, topiramate, lamotrigine, clonazepam
   D. If you have seizures associated with tuberous sclerosis complex, approval also requires:
      1. You are 1 year of age or older
      2. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CANNABIDIOL (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of seizures associated with Dravet syndrome (ICD-10 G40.833), Lennox-Gastaut syndrome (ICD-10 Group G40.81), OR tuberous sclerosis complex (ICD-10 Q85.1)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CANNABIDIOL (Epidiolex)** requires the following rule(s) be met for renewal:
   A. You have seizures associated with ONE of the following:
      1. Dravet syndrome (DS: a rare type of seizure)
      2. Lennox-Gastaut syndrome (LGS: a type of seizure disorder in young children)
      3. Tuberous sclerosis complex (TSC: a rare type of tumor disorder)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Epidiolex.

REFERENCES
Epidiolex [Prescribing Information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; March 2024.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CANNABIDIOL (PART D)

For Part D use only:

CANNABIDIOL (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: DRAVET SYNDROME (DS), LENNOX-GASTAUT SYNDROME (LGS), TUBEROUS SCLEROSIS COMPLEX (TSC): PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: LGS: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING ANTIEPILEPTIC MEDICATIONS: RUFINAMIDE, FELBAMATE, CLOBAZAM, TOPIRAMATE, LAMOTRIGINE, CLONAZEPAM.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CANTHARIDIN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CANTHARIDIN	YCANTH	02578		GPI-10 (9075001000)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of molluscum contagiosum (ICD-10 B08.1) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Ycanth will NOT be used concurrently with another topical agent for the treatment of molluscum contagiosum (e.g., Zelsuvmi [berdazimer], podofilox)

   If yes, **approve for 12 weeks by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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CANTHARIDIN (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CANTHARIDIN (Ycanth)** requires the following rule(s) be met for approval:

A. You have molluscum contagiosum (a viral skin infection)
B. You are 2 years of age or older
C. You will NOT use Ycanth concurrently (at the same time) with another topical medication for the treatment of molluscum contagiosum (a viral skin infection) (such as Zelsuvmi [berdazimer], podofilox)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ycanth.

REFERENCES

Ycanth [Prescribing Information]. West Chester, PA: Verrica Pharmaceuticals, Inc.; October 2024.

For Part D use only:

CANTHARIDIN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 WEEKS
Other Criteria	MOLLUSCUM CONTAGIOSUM (MC): NO CONCURRENT USE WITH ANOTHER TOPICAL AGENT FOR MC (E.G., ZELSUVMI, PODOFILOX).

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CAPIVASERTIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CAPIVASERTIB	TRUQAP	49313		GPI-10 (2153032000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced or metastatic breast cancer (ICD-10 Group C50) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Truqap will be used in combination with Faslodex (fulvestrant)
   - The patient's cancer is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, with one or more PIK3CA/AKT1/PTEN-alterations, as detected by an FDA-approved test
   - The patient has disease progression on or after an endocrine-based regimen (e.g., letrozole, anastrozole, tamoxifen)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of metastatic androgen pathway modulation-naive or -sensitive (mAPMN/S) prostate cancer (ICD-10 C61, Z19.1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Truqap will be used in combination with abiraterone (Zytiga) and prednisone
   - The cancer is PTEN-deficient as detected by an FDA-authorized test

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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CAPIVASERTIB (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: Our guideline named **CAPIVASERTIB (Truqap)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Locally advanced or metastatic breast cancer (breast cancer that has spread to nearby tissue or lymph nodes or to other parts of the body)
   2. Metastatic androgen pathway modulation-naive or -sensitive (mAPMN/S) prostate cancer (cancer that has spread to other parts of the body and has not been treated with, or may respond to, testosterone-lowering treatment)

B. If you have locally advanced or metastatic breast cancer, approval also requires:
   1. You are 18 years of age or older
   2. Truqap will be used together with Faslodex (fulvestrant)
   3. Your breast cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative, with one or more PIK3CA/AKT1/PTEN-mutations (abnormal changes in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test
   4. You have experienced disease progression (your condition has worsened) on or after an endocrine (hormone)-based regimen (such as letrozole, anastrozole, tamoxifen)

C. If you have metastatic androgen pathway modulation-naive or -sensitive prostate cancer, approval also requires:
   1. You are 18 years of age or older
   2. Truqap will be used in combination with abiraterone (Zytiga) and prednisone
   3. Your prostate cancer is PTEN-deficient (loss of a type of gene) as detected by a Food and Drug Administration (FDA)-authorized test

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Truqap.

REFERENCES

Truqap [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; June 2026.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CAPIVASERTIB (PART D)

For Part D use only:

CAPIVASERTIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 11/23
Effective: 07/08/26 Client Approval: 07/26 DMC Approval: 06/26

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CAPLACIZUMAB-YHDP (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CAPLACIZUMAB-YHDP	CABLIVI	45591		GPI-10 (8515102080)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of acquired thrombotic thrombocytopenia purpura (aTTP) (ICD-10 Group M31.1) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Therapy is prescribed by or in consultation with a hematologist
   - Cablivi was previously initiated as part of an FDA-approved treatment regimen in combination with plasma exchange and immunosuppressive therapy within an inpatient setting

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient experienced more than TWO recurrences of aTTP while on Cablivi therapy (i.e., new drop in platelet count requiring repeat plasma exchange during 30 days post-plasma exchange therapy [PEX] and up to 28 days of extended therapy)?

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CAPLACIZUMAB-YHDP (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CAPLACIZUMAB-YHDP (Cablivi)** requires the following rule(s) be met for approval:

A. You have acquired thrombotic thrombocytopenia purpura (aTTP: a type of blood disorder)
B. You are 12 years of age or older
C. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
D. Cablivi was previously initiated as part of a Food and Drug Administration (FDA)-approved treatment regimen in combination with plasma exchange (filtering of blood) and immunosuppressive therapy (treatment that weakens your immune system) within an inpatient setting
E. You have NOT experienced more than TWO recurrences of acquired thrombotic thrombocytopenia purpura (aTTP: a type of blood disorder) while on Cablivi therapy. Recurrences include a new drop in platelet (a type of blood cell) count requiring repeat plasma exchange during 30 days post-plasma exchange therapy (PEX: filtering of blood) and up to 28 days of extended therapy

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cablivi.

REFERENCES

Cablivi [Prescribing Information]. Cambridge, MA: Genzyme Corporation; December 2025.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CAPLACIZUMAB-YHDP (PART D)

For Part D use only:

CAPLACIZUMAB-YHDP (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	ACQUIRED THROMBOTIC THROMBOCYTOPENIA PURPURA (ATTP): PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST.
Coverage Duration	12 MONTHS
Other Criteria	ATTP: 1) CABLIVI WAS PREVIOUSLY INITIATED AS PART OF AN FDA APPROVED TREATMENT REGIMEN IN COMBINATION WITH PLASMA EXCHANGE AND IMMUNOSUPPRESSIVE THERAPY IN AN INPATIENT SETTING, AND 2) HAS NOT EXPERIENCED MORE THAN TWO RECURRENCES OF ATTP WHILE ON CABLIVI THERAPY (I.E., NEW DROP IN PLATELET COUNT REQUIRING REPEAT PLASMA EXCHANGE DURING 30 DAYS POST-PLASMA EXCHANGE THERAPY [PEX] AND UP TO 28 DAYS OF EXTENDED THERAPY).

Created: 03/19
Effective: 01/19/26 Client Approval: 01/26 P&T Approval: 04/19

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CAPMATINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CAPMATINIB HYDROCHLORIDE	TABRECTA	46519		GPI-10 (2153371620)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping, as detected by an FDA-approved test

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CAPMATINIB (Tabrecta)** requires the following rule(s) be met for approval:
   A. You have metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of the body)
   B. You are 18 years of age or older
   C. Your tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping (an abnormal change in a gene that makes MET protein), as detected by a Food and Drug Administration (FDA)-approved test

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CAPMATINIB (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tabrecta.

REFERENCES

Tabrecta [Prescribing Information]. East Hanover, NJ: Novartis; March 2024.

For Part D use only:

CAPMATINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 05/20
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P&T Approval: 07/20

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CARFILZOMIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CARFILZOMIB	KYPROLIS	39338		GPI-10 (2153602500)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory multiple myeloma (MM) (ICD-10 Group C90.0) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient received at least one prior line of therapy (e.g., Velcade [bortezomib], Thalomid [thalidomide], Revlimid [lenalidomide]) **AND** Kyprolis will be used as a single agent?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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CARFILZOMIB (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Has the patient received one to three prior lines of therapy (e.g., Velcade [bortezomib], Thalomid [thalidomide]) **AND** Kyprolis will be used in combination with ONE of the following regimens?
   - Revlimid (lenalidomide) and dexamethasone
   - Dexamethasone
   - Darzalex (daratumumab) and dexamethasone
   - Darzalex Faspro (daratumumab-hyaluronidase-fihj) and dexamethasone
   - Sarclisa (isatuximab) and dexamethasone

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CARFILZOMIB (Kyprolis)** requires the following rule(s) be met for approval:
   A. You have relapsed or refractory multiple myeloma (a type of blood cancer that has returned or did not respond to treatment)
   B. You are 18 years of age or older
   C. You meet ONE of the following:
      1. You have received at least one prior line of multiple myeloma therapy (such as Velcade [bortezomib], Thalomid [thalidomide], Revlimid [lenalidomide]) AND Kyprolis will be used as a single agent (used alone)
      2. You have received one to three prior lines of multiple myeloma therapy (such as Velcade [bortezomib], Thalomid [thalidomide]) AND will be using Kyprolis in combination with ONE of the following:
         a. Revlimid (lenalidomide) and dexamethasone
         b. Dexamethasone
         c. Darzalex (daratumumab) and dexamethasone
         d. Darzalex Faspro (daratumumab-hyaluronidase-fihj) and dexamethasone
         e. Sarclisa (isatuximab) and dexamethasone

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CARFILZOMIB (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kyprolis.

REFERENCES

Kyprolis [Prescribing Information]. Thousand Oaks, CA: Onyx Pharmaceuticals; June 2022.

For Part D use only:

CARFILZOMIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25 Created: 11/12
Commercial Effective: N/A Client Approval: 06/24 P&T Approval: 10/20

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CARGLUMIC ACID (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CARGLUMIC ACID	CARBAGLU, CARGLUMIC ACID	25643		GPI-10 (3090823000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of acute or chronic hyperammonemia (HA) due to N-acetylglutamate synthase (NAGS) deficiency (ICD-10 E72.29) **AND** meet the following criterion?
   - The patient's NAGS gene mutation is confirmed by biochemical or genetic testing

   If yes, **approve by HICL or GPI-10 as follows:**
   - **For acute HA due to NAGS deficiency: approve for 7 days.**
   - **For chronic HA due to NAGS deficiency: approve for 6 months.**

   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of acute hyperammonemia (HA) due to propionic acidemia (PA) (ICD-10 E71.121) as confirmed by **ONE** of the following criteria?
   - The patient has elevated methylcitric acid and normal methylmalonic acid
   - The patient has genetic testing that confirms mutation in the PCCA or PCCB gene

   If yes, **approve for 7 days by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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CARGLUMIC ACID (PART D)

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of acute hyperammonemia (HA) due to methylmalonic acidemia (MMA) (ICD-10 E71.120) as confirmed by **ONE** of the following criteria?
   - The patient has elevated methylmalonic acid, methylcitric acid
   - The patient has genetic testing that confirms mutation in the MMUT, MMA, MMAB or MMADHC genes

   If yes, **approve for 7 days by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.
   Our guideline named **CARGLUMIC ACID (Carbaglu)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Acute or chronic hyperammonemia (HA) due to N-acetylglutamate synthase (NAGS) deficiency (short-term or long-term high ammonia blood levels due to a genetic disorder)
      2. Acute hyperammonemia (HA) due to propionic acidemia (PA) or methylmalonic acidemia (MMA) (short-term high ammonia blood levels due to a genetic disorder)

   B. If you have acute or chronic hyperammonemia due to N-acetylglutamate synthase deficiency, approval also requires:
      1. Your N-acetylglutamate synthase gene mutation (abnormal change in gene) is confirmed by biochemical or genetic testing (types of lab test)

   C. If you have acute hyperammonemia due to propionic acidemia, approval also requires your diagnosis is confirmed by ONE of the following:
      1. You have elevated methylcitric acid and normal methylmalonic acid (substances that indicates presence of a disease)
      2. You had a genetic testing that confirms mutation in the PCCA or PCCB gene (abnormal change in types of genes)

   D. If you have acute hyperammonemia due to methylmalonic acidemia, approval also requires your diagnosis is confirmed by ONE of the following:
      1. You have elevated methylmalonic acid, methylcitric acid (substances that indicates presence of a disease)
      2. You have a genetic testing that confirms mutation in the MMUT, MMA, MMAB or MMADHC genes (abnormal change in types of genes)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CARGLUMIC ACID (PART D)

RENEWAL CRITERIA

NOTE: For the diagnoses of acute HA due to NAGS deficiency or acute HA due to PA or MMA, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of chronic hyperammonemia (HA) due to N-acetylglutamate synthase (NAGS) deficiency (ICD-10 E72.29) **AND** meet the following criterion?
   - The patient has shown clinical improvement

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CARGLUMIC ACID (Carbaglu)** requires the following rule(s) be met for renewal:
   A. You have chronic hyperammonemia (HA) due to N-acetylglutamate synthase (NAGS) (long-term high ammonia blood levels due to a genetic disorder)
   B. You have shown clinical improvement

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Carbaglu.

REFERENCES

Carbaglu [Prescribing Information]. Lebanon, NJ: Recordati Rare Diseases, Inc.; January 2023.

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CARGLUMIC ACID (PART D)

For Part D use only:

CARGLUMIC ACID (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
REQUIRED MEDICAL INFORMATION	INITIAL: ACUTE OR CHRONIC HYPERAMMONEMIA (HA) DUE TO N-ACETYLGLUTAMATE SYNTHASE (NAGS) DEFICIENCY: NAGS GENE MUTATION IS CONFIRMED BY BIOCHEMICAL OR GENETIC TESTING. ACUTE HA DUE TO PROPIONIC ACIDEMIA (PA): 1) CONFIRMED BY ELEVATED METHYLCITRIC ACID AND NORMAL METHYLMALONIC ACID, OR 2) GENETIC TESTING CONFIRMS MUTATION IN THE PCCA OR PCCB GENE. ACUTE HA DUE TO METHYLMALONIC ACIDEMIA (MMA): 1) CONFIRMED BY ELEVATED METHYLMALONIC ACID, METHYLCITRIC ACID, OR 2) GENETIC TESTING CONFIRMS MUTATION IN THE MMUT, MMA, MMAB OR MMADHC GENES.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	ACUTE HA DUE TO NAGS/PA/MMA: 7 DAYS. CHRONIC HA DUE TO NAGS: INITIAL: 6 MOS, RENEWAL: 12 MOS.
Other Criteria	RENEWAL: CHRONIC HA DUE TO NAGS: PATIENT HAS SHOWN CLINICAL IMPROVEMENT.

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 06/22
Client Approval: 08/24
P&T Approval: 01/22

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CASIMERSEN BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CASIMERSEN	AMONDYS-45	47149		GPI-10 (7460002500)	

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, continue to #6.
   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, continue to #6.
   If no, continue to #5.

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

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CASIMERSEN BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

6. Is the drug administered via an implantable pump?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, continue to #7.

7. Is the drug administered using an external pump?

   If yes, continue to #8.
   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

8. Is the drug specifically infused through an external infusion pump covered by Medicare?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CASIMERSEN BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Duchenne muscular dystrophy (DMD) (ICD-10 G71.01) and meet the following criterion?
   - The patient has a confirmed mutation in the DMD gene that is amenable to exon 45 skipping

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CASIMERSEN (Amondys-45)** requires the following rule(s) be met for approval:
   A. You have Duchenne muscular dystrophy (a type of muscle disorder)
   B. You have a confirmed mutation in the DMD gene that is responsive to exon 45 skipping (a type of gene mutation)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CASIMERSEN BvD (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Amondys-45.

The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B. Drugs administered by an implantable pump are covered under Part B. Drugs administered via an external pump are covered under Part B if they are included under the local coverage policy of the applicable Medicare coverage policies (National and/or Local Coverage Policies). Drugs administered via an external pump that are not included under the applicable Medicare coverage policies are covered under Part D. A CMS website to assist with National and Local Coverage Determination for BvD review is http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx.

REFERENCES

Amondys-45 [Prescribing Information]. Cambridge, MA: Sarepta Therapeutics, Inc.; March 2023.

Medicare Prescription Drug Benefit Manual Chapter 6 – Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed July 2, 2024].

For Part D use only:

CASIMERSEN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 03/21
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 04/21

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CELECOXIB-VYSCOXA (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CELECOXIB	VYSCOXA		58139	GPI-14 (66100525001820)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of osteoarthritis (OA) (ICD-10 Groups M15, M16, M17, M18, M19, M47) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a contraindication to or is unable to swallow celecoxib capsules
   - The patient had a trial of or contraindication to ONE of the following preferred agents: generic ibuprofen oral liquid formulation, generic naproxen oral liquid formulation

   If yes, **approve for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a contraindication to or is unable to swallow celecoxib capsules
   - The patient had a trial of or contraindication to ONE of the following preferred agents: generic ibuprofen oral liquid formulation, generic naproxen oral liquid formulation

   If yes, **approve for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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CELECOXIB-VYSCOXA (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a contraindication to or is unable to swallow celecoxib capsules
   - The patient had a trial of or contraindication to ONE of the following preferred agents: generic ibuprofen oral liquid formulation, generic naproxen oral liquid formulation

   If yes, **approve for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

4. Does the patient have a diagnosis of juvenile rheumatoid arthritis (JRA) (ICD-10 M08.3; Group M08.0) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - The patient has a contraindication to or is unable to swallow celecoxib capsules
   - The patient had a trial of or contraindication to ONE of the following preferred agents: generic ibuprofen oral liquid formulation, generic naproxen oral liquid formulation

   If yes, **approve for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CELECOXIB-VYSCOXA** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Osteoarthritis (OA: type of joint condition)
      2. Rheumatoid arthritis (RA: type of joint condition)
      3. Ankylosing spondylitis (AS: type of joint condition)
      4. Juvenile rheumatoid arthritis (JRA: type of joint condition)

   (Denial text continued on next page)

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CELECOXIB-VYSCOXA (PART D)

GUIDELINES FOR USE (CONTINUED)

B. If you have osteoarthritis, approval also requires:
1. You are 18 years of age or older
2. You have a contraindication to (harmful for you to use) or are unable toswallow celecoxib capsules
3. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: generic ibuprofen oral liquid formulation, generic naproxen oral liquid formulation

C. If you have rheumatoid arthritis, approval also requires:
1. You are 18 years of age or older
2. You have a contraindication to (harmful for you to use) or are unable toswallow celecoxib capsules
3. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: generic ibuprofen oral liquid formulation, generic naproxen oral liquid formulation

D. If you have ankylosing spondylitis, approval also requires:
1. You are 18 years of age or older
2. You have a contraindication to (harmful for you to use) or are unable toswallow celecoxib capsules
3. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: generic ibuprofen oral liquid formulation, generic naproxen oral liquid formulation

E. If you have juvenile rheumatoid arthritis, approval also requires:
1. You are 2 years of age or older
2. You have a contraindication to (harmful for you to use) or are unable toswallow celecoxib capsules
3. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: generic ibuprofen oral liquid formulation, generic naproxen oral liquid formulation

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vyscoxa.

REFERENCES

Vyscoxa [Prescribing Information]. Hazlet, NJ: Carwin Pharmaceutical Associates, LLC; July 2025.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CELECOXIB-VYSCOXA (PART D)

For Part D use only:

CELECOXIB-VYSCOXA (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	ALL INDICATIONS: 1) CONTRAINDICATION TO OR UNABLE TO SWALLOW CELECOXIB CAPSULES, AND 2) TRIAL OF OR CONTRAINDICATION TO ONE OF THE FOLLOWING PREFERRED AGENTS: GENERIC IBUPROFEN ORAL LIQUID FORMULATION, GENERIC NAPROXEN ORAL LIQUID FORMULATION.

Created: 10/25
Effective: 11/10/25 Client Approval: 10/25 P&T Approval: 01/26

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CEMIPLIMAB-RWLC (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CEMIPLIMAB-RWLC	LIBTAYO	45284		GPI-10 (2135792340)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of cutaneous squamous cell carcinoma (CSCC) (ICD-10 C44.02, C44.82, C44.92; Groups C44.12, C44.22, C44.32, C44.42, C44.52, C44.62, C44.72) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient's cancer is metastatic or locally advanced AND the patient is not a candidate for curative surgery or curative radiation
   - The patient's cancer is high risk of recurrence after surgery and radiation AND Libtayo will be used as adjuvant treatment

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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CEMIPLIMAB-RWLC (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of metastatic or locally advanced basal cell carcinoma (BCC) (ICD-10 C44.91, C44.01, C44.41, C44.81; Groups C44.11, C44.21, C44.31, C44.51, C44.61, C44.71) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has previously been treated with a hedgehog pathway inhibitor (e.g., Erivedge [vismodegib], Odomzo [sonidegib]) OR for whom a hedgehog pathway inhibitor is not appropriate

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

4. Does the patient have a diagnosis of non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer is metastatic OR locally advanced (where the patient is not a candidate for surgical resection or definitive chemoradiation)
   - The patient's tumors do not have EGFR, ALK, or ROS1 aberrations

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Does the patient meet **ONE** of the following criteria?
   - Libtayo will be used as a single agent AND the patient's tumors have high PD-L1 expression [Tumor Proportion Score (TPS) ≥ 50%], as determined by an FDA-approved test
   - Libtayo will be used in combination with platinum-based chemotherapy (e.g., carboplatin, cisplatin)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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CEMIPLIMAB-RWLC (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CEMIPLIMAB-RWLC (Libtayo)** requires the following rules be met for approval:

A. You have ONE of the following:
   1. Cutaneous squamous cell carcinoma (a type of skin cancer)
   2. Metastatic or locally advanced basal cell carcinoma (a type of skin cancer that has spread to other parts of the body or to nearby tissue or lymph nodes)
   3. Non-small cell lung cancer (a type of lung cancer)

B. If you have cutaneous squamous cell carcinoma, approval also requires:
   1. You are 18 years of age or older
   2. You meet ONE of the following:
      a. Your cancer is metastatic or locally advanced (cancer that has spread to other parts of the body or to nearby tissue or lymph nodes) AND you are not a candidate for curative (to cure) surgery or curative radiation
      b. Your cancer is at high risk of recurrence (returns) after surgery and radiation AND Libtayo will be used as adjuvant (additional) treatment

C. If you have metastatic or locally advanced basal cell carcinoma, approval also requires:
   1. You are 18 years of age or older
   2. You have previously been treated with a hedgehog pathway inhibitor (such as Erivedge [vismodegib], Odomzo [sonidegib]) OR a hedgehog pathway inhibitor is not appropriate for you

(Denial text continued on next page)

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CEMIPLIMAB-RWLC (PART D)

GUIDELINES FOR USE (CONTINUED)

D. If you have non-small cell lung cancer, approval also requires:

1. You are 18 years of age or older
2. Your cancer is metastatic (cancer that has spread to other parts of the body) OR locally advanced (cancer that has spread from where it started to nearby tissue or lymph nodes, where you are not a candidate for surgical resection [remove by surgery] or definitive chemoradiation [a type of cancer treatment])
3. Your tumors do not have EGFR, ALK or ROS1 aberrations (types of abnormal genes)
4. You meet ONE of the following:
   a. Libtayo will be used as a single agent AND your tumors have high PD-L1 (programmed death-ligand: type of protein) expression [Tumor Proportion Score (TPS) at least 50%], as determined by a Food and Drug Administration (FDA)-approved test
   b. Libtayo will be used in combination with platinum-based chemotherapy (such as carboplatin, cisplatin)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Libtayo.

REFERENCES

Libtayo [Prescribing Information]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; October 2025.

For Part D use only:

CEMIPLIMAB-RWLC (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 10/18
Effective: 01/01/26 Client Approval: 01/26 P&T Approval: 01/26

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CENEGERMIN-BKBJ (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CENEGERMIN-BKBJ	OXERVATE	45258		GPI-10 (8677002020)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of neurotrophic keratitis (NK) (ICD-10 Group H16.23) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an ophthalmologist
   - The patient has a medical history supportive of causative etiology for trigeminal nerve damage (e.g., herpes zoster infection, multiple sclerosis, diabetes, ocular surgical damage)
   - The patient has loss of corneal sensitivity, corneal epithelium changes, or loss of tear production
   - The patient is refractory to conservative management (i.e., artificialtears, ocular lubricants, topical antibiotics, therapeutic contact lenses)

   If yes, **approve for 8 weeks by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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CENEGERMIN-BKBJ (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CENEGERMIN-BKBJ (Oxervate)** requires the following rule(s) be met for approval:

A. You have neurotrophic keratitis (an eye disease due to a damaged eye nerve)
B. Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor)
C. You have a medical history that contributes to trigeminal nerve damage (damage to a nerve in the head) (such as herpes zoster infection [shingles virus], multiple sclerosis [type of nerve disorder], diabetes, ocular [eye] surgical damage)
D. You have loss of corneal (part of the eye) sensitivity, corneal epithelium changes, or loss of tear production
E. You are refractory to conservative management (did not respond to other treatments with artificial tears, ocular lubricants, topical antibiotics, therapeutic contact lenses)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Oxervate.

REFERENCES

Oxervate [Prescribing Information]. Boston, MA: Dompe U.S., Inc.; February 2025.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CENEGERMIN-BKBJ (PART D)

For Part D use only:

CENEGERMIN-BKBJ (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	NEUROTROPHIC KERATITIS (NK): PRESCRIBED BY OR IN CONSULTATION WITH AN OPHTHALMOLOGIST.
Coverage Duration	8 WEEKS
Other Criteria	NK: 1) MEDICAL HISTORY SUPPORTIVE OF CAUSATIVE ETIOLOGY FOR TRIGEMINAL NERVE DAMAGE, 2) LOSS OF CORNEAL SENSITIVITY, CORNEAL EPITHELIUM CHANGES, OR LOSS OF TEAR PRODUCTION, AND 3) REFRACTORY TO CONSERVATIVE MANAGEMENT (I.E., ARTIFICIAL TEARS, OCULAR LUBRICANTS, TOPICAL ANTIBIOTICS, THERAPEUTIC CONTACT LENSES).

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CEQUR SIMPLICITY (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BOLUS INSULIN PUMP, 200 UNIT	CEQUR SIMPLICITY	44109		GPI-14 (97051050126220)	Medi-Span: BRAND = CEQUR SIMPLICITY 2U, CEQUR SIMPLICITY 1U
BOLUS INSULIN PUMP, 240 UNIT	CEQUR SIMPLICITY	51428			

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of diabetes mellitus (type 1 or type 2) (ICD-10 Groups E08, E09, E10, E11, E13) and meet **ALL** of the following criteria?
   - The patient is 21 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient follows a maintenance program of at least 3 injections of insulin per day
   - The patient requires bolus insulin dosing in increments of 2 units per bolus
   - The patient has worked with the physician to adjust dose of insulin for the past 6 months and has not met glucose goals
   - The patient had a trial of ONE of the following preferred devices: Omnipod or V-Go

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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CEQUR SIMPLICITY (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient meet **ONE** of the following criteria?
   - The patient's glycosylated hemoglobin level (HbA1c) is greater than 7%
   - The patient has a history of recurring hypoglycemia
   - The patient has wide fluctuations in blood glucose before mealtime
   - The patient experiences the dawn phenomenon with fasting blood glucose levels frequently exceeding 200 mg/dL
   - The patient has a history of severe glycemic excursions (i.e., sudden spikes in blood sugar levels)

   If yes, **approve for 12 months by HICL or GPI-14.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.
   Our guideline named **CEQUR SIMPLICITY** requires the following rule(s) be met for approval:
   A. You have diabetes mellitus (type 1 or type 2) (a disorder with high blood sugar)
   B. You are 21 years of age or older
   C. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
   D. You follow a maintenance program of at least 3 injections of insulin per day
   E. You require bolus insulin dosing in increments of 2 units per bolus
   F. You have worked with your doctor to adjust your dose of insulin for the past 6 months and have not met your glucose (blood sugar) goals
   G. You had a trial of ONE of the following preferred devices: Omnipod or V-Go
   H. You meet ONE of the following:
      1. You have a glycosylated hemoglobin level (HbA1c: a type of lab test) greater than 7 percent
      2. You have a history of recurring hypoglycemia (low blood sugar)
      3. You have wide fluctuations (variations) in blood glucose before mealtime
      4. You experience the dawn phenomenon (abnormal early morning increase in blood sugar) with fasting blood glucose levels frequently exceeding 200 mg/dL
      5. You have a history of severe glycemic excursions (sudden spikes in blood sugar levels)

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CEQUR SIMPLICITY (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of diabetes mellitus (type 1 or type 2) (ICD-10 Groups E08, E09, E10, E11, E13) and meet **ALL** of the following criteria?
   - The patient has shown a positive response to therapy
   - The patient is adherent to physician follow-up visits

   If yes, **approve for 12 months by HICL or GPI-14.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CEQUR SIMPLICITY** requires the following rule(s) be met for renewal:
   A. You have diabetes mellitus (type 1 or type 2) (a disorder with high blood sugar)
   B. You have shown a positive response to therapy
   C. You are adherent to (keeping up with) your doctor follow-up visits

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for CeQur Simplicity.

REFERENCES

CeQur Simplicity. CeQur Corp. Available at: https://myceqursimplicity.com/healthcare-professionals/.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CEQUR SIMPLICITY (PART D)

For Part D use only:

CEQUR SIMPLICITY (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	DIABETES MELLITUS (DM): INITIAL: ONE OF THE FOLLOWING: 1) HBA1C GREATER THAN 7 PERCENT, 2) HISTORY OF RECURRING HYPOGLYCEMIA, 3) WIDE FLUCTUATIONS IN BLOOD GLUCOSE BEFORE MEALTIME, 4) EXPERIENCES THE DAWN PHENOMENON WITH FASTING BLOOD GLUCOSE LEVELS FREQUENTLY EXCEEDING 200 MG/DL, OR 5) HISTORY OF SEVERE GLYCEMIC EXCURSIONS (I.E., SUDDEN SPIKES IN BLOOD SUGAR LEVELS).
Age Restrictions	N/A
Prescriber Restrictions	DM: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST.
Coverage Duration	INITIAL/RENEWAL:12 MONTHS.
Other Criteria	DM: INITIAL: 1) RECEIVING AT LEAST 3 INJECTIONS OF INSULIN PER DAY, 2) REQUIRES BOLUS INSULIN DOSING IN INCREMENTS OF 2 UNITS PER BOLUS, 3) WORKED WITH PHYSICIAN TO ADJUST DOSE OF INSULIN FOR THE PAST 6 MONTHS AND GLUCOSE GOALS HAVE NOT BEEN MET, AND 4) TRIAL OF ONE OF THE FOLLOWING PREFERRED DEVICES: OMNIPOD OR V-GO. RENEWAL: 1) POSITIVE RESPONSE TO THERAPY, AND 2) ADHERENT TO PHYSICIAN FOLLOW-UP VISITS.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CERITINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CERITINIB	ZYKADIA	41111		GPI-10 (21530514000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's tumors are anaplastic lymphoma kinase (ALK)-positive, as detected by an FDA-approved test

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CERITINIB (Zykadia)** requires the following rule(s) be met for approval:
   A. You have metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of the body)
   B. You are 18 years of age or older
   C. Your tumors are anaplastic lymphoma kinase (ALK: a type of enzyme) positive as confirmed by a Food and Drug Administration (FDA)-approved test

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CERITINIB (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zykadia.

REFERENCE

Zykadia [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2021.

For Part D only:

CERITINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 05/14
Client Approval: 06/24
P&T Approval: 10/21

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CERTOLIZUMAB PEGOL (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CERTOLIZUMAB PEGOL	CIMZIA	35554		GPI-10 (5250502010)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Cimzia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

     If yes, continue to #2.
     If no, continue to #3.

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INITIAL CRITERIA (CONTINUED)

2. Does the patient meet **ONE** of the following criteria?
   - The patient is pregnant, breastfeeding, or trying to become pregnant
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Orencia (abatacept)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   - Cimzia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, continue to #4.
   If no, continue to #5.

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CERTOLIZUMAB PEGOL (PART D)

INITIAL CRITERIA (CONTINUED)

4. Does the patient meet **ONE** of the following criteria?
   - The patient is pregnant, breastfeeding, or trying to become pregnant
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Cosentyx (secukinumab)
     - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
     - Selarsdi/Yesintek/ustekinumab-aauz
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Skyrizi (risankizumab-rzaa)
     - Tremfya (guselkumab)
     - Orencia (abatacept)
     - Otezla (apremilast)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

5. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Cimzia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS

   If yes, continue to #6.
   If no, continue to #7.

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CERTOLIZUMAB PEGOL (PART D)

INITIAL CRITERIA (CONTINUED)

6. Does the patient meet **ONE** of the following criteria?
   - The patient is pregnant, breastfeeding, or trying to become pregnant
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Cosentyx (secukinumab)
     - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

7. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Cimzia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, continue to #8.
   If no, continue to #9.

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CERTOLIZUMAB PEGOL (PART D)

INITIAL CRITERIA (CONTINUED)

8. Does the patient meet **ONE** of the following criteria?
   - The patient is pregnant, breastfeeding, or trying to become pregnant
   - The patient had a trial of or contraindication to ONE of the following preferred agents:
     - Selarsdi/Yesintek/ustekinumab-aauz
     - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Skyrizi (risankizumab-rzaa)
     - Tremfya (guselkumab)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

9. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist
   - The patient has psoriasis covering 3% or more of body surface area (BSA) OR psoriatic lesions affecting the hands, feet, face, scalp, or genital area
   - Cimzia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, continue to #10.
   If no, continue to #11.

10. Does the patient meet **ONE** of the following criteria?
    - The patient is pregnant, breastfeeding, or trying to become pregnant
    - The patient had a trial of or contraindication to TWO of the following preferred agents: Cosentyx (secukinumab), Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima, Selarsdi/Yesintek/ustekinumab-aauz, Skyrizi (risankizumab-rzaa), Tremfya (guselkumab), Otezla (apremilast)

    If yes, **approve for 6 months by HICL or GPI-10.**
    APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.
    If no, do not approve.
    DENIAL TEXT: See the initial denial text at the end of the guideline.

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CERTOLIZUMAB PEGOL (PART D)

INITIAL CRITERIA (CONTINUED)

11. Does the patient have a diagnosis of non-radiographic axial spondyloarthritis (nr-axSpA) (ICD-10 Group M45.A) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Therapy is prescribed by or in consultation with a rheumatologist
    - The patient has C-reactive protein (CRP) levels above the upper limit of normal, OR has sacroiliitis on magnetic resonance imaging (MRI)
    - Cimzia will NOT be used concurrently with another systemic biologic (e.g., Taltz [ixekizumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of nr-axSpA
    - The patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam)

    If yes, **approve for 6 months by HICL or GPI-10.**
    APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

    If no, continue to #12.

12. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (pJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
    - The patient is 2 years of age or older
    - Therapy is prescribed by or in consultation with a rheumatologist
    - Cimzia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of pJIA

    If yes, continue to #13.
    If no, do not approve.
    DENIAL TEXT: See the initial denial text at the end of the guideline.

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INITIAL CRITERIA (CONTINUED)

13. Does the patient meet **ONE** of the following criteria?
    - The patient is pregnant, breastfeeding, or trying to become pregnant
    - The patient had a trial of or contraindication to TWO of the following preferred agents:
        - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
        - Xeljanz IR (tofacitinib IR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
        - Orencia (abatacept)
        - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])

    If yes, **approve for 6 months by HICL or GPI-10.**
    APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

    If no, do not approve.

    INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

    Our guideline named **CERTOLIZUMAB PEGOL (Cimzia)** requires the following rule(s) be met for approval:

    A. You have ONE of the following:
        1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
        2. Psoriatic arthritis (PsA: a type of skin and joint condition)
        3. Ankylosing spondylitis (AS: a type of joint condition)
        4. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
        5. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
        6. Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)
        7. Polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition)

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CERTOLIZUMAB PEGOL (PART D)

INITIAL CRITERIA (CONTINUED)

B. If you have moderate to severe rheumatoid arthritis, approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
4. You meet ONE of the following:
   a. You are pregnant, breastfeeding, or trying to become pregnant
   b. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
      ii. Xeljanz (tofacitinib extended-release or immediate-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
      iii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
      iv. Orencia (abatacept)

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CERTOLIZUMAB PEGOL (PART D)

INITIAL CRITERIA (CONTINUED)

C. If you have psoriatic arthritis, approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (skin doctor)
3. You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis
4. You meet ONE of the following:
   a. You are pregnant, breastfeeding, or trying to become pregnant
   b. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Cosentyx (secukinumab)
      ii. Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
      iii. Selarsdi/Yesintek/ustekinumab-aauz
      iv. Xeljanz (tofacitinib extended-release or immediate-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
      v. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
      vi. Skyrizi (risankizumab-rzaa)
      vii. Tremfya (guselkumab)
      viii. Orencia (abatacept)
      ix. Otezla (apremilast)

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CERTOLIZUMAB PEGOL (PART D)

INITIAL CRITERIA (CONTINUED)

D. If you have ankylosing spondylitis, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis
4. You meet ONE of the following:
   a. You are pregnant, breastfeeding, or trying to become pregnant
   b. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Cosentyx (secukinumab)
      ii. Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
      iii. Xeljanz (tofacitinib extended-release or immediate-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima]
      iv. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])

E. If you have moderate to severe Crohn's disease, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
3. You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn’s disease
4. You meet ONE of the following:
   a. You are pregnant, breastfeeding, or trying to become pregnant
   b. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
      i. Selarsdi/Yesintek/ustekinumab-aauz
      ii. Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
      iii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
      iv. Skyrizi (risankizumab-rzaa)
      v. Tremfya (guselkumab)

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CERTOLIZUMAB PEGOL (PART D)

INITIAL CRITERIA (CONTINUED)

F. If you have moderate to severe plaque psoriasis, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a dermatologist (skin doctor)
3. You have psoriasis covering 3% or more of body surface area (BSA) OR psoriatic lesions (patches) affecting the hands, feet, face, scalp, or genital area
4. You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis
5. You meet ONE of the following:
   a. You are pregnant, breastfeeding, or trying to become pregnant
   b. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Cosentyx (secukinumab), Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima, Selarsdi/Yesintek /ustekinumab-aauz, Skyrizi (risankizumab-rzaa), Tremfya (guselkumab), Otezla (apremilast)

G. If you have non-radiographic axial spondyloarthritis, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. Your C-reactive protein (CRP: indicator of inflammation) levels are above the upper limit of normal, OR you have sacroiliitis (inflammation where lower spine and pelvis connect) on magnetic resonance imaging (MRI: type of imaging lab)
4. You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Taltz [ixekizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-radiographic axial spondyloarthritis
5. You have tried or have a contraindication to (harmful for you to use) an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)

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CERTOLIZUMAB PEGOL (PART D)

INITIAL CRITERIA (CONTINUED)

H. If you have polyarticular juvenile idiopathic arthritis, approval also requires:

1. You are 2 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis
4. You meet ONE of the following:
   a. You are pregnant, breastfeeding, or trying to become pregnant
   b. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
      ii. Xeljanz IR (tofacitinib immediate release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
      iii. Orencia (abatacept)
      iv. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])

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CERTOLIZUMAB PEGOL (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9; M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Cimzia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Cimzia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Cimzia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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CERTOLIZUMAB PEGOL (PART D)

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) **AND** meet the following criterion?
   - Cimzia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Cimzia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #6.

6. Does the patient have a diagnosis of non-radiographic axial spondyloarthritis (nr-axSpA) (ICD-10 Group M45.A) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Cimzia will NOT be used concurrently with another systemic biologic (e.g., Taltz [ixekizumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of nr-axSpA

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #7.

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CERTOLIZUMAB PEGOL (PART D)

RENEWAL CRITERIA (CONTINUED)

7. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (pJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Cimzia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of pJIA

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CERTOLIZUMAB PEGOL (Cimzia)** requires the following rule(s) be met for renewal:

   A. You have ONE of the following:
      1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
      2. Psoriatic arthritis (PsA: a type of skin and joint condition)
      3. Ankylosing spondylitis (AS: a type of joint condition)
      4. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
      5. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
      6. Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)
      7. Polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition)

   B. If you have moderate to severe rheumatoid arthritis, renewal also requires:
      1. You continue to benefit from the medication
      2. You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis

   (Renewal denial text continued on next page)

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CERTOLIZUMAB PEGOL (PART D)

RENEWAL CRITERIA (CONTINUED)

C. If you have psoriatic arthritis, renewal also requires:
1. You continue to benefit from the medication
2. You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

D. If you have ankylosing spondylitis, renewal also requires:
1. You continue to benefit from the medication
2. You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis

E. If you have moderate to severe Crohn's disease, renewal also requires:
1. You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease

F. If you have moderate to severe plaque psoriasis, renewal also requires:
1. You continue to benefit from the medication
2. You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis

G. If you have non-radiographic axial spondyloarthritis, renewal also requires:
1. You continue to benefit from the medication
2. You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Taltz [ixekizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-radiographic axial spondyloarthritis

H. If you have polyarticular juvenile idiopathic arthritis, renewal also requires:
1. You continue to benefit from the medication
2. You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis

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CERTOLIZUMAB PEGOL (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Cimzia.

REFERENCES
Cimzia [Prescribing Information]. Smyrna, GA: UCB, Inc.; September 2025.

For Part D use only:

CERTOLIZUMAB PEGOL (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	INITIAL: PLAQUE PSORIASIS (PSO): PSORIASIS COVERING 3 PERCENT OR MORE OF BODY SURFACE AREA OR PSORIATIC LESIONS AFFECTING THE HANDS, FEET, FACE, SCALP, OR GENITAL AREA. NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS (NR-AXSPA): 1) C-REACTIVE PROTEIN (CRP) LEVELS ABOVE THE UPPER LIMIT OF NORMAL, OR 2) SACROILIITIS ON MAGNETIC RESONANCE IMAGING (MRI).
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: RHEUMATOID ARTHRITIS (RA), ANKYLOSING SPONDYLITIS (AS), NR-AXSPA, POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST. CROHNS DISEASE (CD): PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST. PSO: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: RA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, XELJANZ, RINVOQ, ORENCIA. PSA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: COSENTYX, HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, SELARSDI/YESINTEK/USTEKINUMAB-AAUZ, XELJANZ, RINVOQ, SKYRIZI, TREMFYA, ORENCIA, OTEZLA. AS: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: COSENTYX, HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, XELJANZ, RINVOQ. CD: TRIAL OF OR CONTRAINDICATION TO ONE OF THE FOLLOWING PREFERRED AGENTS: SELARSDI/YESINTEK/USTEKINUMAB-AAUZ, HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, RINVOQ, SKYRIZI, TREMFYA. PSO: TRIAL OF OR CONTRAINDICATION TO TWO OF

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	THE FOLLOWING PREFERRED AGENTS: COSENTYX, HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, SELARSDI/YESINTEK/USTEKINUMAB-AAUZ, SKYRIZI, TREMFYA, OTEZLA. NR-AXSPA: TRIAL OF OR CONTRAINDICATION TO AN NSAID. PJIA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, XELJANZ IR, ORENCIA, RINVOQ. INITIAL FOR RA, PSA, PSO, AS, CD, PJIA: TRIAL OF OR CONTRAINDICATION TO THE STEP AGENTS IS NOT REQUIRED IF THE PATIENT IS PREGNANT, BREASTFEEDING, OR TRYING TO BECOME PREGNANT. INITIAL/RENEWAL: ALL INDICATIONS: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL THE MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR SAME INDICATION. RENEWAL FOR RA, PSA, AS, PSO, NR-AXSPA, PJIA: CONTINUES TO BENEFIT FROM THE MEDICATION.

Created: 05/08
Effective: 05/01/26 Client Approval: 04/26 P&T Approval: 04/25

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CETUXIMAB BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CETUXIMAB	ERBITUX	25947		GPI-10 (2136001500)	

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, continue to #6.
   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, continue to #6.
   If no, continue to #5.

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

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CETUXIMAB BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

6. Is the drug administered via an implantable pump?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field)**

   If no, continue to #7.

7. Is the drug administered via an external pump?

   If yes, continue to #8.
   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field)**

8. Is the drug specifically infused through an external infusion pump covered by Medicare?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field.**

   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field)**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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CETUXIMAB BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally or regionally advanced squamous cell carcinoma of the head and neck (SCCHN) (ICD-10 Groups C44.42, C76.0, C00, C06, C09, C10, C32) **AND** meet the following criterion?
   - Erbitux will be used in combination with radiation therapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of recurrent locoregional disease or metastatic squamous cell carcinoma of the head and neck (SCCHN) (ICD-10 Groups C44.42, C76.0, C00, C06, C09, C10, C32) **AND** meet the following criterion?
   - Erbitux will be used in combination with platinum-based therapy (e.g., cisplatin, carboplatin, oxaliplatin) and fluorouracil (5-FU)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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CETUXIMAB BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN) (ICD-10 Groups C44.42, C76.0, C00, C06, C09, C10, C32) **AND** meet the following criterion?
   - The patient has failed prior platinum-based therapy (e.g., cisplatin, carboplatin, oxaliplatin)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

4. Does the patient have a diagnosis of metastatic colorectal cancer (mCRC) (ICD-10 C19)?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Is the patient's cancer KRAS wild-type (without mutation), epidermal growth factor receptor (EGFR)-expressing, as determined by an FDA-approved test, and the patient meets **ONE** of the following criteria?
   - Erbitux will be used in combination with FOLFIRI (irinotecan, 5-fluorouracil, leucovorin)
   - Erbitux will be used in combination with irinotecan AND the patient is refractory to irinotecan-based chemotherapy
   - The patient has failed oxaliplatin-based and irinotecan-based chemotherapy OR the patient is intolerant to irinotecan

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #6.

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GUIDELINES FOR USE (CONTINUED)

6. Does the patient's cancer have a BRAF V600E mutation, as determined by an FDA-approved test, and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Erbitux will be used in combination with Braftovi (encorafenib) after prior therapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CETUXIMAB (Erbitux)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Locally or regionally advanced squamous cell carcinoma of the head and neck (SCCHN) (a type of head and neck cancer that has spread from where it started to nearby tissue or lymph nodes)
      2. Recurrent locoregional disease or metastatic squamous cell carcinoma of the head and neck (SCCHN) (a type of head and neck cancer that has returned or has spread to other parts of the body)
      3. Recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN) (a type of head and neck cancer that has returned or has spread to other parts of the body)
      4. Metastatic colorectal cancer (mCRC) (a type of digestive cancer that has spread to other parts of the body)

   B. If you have locally or regionally advanced squamous cell carcinoma of the head and neck, approval also requires:
      1. Erbitux will be used in combination with radiation therapy

   C. If you have recurrent locoregional disease or metastatic squamous cell carcinoma of the head and neck, approval also requires:
      1. Erbitux will be used in combination with platinum-based therapy (such as cisplatin, carboplatin, oxaliplatin) and 5-fluorouracil (5-FU)

   D. If you have recurrent or metastatic squamous cell carcinoma of the head and neck, approval also requires:
      1. You have previously failed platinum-based therapy (such as cisplatin, carboplatin, oxaliplatin)

   (Denial text continued on next page)

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CETUXIMAB BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

E. If you have metastatic colorectal cancer, approval also requires ONE of the following:

1. Your cancer is KRAS wild-type (a type of gene with NO mutation), epidermal growth factor receptor (EGFR)-expressing, as determined by a Food and Drug Administration (FDA)-approved test, AND you meet ONE of the following:
   a. Erbitux will be used in combination with FOLFIRI (irinotecan, 5-fluorouracil, leucovorin)
   b. Erbitux will be used in combination with irinotecan if you are refractory (resistant) to irinotecan-based chemotherapy
   c. You have failed oxaliplatin-based and irinotecan-based chemotherapy OR you are intolerant to irinotecan
2. Your cancer has a BRAF V600 mutation (abnormal change in a type of gene), as determined by a Food and Drug Administration (FDA)-approved test, and you meet ALL of the following:
   a. You are 18 years of age or older
   b. Erbitux will be used in combination with Braftovi (encorafenib) after prior therapy

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the prescribing information and/or Drug Monograph for Erbitux.

The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B. Drugs administered by an implantable pump are covered under Part B. Drugs administered via an external pump are covered under Part B if they are included under the local coverage policy of the applicable Medicare coverage policies (National and/or Local Coverage Policies). Drugs administered via an external pump that are not included under the applicable Medicare coverage policies are covered under Part D. A CMS website to assist with National and Local Coverage Determination for B versus D review is http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx.

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CETUXIMAB BvD (PART D)

REFERENCES

Erbitux [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; September 2021.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed April 10, 2024].

For Part D use only:

CETUXIMAB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 02/13
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 10/21

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CHENODIOL-CHENODAL (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CHENODIOL	CHENODAL	01364		GPI-10 (5210001000)	BRAND = CHENODAL

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of radiolucent gallstone(s) (ICD-10 Group K80.0) **AND** meet the following criterion?
   - The patient has tried or has a contraindication to ursodiol

   If yes, **approve for 12 months by NDC (FDB) or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CHENODIOL-CHENODAL** requires the following rule(s) be met for approval:
   A. You have radiolucent gallstone(s) (hardened deposit of bile in the gall bladder that is barely seen on X-rays)
   B. You have tried or have a contraindication to (harmful for you to use) ursodiol

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CHENODIOL-CHENODAL (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Chenodal.

REFERENCES

Chenodal [Prescribing Information]. San Diego, CA: Travere Therapeutics; November 2021.

For Part D use only:

CHENODIOL-CHENODAL (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	RADIOLUCENT GALLSTONES: TRIAL OF OR CONTRAINDICATION TO URSODIOL

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CHENODIOL-CTEXLI (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CHENODIOL	CTEXLI	01364		GPI-10 (5270002100)	BRAND = CTEXLI

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of cerebrotendinous xanthomatosis (CTX) (ICD-10 E75.5) **AND** meet the following criterion?
- The patient is 18 years of age or older

If yes, **approve for 12 months by NDC (FDB) or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CHENODIOL-CTEXLI** requires the following rule(s) be met for approval:
A. You have cerebrotendinous xanthomatosis (a type of genetic disorder)
B. You are 18 years of age or older

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CHENODIOL-CTEXLI (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of cerebrotendinous xanthomatosis (CTX) (ICD-10 E75.5) and has experienced improvement as defined by **ONE** of the following?
   - The patient has normalization of elevated serum or urine bile alcohols
   - The patient has normalization of elevated serum cholestanol levels
   - The patient has shown improvement in neurologic and psychiatric symptoms (dementia, pyramidal tract and cerebellar signs)

   If yes, **approve for 12 months by NDC (FDB) or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CHENODIOL-CTEXLI** requires the following rule(s) be met for renewal:
   A. You have cerebrotendinous xanthomatosis (a type of genetic disorder)
   B. You have experienced improvement as defined by ONE of the following:
      1. Normalization of elevated (high levels of) serum (blood) or urine bile alcohols (a type of bile acid)
      2. Normalization of elevated (high levels of) serum (blood) cholestanol (a type of fat) levels
      3. Improvement in neurologic and psychiatric symptoms (dementia [a type of memory disorder], pyramidal tract [a nerve pathway in the brain] and cerebellar [brain] signs)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ctexli.

REFERENCES

Ctexli [Prescribing Information]. Foster City, CA: Mirum Pharmaceuticals, Inc.; February 2025.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CHENODIOL-CTEXLI (PART D)

For Part D use only:

CHENODIOL-CTEXLI (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS
Other Criteria	CEREBROTENDINOUS XANTHOMATOSIS: RENEWAL: IMPROVEMENT AS DEFINED BY 1) NORMALIZATION OF ELEVATED SERUM OR URINE BILE ALCOHOLS, 2) NORMALIZATION OF ELEVATED SERUM CHOLESTANOL LEVELS, OR 3) IMPROVEMENT IN NEUROLOGIC AND PSYCHIATRIC SYMPTOMS (DEMENTIA, PYRAMIDAL TRACT AND CEREBELLAR SIGNS)

Created: 03/25
Effective: 10/04/25 Client Approval: 09/25 P&T Approval: 04/25

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CHORIONIC GONADOTROPIN DvE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CHORIONIC GONADOTROPIN, HUMAN	PREGNYL, NOVAREL, CHORIONIC GONADOTROPIN		10490 10496	GPI-10 (3006202000)	

These are DvE drugs requiring a payment determination for "Part D" or "Non-Part D".

PAYMENT DETERMINATION CRITERIA

1. Does the patient have **ONE** of the following diagnoses?
    - Prepubertal cryptorchidism (ICD-10 Q53.9) NOT due to an anatomic obstruction
    - Hypogonadism secondary to a pituitary deficiency (ICD-10 E23.0) in a male patient

    If yes, **set CMS_DVE_OVR to 'D' and approve for 12 months by HICL or GPI-10. Document in the PA comments: Part D Determination Override.**

    If no, **set CMS_DVE_OVR to 'E' and approve for 12 months by HICL or GPI-10. Document in the PA comments: Payment Determination Override. This is not a Part D indication.**

    NOTE: If the claim rejects after analyzing, then follow the clinical authorization process within HQ notes.

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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CHORIONIC GONADOTROPIN DvE (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the memeber's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the medication being requested for induction of ovulation and pregnancy in an anovulatory, infertile woman?

   If yes, do not approve.
   Set CMS_DVE_OVR to 'E' and enter override within the denied PA for 12 months by HICL or GPI-10.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have **ONE** of the following diagnoses?
   - Prepubertal cryptorchidism (ICD-10 Q53.9) NOT due to an anatomic obstruction
   - Hypogonadism secondary to a pituitary deficiency (ICD-10 E23.0) in a male patient

   - If yes, **approve for 12 months by HICL or GPI-10.**
   NOTE: If the claim rejects for payment determination after analyzing, then follow the above DvE determination criteria.
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   Set CMS_DVE_OVR to 'E' and enter override within the denied PA for 12 months by HICL or GPI-10.
   DENIAL TEXT: See the denial text at the end of the guideline.

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CHORIONIC GONADOTROPIN DvE (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CHORIONIC GONADOTROPIN (Pregnyl, Novarel)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Prepubertal cryptorchidism not due to an anatomic obstruction (your testicles have not descended into your scrotum before puberty and this is not due to a blockage)
   2. Hypogonadism secondary to a pituitary deficiency (low levels of testosterone) and you are a male patient

This medication is not covered under Medicare Part D when used for induction of ovulation and pregnancy in an anovulatory (no release of egg during menstrual cycle), infertile (not able to get pregnant) woman.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

To limit the coverage of chorionic gonadotropin to the Medicare Part D covered indication of prepubertal cryptorchidism not due to anatomic obstruction or hypogonadism secondary to a pituitary deficiency in males, and exclude coverage for induction of ovulation and pregnancy (infertility).

For further information, please refer to the Prescribing Information and/or Drug Monograph for Novarel or Pregnyl.

REFERENCES

Pregnyl [Prescribing Information]. Bloomington, IN: Baxter Oncology GmbH.; March 2023.
Novarel [Prescribing Information]. Parsippany, NJ: Ferring Pharmaceuticals Inc.; May 2023.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements. Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf. [Accessed March 29, 2024].

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CHORIONIC GONADOTROPIN DvE (PART D)

For Part D use only:

CHORIONIC GONADOTROPIN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	INDUCTION OF OVULATION AND PREGNANCY
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25 Created: 10/19
Commercial Effective: N/A Client Approval: 11/24 P&T Approval: 10/19

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CIPAGLUCOSIDASE ALFA-ATGA BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CIPAGLUCOSIDASE ALFA-ATGA	POMBILITI	49231		GPI-10 (3090773005)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	Yes	No	No	Yes	No	No	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit).**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, continue to #6.
   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, continue to #6.
   If no, continue to #5.

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CIPAGLUCOSIDASE ALFA-ATGA BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

6. Is the drug administered via an implantable pump?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, continue to #7.

7. Is the drug administered via an external pump?

   If yes, continue to #8.
   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

8. Is the drug specifically infused through an external infusion pump covered by Medicare?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CIPAGLUCOSIDASE ALFA-ATGA BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) (ICD-10 E74.02) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient weighs at least 40 kgs (88 lbs.)
   - The patient is not improving on their current enzyme replacement therapy (ERT)(e.g., Lumizyme [alglucosidase alfa])
   - Pombiliti will be used in combination with Opfolda (miglustat)

   If yes, **approve for lifetime by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CIPAGLUCOSIDASE ALFA-ATGA (Pombiliti)** requires the following rule(s) be met for approval:
   A. You have late-onset Pompe disease (a type of genetic disorder) due to lysosomal acid alpha-glucosidase (GAA: a type of enzyme) deficiency
   B. You are 18 years of age or older
   C. You weigh at least 40 kilograms (88 pounds)
   D. You are not improving on your current enzyme replacement therapy (ERT) (such as Lumizyme [alglucosidase alfa])
   E. Pombiliti will be used in combination with Opfolda (miglustat)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CIPAGLUCOSIDASE ALFA-ATGA BvD (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Pombiliti.

The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B. Drugs administered by an implantable pump are covered under Part B. Drugs administered via an external pump are covered under Part B if they are included under the local coverage policy of the applicable Medicare coverage policies (National and/or Local Coverage Policies). Drugs administered via an external pump that are not included under the applicable Medicare coverage policies are covered under Part D. A CMS website to assist with National and Local Coverage Determination for B versus D review is http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx

REFERENCES

Pombiliti [Prescribing Information]. Philadelphia, PA: Amicus Therapeutics US, LLC; September 2023.

Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed July 2, 2024].

For Part D use only:

CIPAGLUCOSIDASE ALFA-ATGA (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	LIFETIME
Other Criteria	N/A

Created: 10/23
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 01/24

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ADVANTAGE AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CLADRIBINE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CLADRIBINE	MAVENCLAD, CLADRIBINE		44338	GPI-10 (6240101500)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), including relapsing-remitting disease or active secondary progressive multiple sclerosis, **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient received a total of two years of Mavenclad (cladribine) treatment (i.e., two yearly treatment courses of two cycles in each)?

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, **approve for 48 weeks by HICL or GPI-10.**

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CLADRIBINE (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CLADRIBINE (Mavenclad)** requires the following rule(s) be met for approval:

A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes relapsing-remitting disease (symptoms or disease returns and goes away) or active secondary progressive multiple sclerosis (advanced disease)
B. You are 18 years of age or older
C. You have NOT received a total of two years of Mavenclad (cladribine) treatment (two yearly treatment courses of two cycles in each)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Mavenclad.

REFERENCES

Mavenclad [Prescribing Information]. Boston, MA: EMD Serono, Inc.; May 2026.

For Part D use only:

CLADRIBINE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	48 WEEKS
Other Criteria	RELAPSING FORM OF MULTIPLE SCLEROSIS (MS): HAS NOT RECEIVED A TOTAL OF TWO YEARS OF CLADRIBINE TREATMENT (I.E., TWO YEARLY TREATMENT COURSES OF TWO CYCLES IN EACH).

Created: 04/19
Effective: 08/01/26 Client Approval: 07/26 P&T Approval: 05/19

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CLOBAZAM-SYMPAZAN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CLOBAZAM	SYMPAZAN		45264 45265 45266	GPI-14 (72100007008205, 72100007008210, 72100007008220)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

************Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Lennox-Gastaut syndrome (LGS) (ICD-10 Group G40.81) and meet **ALL** of the following criteria?
   - Sympazan will be used for adjunctive treatment of seizures associated with LGS
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient has a contraindication to or is unable to swallow clobazam tablets or suspension

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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CLOBAZAM-SYMPAZAN (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CLOBAZAM-SYMPAZAN** requires the following rule(s) be met for approval:

A. You have Lennox-Gastaut syndrome (type of seizure disorder in young children)
B. Sympazan will be used for adjunctive (add-on) treatment of seizures associated with Lennox-Gastaut syndrome
C. You are 2 years of age or older
D. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor)
E. You have a contraindication to (harmful for you to use) or are unable to swallow clobazam tablets or suspension

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CLOBAZAM-SYMPAZAN (PART D)

RENEAL CRITERIA

1. Does the patient have a diagnosis of Lennox-Gastaut syndrome (LGS) (ICD-10 Group G40.81)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CLOBAZAM-SYMPAZAN** requires the following rule(s) be met for renewal:
   A. You have Lennox-Gastaut syndrome (type of seizure disorder in young children)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Sympazan.

REFERENCES
Sympazan [Prescribing Information]. Warren, NJ. Aquestive Therapeutics; March 2024.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CLOBAZAM-SYMPAZAN (PART D)

For Part D use only:

CLOBAZAM-SYMPAZAN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: LENNOX-GASTAUT SYNDROME (LGS): THERAPY IS PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS
Other Criteria	LGS: INITIAL: CONTRAINDICATION TO OR UNABLE TO SWALLOW CLOBAZAM TABLETS OR SUSPENSION.

Created: 11/07
Effective: 09/01/25 Client Approval: 08/25 P&T Approval: 07/25

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PLUS CLOSED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CLONIDINE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CLONIDINE HCL	JAVADIN	00113		GPI-10 (3620101010)	BRAND = JAVADIN

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of hypertension (ICD-10 I10) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a contraindication to or is unable to swallow clonidine tablets

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CLONIDINE (Javadin)** requires the following rule(s) be met for approval:
   A. You have hypertension (high blood pressure)
   B. You are 18 years of age or older
   C. You have a contraindication to (harmful for you to use) or are unable to swallow clonidine tablets

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CLONIDINE (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Javadin.

REFERENCES

Javadin [Prescribing Information]. Woburn, MA: Azurity Pharmaceuticals, Inc.; October 2025.

For Part D use only:

CLONIDINE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	HYPERTENSION (HTN): CONTRAINDICATION TO OR UNABLE TO SWALLOW CLONIDINE TABLETS.

Created: 12/25
Effective: 12/15/25 Client Approval: 12/25 P&T Approval: 01/26

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

COBIMETINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
COBIMETINIB FUMARATE	COTELLIC	42796		GPI-10 (2153353020)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic melanoma (ICD-10 Group C43) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's tumor has a BRAF V600E or V600K mutation
   - Cotellic will be used in combination with vemurafenib (Zelboraf)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of histiocytic neoplasm (ICD-10 C96.A, C96.0, C96.5, C96.6, D76.1, D76.3, J84.82) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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COBIMETINIB (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **COBIMETINIB (Cotellic)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Unresectable or metastatic melanoma (skin cancer that cannot be completely removed with surgery or has spread to other parts of the body)
   2. Histiocytic neoplasm (a type of white blood cell disorder)

B. If you have unresectable or metastatic melanoma, approval also requires:
   1. You are 18 years of age or older
   2. Your tumor has a BRAF V600E or V600K mutation (abnormal change in gene)
   3. Cotellic will be used in combination with vemurafenib (Zelboraf)

C. If you have histiocytic neoplasm, approval also requires:
   1. You are 18 years of age or older

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cotellic.

REFERENCES

Cotellic [Prescribing Information]; San Francisco, CA: Genentech USA, Inc.; March 2023.

For Part D use only:

COBIMETINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 11/15
Effective: 07/01/25 Client Approval: 05/25 P&T Approval: 01/23

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

COLCHICINE-LODOCO (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
COLCHICINE	LODOCO		54457	GPI-10 (4022003000)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of established atherosclerotic disease or have multiple risk factors for cardiovascular disease and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Lodoco will be used to reduce the risk of myocardial infarction (MI), stroke, coronary revascularization, and cardiovascular death

   If yes, **approve for 12 months by GPID or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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COLCHICINE-LODOCO (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **COLCHICINE-LODOCO** requires the following rule(s) be met for approval:

A. You have established atherosclerotic disease (a type of heart condition) OR you have multiple risk factors for cardiovascular disease (heart disease)
B. You are 18 years of age or older
C. Lodoco will be used to prevent a myocardial infarction (MI: heart attack), stroke, coronary revascularization (a type of heart surgery), and cardiovascular death

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lodoco.

REFERENCES

Lodoco [Prescribing Information]. Parsippany, NJ: AGEPHA Pharma USA, LLC; June 2023.

For Part D use only:

COLCHICINE-LODOCO (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 09/23
Client Approval: 08/24
P&T Approval: 10/23

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

COLLAGENASE INJECTION BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
COLLAGENASE CLOSTRIDIUM HISTOLYTICUM	XIAFLEX		28257	GPI-10 (9935003500)	

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #5.

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COLLAGENASE INJECTION BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

If yes, **Refer to plan. (The health plan makes the final payment determination decision)**

- **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
- **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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COLLAGENASE INJECTION BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Dupuytren's contracture (ICD-10 M72.0) with a palpable cord and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The prescriber has completed Xiaflex training as provided by the Risk Evaluation and Mitigation Strategy (REMS) program

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of Peyronie's disease (ICD-10 N48.6) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is a male
   - The patient has a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy
   - The prescriber has completed Xiaflex training as provided by the Risk Evaluation and Mitigation Strategy (REMS) program

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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COLLAGENASE INJECTION BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **COLLAGENASE INJECTION (Xiaflex)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Dupuytren's contracture (a genetic disorder) with a palpable cord (thick cord in the palm of the hand that can be felt)
   2. Peyronie's disease (painful erection and a curved penis caused by scar tissue)

B. Your doctor has completed Xiaflex training as provided by the Risk Evaluation and Mitigation Strategy (REMS) program

C. If you have Dupuytren's contracture with a palpable cord, approval also requires:
   1. You are 18 years of age or older

D. If you have Peyronie's disease, approval also requires:
   1. You are 18 years of age or older
   2. You are a male
   3. You have a palpable plaque (scar tissue) and curvature deformity (abnormality) of at least 30 degrees at the start of therapy (painful erection and a curved penis caused by scar tissue)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xiaflex. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Xiaflex [Prescribing Information]. Malvern, PA: Auxilium Pharmaceuticals, LLC; July 2023.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed March 26, 2025].

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

COLLAGENASE INJECTION BvD (PART D)

For Part D use only:

COLLAGENASE INJECTION (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	DUPUYTRENS CONTRACTURE, PEYRONIES DISEASE: COMPLETED XIAFLEX TRAINING
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 03/10
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 11/16

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

COPPER (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
COPPER HISTIDINATE	ZYCUBO	51085		GPI-10 (7990001016)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure THE requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Menkes disease (ICD-10 E83.09) **AND** meet the following criterion?
   - The patient is 17 years of age or younger

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **COPPER (Zycubo)** requires the following rule(s) be met for approval:
   A. You have Menkes disease (a type of genetic disorder)
   B. You are 17 years of age or younger

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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COPPER (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zycubo.

REFERENCES

Zycubo [Prescribing Information]. Solana Beach, CA: Sentynl Therapeutics, Inc.; January 2026.

For Part D use only:

COPPER (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	MENKES DISEASE: 17 YEARS OF AGE OR YOUNGER
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 02/26
Effective: 02/07/26 Client Approval: 02/26 P&T Approval: 04/26

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ADVANTAGE AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CORTICOTROPIN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CORTICOTROPIN	ACTHAR, ACTHAR SELFJECT, CORTROPHIN	02830		GPI-10 (3030001000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the product being ordered for diagnostic purposes?

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of infantile spasms (ICD-10 Group G40.82) **AND** meet the following criterion?
   - The patient is younger than 2 years of age

   If yes, **approve for 28 days by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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CORTICOTROPIN (PART D)

INITIAL CRITERIA (CONTINUED)

3. Is the patient being treated for an acute exacerbation of multiple sclerosis (ICD-10 G35) and meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to intravenous (IV) corticosteroids

   If yes, **approve for 28 days by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

4. Is the patient diagnosed with **ONE** of the following FDA approved indications?
   - A rheumatic disorder
     - Psoriatic arthritis (ICD-10 Group L40.5)
     - Rheumatoid arthritis, including juvenile rheumatoid arthritis (ICD-10 M06.9; Groups M05.7, M05.8, M05.9, M06.0, M06.8, M08.2)
     - Ankylosing spondylitis (ICD-10 Group M45. Exclude M45.A)
   - A collagen disease
     - Systemic lupus erythematosus (ICD-10 Group M32)
     - Systemic dermatomyositis (polymyositis) (ICD-10 M36.0; Group M33)
   - A dermatologic disease
     - Severe erythema multiforme (ICD-10 Group L51)
     - Stevens-Johnson syndrome (ICD-10 L51.1, L51.3)
   - An allergic disease
     - Serum sickness (ICD-10 T80.69XA; Group T80.6)
   - An ophthalmic disease
     - Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa (such as keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, or anterior segment inflammation)
   - A respiratory disease
     - Symptomatic sarcoidosis (ICD-10 Group D86)
   - An edematous state
     - To induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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CORTICOTROPIN (PART D)

INITIAL CRITERIA (CONTINUED)

5. Does the patient meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a rheumatologist, dermatologist, allergist/immunologist, ophthalmologist, pulmonologist or nephrologist
   - The patient had a trial of or contraindication to intravenous (IV) corticosteroids

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CORTICOTROPIN (Acthar, Cortrophin)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Infantile spasms (a type of seizure disorder in infancy and childhood)
      2. Acute exacerbation (sudden worsening of your symptoms) of multiple sclerosis (MS: a type of nerve disorder)
      3. Rheumatic disorders (disease affecting joints in the body)
         a. Psoriatic arthritis (a type of skin and joint condition)
         b. Rheumatoid arthritis (including juvenile rheumatoid arthritis: a type of joint condition)
         c. Ankylosing spondylitis (a type of joint condition)
      4. Collagen disease (diseases associated with defects in collagen)
         a. Systemic lupus erythematosus (a type of immune condition)
         b. Systemic dermatomyositis (polymyositis: a type of muscle and skin disorder)
      5. Dermatologic disease (diseases relating to the skin)
         a. Severe erythema multiforme (a type of immune condition)
         b. Stevens-Johnson syndrome (a serious skin disorder)
      6. Allergic disease
         a. Serum sickness (a type of immune hypersensitivity reaction)
      7. Ophthalmic disease (diseases involving the eye)
         a. Severe acute and chronic allergic and inflammatory processes involving the eye and its parts (such as keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, or anterior segment inflammation)

   (Initial denial text continued on next page)

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CORTICOTROPIN (PART D)

INITIAL CRITERIA (CONTINUED)

8. Respiratory disease (disease involving the lungs)
   a. Symptomatic sarcoidosis (a type of inflammatory disorder)
9. Edematous state (accumulation of excessive amount of fluid)
   a. To induce a diuresis (excessive urination) or a remission (reduction) of proteinuria (urine in protein) in the nephrotic syndrome without uremia of the idiopathic type, or that due to lupus erythematosus

B. If you have infantile spasms, approval also requires:
1. You are younger than 2 years of age

C. If you have an acute exacerbation of multiple sclerosis, approval also requires:
1. You are 18 years of age or older
2. You have tried or have a contraindication to (harmful for you to use) IV (intravenous: injection into the vein) corticosteroids

D. For all other Food and Drug Administration (FDA) approved indications (except infantile spasms and multiple sclerosis), approval also requires:
1. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor), dermatologist (a type of skin doctor), allergist/immunologist (a type of allergy/immune system doctor), ophthalmologist (a type of eye doctor), pulmonologist (a type of lung/breathing doctor) or nephrologist (a type of kidney doctor)
2. You have tried or have a contraindication to (harmful for you to use) IV (intravenous: injection into the vein) corticosteroids

NOTE: Our guideline does not approve corticotropin for diagnostic purposes (please consider cosyntropin [Cortrosyn]).

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CORTICOTROPIN (PART D)

RENEWAL CRITERIA

NOTE: For the diagnosis of infantile spasms or multiple sclerosis, please refer to the Initial Criteria section.

1. Is the patient diagnosed with **ONE** of the following FDA approved indications?
   - A rheumatic disorder
     - Psoriatic arthritis (ICD-10 Group L40.5)
     - Rheumatoid arthritis, including juvenile rheumatoid arthritis (ICD-10 M06.9; Groups M05.7, M05.8, M05.9, M06.0, M06.8, M08.2)
     - Ankylosing spondylitis (ICD-10 Group M45. Exclude M45.A)
   - A collagen disease
     - Systemic lupus erythematosus (ICD-10 Group M32)
     - Systemic dermatomyositis (polymyositis) (ICD-10 M36.0; Group M33)
   - A dermatologic disease
     - Severe erythema multiforme (ICD-10 Group L51)
     - Stevens-Johnson syndrome (ICD-10 L51.1, L51.3)
   - An allergic disease
     - Serum sickness (ICD-10 T80.69XA; Group T80.6)
   - An ophthalmic disease
     - Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa (such as keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, or anterior segment inflammation)
   - A respiratory disease
     - Symptomatic sarcoidosis (ICD-10 Group D86)
   - An edematous state
     - To induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet the following criterion?
   - The patient demonstrated clinical benefit while on therapy as indicated by symptom resolution and/or normalization of laboratory tests

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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CORTICOTROPIN (PART D)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CORTICOTROPIN (Acthar Gel, Cortrophin)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Rheumatic disorders (disease affecting joints in the body)
      a. Psoriatic arthritis (a type of skin and joint condition)
      b. Rheumatoid arthritis (including juvenile rheumatoid arthritis: a type of joint condition)
      c. Ankylosing spondylitis (a type of joint condition)
   2. Collagen disease (diseases associated with defects in collagen)
      a. Systemic lupus erythematosus (a type of immune condition)
      b. Systemic dermatomyositis (polymyositis: a type of muscle and skin disorder)
   3. Dermatologic disease (diseases relating to the skin)
      a. Severe erythema multiforme (a type of immune condition)
      b. Stevens-Johnson syndrome (a serious skin disorder)
   4. Allergic disease
      a. Serum sickness (a type of immune hypersensitivity reaction)
   5. Ophthalmic disease (diseases involving the eye)
      a. Severe acute and chronic allergic and inflammatory processes involving the eye and its parts (such as keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, or anterior segment inflammation)
   6. Respiratory disease (disease involving the lungs)
      a. Symptomatic sarcoidosis (a type of inflammatory disorder)
7. Edematous state (accumulation of excessive amount of fluid)
      a. To induce a diuresis (excessive urination) or a remission (reduction) of proteinuria (urine in protein) in the nephrotic syndrome without uremia of the idiopathic type, or that due to lupus erythematosus

B. You have experienced a clinical benefit while on treatment as indicated by symptom resolution (improvement) and/or normalization of laboratory tests

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CORTICOTROPIN (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Acthar Gel.

REFERENCES

Acthar Gel [Prescribing Information]. Bridgewater, NJ: Mallinckrodt ARD LLC.; February 2024.

For Part D use only:

CORTICOTROPIN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	INITIAL: NOT APPROVED FOR DIAGNOSTIC PURPOSES.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: ALL FDA APPROVED INDICATIONS EXCEPT INFANTILE SPASMS AND MULTIPLE SCLEROSIS (MS): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST, DERMATOLOGIST, ALLERGIST/IMMUNOLOGIST, OPHTHALMOLOGIST, PULMONOLOGIST OR NEPHROLOGIST.
Coverage Duration	INFANTILE SPASMS AND MS: 28 DAYS. ALL OTHER FDA APPROVED INDICATIONS: INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: ALL FDA APPROVED INDICATIONS EXCEPT INFANTILE SPASMS: TRIAL OF OR CONTRAINDICATION TO INTRAVENOUS (IV) CORTICOSTEROIDS. RENEWAL: ALL FDA APPROVED INDICATIONS EXCEPT INFANTILE SPASMS AND MS: DEMONSTRATED CLINICAL BENEFIT WHILE ON THERAPY AS INDICATED BY SYMPTOM RESOLUTION AND/OR NORMALIZATION OF LABORATORY TESTS. PART B BEFORE PART D STEP THERAPY, APPLIES ONLY TO BENEFICIARIES IN AN MA-PD PLAN.

Core	Advantage	Plus
No	Yes	Yes

Part D Effective: 01/01/25 Created: 11/07
Commercial Effective: N/A Client Approval: 11/24 P&T Approval: 04/20

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CRINECERFONT CAPSULE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CRINECERFONT	CRENESSITY	50097		GPI-10 (3032102000)	FORM = CAPSULE

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of classic congenital adrenal hyperplasia (CAH) and meet **ALL** of the following criteria?
   - The patient is 4 years of age or older
   - Crenessity will be used as adjunctive treatment with glucocorticoid replacement therapy

   If yes, **approve all strengths for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CRINECERFONT CAPSULE (Crenessity)** requires the following rule(s) be met for approval:
   A. You have classic congenital adrenal hyperplasia (CAH: a type of rare genetic condition)
   B. You are 4 years of age or older
   C. Crenessity will be used as adjunctive (additional) treatment with glucocorticoid replacement therapy (a type of treatment)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CRINECERFONT CAPSULE (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Crenessity.

REFERENCES

Crenessity [Prescribing Information]. San Diego, CA: Neurocrine Biosciences, Inc.; December 2024.

For Part D use only:

CRINECERFONT CAPSULE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 12/24
Effective: 04/29/26 Client Approval: 04/26 P&T Approval: 01/25

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CRINECERFONT SOLUTION (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CRINECERFONT	CRENESSITY		56706	GPI-14 (30321020002020)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of classic congenital adrenal hyperplasia (CAH) and meet **ALL** of the following criteria?
   - The patient is 4 years of age or older
   - Crenessity will be used as adjunctive treatment with glucocorticoid replacement therapy
   - The patient is unable to swallow Crenessity capsules

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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CRINECERFONT SOLUTION (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CRINECERFONT SOLUTION (Crenessity)** requires the following rule(s) be met for approval:

A. You have classic congenital adrenal hyperplasia (CAH: a type of rare genetic condition)
B. You are 4 years of age or older
C. Crenessity will be used as adjunctive (additional) treatment with glucocorticoid replacement therapy (a type of treatment)
D. You are unable to swallow Crenessity capsules

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Crenessity.

REFERENCES

Crenessity [Prescribing Information]. San Diego, CA: Neurocrine Biosciences, Inc.; December 2024.

For Part D use only:

CRINECERFONT SOLUTION (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	CLASSIC CONGENITAL ADRENAL HYPERPLASIA: UNABLE TO SWALLOW CRENESSITY CAPSULES.

Created: 12/24
Effective: 04/29/26 Client Approval: 04/26 P&T Approval: 01/25

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CRIZANLIZUMAB-TMCA BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CRIZANLIZUMAB-TMCA	ADAKVEO	46209		GPI-10 (8280702070)	

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #5.

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CRIZANLIZUMAB-TMCA BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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CRIZANLIZUMAB-TMCA BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of sickle cell disease (ICD-10 Group D57) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with a hematologist

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient 16 to 17 years of age?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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CRIZANLIZUMAB-TMCA BvD (PART D)

INITIAL CRITERIA (CONTINUED)

3. Is the patient 18 years of age or older and meet **ONE** of the following criteria?
   - The patient had at least 2 sickle cell crises in the past year (a sickle cell crisis is defined as a visit to an emergency room/medical facility for sickle cell disease-related pain which was treated with a parenterally administered narcotic or parenterally administered ketorolac, the occurrence of acute chest syndrome, priapism, or splenic sequestration)
   - The patient is having sickle-cell associated symptoms (e.g., pain or anemia) which are interfering with activities of daily living
   - The patient has a history of or has recurrent acute chest syndrome (ACS)

   If yes, **approve for 12 months by HICL or GPI-10**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CRIZANLIZUMAB-TMCA (Adakveo)** requires the following rule(s) be met for approval:
   A. You have sickle cell disease (type of red blood cell disorder)
   B. You are 16 years of age or older
   C. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
   D. If you are 18 years of age or older, approval also requires ONE of the following:
      1. You had at least 2 sickle cell crises in the past year. A sickle cell crisis is defined as a visit to an emergency room/medical facility for sickle cell disease-related pain which was treated with a parenterally administered (given into the vein) narcotic or parenterally administered ketorolac, the occurrence of acute chest syndrome (ACS: chest pain, cough, fever and low oxygen levels), priapism (prolonged erection of penis), or splenic sequestration (suppressing spleen)
      2. You are having sickle-cell associated symptoms (such as pain or anemia) which are interfering with activities of daily living
      3. You have a history of or have recurrent acute chest syndrome (ACS: chest pain, cough, fever and low oxygen levels)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CRIZANLIZUMAB-TMCA BvD (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of sickle cell disease (ICD-10 Group D57) **AND** meet the following criterion?
   - The patient has maintained or experienced a reduction in acute complications of sickle cell disease (e.g., number of sickle cell crises, hospitalizations, acute chest syndrome [ACS])

   If yes, **approve for lifetime by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CRIZANLIZUMAB-TMCA (Adakveo)** requires the following rule(s) be met for renewal:
   A. You have sickle cell disease (type of red blood cell disorder)
   B. You have maintained or experienced a reduction in acute (short term) complications of sickle cell disease (such as the number of sickle cell crises, hospitalizations, acute chest syndrome [chest pain, cough, fever and low oxygen levels])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Adakveo. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Adakveo [Prescribing Information]. East Hanover, New Jersey: Novartis Pharmaceuticals Corporation; September 2022.

Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed July 2, 2024].

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CRIZANLIZUMAB-TMCA BvD (PART D)

For Part D use only:

CRIZANLIZUMAB-TMCA (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	SICKLE CELL DISEASE (SCD): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST
Coverage Duration	INITIAL: 12 MONTHS. RENEWAL: LIFETIME
Other Criteria	SCD: INITIAL: AGES 18 YEARS OR OLDER: 1) AT LEAST 2 SICKLE CELL CRISES IN THE PAST YEAR, 2) SICKLE-CELL ASSOCIATED SYMPTOMS WHICH ARE INTERFERING WITH ACTIVITIES OF DAILY LIVING, OR 3) HISTORY OF OR HAS RECURRENT ACUTE CHEST SYNDROME. AGES 16 TO 17 YEARS: APPROVED WITHOUT ADDITIONAL CRITERIA. RENEWAL: MAINTAINED OR EXPERIENCED A REDUCTION IN ACUTE COMPLICATIONS OF SCD.

Created: 11/19
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 10/19

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CRIZOTINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CRIZOTINIB	XALKORI	37916		GPI-10 (2153051700)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient's tumor is anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test
   - The patient's tumor is ROS1-positive as detected by an FDA-approved test

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient have a diagnosis of relapsed or refractory, systemic anaplastic large cell lymphoma (ALCL) (ICD-10 Group C84.6) and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - The patient's tumor is anaplastic lymphoma kinase (ALK)-positive

   If yes, continue to #5.
   If no, continue to #4.

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CRIZOTINIB (PART D)

GUIDELINES FOR USE (CONTINUED)

4. Does the patient have a diagnosis of unresectable, recurrent, or refractory inflammatory myofibroblastic tumor (IMT) and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - The patient's tumor is anaplastic lymphoma kinase (ALK)-positive

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Is the request for Xalkori (200mg or 250mg) capsules?

   If yes, **approve both 200mg and 250mg capsules for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #6.

6. Is the request for Xalkori (20mg, 50mg or 150mg) pellets **AND** the patient meets the following criterion?
   - The patient is unable to swallow capsules

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CRIZOTINIB (Xalkori)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of the body)
      2. Relapsed (disease that has returned) or refractory (disease does not respond to treatment), systemic anaplastic large cell lymphoma (ALCL: a type of blood cell cancer)
      3. Unresectable (unable to remove by surgery), recurrent, or refractory (disease does not respond to treatment) inflammatory myofibroblastic tumor (IMT: a rare type of tumor)

   (Denial text continued on next page)

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CRIZOTINIB (PART D)

GUIDELINES FOR USE (CONTINUED)

B. If you have metastatic non-small cell lung cancer, approval also requires:
1. You are 18 years of age or older
2. Your tumor is anaplastic lymphoma kinase (ALK: a type of enzyme)-positive or ROS1 (a type of gene)-positive as detected by a Food and Drug Administration (FDA)-approved test

C. If you have relapsed or refractory systemic anaplastic large cell lymphoma, approval also requires:
1. You are 1 year of age or older
2. Your tumor is anaplastic lymphoma kinase (ALK: a type of enzyme)-positive

D. If you have unresectable, recurrent, or refractory inflammatory myofibroblastic tumor, approval also requires:
1. You are 1 year of age or older
2. Your tumor is anaplastic lymphoma kinase (ALK: a type of enzyme)-positive

E. If the request is for Xalkori oral pellets, approval also requires:
1. You are not able to swallow capsules

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Xalkori.

REFERENCE
Xalkori [Prescribing Information]. New York, New York: Pfizer Inc.; September 2023.

For Part D use only:

CRIZOTINIB CAPSULE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

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CRIZOTINIB (PART D)

CRIZOTINIB PELLETS (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	NON-SMALL CELL LUNG CANCER (NSCLC), ANAPLASTIC LARGE CELL LYMPHOMA (ALCL), INFLAMMATORY MYOFIBROBLASTIC TUMOR (IMT): UNABLE TO SWALLOW CAPSULES.

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 11/07
Client Approval: 06/24
P&T Approval: 01/24

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CROVALIMAB-AKKZ BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CROVALIMAB-AKKZ	PIASKY	49703		GPI-10 (8580503030)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	Yes	No	No	Yes	No	No	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit).**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #5.

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CROVALIMAB-AKKZ BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

If yes, **Refer to plan. (The health plan makes the final payment determination decision).**

- **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
- **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CROVALIMAB-AKKZ BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) (ICD-10 D59.5) and meet **ALL** of the following criteria?
   - The patient is 13 years of age or older
   - The patient weighs at least 40 kgs (88 lbs)
   - Therapy is prescribed by or in consultation with a hematologist
   - The patient has flow cytometry demonstrating at least 2 different GPI-protein deficiencies (e.g., CD55, CD59) on at least 2 cell lineages (e.g., erythrocytes, granulocytes) AND a PNH granulocyte clone size of 10 percent or greater
   - Piasky will NOT be used concurrently with C5 complement inhibitor therapy (e.g., Ultomiris [ravulizumab-cwvz], Soliris [eculizumab]), C3 complement inhibitor therapy (e.g., Empaveli [pegcetacoplan]) or Factor B inhibitor therapy (e.g., Fabhalta [iptacopan])

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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CROVALIMAB-AKKZ BvD (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CROVALIMAB-AKKZ (Piasky)** requires the following rule(s) be met for approval:

A. You have paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
B. You are 13 years of age or older
C. You weigh at least 40 kilograms (88 pounds)
D. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
E. You have flow cytometry (a type of lab test) demonstrating at least 2 different GPI-protein deficiencies (you are missing a certain type of protein, such as CD55, CD59) on at least 2 cell lineages (types of cells, such as erythrocytes [red blood cells], granulocytes [a type of white blood cell]) AND a PNH granulocyte clone size of 10 percent or greater
F. You will NOT use Piasky concurrently (at the same time) with C5 complement inhibitor therapy (such as Ultomiris [ravulizumab-cwvz], Soliris [eculizumab]), C3 complement inhibitor therapy (such as Empaveli [pegcetacoplan]) or Factor B inhibitor therapy (e.g., Fabhalta [iptacopan])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CROVALIMAB-AKKZ BvD (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) (ICD-10 D59.5) and meet **ALL** of the following criteria?
   - The patient has had a clinical benefit (e.g., reduction in number of blood transfusions, improvement/stabilization of lactate dehydrogenase and hemoglobin levels) compared to baseline
   - Piasky will NOT be used concurrently with C5 complement inhibitor therapy (e.g., Ultomiris [ravulizumab-cwvz], Soliris [eculizumab]), C3 complement inhibitor therapy (e.g., Empaveli [pegcetacoplan]) or Factor B inhibitor therapy (e.g., Fabhalta [iptacopan])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CROVALIMAB-AKKZ (Piasky)** requires the following rule(s) be met for renewal:
   A. You have paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
   B. You have had a clinical benefit (such as reduction in number of blood transfusions, improvement/stabilization of lactate dehydrogenase [an enzyme] and hemoglobin [type of protein in red blood cells] levels) compared to baseline (before you started treatment)
   C. You will NOT use Piasky concurrently (at the same time) with C5 complement inhibitor therapy (such as Ultomiris [ravulizumab-cwvz], Soliris [eculizumab]), C3 complement inhibitor therapy (such as Empaveli [pegcetacoplan]) or Factor B inhibitor therapy (e.g., Fabhalta [iptacopan])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Piasky. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

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CROVALIMAB-AKKZ BvD (PART D)

REFERENCES

Piasky [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; June 2024.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed April 4, 2025].

For Part D use only:

CROVALIMAB-AKKZ (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	INITIAL: PAROXYSMAL NOCTURNAL HEMOGLOBINURIA (PNH): DIAGNOSIS CONFIRMED VIA FLOW CYTOMETRY: 1) AT LEAST TWO DIFFERENT GPI PROTEIN DEFICIENCIES ON AT LEAST TWO CELL LINEAGES, AND 2) PNH GRANULOCYTE CLONE SIZE OF 10 PERCENT OR GREATER.
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: PNH: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	PNH: INITIAL: 1) NO CONCURRENT USE WITH C5 COMPLEMENT INHIBITOR THERAPY (E.G., ULTOMIRIS, SOLIRIS), C3 COMPLEMENT INHIBITOR THERAPY (E.G., EMPAVELI), OR FACTOR B INHIBITOR THERAPY (E.G., FABHALTA). RENEWAL: 1) CLINICAL BENEFIT COMPARED TO BASELINE, AND 2) NO CONCURRENT USE WITH C5 COMPLEMENT INHIBITOR THERAPY, C3 COMPLEMENT INHIBITOR THERAPY, OR FACTOR B INHIBITOR THERAPY.

Created: 07/24
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 07/24

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CYCLOPHOSPHAMIDE BVD DETERMINATION (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CYCLOPHOSPHAMIDE	CYCLOPHOSPHAMIDE		35317 35318 38360 38361	GPI-14 (21101020000105, 21101020000110, 21101020000305, 21101020000310)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request then a verbal MRF must be completed. Please check the applicable CS note for processing.

NOTE: For oral cyclophosphamide, this PA is for administrative Step Override purposes to determine Medicare Part B versus Medicare Part D funding.

GUIDELINES FOR USE

1. Is the drug being used to treat a cancerous condition?

   If yes, **approve for lifetime by GPID or GPI-14 for all strengths under Part B. (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field)**
   If no, continue to #2.

2. Is the drug being used for the prevention of an organ transplant rejection **AND** the patient has the ESRD TRANS or TRANSPLANT flag on their Member Attribute screen in MedAccess?

   If yes, **approve for lifetime by GPID or GPI-14 for all strengths under Part B. (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field)**

   If no, **approve for 12 months by GPID or GPI-14 for all strengths under Part D as follows:**
   - **Populate the B vs. D field with a 'D' in the PA override field, AND**
   - **Override the administrative step therapy required restriction**

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CYCLOPHOSPHAMIDE BVD DETERMINATION (PART D)

RATIONALE

This drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination.
The 2019 Call Letter provided new guidance on how Part D sponsors are expected to determine whether immunosuppressants are coverable under Part D. Beginning in 2019, when the Part D plan receives new information from CMS (in MARx, ABII, or through a CMS program audit) indicating a Medicare covered transplant, it should rely on the new CMS information from that point forward, even if it is in conflict with the plan's prior research. ABII will not include renal transplants at this time, plans will continue to rely on MARx for renal transplant information).

REFERENCES

Medicare Prescription Drug Benefit Manual Chapter 6 – Part D Drugs and Formulary Requirements, Appendix C- Summary of Coverage Policy Medicare Part B Versus Part D Coverage Issues. Rev 10, 02-19-10. Available at: http://www.cms.gov/PrescriptionDrugCovContra/12_PartDManuals.asp. [Accessed July 11, 2024].

Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. Available at: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf [Accessed July 11, 2024].

Medicare Prescription Drug Benefit Manual – Chapter 14: Coordination of Benefits (Rev 18, 07-11-24). Available at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter-14-Coordination-of-Benefits-v09-14-2018.pdf [Accessed July 11, 2024].

For Part D use only:

CYCLOPHOSPHAMIDE BVD DETERMINATION (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	PART D DOES NOT COVER THIS DRUG WHEN USED FOR A MEDICARE APPROVED ORGAN TRANSPLANT OR CANCER INDICATION
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	PART B: LIFETIME, PART D: 12 MONTHS.
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 11/07
Client Approval: 08/24
P&T Approval: 11/16

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CYCLOSPORINE - VERKAZIA (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CYCLOSPORINE	VERKAZIA		46848	GPI-14 (86720020001630)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of vernal keratoconjunctivitis (VKC) (ICD-10 Group H16.26) **AND** meet the following criterion?
   - The patient had a trial of or contraindication to cromolyn sodium 4% ophthalmic solution

   If yes, **approve for 12 months by GPID or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CYCLOSPORINE - VERKAZIA** requires the following rule(s) be met for approval:
   A. You have vernal keratoconjunctivitis (allergic eye disease)
   B. You have tried or have a contraindication to (harmful for you to use) cromolyn sodium 4% ophthalmic (eye) solution

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CYCLOSPORINE - VERKAZIA (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Verkazia.

REFERENCES

Verkazia [Prescribing Information]. Emeryville, CA: Santen Inc.; June 2022.

For Part D use only:

CYCLOSPORINE - VERKAZIA (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	VERNAL KERATOCONJUNCTIVITIS: TRIAL OF OR CONTRAINDICATION TO CROMOLYN SODIUM 4% OPHTHALMIC SOLUTION.

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 08/22
Client Approval: 06/24
P&T Approval: 07/22

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CYSTEAMINE BITARTRATE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CYSTEAMINE BITARTRATE	PROCYSBI		34656 34657 47723 47724	GPI-14 (56400030106520), (56400030103040), (56400030106530), (56400030103020)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of nephropathic cystinosis (ICD-10 E72.04) and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - The patient had a trial of or contraindication to Cystagon

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths of Procysbi.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CYSTEAMINE BITARTRATE (Procysbi)** requires the following rule(s) be met for approval:
   A. You have nephropathic cystinosis (a type of genetic disease)
   B. You are 1 year of age or older
   C. You have tried or have a contraindication to (harmful for you to use) Cystagon

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CYSTEAMINE BITARTRATE (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Procysbi.

REFERENCES
Procysbi [Prescribing Information]. Lake Forest, IL: Horizon Therapeutics USA; February 2022.

For Part D use only:

CYSTEAMINE BITARTRATE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	NEPHROPATHIC CYSTINOSIS: TRIAL OF OR CONTRAINDICATION TO CYSTAGON.

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 10/20
Client Approval: 08/24
P&T Approval: 05/20

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CYSTEAMINE HYDROCHLORIDE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CYSTEAMINE HCL	CYSTARAN, CYSTADROPS	37567		GPI-10 (8680552510)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of cystinosis (ICD-10 E72.04) **AND** meet the following criterion?
   - The patient has corneal cystine crystal accumulation or deposits

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CYSTEAMINE HYDROCHLORIDE (Cystaran, Cystadrops)** requires the following rule(s) be met for approval:
   A. You have cystinosis (a type of genetic disorder)
   B. You have corneal cystine crystal accumulation or deposits (a type of amino acid buildup in the eye)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CYSTEAMINE HYDROCHLORIDE (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cystaran/Cystadrops.

REFERENCES

Cystaran [Prescribing Information]. Gaithersburg, MD: Leadiant Biosciences, Inc.; May 2018.
Cystadrops [Prescribing Information]. Lebanon, NJ: Recordati Rare Diseases Inc.; August 2020.

For Part D use only:

CYSTEAMINE HYDROCHLORIDE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 11/21
Effective: 01/01/26 Client Approval: 01/26 P&T Approval: 10/20

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DABIGATRAN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DABIGATRAN ETEXILATE MESYLATE	PRADAXA	35604		GPI-10 (8333703020)	DOSAGE FORM = PELET PACK (FDB), PACK (Medi-Span)

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the request for the treatment of a venous thromboembolic event (VTE) (ICD-10 Groups I82.4, I82.5, I82.62, I82.72, I82.9, I26) **AND** the patient meets the following criterion?
   - The patient has been treated with a parenteral anticoagulation agent for at least 5 days

   If yes, continue to #3.
   If no, continue to #2.

2. Is the request to reduce the risk of venous thromboembolic event (VTE) recurrence **AND** the patient meets the following criterion?
   - The patient has been previously treated

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - The patient is 3 months to 7 years of age
   - The patient is 8 to 11 years of age AND unable to swallow dabigatran (Pradaxa) capsules

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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DABIGATRAN (PART D)

GUIDELINES FOR USE (CONTINUED)

4. Has the patient had a trial of or contraindication to rivaroxaban (Xarelto) suspension?

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DABIGATRAN (Pradaxa)** requires the following rule(s) be met for approval:

A. The request is for ONE of the following:
   1. Treatment of a venous thromboembolic event (VTE: blood clot in the vein)
   2. To reduce the risk of a venous thromboembolic event recurrence (happening again)

B. If the request is for the treatment of a venous thromboembolic event, approval also requires:
   1. You have been treated with a parenteral (injected into the vein) anticoagulation agent (a type of medication that prevents blood clot formation) for at least 5 days
   2. You meet ONE of the following:
      a. You are 3 months to 7 years of age
      b. You are 8 to 11 years of age AND are unable to swallow dabigatran (Pradaxa) capsules
   3. You had a trial of or contraindication to (harmful for you to use) rivaroxaban (Xarelto) suspension

C. If the request is to reduce the risk of venous thromboembolic event recurrence, approval also requires:
   1. You have been previously treated
   2. You meet ONE of the following:
      a. You are 3 months to 7 years of age
      b. You are 8 to 11 years of age AND are unable to swallow dabigatran (Pradaxa) capsules
   3. You had a trial of or contraindication to (harmful for you to use) rivaroxaban (Xarelto) suspension

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DABIGATRAN (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Pradaxa.

REFERENCES

Pradaxa [Prescribing Information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; November 2023.

For Part D use only:

DABIGATRAN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	TREATMENT OR REDUCTION IN RISK OF RECURRENCE OF VENOUS THROMBOEMBOLIC EVENT (VTE): 1) TRIAL OF OR CONTRAINDICATION TO RIVAROXABAN SUSPENSION, AND 2) 8 TO 11 YEARS OLD: UNABLE TO SWALLOW DABIGATRAN CAPSULES.

Created: 05/23
Effective: 07/01/25 Client Approval: 05/25 P&T Approval 04/23

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DABRAFENIB CAPSULES (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DABRAFENIB MESYLATE	TAFINLAR		34723 34724	GPI-14 (21532025100120) (21532025100130)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic melanoma (ICD-10 Group C43) and meet **ONE** of the following criteria?
   - The patient has a BRAF V600E mutation as detected by an FDA-approved test AND Tafinlar will be used as a single agent
   - The patient has a BRAF V600E or V600K mutation as detected by an FDA-approved test AND Tafinlar will be used in combination with Mekinist (trametinib)

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of melanoma (ICD-10 Group C43) and meet **ALL** of the following criteria?
   - The patient has a BRAF V600E or V600K mutation as detected by an FDA-approved test
   - Tafinlar will be used in combination with Mekinist (trametinib) for adjuvant treatment
   - There is involvement of lymph node(s) following complete resection

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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DABRAFENIB CAPSULES (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient has a BRAF V600E mutation as detected by an FDA-approved test
   - Tafinlar will be used in combination with Mekinist (trametinib)

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

4. Does the patient have a diagnosis of locally advanced or metastatic anaplastic thyroid cancer (ATC) (ICD-10 C73) and meet **ALL** of the following criteria?
   - The patient has a BRAF V600E mutation
   - Tafinlar will be used in combination with Mekinist (trametinib)
   - The patient has no satisfactory locoregional treatment options available

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Does the patient have a diagnosis of unresectable or metastatic solid tumor and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - The patient has a BRAF V600E mutation
   - Tafinlar will be used in combination with Mekinist (trametinib)
   - The patient's disease has progressed following prior treatment and has no satisfactory alternative treatment options

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #6.

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DABRAFENIB CAPSULES (PART D)

GUIDELINES FOR USE (CONTINUED)

6. Does the patient have a diagnosis of low-grade glioma (LGG) (ICD-10 D33.2) and meet **ALL** of the following criteria?
   - The patient is 1 to 17 years of age
   - The patient has a BRAF V600E mutation
   - Tafinlar will be used in combination with Mekinist (trametinib)
   - The patient requires systemic therapy

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DABRAFENIB CAPSULES (Tafinlar)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Unresectable or metastatic melanoma (skin cancer that cannot be completely removed by surgery or has spread to other parts of the body)
      2. Melanoma (a type of skin cancer)
      3. Metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body)
      4. Locally advanced or metastatic anaplastic thyroid cancer (ATC: a type of thyroid cancer that has spread from where it started to nearby tissue or lymph nodes or it has spread to other parts of the body)
      5. Unresectable or metastatic solid tumor (a tumor that cannot be completely removed by surgery or has spread to other parts of the body)
      6. Low-grade glioma (LGG: a type of brain cancer)

   B. If you have unresectable or metastatic melanoma, approval also requires ONE of the following:
      1. You have a BRAF V600E mutation (type of gene mutation) as detected by an FDA (Food and Drug Administration)-approved test AND Tafinlar will be used as a single agent (by itself)
      2. You have a BRAF V600E or V600K mutation (types of gene mutation) as detected by an FDA (Food and Drug Administration)-approved test AND Tafinlar will be used in combination with Mekinist (trametinib)

   (Denial text continued on next page)

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DABRAFENIB CAPSULES (PART D)

GUIDELINES FOR USE (CONTINUED)

C. If you have melanoma, approval also requires:
1. You have a BRAF V600E or V600K mutation (type of gene mutations) as detected by an FDA (Food and Drug Administration)-approved test
2. Tafinlar will be used in combination with Mekinist (trametinib) for adjuvant (additional) treatment
3. There is involvement of lymph node(s) following complete resection (remove by surgery)

D. If you have metastatic non-small cell lung cancer, approval also requires:
1. You have a BRAF V600E mutation (type of gene mutation) as detected by an FDA (Food and Drug Administration)-approved test
2. Tafinlar will be used in combination with Mekinist (trametinib)

E. If you have locally advanced or metastatic anaplastic thyroid cancer, approval also requires:
1. You have a BRAF V600E mutation (type of gene mutation)
2. Tafinlar will be used in combination with Mekinist (trametinib)
3. You have no satisfactory locoregional (restricted to a localized region of the body) treatment options available

F. If you have an unresectable or metastatic solid tumor, approval also requires:
1. You are 1 year of age or older
2. You have a BRAF V600E mutation (type of gene mutation)
3. Tafinlar will be used in combination with Mekinist (trametinib)
4. Your disease has progressed following prior treatment and has no satisfactory alternative treatment options

G. If you have low-grade glioma, approval also requires:
1. You are 1 to 17 years of age
2. You have a BRAF V600E mutation (type of gene mutation)
3. Tafinlar will be used in combination with Mekinist (trametinib)
4. You require systemic therapy (treatment that targets the entire body)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Tafinlar.

REFERENCES
Tafinlar [Prescribing Information]. East Hanover, New Jersey: Novartis Pharmaceuticals Corporation; March 2024.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DABRAFENIB CAPSULES (PART D)

For Part D use only:

DABRAFENIB CAPSULES (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25 Created: 11/07
Commercial Effective: N/A Client Approval: 06/24 P&T Approval: 10/23

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DABRAFENIB SUSPENSION (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DABRAFENIB MESYLATE	TAFINLAR		53863	GPI-14 (21532025107320)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic melanoma (ICD-10 Group C43) and meet **ONE** of the following criteria?
   - The patient has a BRAF V600E mutation as detected by an FDA-approved test AND Tafinlar will be used as a single agent
   - The patient has a BRAF V600E or V600K mutation as detected by an FDA-approved test AND Tafinlar will be used in combination with Mekinist (trametinib)

   If yes, continue to #7.
   If no, continue to #2.

2. Does the patient have a diagnosis of melanoma (ICD-10 Group C43) and meet **ALL** of the following criteria?
   - The patient has a BRAF V600E or V600K mutation as detected by an FDA-approved test
   - Tafinlar will be used in combination with Mekinist (trametinib) for adjuvant treatment
   - There is involvement of lymph node(s) following complete resection

   If yes, continue to #7.
   If no, continue to #3.

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DABRAFENIB SUSPENSION (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient has a BRAF V600E mutation as detected by an FDA-approved test
   - Tafinlar will be used in combination with Mekinist (trametinib)

   If yes, continue to #7.
   If no, continue to #4.

4. Does the patient have a diagnosis of locally advanced or metastatic anaplastic thyroid cancer (ATC) (ICD-10 C73) and meet **ALL** of the following criteria?
   - The patient has a BRAF V600E mutation
   - Tafinlar will be used in combination with Mekinist (trametinib)
   - The patient has no satisfactory locoregional treatment options available

   If yes, continue to #7.
   If no, continue to #5.

5. Does the patient have a diagnosis of unresectable or metastatic solid tumor and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - The patient has a BRAF V600E mutation
   - Tafinlar will be used in combination with Mekinist (trametinib)
   - The patient's disease has progressed following prior treatment and have no satisfactory alternative treatment options

   If yes, continue to #7.
   If no, continue to #6.

6. Does the patient have a diagnosis of low-grade glioma (LGG) (ICD-10 D33.2) and meet **ALL** of the following criteria?
   - The patient is 1 to 17 years of age
   - The patient has a BRAF V600E mutation
   - Tafinlar will be used in combination with Mekinist (trametinib)
   - The patient requires systemic therapy

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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DABRAFENIB SUSPENSION (PART D)

GUIDELINES FOR USE (CONTINUED)

7. Is the patient unable to swallow Tafinlar (dabrafenib) capsules?

If yes, **approve for 12 months by GPID or GPI-14.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DABRAFENIB SUSPENSION (Tafinlar)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Unresectable or metastatic melanoma (skin cancer that cannot be completely removed by surgery or has spread to other parts of the body)
   2. Melanoma (a type of skin cancer)
   3. Metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body)
   4. Locally advanced or metastatic anaplastic thyroid cancer (ATC: a type of thyroid cancer that has spread from where it started to nearby tissue or lymph nodes, or it has spread to other parts of the body)
   5. Unresectable or metastatic solid tumor (a tumor that cannot be completely removed by surgery or has spread to other parts of the body)
   6. Low-grade glioma (LGG: a type of brain cancer)

B. You are unable to swallow Tafinlar (dabrafenib) capsules

C. If you have unresectable or metastatic melanoma, approval also requires ONE of the following:
   1. You have a BRAF V600E mutation (type of gene mutation) as detected by a Food and Drug Administration (FDA)-approved test AND Tafinlar will be used as a single agent (by itself)
   2. You have a BRAF V600E or V600K mutation (types of gene mutation) as detected by a Food and Drug Administration (FDA)-approved test AND Tafinlar will be used in combination with Mekinist (trametinib)

D. If you have melanoma, approval also requires:
   1. You have a BRAF V600E or V600K mutation (type of gene mutations) as detected by a Food and Drug Administration (FDA)-approved test
   2. Tafinlar will be used in combination with Mekinist (trametinib) for adjuvant (additional) treatment
   3. There is involvement of lymph node(s) following complete resection (remove by surgery)

(Denial text continued on next page)

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DABRAFENIB SUSPENSION (PART D)

GUIDELINES FOR USE (CONTINUED)

E. If you have metastatic non-small cell lung cancer, approval also requires:
1. You have a BRAF V600E mutation (type of gene mutation) as detected by a Food and Drug Administration (FDA)-approved test
2. Tafinlar will be used in combination with Mekinist (trametinib)

F. If you have locally advanced or metastatic anaplastic thyroid cancer, approval also requires:
1. You have a BRAF V600E mutation (type of gene mutation)
2. Tafinlar will be used in combination with Mekinist (trametinib)
3. You have no satisfactory locoregional (restricted to a localized region of the body) treatment options available

G. If you have an unresectable or metastatic solid tumor, approval also requires:
1. You are 1 year of age or older
2. You have a BRAF V600E mutation (type of gene mutation)
3. Tafinlar will be used in combination with Mekinist (trametinib)
4. Your disease has progressed following prior treatment and have no satisfactory alternative treatment options

H. If you have low-grade glioma, approval also requires:
1. You are 1 to 17 years of age
2. You have a BRAF V600E mutation (type of gene mutation)
3. Tafinlar will be used in combination with Mekinist (trametinib)
4. You require systemic therapy (treatment that targets the entire body)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Tafinlar.

REFERENCES
Tafinlar [Prescribing Information]. East Hanover, New Jersey: Novartis Pharmaceuticals Corporation; August 2023.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DABRAFENIB SUSPENSION (PART D)

For Part D use only:

DABRAFENIB SUSPENSION (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	UNABLE TO SWALLOW TAFINILAR CAPSULES.

Part D Effective: 01/01/25 Created: 05/23
Commercial Effective: N/A Client Approval: 08/24 P&T Approval: 10/23

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DACOMITINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DACOMITINIB	VIZIMPRO	45283		GPI-10 (2136001900)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient's tumor has epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations, as detected by an FDA-approved test
   - Vizimpro will NOT be used concurrently with an epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor (e.g., Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib], Tagrisso [osimertinib])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DACOMITINIB (Vizimpro)** requires the following rule(s) be met for approval:
   A. You have metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of the body)
   B. Your tumor has epidermal growth factor receptor (EGFR: type of protein) exon 19 deletion or exon 21 L858R substitution mutations (abnormal changes in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test
   C. You will NOT use Vizimpro concurrently (at the same time) with an epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor (such as Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib], Tagrisso [osimertinib])

   (Denial text continued on next page)

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DACOMITINIB (PART D)

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vizimpro.

REFERENCES

Vizimpro [Prescribing Information]. New York, NY: Pfizer Labs; December 2020.

For Part D use only:

DACOMITINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC): NOT ON CONCURRENT THERAPY WITH AN EGFR TYROSINE KINASE-INHIBITOR.

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 10/18
Client Approval: 06/24
P&T Approval: 04/22

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DALFAMPRIDINE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DALFAMPRIDINE	AMPYRA, DALFAMPRIDINE ER	13907		GPI-10 (6240603000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of multiple sclerosis (MS) (ICD-10 G35) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient has symptoms of a walking disability (e.g., mild to moderate bilateral lowerextremity weakness, unilateral weakness with lower extremity or truncal ataxia)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DALFAMPRIDINE (Ampyra)** requires the following rule(s) be met for approval:
   A. You have multiple sclerosis (MS: a type of nerve disorder)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor)
   D. You have symptoms of a walking disability (such as mild to moderate bilateral [bothsides] lower extremity weakness, unilateral [one side] weakness with lower extremity or truncal ataxia [impaired balance or coordination])

   (Initial denial text continued on next page)

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DALFAMPRIDINE (PART D)

INITIAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DALFAMPRIDINE (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of multiple sclerosis (MS) (ICD-10 G35) **AND** meet the following criterion?
   - The patient has an improvement in their walking ability

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DALFAMPRIDINE (Ampyra)** requires the following rule(s) be met for renewal:
   A. You have multiple sclerosis (MS: a type of nerve disorder)
   B. You have an improvement in your ability to walk

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ampyra.

REFERENCES

Ampyra [Prescribing Information]. Raleigh, NC: Accord Healthcare Inc.; December 2024.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DALFAMPRIDINE (PART D)

For Part D use only:

DALFAMPRIDINE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	MULTIPLE SCLEROSIS (MS): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS
Other Criteria	MS: INITIAL: HAS SYMPTOMS OF A WALKING DISABILITY (E.G., MILD TO MODERATE BILATERAL LOWER EXTREMITY WEAKNESS, UNILATERAL WEAKNESS PLUS LOWER EXTREMITY OR TRUNCAL ATAXIA). RENEWAL: IMPROVEMENT IN WALKING ABILITY.

Created: 11/07
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 07/22

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DANICOPAN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DANICOPAN	VOYDEYA	49483		GPI-10 (8580852000)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) (ICD-10 D59.5) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a hematologist
   - Voydeya will be used for the treatment of extravascular hemolysis (EVH)
   - The patient has anemia (Hgb level less than or equal to 9.5 g/dL) with an absolute reticulocyte count of at least 120 x 10^9/L
   - The patient has flow cytometry demonstrating at least 2 different GPI-protein deficiencies (e.g., CD55, CD59) on at least 2 cell lineages (e.g., erythrocytes, granulocytes) AND a PNH granulocyte clone size of at least 10 percent
   - Voydeya will be used concurrently with C5 complement inhibitor therapy (e.g., Ultomiris [ravulizumab-cwvz], Soliris [eculizumab], Piasky [crovalimab])
   - Voydeya will NOT be used concurrently with C3 complement inhibitor therapy (e.g., Empaveli [pegcetacoplan]) or Factor B inhibitor therapy (e.g., Fabhalta [iptacopan])

   If yes, **approve for 4 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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DANICOPAN (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DANICOPAN (Voydeya)** requires the following rule(s) be met for approval:

A. You have paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
D. You will use Voydeya for the treatment of extravascular hemolysis (EVH: break down of blood cells outside of your blood stream)
E. You have anemia (a hemoglobin [Hgb: a type of protein in red blood cells] level less than or equal to 9.5 g/dL) with an absolute reticulocyte (immature red blood cell) count of at least 120 x 10^9/L
F. You have flow cytometry (a type of lab test) demonstrating at least 2 different GPI-protein deficiencies (missing a certain type of protein, such as CD55, CD59) on at least 2 cell lineages (types of cells, such as erythrocytes [red blood cells], granulocytes [a type of white blood cell]) AND a PNH granulocyte clone size of at least 10 percent
G. You will use Voydeya concurrently (at the same time) with C5 complement inhibitor therapy (such as Ultomiris [ravulizumab-cwvz], Soliris [eculizumab], Piasky [crovalimab])
H. You will NOT use Voydeya concurrently (at the same time) with C3 complement inhibitor therapy (such as Empaveli [pegcetacoplan]) or Factor B inhibitor therapy (such as Fabhalta [iptacopan])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DANICOPAN (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) (ICD-10 D59.5) and meet **ALL** of the following criteria?
   - The patient has experienced a clinical benefit (e.g., improvement in hemoglobin levels) compared to baseline
   - Voydeya will be used concurrently with C5 complement inhibitor therapy (e.g., Ultomiris [ravulizumab-cwvz], Soliris [eculizumab], Piasky [crovalimab])
   - Voydeya will NOT be used concurrently with C3 complement inhibitor therapy (e.g., Empaveli [pegcetacoplan]) or Factor B inhibitor therapy (e.g., Fabhalta [iptacopan])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DANICOPAN (Voydeya)** requires the following rule(s) be met for renewal:
   A. You have paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
   B. You have experienced a clinical benefit (such as an improvement in hemoglobin [Hgb: a type of protein in red blood cells] levels) compared to baseline (before you started treatment)
   C. You will use Voydeya concurrently (at the same time) with C5 complement inhibitor therapy (such as Ultomiris [ravulizumab-cwvz], Soliris [eculizumab], Piasky [crovalimab])
   D. You will NOT use Voydeya concurrently (at the same time) with C3 complement inhibitor therapy (such as Empaveli [pegcetacoplan]) or Factor B inhibitor therapy (such as Fabhalta [iptacopan])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Voydeya.

REFERENCES
Voydeya [Prescribing Information]. Boston, MA: Alexion Pharmaceuticals, Inc.; March 2024.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DANICOPAN (PART D)

For Part D use only:

DANICOPAN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	PAROXYSMAL NOCTURNAL HEMOGLOBINURIA (PNH): INITIAL: 1) PNH CONFIRMED VIA FLOW CYTOMETRY BY DEMONSTRATING AT LEAST TWO DIFFERENT GPI PROTEIN DEFICIENCIES ON AT LEAST TWO CELL LINEAGES AND PNH GRANULOCYTE CLONE SIZE OF AT LEAST 10 PERCENT, AND 2) EXTRAVASCULAR HEMOLYSIS (EVH) CONFIRMED BY ANEMIA (HGB LEVEL LESS THAN OR EQUAL TO 9.5 G/DL) WITH AN ABSOLUTE RETICULOCYTE COUNT OF AT LEAST 120 X 10^9/L.
Age Restrictions	N/A
Prescriber Restrictions	PNH: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST.
Coverage Duration	INITIAL: 4 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	PNH: INITIAL: 1) USED WITH A C5 COMPLEMENT INHIBITOR, AND 2) NO CONCURRENT USE WITH A C3 COMPLEMENT INHIBITOR OR FACTOR B INHIBITOR. RENEWAL: 1) CLINICAL BENEFIT WHILE ON VOYDEYA COMPARED TO BASELINE, 2) USED WITH A C5 COMPLEMENT INHIBITOR, AND 3) NO CONCURRENT USE WITH A C3 COMPLEMENT INHIBITOR OR FACTOR B INHIBITOR.

Part D Effective: 09/01/24 Created: 08/24
Commercial Effective: N/A Client Approval: 08/24 P&T Approval: 07/24

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DARATUMUMAB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DARATUMUMAB	DARZALEX	42814		GPI-10 (2135402700)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a newly diagnosed multiple myeloma (ICD-10 Group C90.0) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, continue to #4.

2. Is the patient ineligible for autologous stem cell transplant and meets **ONE** of the following criteria?
   - Darzalex will be used in combination with lenalidomide (Revlimid) and dexamethasone
   - Darzalex will be used in combination with bortezomib (Velcade), melphalan, and prednisone

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Is the patient eligible for autologous stem cell transplant **AND** meets the following criterion?
   - Darzalex will be used in combination with bortezomib (Velcade), thalidomide (Thalomid), and dexamethasone

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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DARATUMUMAB (PART D)

GUIDELINES FOR USE (CONTINUED)

4. Does the patient have a diagnosis of relapsed or refractory multiple myeloma (ICD-10 Group C90.0) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #5.
   If no, continue to #6.

5. Does the patient meet **ONE** of the following criteria?
   - The patient has received at least one prior therapy, AND Darzalex will be used in combination with lenalidomide (Revlimid) and dexamethasone
   - The patient has received one to three prior lines of therapy, AND Darzalex will be used in combination with carfilzomib (Kyprolis) and dexamethasone

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

6. Does the patient have a diagnosis of multiple myeloma (ICD-10 Group C90.0) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

7. Has the patient received at least one prior therapy **AND** meet the following criterion?
   - Darzalex will be used in combination with bortezomib (Velcade) and dexamethasone

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #8.

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DARATUMUMAB (PART D)

GUIDELINES FOR USE (CONTINUED)

8. Has the patient received at least two prior therapies, including lenalidomide (Revlimid) and a proteasome inhibitor [e.g., bortezomib (Velcade), carfilzomib (Kyprolis), ixazomib (Ninlaro)] **AND** the patient meets the following criterion?
   - Darzalex will be used in combination with pomalidomide (Pomalyst) and dexamethasone

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #9.

9. Will Darzalex be used as monotherapy (not in combination with a proteasome inhibitor or immunomodulatory agent)?

   If yes, continue to #10.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

10. Has the patient received at least three prior lines of therapy including agents from **BOTH** of the following drug classes?
    - Proteasome inhibitors (PI) [e.g., bortezomib (Velcade), carfilzomib (Kyprolis), ixazomib (Ninlaro)]
    - Immunomodulatory agents [e.g., lenalidomide (Revlimid), pomalidomide (Pomalyst), thalidomide (Thalomid)]

    If yes, **approve for 12 months by HICL or GPI-10.**
    APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

    If no, continue #11.

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DARATUMUMAB (PART D)

GUIDELINES FOR USE (CONTINUED)

11. Is the patient refractory to an agent from **BOTH** of the following drug classes?
    - Proteasome inhibitors (PI) [e.g., bortezomib (Velcade), carfilzomib (Kyprolis), ixazomib (Ninlaro)]
    - Immunomodulatory agents [e.g., lenalidomide (Revlimid), pomalidomide (Pomalyst), thalidomide (Thalomid)]

    If yes, **approve for 12 months by HICL or GPI-10.**
    APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

    If no, do not approve.

    DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

    Our guideline named **DARATUMUMAB (Darzalex)** requires the following rule(s) be met for approval:
    A. You have multiple myeloma (type of blood cancer)
    B. You are 18 years of age or older
    C. You meet ONE of the following:
        1. You have newly diagnosed multiple myeloma, are not eligible for autologous stem cell transplant (cells from your own body), AND will receive Darzalex in combination with lenalidomide (Revlimid) and dexamethasone
        2. You have newly diagnosed multiple myeloma, are not eligible for autologous stem cell transplant (cells from your own body), AND will receive Darzalex in combination with bortezomib (Velcade), melphalan, and prednisone
        3. You have newly diagnosed multiple myeloma, are eligible for autologous stem cell transplant (cells from your own body), AND will receive Darzalex in combination with bortezomib (Velcade), thalidomide (Thalomid), and dexamethasone
        4. You have relapsed or refractory multiple myeloma (blood cell cancer that has returned or is not responsive to treatment), received at least one prior therapy AND will receive Darzalex in combination with lenalidomide (Revlimid) and dexamethasone
        5. You have relapsed or refractory multiple myeloma (blood cell cancer that has returned or is not responsive to treatment), received one to three prior lines of therapy AND will receive Darzalex in combination with carfilzomib (Kyprolis) and dexamethasone
        6. You have received at least one prior therapy AND will receive Darzalex in combination with bortezomib (Velcade) and dexamethasone

    (Denial text continued on next page)

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DARATUMUMAB (PART D)

GUIDELINES FOR USE (CONTINUED)

7. You have received at least two prior therapies, including lenalidomide and a proteasome inhibitor (such as bortezomib [Velcade], carfilzomib [Kyprolis], ixazomib [Ninlaro]) AND will receive Darzalex in combination with pomalidomide (Pomalyst) and dexamethasone
8. You will receive Darzalex as monotherapy (one drug), AND have received at least three prior lines of therapy, including a proteasome inhibitor (such as bortezomib [Velcade], carfilzomib [Kyprolis], ixazomib [Ninlaro]) and an immunomodulatory agent (such as lenalidomide [Revlimid], pomalidomide [Pomalyst], thalidomide [Thalomid])
9. You will receive Darzalex as monotherapy (one drug), AND are refractory (disease does not respond to treatment) to both a proteasome inhibitor (such as bortezomib [Velcade], carfilzomib [Kyprolis], ixazomib [Ninlaro]) and an immunomodulatory agent (such as lenalidomide [Revlimid], pomalidomide [Pomalyst], thalidomide [Thalomid])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Darzalex.

REFERENCES

Darzalex [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; January 2023.

For Part D use only:

DARATUMUMAB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 11/15
Effective: 01/01/26 Client Approval: 01/26 P&T Approval: 10/20

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DARATUMUMAB-HYALURONIDASE-FIHJ (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DARATUMUMAB-HYALURONIDASE-FIHJ	DARZALEX FASPRO	46509		GPI-10 (2199000215)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of multiple myeloma (ICD-10 Group C90.0) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, continue to #9.

2. Is the patient newly diagnosed?

   If yes, continue to #3.
   If no, continue to #5.

3. Is the patient ineligible for an autologous stem cell transplant and meets **ONE** of the following criteria?
   - Darzalex Faspro will be used in combination with bortezomib (Velcade), melphalan, and prednisone
   - Darzalex Faspro will be used in combination with lenalidomide (Revlimid) and dexamethasone
   - Darzalex Faspro will be used in combination with bortezomib (Velcade), lenalidomide (Revlimid) and dexamethasone

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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DARATUMUMAB-HYALURONIDASE-FIHJ (PART D)

GUIDELINES FOR USE (CONTINUED)

4. Is the patient eligible for an autologous stem cell transplant and meets **ONE** of the following criteria?
   - Darzalex Faspro will be used in combination with bortezomib (Velcade), lenalidomide (Revlimid), and dexamethasone for induction and consolidation treatment
   - Darzalex Faspro will be used in combination with bortezomib (Velcade), thalidomide (Thalomid), and dexamethasone

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Is the patient's disease relapsed or refractory and the patient meets **ONE** of the following criteria?
   - The patient has received at least one prior therapy, AND Darzalex Faspro will be used in combination with lenalidomide (Revlimid) and dexamethasone
   - The patient has received one to three prior lines of therapy, AND Darzalex Faspro will be used in combination with carfilzomib (Kyprolis) and dexamethasone

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #6.

6. Has the patient received at least one prior therapy **AND** meets the following criterion?
   - Darzalex Faspro will be used in combination with bortezomib (Velcade) and dexamethasone

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #7.

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DARATUMUMAB-HYALURONIDASE-FIHJ (PART D)

GUIDELINES FOR USE (CONTINUED)

7. Has the patient received at least one prior line of therapy, including lenalidomide (Revlimid) anda proteasome inhibitor [e.g., bortezomib (Velcade), carfilzomib (Kyprolis), ixazomib (Ninlaro)] **AND** meets the following criterion?
   - Darzalex Faspro will be used in combination with pomalidomide (Pomalyst) and dexamethasone

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #8.

8. Will Darzalex Faspro be used as monotherapy and the patient meets **ONE** of the following criteria?
   - The patient has received at least three prior lines of therapy, including a proteasome inhibitor (e.g., bortezomib [Velcade], carfilzomib [Kyprolis], ixazomib [Ninlaro]) and an immunomodulatory agent (e.g., lenalidomide [Revlimid], pomalidomide [Pomalyst], thalidomide [Thalomid])
   - The patient is refractory to both a proteasome inhibitor (e.g., bortezomib [Velcade], carfilzomib [Kyprolis], ixazomib [Ninlaro]) and an immunomodulatory agent (e.g., lenalidomide [Revlimid], pomalidomide [Pomalyst], thalidomide [Thalomid])
   - The patient has high-risk smoldering multiple myeloma

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

9. Does the patient have newly diagnosed light chain (AL) amyloidosis (ICD-10 E85.81) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Darzalex Faspro will be used in combination with bortezomib (Velcade), cyclophosphamide, and dexamethasone

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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DARATUMUMAB-HYALURONIDASE-FIHJ (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DARATUMUMAB-HYALURONIDASE-FIHJ (Darzalex Faspro)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Multiple myeloma (a type of blood cancer)
   2. Newly diagnosed light chain (AL) amyloidosis (a buildup of proteins in the tissues causing organ dysfunction)

B. You are 18 years of age or older

C. If you have multiple myeloma, approval also requires ONE of the following:
   1. Your disease is newly diagnosed and you meet ONE of the following:
      a. You are NOT eligible for an autologous stem cell transplant (a type of procedure to replace damaged bone marrow with cells from your own body) and you meet ONE of the following:
         i. You will use Darzalex Faspro in combination with bortezomib (Velcade), melphalan, and prednisone
         ii. You will use Darzalex Faspro in combination with lenalidomide (Revlimid) and dexamethasone
         iii. You will use Darzalex Faspro in combination with bortezomib (Velcade), lenalidomide (Revlimid) and dexamethasone
      b. You are eligible for an autologous stem cell transplant (a type of procedure to replace damaged bone marrow with cells from your own body) and you meet ONE of the following:
         i. You will use Darzalex Faspro in combination with bortezomib (Velcade), lenalidomide (Revlimid), and dexamethasone for induction (start of treatment) and consolidation treatment (treatment following initial therapy)
         ii. You will use Darzalex Faspro in combination with bortezomib (Velcade), thalidomide (Thalomid), and dexamethasone
   2. Your disease is relapsed or refractory (disease has returned or did not respond to treatment) and you meet ONE of the following:
      a. You have received at least one prior therapy AND you will use Darzalex Faspro in combination with lenalidomide (Revlimid) and dexamethasone
      b. You have received one to three prior lines of therapy AND you will use Darzalex Faspro in combination with carfilzomib (Kyprolis) and dexamethasone
   3. You have received at least one prior therapy AND you will use Darzalex Faspro in combination with bortezomib (Velcade) and dexamethasone
   4. You have received at least one prior line of therapy, including lenalidomide (Revlimid) and a proteasome inhibitor (such as bortezomib [Velcade], carfilzomib [Kyprolis], ixazomib [Ninlaro]), AND you will use Darzalex Faspro in combination with pomalidomide (Pomalyst) and dexamethasone

(Denial text continued on next page)

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DARATUMUMAB-HYALURONIDASE-FIHJ (PART D)

GUIDELINES FOR USE (CONTINUED)

5. You will use Darzalex Faspro as monotherapy (one drug treatment) and meet ONE of the following:
   a. You have received at least three prior lines of therapy, including a proteasome inhibitor (such as bortezomib [Velcade], carfilzomib [Kyprolis], ixazomib [Ninlaro]) AND an immunomodulatory agent (such as lenalidomide [Revlimid], pomalidomide [Pomalyst], thalidomide [Thalomid])
   b. You are refractory (disease did not respond to treatment) to both a proteasome inhibitor (such as bortezomib [Velcade], carfilzomib [Kyprolis], ixazomib [Ninlaro]) AND an immunomodulatory agent (such as lenalidomide [Revlimid], pomalidomide [Pomalyst], thalidomide [Thalomid])
   c. You have high-risk smoldering multiple myeloma (the stage before active disease)

D. If you have newly diagnosed light chain amyloidosis, approval also requires:

1. You will use Darzalex Faspro in combination with bortezomib (Velcade), cyclophosphamide, and dexamethasone

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Darzalex Faspro.

REFERENCES

Darzalex Faspro [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; January 2026.

For Part D use only:

DARATUMUMAB-HYALURONIDASE-FIHJ (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 05/20
Effective: 02/11/26 Client Approval: 02/26 P&T Approval: 04/26

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STANDARD PART D
PRIOR AUTHORIZATION GUIDELINES

DARAXONRASIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DARAXONRASIB	RASONQUE	51500		GPI-10 (2153432000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic pancreatic adenocarcinoma (ICD-10 Group C25) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an oncologist
   - The patient has received at least one prior systemic therapy OR is not a candidate for a multiagent systemic therapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: Our guideline named **DARAXONRASIB (Rasonque)** requires the following rule(s) be met for approval:
   A. You have metastatic pancreatic adenocarcinoma (a type of pancreas cancer that has spread to other parts of the body)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with an oncologist (a type of cancer doctor)
   D. You have received at least one prior systemic therapy (treatment that targets the entire body) OR you are not a candidate for a multiagent systemic therapy

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Rasonque.

REFERENCES
Rasonque [Prescribing Information]. Redwood City, CA: Revolution Medicines, Inc.; August 2026.

Created: 09/26
Effective: 09/09/26 DMC Approval: 09/09/26

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DARBEPOETIN ALFA (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DARBEPOETIN ALFA IN POLYSORBAT	ARANESP	22890		GPI-10 (8240101510)	

PAYMENT DETERMINATION CRITERIA

1. Does the patient have a diagnosis of end stage renal disease (ESRD) and is on dialysis (ICD-10 N18.6)?

   If yes, **do NOT approve under Part D. Finalize as follows:**

   PAC NOTE: Please defer to a pharmacist for denial.

   CLINICAL SPECIALIST NOTE: This medication is included in the bundled dialysis facility payment which is paid under Medicare Part B and is not a Part D eligible drug. Please follow your internal procedures for denial.

   If no, review the clinical criteria for Part D coverage below if applicable. (**NOTE:** If the ESRD_Dialysis attribute is present, select the 'ESRD' Override Type within the PA, which is available in the 'Additional Overrides' section.)

Guideline interpretation beyond this point requires Clinical/Technician review.

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DARBEPOETIN ALFA (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of anemia due to chronic kidney disease (CKD) (ICD-10 D63.1) and meet **ALL** of the following criteria?
   - The patient had a trial of or contraindication to the preferred agent: Retacrit (epoetin alfa-epbx)
   - The patient's hemoglobin level is less than 10 g/dL

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of anemia due to the effects of concomitantly administered cancer chemotherapy (ICD-10 D64.81) and meet **ALL** of the following criteria?
   - The patient had a trial of or contraindication to the preferred agent: Retacrit (epoetin alfa-epbx)
   - The patient's hemoglobin level is less than 10 g/dL

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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DARBEPOETIN ALFA (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DARBEPOETIN ALFA (Aranesp)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Anemia (low amount of healthy red blood cells) due to chronic kidney disease (CKD)
   2. Anemia due to the effects of concomitantly administered (given at the same time) cancer chemotherapy

B. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Retacrit (epoetin alfa-epbx)

C. Your hemoglobin level (type of blood test) is less than 10 g/dL

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DARBEPOETIN ALFA (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of anemia due to chronic kidney disease (CKD) (ICD-10 D63.1) **AND** meet the following criterion?
   - The patient is NOT receiving dialysis treatment
     [Note: If the patient is currently receiving dialysis treatment, the requested medication is included in the bundle dialysis facility payment which is paid under Medicare Part B]. Please refer to CRITERIA FOR PART B vs PART D DETERMINATION above.

     If yes, continue to #2.
     If no, continue to #4.

2. Is the patient an adult (18 years of age or older) and meets **ONE** of the following criteria?
   - The patient's hemoglobin level is less than 10 g/dL
   - The patient's hemoglobin level has reached 10 g/dL and the dose is being or has been reduced/interrupted to decrease the need for blood transfusions

     If yes, **approve for 12 months by HICL or GPI-10.**
     APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

     If no, continue to #3.

3. Is the request for a pediatric (less than 18 years of age) patient and meets **ONE** of the following criteria?
   - The patient's hemoglobin level is less than 10 g/dL
   - The patient's hemoglobin level has approached or exceeds 12 g/dL and the dose is being or has been reduced/interrupted to decrease the need for blood transfusions

     If yes, **approve for 12 months by HICL or GPI-10.**
     APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

     If no, do not approve.
     DENIAL TEXT: See the renewal denial text at the end of the guideline.

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DARBEPOETIN ALFA (PART D)

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of anemia due to the effects of concomitantly administered cancer chemotherapy (ICD-10 D64.81) and meet **ONE** of the following criteria?
   - The patient's hemoglobin level is less than 10 g/dL
   - The patient's hemoglobin level does not exceed a level needed to avoid red blood cell (RBC) transfusion

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DARBEPOETIN ALFA (Aranesp)** requires the following rules be met for renewal.

   A. You have ONE of the following:
      1. Anemia (low amount of healthy red blood cells) due to chronic kidney disease (CKD)
      2. Anemia due to the effects of concomitantly administered (given at the same time) cancer chemotherapy

   B. If you are an adult with anemia due to chronic kidney disease, renewal also requires:
      1. You are NOT receiving dialysis treatment (process of removing excess water, toxins from the blood)
      2. Your hemoglobin level (type of blood test) is less than 10 g/dL OR has reached 10 g/dL and your dose is being or has been reduced/interrupted to decrease the need for blood transfusions

   C. If you are a pediatric patient with anemia due to chronic kidney disease, renewal also requires:
      1. You are NOT receiving dialysis treatment (process of removing excess water, toxins from the blood)
      2. Your hemoglobin level (a type of blood test) is less than 10 g/dL OR has approached or exceeds 12 g/dL and your dose is being or has been reduced/interrupted to decrease the need for blood transfusions

   D. If you have anemia due to the effects of concomitantly administered cancer chemotherapy, renewal also requires ONE of the following:
      1. Your hemoglobin level (type of blood test) is less than 10 g/dL
      2. Your hemoglobin level does not exceed a level needed to avoid red blood cell (RBC) transfusion

   (Renewal denial text continued on next page)

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DARBEPOETIN ALFA (PART D)

RENEWAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Patients identified as Part D (ESRD) undergoing dialysis will be directed to a dialysis treatment center and have their ESA included in the bundled dialysis facility payment, which is paid under Medicare Part B.

For further information, please refer to the Prescribing Information and/or Drug Monograph for Aranesp.

REFERENCES

Aranesp [Prescribing Information]. Thousand Oaks, CA: Amgen; January 2019.

For Part D use only:

DARBEPOETIN ALFA (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	INITIAL: CHRONIC KIDNEY DISEASE (CKD), CANCER CHEMOTHERAPY: HEMOGLOBIN LEVEL IS LESS THAN 10G/DL. RENEWAL: 1) CKD IN ADULTS NOT ON DIALYSIS: (A) HEMOGLOBIN LEVEL IS LESS THAN 10G/DL, OR (B) HEMOGLOBIN LEVEL HAS REACHED 10G/DL AND THE DOSE IS BEING OR HAS BEEN REDUCED/INTERRUPTED TO DECREASE THE NEED FOR BLOOD TRANSFUSIONS. 2) CKD IN PEDIATRIC PATIENTS: (A) HEMOGLOBIN LEVEL IS LESS THAN 10G/DL, OR (B) HEMOGLOBIN LEVEL HAS APPROACHED OR EXCEEDS 12G/DL AND THE DOSE IS BEING OR HAS BEEN REDUCED/INTERRUPTED TO DECREASE THE NEED FOR BLOOD TRANSFUSIONS. 3) CANCER CHEMOTHERAPY: (A) HEMOGLOBIN LEVEL IS LESS THAN 10G/DL, OR (B) HEMOGLOBIN LEVEL DOES NOT EXCEED A LEVEL NEEDED TO AVOID RBC TRANSFUSION.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: CKD, CANCER CHEMOTHERAPY: TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT: RETACRIT. RENEWAL: CKD: NOT RECEIVING DIALYSIS

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	TREATMENT. THIS DRUG MAY BE EITHER BUNDLED WITH AND COVERED UNDER END STAGE RENAL DISEASE DIALYSIS RELATED SERVICES OR COVERED UNDER MEDICARE D DEPENDING UPON THE CIRCUMSTANCES.

Created: 10/19
Effective: 05/12/25 Client Approval: 04/25 P&T Approval: 10/23

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DARIDOREXANT (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DARIDOREXANT HCL	QUVIVIQ	47751		GPI-10 (6050002010)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of insomnia (ICD-10 Group G47.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Quviviq will NOT be used concurrently with Z hypnotics (e.g., Lunesta [eszopiclone], Sonata [zaleplon], Ambien [zolpidem]) or benzodiazepines (e.g., estazolam, Restoril [temazepam], triazolam [Halcion]) for sleep
   - The patient does NOT have narcolepsy
   - The patient had a trial of or contraindication to Belsomra
   - The patient had a trial of or contraindication to ONE of the following generic insomnia agents: eszopiclone (Lunesta), zaleplon (Sonata), zolpidem IR (Ambien)

   If yes, **approve for 3 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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DARIDOREXANT (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DARIDOREXANT (Quviviq)** requires the following rule(s) be met for approval:

A. You have insomnia (a type of sleep condition)
B. You are 18 years of age or older
C. You will NOT use Quviviq concurrently (at the same time) with Z hypnotics (such as Lunesta [eszopiclone], Sonata [zaleplon], Ambien [zolpidem]) or benzodiazepines (such as estazolam, Restoril [temazepam], Halcion [triazolam]) for sleep
D. You do NOT have narcolepsy (a type of sleep condition)
E. You had a trial of or contraindication to (harmful for you to use) Belsomra
F. You had a trial of or contraindication to (harmful for you to use) ONE of the following generic insomnia drugs: eszopiclone (Lunesta), zaleplon (Sonata), zolpidem immediate-release (Ambien)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DARIDOREXANT (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of insomnia (ICD-10 Group G47.0) and meet **ALL** of the following criteria?
   - The patient has experienced improvement in insomnia symptoms but is NOT currently a candidate for discontinuation
   - Quviviq will NOT be used concurrently with Z hypnotics (e.g., Lunesta [eszopiclone], Sonata [zaleplon], Ambien [zolpidem]) or benzodiazepines (e.g., estazolam, Restoril [temazepam], Halcion [triazolam]) for sleep

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DARIDOREXANT (Quviviq)** requires the following rule(s) be met for renewal:
   A. You have insomnia (a type of sleep condition)
   B. You have experienced improvement in insomnia symptoms but are NOT currently a candidate for discontinuation
   C. You will NOT use Quviviq concurrently (at the same time) with Z hypnotics (such as Lunesta [eszopiclone], Sonata [zaleplon], Ambien [zolpidem]) or benzodiazepines (such as estazolam, Restoril [temazepam], Halcion [triazolam]) for sleep

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Quviviq.

REFERENCES
Quviviq [Prescribing Information]. Radnor, PA: Idorsia Pharmaceuticals US, Inc.; September 2024.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DARIDOREXANT (PART D)

For Part D use only:

DARIDOREXANT (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	INITIAL: 3 MONTHS. RENEWAL: 6 MONTHS.
Other Criteria	INSOMNIA: INITIAL: 1) NO CONCURRENT USE WITH Z HYPNOTICS OR BENZODIAZEPINES FOR SLEEP, 2) DOES NOT HAVE NARCOLEPSY, AND 3) TRIAL OF OR CONTRAINDICATION TO BELSOMRA AND ONE OF THE FOLLOWING GENERIC INSOMNIA AGENTS: ESZOPICLONE, ZALEPLON, ZOLPIDEM IR. RENEWAL: 1) IMPROVEMENT OF INSOMNIA SYMPTOMS BUT CURRENTLY NOT A CANDIDATE FOR DISCONTINUATION, AND 2) NO CONCURRENT USE WITH Z HYPNOTICS OR BENZODIAZEPINES FOR SLEEP.

Created: 05/22
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 10/21

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DAROLUTAMIDE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DAROLUTAMIDE	NUBEQA	45909		GPI-10 (2140242500)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of non-metastatic castration resistant prostate cancer (nmCRPC) (ICD-10 Z19.2, C61) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #3.
   If no, continue to #2.

2. Does the patient have a diagnosis of metastatic castration-sensitive prostate cancer (mCSPC) (ICD-10 Z19.1, C61) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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DAROLUTAMIDE (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient meet **ONE** of the following criteria?
   - The patient has received a bilateral orchiectomy
   - The patient has a castrate level of testosterone (i.e., less than 50 ng/dL)
   - Nubeqa will be used concurrently with a gonadotropin releasing hormone (GnRH) analog (e.g., Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DAROLUTAMIDE (Nubeqa)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Non-metastatic castration resistant prostate cancer (nmCRPC: prostate cancer that has not spread to other parts of the body and does not respond to hormone therapy)
      2. Metastatic castration-sensitive prostate cancer (mCSPC: prostate cancer that has spread to other parts of the body and responds to hormone therapy)
   B. You are 18 years of age or older
   C. You meet ONE of the following:
      1. You have received a bilateral orchiectomy (both testicles have been surgically removed)
      2. You have a castrate level of testosterone (blood testosterone levels are less than 50 ng/dL)
      3. Nubeqa will be used concurrently (at the same time) with a gonadotropin releasing hormone analog (such as Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DAROLUTAMIDE (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nubeqa.

REFERENCES

Nubeqa [Prescribing Information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; June 2025.

For Part D use only:

DAROLUTAMIDE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	NON-METASTATIC CASTRATION-RESISTANT PROSTATE CANCER (NMCRPC), METASTATIC CASTRATION-SENSITIVE PROSTATE CANCER (MCSPC): 1) RECEIVED A BILATERAL ORCHIECTOMY, 2) CASTRATE LEVEL OF TESTOSTERONE (I.E., LESS THAN 50 NG/DL), OR 3) CONCURRENT USE WITH A GONADOTROPIN RELEASING HORMONE (GNRH) ANALOG.

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Effective: 01/01/26 Client Approval: 12/25 P&T Approval: 10/22

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DASATINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DASATINIB	SPRYCEL, DASATINIB	33855		GPI-10 (2153182000)	BRAND ≠ PHYRAGO

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) (ICD-10 Group C92.1)?

   If yes, continue to #2.
   If no, continue to #4.

2. Is the Ph+ CML in chronic phase (CP) and the patient meets **ONE** of the following criteria?
   - The patient is 18 years of age or older AND is newly diagnosed (e.g., starting or previously started treatment with the requested medication at the time of diagnosis)
   - The patient is between 1 and 17 years of age

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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DASATINIB (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Is the Ph+ CML in chronic, accelerated, myeloid or lymphoid blast phase and the patient meets **ALL** of the following criteria?
- The patient is 18 years of age or older
- The patient has a resistance or intolerance to prior therapy including imatinib (Gleevec)
- The patient had a mutational analysis prior to initiation AND the requested medication is appropriate based onthe NCCN guideline table for treatment recommendations based on BCR-ABL1 mutation profile *(Please see header CML-5 of the current NCCN guidelines)*

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient have a diagnosis of Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) (ICD-10 Group C91.0)?

If yes, continue to #5.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

5. Is the patient 18 years of age or older **AND** has a resistance or intolerance to prior therapy [e.g., imatinib (Gleevec), nilotinib (Tasigna)]?

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #6.

6. Is the patient between 1 and 17 years of age and meets **ALL** of the following criteria?
- The patient is newly diagnosed (e.g., starting or previously started treatment with the requested medication at the time of diagnosis)
- The requested medication will be used in combination with chemotherapy

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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DASATINIB (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DASATINIB (Sprycel)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML: a type of blood cell cancer)
   2. Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL: a type of blood cell cancer)

B. If you have Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase, approval also requires ONE of the following:
   1. You are 18 years of age or older AND you are newly diagnosed (such as you are starting or previously started treatment with the requested medication at the time your condition was identified)
   2. You are between 1 and 17 years of age

C. If you have Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase, accelerated phase, myeloid or lymphoid blast phase, approval also requires:
   1. You are 18 years of age or older
   2. You have resistance (medication no longer works as well) or intolerance (side effect) to prior therapy including imatinib (Gleevec)
   3. You had a mutational analysis (a type of lab test) prior to start of therapy AND the requested medication is appropriate based on the National Comprehensive Cancer Network (NCCN) guideline table for treatment recommendations based on BCR-ABL1 mutation (breakpoint cluster region-Abelson murine leukemia 1: a type of abnormal gene) profile

D. If you have Philadelphia chromosome-positive acute lymphoblastic leukemia, approval also requires ONE of the following:
   1. You are 18 years of age or older AND have a resistance (medication no longer works as well) or intolerance (side effect) to prior therapy (such as imatinib [Gleevec] or nilotinib [Tasigna])
   2. You are between 1 and 17 years of age; you are newly diagnosed (such as you are starting or previously started treatment with the requested medication at the time your condition was identified); AND you will be using the requested medication in combination with chemotherapy (medications used to treat cancer)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DASATINIB (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sprycel.

REFERENCES

Sprycel [Prescribing information]. Princeton, NJ: Bristol-Myers Squibb; July 2024.

For Part D use only:

DASATINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	PREVIOUSLY TREATED PHILADELPHIA CHROMOSOME-POSITIVE CHRONIC MYELOID LEUKEMIA (Ph+ CML): MUTATIONAL ANALYSIS PRIOR TO INITIATION AND DASATINIB IS APPROPRIATE PER NCCN GUIDELINE TABLE FOR TREATMENT RECOMMENDATIONS BASED ON BCR-ABL1 MUTATION PROFILE.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 11/07
Effective: 10/01/25 Client Approval: 09/25 P&T Approval: 01/22

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DASATINIB-PHYRAGO (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DASATINIB	PHYRAGO	33855		GPI-10 (2153182000)	BRAND = PHYRAGO

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) (ICD-10 Group C92.1) **AND** meet the following criterion?
   - The patient has a contraindication to generic dasatinib

   If yes, continue to #2.
   If no, continue to #4.

2. Is the Ph+ CML in chronic phase (CP) and the patient meets **ONE** of the following criteria?
   - The patient is 18 years of age or older AND is newly diagnosed (e.g., starting or previously started treatment with Phyrago at the time of diagnosis)
   - The patient is between 1 and 17 years of age

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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DASATINIB-PHYRAGO (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Is the Ph+ CML in chronic, accelerated, myeloid or lymphoid blast phase, and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a resistance or intolerance to prior therapy including imatinib (Gleevec)
   - The patient had a mutational analysis prior to initiation AND Phyrago is appropriate based on the NCCN guideline table for treatment recommendations based on BCR-ABL1 mutation profile *(Please see header CML-5 of the current NCCN guidelines)*

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient have a diagnosis of Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) (ICD-10 Group C91.0) **AND** meet the following criterion?
   - The patient has a contraindication to generic dasatinib

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Is the patient 18 years of age or older **AND** has a resistance or intolerance to prior therapy (e.g., imatinib [Gleevec], nilotinib [Tasigna])?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #6.

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DASATINIB-PHYRAGO (PART D)

GUIDELINES FOR USE (CONTINUED)

6. Is the patient between 1 and 17 years of age and meets **ALL** of the following criteria?
   - The patient is newly diagnosed (e.g., starting or previously started treatment with Phyrago at the time of diagnosis)
   - Phyrago will be used in combination with chemotherapy

   If yes, **approve for 12 months by HICL or GPI-10**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DASATINIB (Phyrago)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML: a type of blood cell cancer)
      2. Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL: a type of blood cell cancer)

   B. If you have Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase, approval also requires:
      1. You have a contraindication to (harmful for you to use) generic dasatinib
      2. You meet ONE of the following:
         a. You are 18 years of age or older AND you are newly diagnosed (such as you are starting or previously started treatment with Phyrago at the time your condition was identified)
         b. You are between 1 and 17 years of age

   C. If you have Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase, accelerated phase, myeloid or lymphoid blast phase, approval also requires:
      1. You are 18 years of age or older
      2. You have a contraindication to (harmful for you to use) generic dasatinib
      3. You have resistance (medication no longer works) or intolerance (side effect) to prior therapy including imatinib (Gleevec)
      4. You had a mutational analysis (a type of lab test) prior to the start of therapy AND Phyrago is appropriate based on the National Comprehensive Cancer Network (NCCN) guideline table for treatment recommendations based on BCR-ABL1 mutation (breakpoint cluster region-Abelson murine leukemia 1: a type of abnormal gene) profile

   (Denial text continued on next page)

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DASATINIB-PHYRAGO (PART D)

GUIDELINES FOR USE (CONTINUED)

D. If you have Philadelphia chromosome-positive acute lymphoblastic leukemia, approval also requires:

1. You have a contraindication to (harmful for you to use) generic dasatinib
2. You meet ONE of the following:
   a. You are 18 years of age or olderAND have a resistance (medication no longer works) or intolerance (side effect) to prior therapy (such as imatinib [Gleevec], nilotinib [Tasigna])
   b. You are between 1 and 17 years of age; you are newly diagnosed (such as you are starting or previously started treatment with Phyrago at the time your condition was identified); AND you will be using Phyrago in combination with chemotherapy (medications used to treat cancer)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Phyrago.

REFERENCES

Phyrago [Prescribing information]. San Jose, CA: Handa Therapeutics, LLC; August 2025.

For Part D use only:

DASATINIB-PHYRAGO (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	PREVIOUSLY TREATED PHILADELPHIA CHROMOSOME-POSITIVE CHRONIC MYELOID LEUKEMIA (PH+ CML): MUTATIONAL ANALYSIS PRIOR TO INITIATION AND DASATINIB IS APPROPRIATE PER NCCN GUIDELINE TABLE FOR TREATMENT RECOMMENDATIONS BASED ON BCR-ABL1 MUTATION PROFILE.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	ALL INDICATIONS: CONTRAINDICATION TO GENERIC DASATINIB.

Created: 09/25
Effective: 10/01/25 Client Approval: 09/25 P&T Approval: 01/22

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DATOPOTAMAB DERUXTECAN-DLNK (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DATOPOTAMAB DERUXTECAN-DLNK	DATROWAY	50179		GPI-10 (2155102020)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic breast cancer (ICD-10 Group C50) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient's cancer is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative (IHC 0, IHC 1+, or IHC 2+/ISH-) AND the patient has received prior endocrine-based therapy (e.g., letrozole, anastrozole, tamoxifen) and chemotherapy for unresectable or metastatic disease
   - The patient's cancer is triple-negative (TNBC) AND the patient is not a candidate for PD-1/PD-L1 inhibitor therapy (e.g., Keytruda [pembrolizumab])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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DATOPOTAMAB DERUXTECAN-DLNK (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer is epidermal growth factor receptor (EGFR)-mutated
   - The patient has received prior EGFR-directed therapy (e.g., Tagrisso [osimertinib]) and platinum-based chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DATOPOTAMAB DERUXTECAN-DLNK (Datroway)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Unresectable or metastatic breast cancer (a type of breast cancer that cannot be removed by surgery or has spread to other parts of the body)
      2. Locally advanced or metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread from where it started to nearby tissue/lymph nodes or to other parts of the body)

   B. If you have unresectable or metastatic breast cancer, approval also requires:
      1. You are 18 years of age or older
      2. You meet ONE of the following:
         a. Your cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative (IHC 0, IHC 1+, or IHC 2+/ISH- [type of lab test]) AND you had prior endocrine (hormone)-based therapy (such as letrozole, anastrozole, tamoxifen) and chemotherapy (medications used to treat cancer) for unresectable or metastatic disease
         b. Your cancer is triple-negative (TNBC: a type of breast cancer) AND you are not a candidate for PD-1 (programmed cell death 1: a type of protein)/PD-L1 (programmed death-ligand 1: a type of protein) inhibitor therapy (such as Keytruda [pembrolizumab])

   (Denial text continued on next page)

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DATOPOTAMAB DERUXTECAN-DLNK (PART D)

GUIDELINES FOR USE (CONTINUED)

C. If you have locally advanced or metastatic non-small cell lung cancer, approval also requires:

1. You are 18 years of age or older
2. Your cancer is epidermal growth factor receptor (EGFR: a type of protein)-mutated (abnormal change in a type of gene)
3. You have received prior epidermal growth factor receptor (EGFR: a type of protein)-directed therapy (such as Tagrisso [osimertinib]) and platinum-based chemotherapy (such as cisplatin, carboplatin, oxaliplatin)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Datroway.

REFERENCES

Datroway [Prescribing Information]. Basking Ridge, NJ: Daiichi Sankyo, Inc.; May 2026.

For Part D use only:

DATOPOTAMAB DERUXTECAN-DLNK (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 01/25
Effective: 06/24/26 Client Approval: 06/26 DMC Approval: 06/16/26

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DAXIBOTULINUMTOXINA-LANM BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DAXIBOTULINUMTOXINA-LANM	DAXXIFY	48287		GPI-10 (7440002015)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	Yes	No	No	Yes	No	No	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #5.

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DAXIBOTULINUMTOXINA-LANM BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override)**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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DAXIBOTULINUMTOXINA-LANM BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the request for treatment of a cosmetic indication (e.g., wrinkles - glabellar lines, lateral canthal lines, forehead lines) (ICD-10 L98.8; Group L81)?

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of cervical dystonia (ICD-10 G24.3) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Dysport (abobotulinumtoxinA), Myobloc (rimabotulinumtoxinB), Xeomin (incobotulinumtoxinA)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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DAXIBOTULINUMTOXINA-LANM BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DAXIBOTULINUMTOXINA-LANM (Daxxify)** requires the following rule(s) be met for approval:

A. You have cervical dystonia (a type of muscle condition)
B. You are 18 years of age or older
C. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Dysport (abobotulinumtoxinA), Myobloc (rimabotulinumtoxinB), Xeomin (incobotulinumtoxinA)

NOTE: This medication will not be approved for the treatment of a cosmetic indication (such as wrinkles - glabellar [between the eyebrows] lines, lateral canthal [outer corner of eye] lines, forehead lines).

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Daxxify. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Daxxify [Prescribing Information]. Newark, CA: Revance Therapeutics, Inc.; November 2023.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed January 9, 2026].

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DAXIBOTULINUMTOXINA-LANM BVD (PART D)

For Part D use only:

DAXIBOTULINUMTOXINA-LANM (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	COSMETIC DIAGNOSIS.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	CERVICAL DYSTONIA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: DYSPORT, MYOBLOC, XEOMIN.

Created: 01/26
Effective: 01/26/26 Client Approval: 01/26 P&T Approval: 10/23

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DECITABINE/CEDAZURIDINE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DECITABINE/ CEDAZURIDINE	INQOVI	46686		GPI-10 (2199000225)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of myelodysplastic syndromes (MDS) (ICD-10 Group D46) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has an International Prognostic Scoring System (IPSS) group of intermediate-1, intermediate-2, or high-risk

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of chronic myelomonocytic leukemia (CMML) (ICD-10 C93.1) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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DECITABINE/CEDAZURIDINE (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of acute myeloid leukemia (AML) (ICD-10 Group C92.0) and meet **ALL** of the following criteria?
   - The patient is newly diagnosed (e.g., starting or previously started Inqovi treatment at the time of diagnosis)
   - Inqovi will be used in combination with Venclexta (venetoclax)

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient meet **ONE** of the following criteria?
   - The patient is 75 years of age or older
   - The patient is 18 years of age or older with comorbidities that preclude the use of intensive induction chemotherapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DECITABINE/CEDAZURIDINE (Inqovi)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Myelodysplastic syndromes (MDS: a type of blood cancer)
      2. Chronic myelomonocytic leukemia (CMML: a type of blood cancer)
      3. Acute myeloid leukemia (AML: a type of blood and bone marrow cancer)

   B. If you have myelodysplastic syndromes, approval also requires:
      1. You are 18 years of age or older
      2. You have an International Prognostic Scoring System (IPSS: a tool for evaluating severity of myelodysplastic syndrome) group of intermediate-1, intermediate-2, or high-risk

   C. If you have chronic myelomonocytic leukemia, approve also requires:
      1. You are 18 years of age or older

   (Denial text continued on next page)

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DECITABINE/CEDAZURIDINE (PART D)

GUIDELINES FOR USE (CONTINUED)

D. If you have acute myeloid leukemia, approval also requires:

1. You are newly diagnosed (such as you are starting or previously started Inqovi treatment at the time your condition was identified)
2. Inqovi will be used in combination with Venclexta (venetoclax)
3. You meet ONE of the following:
   a. You are 75 years of age or older
   b. You are 18 years of age or older with comorbidities (additional diseases) that prevent the use of intensive induction chemotherapy (a type of therapy to treat cancer)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Inqovi.

REFERENCES

Inqovi [Prescribing Information]. Princeton, NJ: Taiho Oncology, Inc.; May 2026.

For Part D use only:

DECITABINE/CEDAZURIDINE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 08/20
Effective: 06/10/26 Client Approval: 06/26 DMC Approval: 05/27/26

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DEFERASIROX (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DEFERASIROX	EXJADE, JADENU, JADENU SPRINKLE, DEFERASIROX	33337		GPI-10 (9310002500)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of chronic iron overload due to blood transfusions (transfusion dependent) (ICD-10 E83.111) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a hematologist or hematologist/oncologist
   - The patient has serum ferritin levels that are consistently greater than 1000 mcg/L

   If yes, continue to #3.
   If no, continue to #2.

2. Does the patient have a diagnosis of thalassemia (ICD-10 Group D56) and meet **ALL** of the following criteria?
   - The patient is 10 years of age or older
   - The patient has chronic iron overload resulting from non-transfusion dependent thalassemia (NTDT) syndrome
   - Therapy is prescribed by or in consultation with a hematologist or hematologist-oncologist
   - The patient has serum ferritin levels that are consistently greater than 300 mcg/L (at least two lab values in the previous 3 months)
   - The patient has a liver iron concentration (LIC) of at least 5 mg Fe/g of liver dry weight

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at end of guideline.

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DEFERASIROX (PART D)

INITIAL CRITERIA (CONTINUED)

3. Is the request for Exjade (deferasirox) tablet for oral suspension or Jadenu (deferasirox) tablets?

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths of both Exjade (deferasirox) tablet for oral suspension and Jadenu (deferasirox) tablets.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

4. Is the request for Jadenu (deferasirox) sprinkle packets **AND** the patient meets the following criterion?
   - The patient had a trial of or contraindication to generic deferasirox tablet OR deferasirox tablet for oral suspension

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DEFERASIROX (Exjade, Jadenu, Jadenu Sprinkle)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Chronic iron overload due to blood transfusions (too much iron in the body caused by blood transfers)
      2. Thalassemia (a type of blood disorder)

   B. If you have chronic iron overload due to blood transfusions, approval also requires:
      1. You are 2 years of age or older
      2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or hematologist/oncologist (a type of cancer doctor)
      3. Your serum ferritin levels (a type of lab test) are consistently greater than 1000 mcg/L

   (Initial denial text continued on next page)

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DEFERASIROX (PART D)

INITIAL CRITERIA (CONTINUED)

C. If you have thalassemia, approval also requires:
1. You are 10 years of age or older
2. You have chronic iron overload (too much iron in the body) resulting from non-transfusion dependent thalassemia (NDDT: type of blood disorder that does not require regular blood transfusion) syndrome
3. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or hematologist-oncologist (a type of cancer doctor)
4. Your serum ferritin levels (a type of lab test) are consistently greater than 300 mcg/L (at least TWO lab values in the previous 3 months)
5. You have a liver iron concentration (LIC) of at least 5 mg of iron per gram (Fe/g) of liver dry weight

D. If you are requesting Jadenu (deferasirox) sprinkle packets, approval also requires:
1. You have tried or have a contraindication to (harmful for you to use) generic deferasirox tablet OR deferasirox tablet for oral suspension

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DEFERASIROX (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of chronic iron overload due to blood transfusions (ICD-10 E83.111) **AND** meet the following criterion?
   - The patient has serum ferritin levels that are consistently greater than 500 mcg/L

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of thalassemia (ICD-10 Group D56) and meet **ONE** of the following criteria?
   - The patient has serum ferritin levels that are consistently greater than 300 mcg/L (at least two lab values in the previous 3 months)
   - The patient has a liver iron concentration (LIC) of at least 3 mg Fe/g of liver dry weight (*Liver iron concentration supersedes serum ferritin level when both measurements are available*)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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DEFERASIROX (PART D)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DEFERASIROX (Exjade, Jadenu, Jadenu Sprinkle)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Chronic iron overload due to blood transfusions (too much iron in the body caused by blood transfers)
   2. Thalassemia (a type of blood disorder)

B. If you have chronic iron overload due to blood transfusions, renewal also requires:
   1. Your serum ferritin levels (a type of lab test) are consistently greater than 500 mcg/L

C. If you have thalassemia, renewal also requires ONE of the following:
   1. Your serum ferritin levels (a type of lab test) are consistently greater than 300 mcg/L (at least TWO lab values in the previous 3 months)
   2. You have a liver iron concentration (LIC) of at least 3 mg of iron per gram (Fe/g) of liver dry weight

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the prescribing information and/or drug monograph for Exjade and Jadenu.

REFERENCES

Jadenu [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2020.

Exjade [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2020.

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DEFERASIROX (PART D)

For Part D use only:

DEFERASIROX (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	INITIAL: CHRONIC IRON OVERLOAD DUE TO BLOOD TRANSFUSIONS: SERUM FERRITIN LEVEL CONSISTENTLY ABOVE 1000 MCG/L. CHRONIC IRON OVERLOAD IN NON-TRANSFUSION DEPENDENT THALASSEMIA (NTDT): 1) SERUM FERRITIN LEVEL CONSISTENTLY ABOVE 300 MCG/L (AT LEAST TWO LAB VALUES IN THE PREVIOUS THREE MONTHS), AND 2) LIVER IRON CONCENTRATION (LIC) OF 5 MG FE/G OF LIVER DRY WEIGHT OR GREATER. RENEWAL: CHRONIC IRON OVERLOAD DUE TO BLOOD TRANSFUSIONS: SERUM FERRITIN LEVEL CONSISTENTLY ABOVE 500 MCG/L. NTDT: 1) SERUM FERRITIN LEVEL CONSISTENTLY ABOVE 300 MCG/L (AT LEAST TWO LAB VALUES IN THE PREVIOUS THREE MONTHS) OR 2) LIC OF 3 MG FE/G OF LIVER DRY WEIGHT OR GREATER.
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: CHRONIC IRON OVERLOAD DUE TO BLOOD TRANSFUSIONS OR NTDT: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR HEMATOLOGIST/ONCOLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: CHRONIC IRON OVERLOAD DUE TO BLOOD TRANSFUSIONS OR NTDT: DEFERASIROX SPRINKLE PACKETS: TRIAL OF OR CONTRAINDICATION TO GENERIC DEFERASIROX ORAL TABLET OR TABLET FOR ORAL SUSPENSION.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DEFERIPRONE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DEFERIPRONE	FERRIPROX, DEFERIPRONE	18544		GPI-10 (9310002800)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of thalassemia (ICD-10 Group D56) and meet **ALL** of the following criteria?
   - The patient has transfusional iron overload
   - Therapy is prescribed by or in consultation with a hematologist or hematologist-oncologist

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient had a trial of, contraindication to, intolerable toxicities with, or clinically significant adverse effects with a formulary version of deferasirox (Exjade, Jadenu) OR deferoxamine (Desferal)
   - The patient's current chelation therapy (i.e., Exjade [deferasirox], Jadenu [deferasirox], or Desferal [deferoxamine]) is inadequate

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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DEFERIPRONE (PART D)

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of sickle cell disease (ICD-10 Group D57) or anemia (ICD-10 Group D64) and meet **ALL** of the following criteria?
   - The patient has transfusional iron overload
   - Therapy is prescribed by or in consultation with a hematologist or hematologist-oncologist
   - The patient had a trial of or contraindication to a formulary version of deferasirox (Exjade, Jadenu) OR deferoxamine (Desferal)

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Is the request for Ferriprox (deferiprone) tablets **AND** the patient meets the following criterion?
   - The patient is 8 years of age or older

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Is the request for Ferriprox (deferiprone) oral solution **AND** the patient meets the following criterion?
   - The patient is 3 years of age or older

   If yes, **approve for 6 months by GPID or GPI-14 for the oral solution formulation.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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DEFERIPRONE (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DEFERIPRONE (Ferriprox)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Thalassemia (a blood disorder)
   2. Sickle cell disease (a type of blood disorder)
   3. Anemia (a type of blood disorder)

B. If you have thalassemia, approval also requires:
   1. You have transfusional iron overload (too much iron in the body caused by blood transfusions)
   2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or hematologist-oncologist (a type of cancer doctor)
   3. You meet ONE of the following:
      a. You had a trial of, contraindication to (harmful for you to use), intolerable toxicities with, or clinically significant adverse effects with a formulary version of deferasirox (Exjade, Jadenu) OR deferoxamine (Desferal)
      b. Your current chelation therapy (a type of drug that lowers iron level) (Exjade [deferasirox], Jadenu [deferasirox], or Desferal [deferoxamine]) is not working well enough

C. If you have sickle cell disease or anemia, approval also requires:
   1. You have transfusional iron overload (too much iron in the body caused by blood transfusions)
   2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or hematologist-oncologist (a type of cancer doctor)
   3. You have tried or have a contraindication to (harmful for you to use) a formulary version of deferasirox (Exjade, Jadenu) OR deferoxamine (Desferal)

D. If the request is for Ferriprox (deferiprone) tablets, approval also requires:
   1. You are 8 years of age or older

E. If the request is for Ferriprox (deferiprone) oral solution, approval also requires:
   1. You are 3 years of age or older

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DEFERIPRONE (PART D)

RENEWAL CRITERIA

1. Does the patient have **ONE** of the following diagnoses?
   - Thalassemia (ICD-10 Group D56)
   - Sickle cell disease (ICD-10 Group D57)
   - Anemia (ICD-10 Group D64)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet the following criterion?
   - The patient's serum ferritin levels are consistently above 500 mcg/L (at least two lab values in the previous 3 months)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

3. Is the request for Ferriprox (deferiprone) tablets **AND** the patient meets the following criterion?
   - The patient is 8 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

4. Is the request for Ferriprox (deferiprone) oral solution **AND** the patient meets the following criterion?
   - The patient is 3 years of age or older

   If yes, **approve for 12 months by GPID or GPI-14 for the oral solution formulation.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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DEFERIPRONE (PART D)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DEFERIPRONE (Ferriprox)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Thalassemia (a type of blood disorder)
   2. Sickle cell disease (a type of blood disorder)
   3. Anemia (a type of blood disorder)

B. Your serum ferritin levels (a type of lab test) are consistently above 500 mcg/L (at least TWO lab values in the previous 3 months)

C. If the request is for Ferriprox (deferiprone) tablets, renewal also requires:
   1. You are 8 years of age or older

D. If the request is for Ferriprox (deferiprone) oral solution, renewal also requires:
   1. You are 3 years of age or older

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ferriprox.

REFERENCES

Ferriprox Tablets [Prescribing Information]. Toronto, Ontario, Canada: Apotex Inc.; July 2023.
Ferriprox Oral Solution [Prescribing Information]. Toronto, Ontario, Canada: Apotex Inc.; November 2021.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DEFERIPRONE (PART D)

For Part D Use only:

DEFERIPRONE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	TRANSFUSIONAL IRON OVERLOAD: RENEWAL: SERUM FERRITIN LEVELS CONSISTENTLY ABOVE 500 MCG/L (AT LEAST TWO LAB VALUES IN THE PREVIOUS THREE MONTHS).
Age Restrictions	N/A
Prescriber Restrictions	TRANSFUSIONAL IRON OVERLOAD: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR HEMATOLOGIST/ONCOLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: TRANSFUSIONAL IRON OVERLOAD DUE TO THALASSEMIA SYNDROMES: 1) TRIAL OF, CONTRAINDICATION, INTOLERABLE TOXICITIES, OR CLINICALLY SIGNIFICANT ADVERSE EFFECTS TO A FORMULARY VERSION OF DEFERASIROX OR DEFEROXAMINE, OR 2) CURRENT CHELATION THERAPY (I.E., FORMULARY VERSION OF DEFERASIROX OR DEFEROXAMINE) IS INADEQUATE. TRANSFUSIONAL IRON OVERLOAD DUE TO SICKLE CELL DISEASE OR OTHER ANEMIAS: TRIAL OF OR CONTRAINDICATION TO A FORMULARY VERSION OF DEFERASIROX OR DEFEROXAMINE.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DEFEROXAMINE BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DEFEROXAMINE MESYLATE	DESFERAL MESYLATE , DEFEROXAMINE MESYLATE	01104		GPI-10 (9300002010)	

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Does the patient have a diagnosis of end stage renal disease (ESRD) (ICD-10 N18.6) and is on dialysis?

   If yes, please process as follows:

   CSR Note: If the caller is a physician, member, and/or AOR, please initiate a verbal PA intake request in MR3. If the caller is a pharmacy, please advise the pharmacy to bill the medication as part of the bundled dialysis facility payment or that the pharmacy contact the provider or member to submit a PA for further review.

   PAC Note: Please defer to a pharmacist for denial.

   Clinical specialist Note: This medication is included in the bundled dialysis facility payment and is not a Part D eligible drug. Please follow the process within the HQ notes and internal procedures for denial.

   If no, continue to #2.

2. Is this a pharmacy call?

   If yes, continue to #4.
   If no, continue to #3.

3. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #4.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

4. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, continue to #7.
   If no, continue to #5.

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DEFEROXAMINE BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, continue to #7.
   If no, continue to #6.

6. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field). If MI does not process Part B for the client, refer the caller/request back to the Health plan).**

7. Is the drug administered via an implantable pump?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field. If MI does not process Part B for the client, refer the caller/request back to the Health plan).**

   If no, continue to #8.

8. Is the drug administered via an external pump?

   If yes, continue to #9.
   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

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DEFEROXAMINE BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

9. Is the drug specifically infused through an external infusion pump covered by Medicare?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field. If MI does not process Part B for the client, refer the caller/request back to the Health plan).**

   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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DEFEROXAMINE BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of acute iron intoxication (ICD-10 Group T45.4)?

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of transfusional iron overload with chronic anemia and meet **ALL** of the following criteria?
   - The patient is 3 years of age or older
   - Therapy is prescribed by or in consultation with a hematologist or hematologist-oncologist
   - The patient's serum ferritin levels are consistently greater than 1000 mcg/L (at least two lab values in the previous 3 months)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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DEFEROXAMINE BvD (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DEFEROXAMINE (Desferal)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Acute (short-term) iron intoxication
   2. Transfusional iron overload with chronic anemia (too much iron in the body caused by blood transfusions due to a long-term blood condition)

B. If you have transfusional iron overload with chronic anemia, approval also requires:
   1. You are 3 years of age or older
   2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or hematologist-oncologist (a type of cancer doctor)
   3. Your serum ferritin levels (a type of lab test) are consistently greater than 1000 mcg/L (at least TWO lab values in the previous 3 months)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DEFEROXAMINE BvD (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of acute iron intoxication (ICD-10 Group T45.4)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of transfusional iron overload with chronic anemia **AND** meet the following criterion?
   - The patient's serum ferritin levels are consistently greater than 500 mcg/L (at least two lab values in the previous 3 months)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DEFEROXAMINE (Desferal)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Acute (short-term) iron intoxication
      2. Transfusional iron overload with chronic anemia (too much iron in the body caused by blood transfusions due to a long-term blood condition)

   B. If you have transfusional iron overload with chronic anemia, renewal also requires:
      1. Your serum ferritin levels (a type of lab test) are consistently greater than 500 mcg/L (at least two lab values in the previous 3 months)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DEFEROXAMINE BvD (PART D)

RATIONALE

For further information, please refer to the prescribing information and/or Drug monograph for Desferal.

The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B. Drugs administered by an implantable pump are covered under Part B. Drugs administered via an external pump are covered under Part B if they are included under the local coverage policy of the applicable Medicare coverage policies (National and/or Local Coverage Policies). Drugs administered via an external pump that are not included under the applicable Medicare coverage policies are covered under Part D. A CMS website to assist with National and Local Coverage Determination for B versus D review is http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Patients identified as Part D End Stage Renal Disease (ESRD) undergoing dialysis will be directed to a dialysis treatment center and have their ESRD treatment related drug included in the bundled dialysis facility payment.

REFERENCES

Desferal [Package Insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2022.

deferoxamine mesylate [Package Insert]. Lake Forest, IL: Hospira, Inc.; November 2023.

Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed April 4, 2024].

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DEFEROXAMINE BvD (PART D)

For Part D use only:

DEFEROXAMINE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	TRANSFUSIONAL IRON OVERLOAD DUE TO CHRONIC ANEMIA: INITIAL: SERUM FERRITIN LEVELS CONSISTENTLY ABOVE 1000 MCG/L (AT LEAST TWO LAB VALUES IN THE PREVIOUS THREE MONTHS). RENEWAL: SERUM FERRITIN LEVELS CONSISTENTLY ABOVE 500 MCG/L (AT LEAST TWO LAB VALUES IN THE PREVIOUS THREE MONTHS).
Age Restrictions	TRANSFUSIONAL IRON OVERLOAD DUE TO CHRONIC ANEMIA: INITIAL: 3 YEARS OR OLDER.
Prescriber Restrictions	TRANSFUSIONAL IRON OVERLOAD DUE TO CHRONIC ANEMIA: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR HEMATOLOGIST/ONCOLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	THIS DRUG MAY BE EITHER BUNDLED WITH AND COVERED UNDER END STAGE RENAL DISEASE DIALYSIS RELATED SERVICES OR COVERED UNDER MEDICARE D DEPENDING UPON THE CIRCUMSTANCES.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DEFLAZACORT (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DEFLAZACORT	EMFLAZA , DEFLAZACORT, JAYTHARI, KYMBEE, PYQUVI	11668		GPI-10 (2210001700)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Duchenne muscular dystrophy (DMD) (ICD-10 G71.01) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient's diagnosis of DMD is confirmed by genetic testing

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Has the patient tried prednisone or prednisolone?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Did the patient experience an adverse effect (e.g., weight gain) on prednisone or prednisolone?

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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DEFLAZACORT (PART D)

INITIAL CRITERIA (CONTINUED)

4. Did the patient experience a lack of efficacy with prednisone or prednisolone and meets **ALL** of the following criteria?
   - The patient is not in Stage 1 of the disease (the pre-symptomatic phase)
   - Steroid myopathy has been ruled out
   - The patient has experienced deterioration in ambulation, functional status, or pulmonary function that is consistent with advancing disease

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DEFLAZACORT (Emflaza, Jaythari, Kymbee, Pyquvi)** requires the following rule(s) be met for approval:
   A. You have Duchenne muscular dystrophy (DMD: a type of muscle disorder)
   B. You are 2 years of age or older
   C. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
   D. Your diagnosis of Duchenne muscular dystrophy is confirmed by genetic testing
   E. You have tried prednisone or prednisolone and meet ONE of the following:
      1. You have experienced an adverse effect (side effects such as weight gain) on prednisone or prednisolone
      2. Prednisone or prednisolone did not work for you, and you meet ALL of the following:
         a. You are not in Stage 1 of the disease (the pre-symptomatic phase)
         b. There is no steroid myopathy (muscle disease due to steroid use)
         c. You have experienced a decrease in your walking, functional status, or breathing that is consistent with advancing disease

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DEFLAZACORT (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Duchenne muscular dystrophy (DMD) (ICD-10 G71.01)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Has the patient maintained or demonstrated a less than expected decline in ambulatory ability in muscle function assessments [e.g., 6-minute walking distance (6MWD), time to ascend/descend 4 stairs, rise from floor time (Gower's maneuver), 10-meter run/walk time, North Star Ambulatory Assessment (NSAA), Physician global Assessments (PGA)]?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Has the patient maintained or demonstrated a less than expected decline in other muscle function assessments [e.g., pulmonary function (FVC, PFTs), cardiac function, upper limb strength measures (propelling a wheelchair 30 feet), Physician Global Assessments (PGA)]?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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DEFLAZACORT (PART D)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DEFLAZACORT (Emflaza, Jaythari, Kymbee, Pyquvi)** requires the following rule(s) be met for renewal:

A. You have Duchenne muscular dystrophy (DMD: a type of muscle disorder)
B. You meet ONE of the following:
    1. You have maintained or have a less than expected decrease in your ability to walk in muscle function tests [such as 6-minute walking distance (6MWD), time to ascend/descend 4 stairs, rise from floor time (Gower's maneuver), 10-meter run/walk time, North Star Ambulatory Assessment (NSAA), Physician global Assessments (PGA)]
    2. You have maintained or have a less than expected decrease in other muscle function tests [such as pulmonary (breathing) function (FVC, PFTs), cardiac (heart) function, upper limb strength measures (propelling a wheelchair 30 feet), Physician Global Assessments (PGA)]

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Emflaza, Jaythari, Kymbee, and Pyquvi.

REFERENCES

Emflaza [Prescribing Information]. Warren, NJ: PTC Therapeutics, Inc.; June 2024.
Jaythari [PrescribingInformation]. Pennington, NJ: Zydus Pharmaceuticals (USA), Inc.; May 2025.
Kymbee [Prescribing Information]. Maple Grove, MN: Upsher-Smith Laboratories, LLC; July 2025.
Pyquvi [Prescribing Information]. Piscataway, NJ: Aucta Pharmaceuticals, Inc.; February 2025.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DEFLAZACORT (PART D)

For Part D use only:

DEFLAZACORT (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	DUCHENNE MUSCULAR DYSTROPHY (DMD): INITIAL: DIAGNOSIS CONFIRMED BY GENETIC TESTING.
Age Restrictions	N/A
Prescriber Restrictions	DMD: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	DMD: INITIAL: TRIAL OF PREDNISONE OR PREDNISOLONE AND EXPERIENCED: 1) ADVERSE EFFECTS FROM PREDNISONE OR PREDNISOLONE, OR 2) LACK OF EFFICACY WITH PREDNISONE OR PREDNISOLONE AND: (A) PATIENT IS NOT IN STAGE 1 (PRE-SYMPTOMATIC PHASE), (B) STEROID MYOPATHY HAS BEEN RULED OUT, AND (C) DETERIORATION IN AMBULATION, FUNCTIONAL STATUS, OR PULMONARY FUNCTION CONSISTENT WITH ADVANCING DISEASE. RENEWAL: MAINTAINED OR DEMONSTRATED A LESS THAN EXPECTED DECLINE IN AMBULATORY ABILITY IN MUSCLE FUNCTION ASSESSMENTS OR OTHER MUSCLE FUNCTION ASSESSMENTS (E.G., PULMONARY OR CARDIAC FUNCTION).

Created: 02/17
Effective: 12/01/25 Client Approval: 11/25 P&T Approval: 07/19

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DELAFLOXACIN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DELAFLOXACIN MEGLUMINE	BAXDELA		43532	GPI-14 (05000025100320)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of an acute bacterial skin and skin structure infection (ABSSSI) and meet **ALL** of the following?
   - The patient is 18 years of age or older
   - The patient's ABSSSI infection is caused by any of the following susceptible microorganisms: *Staphylococcus aureus (including methicillin-resistant [MRSA] and methicillin-susceptible [MSSA] isolates), Staphylococcus haemolyticus*, *Staphylococcus lugdunensis, Streptococcus agalactiae*, *Streptococcus anginosus Group (including Streptococcus anginosus, Streptococcus intermedius, and Streptococcus constellatus), Streptococcus pyogenes, Enterococcus faecalis, Escherichia coli, Enterobacter cloacae, Klebsiella pneumoniae,* or *Pseudomonas aeruginosa*

   If yes, continue to #2.
   If no, continue to #5.

2. Is therapy prescribed by or in consultation with an infectious disease (ID) specialist?

   If yes, **approve for 1 month by HICL or GPI-10 for one fill.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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DELAFLOXACIN (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Has an antimicrobial susceptibility test been performed that meets **ALL** of the following criteria?
   - The results from the infection site culture indicate pathogenic organism(s) with resistance to ONE standard of care agent for ABSSSI (e.g., sulfamethoxazole/trimethoprim, levofloxacin, clindamycin, cephalexin, vancomycin)
   - The results from the infection site culture indicate pathogenic organism(s) with susceptibility to Baxdela

   If yes, **approve for 1 month by HICL or GPI-10 for one fill.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

4. Does the patient meet **ALL** of the following criteria?
   - Antimicrobial susceptibility results are unavailable
   - The patient had a trial of or contraindication to ONE of the following agents for ABSSSI:
     - Gram positive targeting antibiotic (e.g., linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin)
     - Penicillin antibiotic (e.g., amoxicillin)
     - Fluoroquinolone antibiotic (e.g., levofloxacin, ciprofloxacin, moxifloxacin)
     - Cephalosporin antibiotic (e.g., ceftriaxone, cephalexin, cefazolin)

   If yes, **approve for 1 month by HICL or GPI-10 for one fill.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Does the patient have a diagnosis of community-acquired bacterial pneumonia (CABP) (ICD-10 J15.9) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's CABP infection is caused by any of the following susceptible microorganisms: *Streptococcus pneumoniae, Staphylococcus aureus (methicillin-susceptible* [MSSA] *isolates only), Klebsiella pneumoniae, Escherichia coli, Pseudomonas aeruginosa, Haemophilus influenzae, Haemophilus parainfluenzae, Chlamydia pneumoniae, Legionella pneumophila,* or *Mycoplasma pneumoniae*

   If yes, continue to #6.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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DELAFLOXACIN (PART D)

GUIDELINES FOR USE (CONTINUED)

6. Is the request for continuation of care from an inpatient setting?

   If yes, **approve for 1 month by HICL or GPI-10 for one fill.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #7.

7. Is therapy prescribed by or in consultation with an infectious disease (ID) specialist?

   If yes, **approve for 1 month by HICL or GPI-10 for one fill.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #8.

8. Has an antimicrobial susceptibility test been performed that meets **ALL** of the following criteria?
   - The results from the infection site culture indicate pathogenic organism(s) with resistance to TWO standard of care agents for CABP (e.g., macrolide [e.g., azithromycin], doxycycline, alternative fluoroquinolone [e.g., levofloxacin, moxifloxacin], beta-lactam [e.g., amoxicillin, ceftriaxone], linezolid)
   - The results from the infection site culture indicate pathogenic organism(s) with susceptibility to Baxdela

   If yes, **approve for 1 month by HICL or GPI-10 for one fill.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #9.

9. Does the patient meet **ALL** of the following criteria?
   - Antimicrobial susceptibility results are unavailable
   - The patient had a trial of or contraindication to TWO standard of care agents for CABP (e.g., macrolide [azithromycin], doxycycline, levofloxacin, moxifloxacin, beta-lactam [amoxicillin, ceftriaxone], linezolid)

   If yes, **approve for 1 month by HICL or GPI-10 for one fill.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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DELAFLOXACIN (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DELAFLOXACIN (Baxdela)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Acute bacterial skin and skin structure infection (ABSSSI: a type of skin condition)
   2. Community-acquired bacterial pneumonia (CABP: type of lung infection)

B. If you have an acute bacterial skin and skin structure infection, approval also requires:
   1. You are 18 years of age or older
   2. Your infection is caused by any of the following bacteria: Staphylococcus aureus (including methicillin-resistant [MRSA] and methicillin-susceptible [MSSA] isolates), Staphylococcus haemolyticus, Staphylococcus lugdunensis, Streptococcus agalactiae, Streptococcus anginosus Group (including Streptococcus anginosus, Streptococcus intermedius, and Streptococcus constellatus), Streptococcus pyogenes, Enterococcus faecalis, Escherichia coli, Enterobacter cloacae, Klebsiella pneumoniae, or Pseudomonas aeruginosa
   3. You meet ONE of the following:
      a. Therapy is prescribed by or in consultation with an infectious disease specialist (a doctor who specializes in the treatment of infections)
      b. Your antimicrobial susceptibility testing (lab test that shows what medications work on which bacteria) shows ALL of the following:
         i. The bacteria at the infection site are resistant (medication will not work for that bacteria) to ONE standard of care medication for acute bacterial skin and skin structure infection (such as sulfamethoxazole/trimethoprim, levofloxacin, clindamycin, cephalexin, vancomycin)
         ii. Baxdela will work against the bacteria
      c. If antimicrobial susceptibility results (lab test that shows what medications work on which bacteria) are not available, approval requires that you had a trial of or contraindication to (harmful for you to use) ONE of the following medications for acute bacterial skin and skin structure infection: a penicillin (such as amoxicillin), a fluoroquinolone (such as levofloxacin, ciprofloxacin, moxifloxacin), a cephalosporin (such as ceftriaxone, cephalexin, cefazolin), or a gram positive targeting antibiotic (such as linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin)

(Denial text continued on next page)

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DELAFLOXACIN (PART D)

GUIDELINES FOR USE (CONTINUED)

C. If you have community-acquired bacterial pneumonia, approval also requires:

1. You are 18 years of age or older
2. Your infection is caused by any of the following bacteria: Streptococcus pneumoniae, Staphylococcus aureus (methicillin-susceptible [MSSA] isolates only), Klebsiella pneumoniae, Escherichia coli, Pseudomonas aeruginosa, Haemophilus influenzae, Haemophilus parainfluenzae, Chlamydia pneumoniae, Legionella pneumophila or Mycoplasma pneumoniae
3. You meet ONE of the following:
   a. Your request is for continuation of care from an inpatient setting (a healthcare facility where medical treatment is given overnight or longer)
   b. Therapy is prescribed by or in consultation with an infectious disease specialist (a doctor who specializes in the treatment of infections)
   c. Your antimicrobial susceptibility testing (lab test showing what medications work on which bacteria) shows ALL of the following:
      i. The bacteria at the infection site are resistant (medication will not work for that bacteria) to TWO standard of care medications for community-acquired bacterial pneumonia (CABP: a type of lung infection) (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid)
      ii. Baxdela will work against the bacteria
   d. If antimicrobial susceptibility results (lab test that shows what medications work on which bacteria) are not available, we require that you had a trial of or contraindication to (harmful for you to use) TWO standard of care medications for community-acquired bacterial pneumonia (CABP: a type of lung infection) (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Baxdela.

REFERENCES

Baxdela [Prescribing Information]. Lincolnshire, IL: Melinta Therapeutics, Inc.; December 2023.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DELAFLOXACIN (PART D)

For Part D use only:

DELAFLOXACIN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	ONE MONTH
Other Criteria	ACUTE BACTERIAL SKIN AND SKIN STRUCTURE INFECTION (ABSSSI): 1) PRESCRIBED BY OR IN CONSULTATION WITH AN INFECTIOUS DISEASE SPECIALIST, 2) ANTIMICROBIAL SUSCEPTIBILITY TESTING SHOWS SUSCEPTIBILITY TO BAXDELA AND RESISTANCE TO ONE STANDARD OF CARE AGENT FOR ABSSSI, OR 3) IF SENSITIVITY RESULTS ARE UNAVAILABLE: TRIAL OF OR CONTRAINDICATION TO ONE OF THE FOLLOWING AGENTS FOR ABSSSI: A PENICILLIN, A FLUOROQUINOLONE, A CEPHALOSPORIN, A GRAM POSITIVE TARGETING ANTIBIOTIC. COMMUNITY-ACQUIRED BACTERIAL PNEUMONIA (CABP): 1) CONTINUATION OF CARE FROM INPATIENT SETTING, 2) PRESCRIBED BY OR IN CONSULTATION WITH AN INFECTIOUS DISEASE SPECIALIST, 3) ANTIMICROBIAL SUSCEPTIBILITY TESTING SHOWS SUSCEPTIBILITY TO BAXDELA AND RESISTANCE TO TWO STANDARD OF CARE AGENTS FOR CABP, OR 4) IF SENSITIVITY RESULTS ARE UNAVAILABLE: TRIAL OF OR CONTRAINDICATION TO TWO STANDARD OF CARE AGENTS FOR CABP.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DELGOCITINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DELGOCITINIB	ANZUPGO	50242		GPI-10 (9027202000)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe chronic hand eczema (CHE) (ICD-10 L30.8, L30.9) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a modified Investigator's Global Assessment for Chronic Hand Eczema (IGA-CHE) score of 3 or 4
   - The patient had a trial of or contraindication to a topical corticosteroid of medium potency or greater (e.g., triamcinolone 0.1% cream or ointment, mometasone furoate 0.1% ointment, fluocinonide 0.05% cream, halobetasol propionate 0.05% ointment) OR a topical calcineurin inhibitor (e.g., Elidel [pimecrolimus], Protopic [tacrolimus])
   - The patient had a trial of or contraindication to Eucrisa (crisaborole)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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DELGOCITINIB (PART D)

INITIAL CRITERIA (CONTINUED)

2. Will Anzupgo be used concurrently with **ANY** of the following for the treatment of atopic dermatitis?
   - Other non-steroidal topicals (e.g., calcineurin inhibitors [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)], PDE-4 inhibitors [e.g., Eucrisa (crisaborole), Zoryve (roflumilast)], JAKinhibitors [e.g., Opzelura (ruxolitinib)], AhR agonists [e.g., Vtama (tapinarof)])
   - Systemic therapeutic biologics (e.g., Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
   - Other JAK inhibitors (e.g., Rinvoq [upadacitinib], Cibinqo [abrocitinib])
   - Potent immunosuppressants (e.g., azathioprine, cyclosporine)

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, **approve for 4 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DELGOCITINIB (Anzupgo)** requires the following rule(s) be met for approval:
   A. You have moderate to severe chronic hand eczema (CHE: a type of skin condition)
   B. You are 18 years of age or older
   C. You have a modified Investigator's Global Assessment for Chronic Hand Eczema (IGA-CHE: a tool for evaluating the severity of your condition) score of 3 or 4
   D. You have tried or have a contraindication to (harmful for you to use) a topical corticosteroid of medium potency or greater (such as triamcinolone 0.1% cream or ointment, mometasone furoate 0.1% ointment, fluocinonide 0.05% cream, halobetasol propionate 0.05% ointment) OR a topical calcineurin inhibitor (such as Elidel [pimecrolimus], Protopic [tacrolimus])
   E. You have tried or have a contraindication to (harmful for you to use) Eucrisa (crisaborole)
   (Initial denial text continued on next page)

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DELGOCITINIB (PART D)

INITIAL CRITERIA (CONTINUED)

F. You will NOT use Anzupgo concurrently (at the same time) with ANY of the following for the treatment of atopic dermatitis (a type of skin condition):
   1. Other non-steroidal topicals (such as calcineurin inhibitors [such as Elidel (pimecrolimus), Protopic (tacrolimus)], PDE-4 [phosphodiesterase-4] inhibitors [such as Eucrisa (crisaborole), Zoryve (roflumilast)], JAK [Janus kinase] inhibitors [such as Opzelura (ruxolitinib)], AhR [aryl hydrocarbon receptor] agonists [such as Vtama (tapinarof)])
   2. Systemic therapeutic biologics (such as Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
   3. Other JAK (Janus kinase) inhibitors (such as Rinvoq [upadacitinib], Cibinqo [abrocitinib])
   4. Potent immunosuppressants (such as azathioprine, cyclosporine)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DELGOCITINIB (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe chronic hand eczema (CHE) (ICD-10 L30.8, L30.9) **AND** meet the following criterion?
   - The patient has had improvement of symptoms

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Will Anzupgo be used concurrently with **ANY** of the following for the treatment of atopic dermatitis?
   - Other non-steroidal topicals (e.g., calcineurin inhibitors [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)], PDE-4 inhibitors [e.g., Eucrisa (crisaborole), Zoryve (roflumilast)], JAK inhibitors [e.g., Opzelura (ruxolitinib)], AhR agonists [e.g., Vtama (tapinarof)])
   - Systemic therapeutic biologics (e.g., Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
   - Other JAK inhibitors (e.g., Rinvoq [upadacitinib], Cibinqo [abrocitinib])
   - Potent immunosuppressants (e.g., azathioprine, cyclosporine)

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

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DELGOCITINIB (PART D)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DELGOCITINIB (Anzupgo)** requires the following rule(s) be met for renewal:

A. You have moderate to severe chronic hand eczema (CHE: a type of skin condition)
B. You have had improvement of symptoms
C. You will NOT use Anzupgo concurrently (at the same time) with ANY of the following for the treatment of atopic dermatitis (a type of skin condition):
    1. Other non-steroidal topicals (such as calcineurin inhibitors [such as Elidel (pimecrolimus), Protopic (tacrolimus)], PDE-4 [phosphodiesterase-4] inhibitors [such as Eucrisa (crisaborole), Zoryve (roflumilast)], JAK [Janus kinase] inhibitors [such as Opzelura (ruxolitinib)], AhR [aryl hydrocarbon receptor] agonists [such as Vtama (tapinarof)])
    2. Systemic therapeutic biologics (such as Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
    3. Other JAK (Janus kinase) inhibitors (such as Rinvoq [upadacitinib], Cibinqo [abrocitinib])
    4. Potent immunosuppressants (such as azathioprine, cyclosporine)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Anzupgo.

REFERENCES

Anzupgo [Prescribing Information]. Madison, NJ: LEO Pharma A/S; July 2025.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DELGOCITINIB (PART D)

For Part D use only:

DELGOCITINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	CHRONIC HAND ECZEMA (CHE): INITIAL: MODIFIED INVESTIGATORS GLOBAL ASSESSMENT FOR CHE (IGA-CHE) SCORE OF 3 OR 4.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	INITIAL: 4 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	CHE: INITIAL: TRIAL OF OR CONTRAINDICATION TO: 1) A TOPICAL CORTICOSTEROID OF MEDIUM POTENCY OR GREATER OR A TOPICAL CALCINEURIN INHIBITOR, AND 2) EUCRISA. INITIAL/RENEWAL: NO CONCURRENT USE WITH ANY OF THE FOLLOWING FOR ATOPIC DERMATITIS: 1) NON-STEROIDAL TOPICALS (E.G., CALCINEURIN INHIBITORS, PDE-4 INHIBITORS, JAK INHIBITORS, AHR AGONISTS), 2) SYSTEMIC THERAPEUTIC BIOLOGICS, 3) OTHER JAK INHIBITORS, OR 4) POTENT IMMUNOSUPPRESSANTS (E.G., AZATHIOPRINE, CYCLOSPORINE). RENEWAL: IMPROVEMENT OF SYMPTOMS.

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CORE, ADVANTAGE, PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DENOSUMAB-BMWO - OSENVELT BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DENOSUMAB-BMWO	OSENVELT		57292	GPI-14 (30044530222030)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	Yes	No	Yes	Yes	No	Yes	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit).**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #5.

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DENOSUMAB-BMWO - OSENVELT BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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DENOSUMAB-BMWO - OSENVELT BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of multiple myeloma (ICD-10 Group C90.0) OR bone metastases from solid tumors **AND** meet the following criterion?
   - Osenvelt will be used to prevent skeletal-related events (e.g., bone fractures, bone pain requiring radiation)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of giant cell tumor of bone (ICD-10 D48.0) **AND** meet the following criterion?
   - The patient's tumor is unresectable or surgical resection is likely to result in severe morbidity

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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DENOSUMAB-BMWO - OSENVELT BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of hypercalcemia of malignancy **AND** meet the following criterion?
   - The patient is refractory to a bisphosphonate therapy (e.g., Fosamax [alendronate], Actonel [risedronate], Boniva [ibandronate])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DENOSUMAB-BMWO - OSENVELT** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Multiple myeloma (a type of blood cancer)
      2. Bone metastases from a solid tumor (tumor has spread to the bone)
      3. Giant cell tumor of bone (noncancerous tumor)
      4. Hypercalcemia (high level of calcium in the blood) of malignancy (cancer)

   B. If you have multiple myeloma or bone metastases from a solid tumor, approval also requires:
      1. Osenvelt will be used to prevent skeletal-related events (such as bone fractures, bone pain requiring radiation [a type of treatment])

   C. If you have giant cell tumor of bone, approval also requires:
      1. Your tumor is unresectable (unable to remove by surgery) or surgical resection (removal) is likely to result in severe morbidity (illness)

   D. If you have hypercalcemia of malignancy, approval also requires:
      1. You are refractory (disease did not respond to treatment) to a prior bisphosphonate therapy (such as Fosamax [alendronate], Actonel [risedronate], Boniva [ibandronate])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DENOSUMAB-BMWO - OSENVELT BvD (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Osenvelt.
The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Osenvelt [Prescribing Information]. Jersey City, NJ: CELLTRION USA, Inc.; February 2025.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed July 29, 2025].

For Part D use only:

DENOSUMAB-BMWO - OSENVELT (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 08/25
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 04/23

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DENOSUMAB-XGEVA (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DENOSUMAB	XGEVA		29261	GPI-14 (30044530002030)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of multiple myeloma (ICD-10 Group C90.0) OR bone metastases from solid tumor **AND** meet the following criterion?
   - Xgeva will be used to prevent skeletal-related events (e.g., bone fractures, bone pain requiring radiation)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of giant cell tumor of bone (ICD-10 D48.0) **AND** meet the following criterion?
   - The patient's tumor is unresectable or surgical resection is likely to result in severe morbidity

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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DENOSUMAB-XGEVA (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of hypercalcemia of malignancy **AND** meet the following criterion?
   - The patient is refractory to a bisphosphonate therapy (e.g., Fosamax [alendronate], Actonel [risedronate], Boniva [ibandronate])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DENOSUMAB-XGEVA** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Multiple myeloma (a type of blood cancer) or bone metastases from a solid tumor (abnormal mass)
      2. Giant cell tumor of bone (noncancerous tumor)
      3. Hypercalcemia (high level of calcium in the blood) of malignancy (cancer)
   B. If you have multiple myeloma or bone metastases from a solid tumor, approval also requires:
      1. Xgeva is being used to prevent skeletal-related events (such as bone fractures, bone pain requiring radiation)
   C. If you have giant cell tumor of bone, approval also requires:
      1. Your tumor is unresectable (unable to remove by surgery) or surgical removal is likely to result in severe morbidity (illness)
   D. If you have hypercalcemia of malignancy, approval also requires:
      1. You are refractory (disease did not respond to treatment) to a prior bisphosphonate therapy (such as Fosamax [alendronate], Actonel [risedronate], Boniva [ibandronate])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the prescribing information and/or Drug Monograph for Xgeva.

REFERENCES
Xgeva [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; June 2020.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DENOSUMAB-XGEVA (PART D)

For Part D use only:

DENOSUMAB-XGEVA (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25 Created: 11/07
Commercial Effective: N/A Client Approval: 08/24 P&T Approval: 01/18

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DEPEMOKIMAB-ULAA BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DEPEMOKIMAB-ULAA	EXDENSUR	51066		GPI-10 (4460403000)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	Yes	No	No	Yes	No	No	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit).**

3. Is the internal HQ code AHF01,ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #5.

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DEPEMOKIMAB-ULAA BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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DEPEMOKIMAB-ULAA BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of severe asthma with an eosinophilic phenotype (ICD-10 J82.83) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Therapy is prescribed by or in consultation with a physician specializing in allergy or pulmonary medicine
   - The patient has a blood eosinophil level of at least 150 cells/mcL within the last 12 months
   - Exdensur will be used in combination with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (ICS) (e.g., beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (e.g., a long-acting inhaled beta2-agonist [e.g., salmeterol, formoterol], a long-acting muscarinic antagonist [e.g., Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [e.g., montelukast, zafirlukast], theophylline)
   - Exdensur will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of eosinophilic phenotype asthma
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Fasenra (benralizumab), Nucala (mepolizumab), Dupixent (dupilumab)

     If yes, continue to #2.
     If no, do not approve.
     DENIAL TEXT: See the initial denial text at the end of the guideline.

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DEPEMOKIMAB-ULAA BvD (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient meet **ONE** of the following criteria?
   - The patient experienced at least ONE asthma exacerbation requiring systemic corticosteroid (e.g. prednisone) burst lasting at least 3 days within the past 12 months
   - The patient experienced at least ONE serious asthma exacerbation requiring hospitalization or emergency room visit within the past 12 months

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Does the patient have poor symptom control despite current therapy as evidenced by at least **THREE** of the following within the past 4 weeks?
   - Daytime asthma symptoms more than twice per week
   - Any night waking due to asthma
   - Use of a short-acting inhaled beta2-agonist (SABA) reliever (e.g., albuterol) for symptoms more than twice per week
   - Any activity limitation due to asthma

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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DEPEMOKIMAB-ULAA BvD (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DEPEMOKIMAB-ULAA (Exdensur)** requires the following rule(s) be met for approval:

A. You have severe eosinophilic phenotype asthma (a type of inflammatory asthma)
B. You are 12 years of age or older
C. Therapy is prescribed by or in consultation with a doctor specializing in allergy or pulmonary (lung/breathing) medicine
D. You have a blood eosinophil level (type of white blood cell) of at least 150 cells/mcL within the last 12 months
E. Exdensur will be used in combination with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis), such as a long-acting inhaled beta2-agonist (such as salmeterol, formoterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast), or theophylline
F. You will NOT use Exdensur concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic phenotype asthma (a type of inflammatory asthma)
G. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Fasenra (benralizumab), Nucala (mepolizumab), Dupixent (dupilumab)
H. You meet ONE of the following:
    1. You have experienced at least ONE asthma exacerbation (worsening of symptoms) requiring systemic corticosteroid (such as prednisone) burst lasting at least 3 days within the past 12 months
    2. You have experienced at least ONE serious asthma exacerbation requiring hospitalization or emergency room visit within the past 12 months
    3. You have poor symptom control despite current therapy as evidenced by at least THREE of the following within the past 4 weeks:
        i. Daytime asthma symptoms more than twice per week
        ii. Any night waking due to asthma
        iii. Use of a short-acting inhaled beta2-agonist reliever (such as albuterol) for symptoms more than twice per week
        iv. Any activity limitation due to asthma

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DEPEMOKIMAB-ULAA BvD (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of severe asthma with an eosinophilic phenotype (ICD-10 J82.83) and meet **ALL** of the following criteria?
   - The patient will continue to use an inhaled corticosteroid (ICS) (e.g., beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (e.g., a long-acting inhaled beta2-agonist [e.g., salmeterol, formoterol], a long-acting muscarinic antagonist [e.g., Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [e.g., montelukast, zafirlukast], theophylline)
   - Exdensur will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of eosinophilic phenotype asthma

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Has the patient shown a clinical response as evidenced by **ONE** of the following?
   - Reduction in asthma exacerbations from baseline
   - Decreased utilization of rescue medications (e.g., albuterol)
   - Increase in percent predicted FEV1 from pretreatment baseline
   - Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DEPEMOKIMAB-ULAA (Exdensur)** requires the following rule(s) be met for renewal:
   A. You have severe eosinophilic phenotype asthma (a type of inflammatory asthma)
   B. You will continue to use an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis) such as a long-acting inhaled beta2-agonist (such as salmeterol, formoterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast), or theophylline

   (Renewal denial text continued on the next page)

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DEPEMOKIMAB-ULAA BvD (PART D)

RENEWAL CRITERIA (CONTINUED)

C. You will NOT use Exdensur concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic phenotype asthma (a type of inflammatory asthma)
D. You have shown a clinical response as evidenced by ONE of the following:
   1. You have experienced a reduction in asthma exacerbations (worsening of symptoms) from baseline
   2. You have decreased your use of rescue medications (such as albuterol)
   3. Your percent predicted FEV1 (amount of air exhaled in one second) has increased from pretreatment baseline (before starting Exdensur)
   4. You have experienced a reduction in severity or frequency of asthma-related symptoms (such as wheezing, shortness of breath, coughing)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Exdensur. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Exdensur [Prescribing Information]. Philadelphia, PA: GlaxoSmithKline LLC; November 2025.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed December 29, 2025].

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DEPEMOKIMAB-ULAA BvD (PART D)

For Part D use only:

DEPEMOKIMAB-ULAA (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	ASTHMA WITH AN EOSINOPHILIC PHENOTYPE: INITIAL: BLOOD EOSINOPHIL LEVEL OF AT LEAST 150 CELLS/MCL WITHIN THE LAST 12 MONTHS.
Age Restrictions	N/A
Prescriber Restrictions	ASTHMA: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A PHYSICIAN SPECIALIZING IN ALLERGY OR PULMONARY MEDICINE.
Coverage Duration	ASTHMA: INITIAL: 6 MO. RENEWAL: 12 MOS.
Other Criteria	ASTHMA: INITIAL: 1) CONCURRENT THERAPY WITH A MEDIUM, HIGH-DOSE, OR MAXIMALLY TOLERATED DOSE OF AN INHALED CORTICOSTEROID (ICS) AND ONE OTHER MAINTENANCE MEDICATION, 2) ONE ASTHMA EXACERBATION REQUIRING SYSTEMIC CORTICOSTEROID BURST LASTING AT LEAST 3 DAYS WITHIN THE PAST 12 MONTHS, OR ONE SERIOUS EXACERBATION REQUIRING HOSPITALIZATION OR ER VISIT WITHIN THE PAST 12 MONTHS, OR POOR SYMPTOM CONTROL DESPITE CURRENT THERAPY AS EVIDENCED BY AT LEAST THREE OF THE FOLLOWING WITHIN THE PAST 4 WEEKS: (A) DAYTIME ASTHMA SYMPTOMS MORE THAN TWICE PER WEEK, (B) ANY NIGHT WAKING DUE TO ASTHMA, (C) SABA RELIEVER FOR SYMPTOMS MORE THAN TWICE PER WEEK, (D) ANY ACTIVITY LIMITATION DUE TO ASTHMA, AND 3) TRIAL OF OR CONTRAINDICATION TO TWO OF THE PREFERRED AGENTS: FASENRA, NUCALA, DUPIXENT. INITIAL/RENEWAL: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION. RENEWAL: 1) CONTINUED USE OF AN ICS AND ONE OTHER MAINTENANCE MEDICATION, AND 2) CLINICAL RESPONSE AS EVIDENCED BY: (A) REDUCTION IN ASTHMA EXACERBATIONS FROM BASELINE, (B) DECREASED UTILIZATION OF RESCUE MEDICATIONS, (C) INCREASE IN PERCENT PREDICTED FEV1 FROM PRETREATMENT BASELINE, OR (D) REDUCTION IN SEVERITY OR FREQUENCY OF ASTHMA-RELATED SYMPTOMS.

Created: 12/25
Effective: 01/12/26 Client Approval: 12/25 P&T Approval: 10/25

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DESMOPRESSIN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DESMOPRESSIN ACETATE	DESMODA		58877	GPI-14 (30201010102065)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of central diabetes insipidus (ICD-10 E23.2) **AND** meet the following criterion?
   - The patient has a contraindication to or is unable to swallow desmopressin tablets

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DESMOPRESSIN (Desmoda)** requires the following rule(s) be met for approval:
   A. You have central diabetes insipidus (a type of hormone disorder)
   B. You have a contraindication to (harmful for you to use) or are unable toswallow desmopressin tablets

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DESMOPRESSIN (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Desmoda.

REFERENCES
Desmoda [Prescribing Information]. Deer Park, IL: Eton Pharmaceuticals, Inc.; February 2026.

For Part D use only:

DESMOPRESSIN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	CENTRAL DIABETES INSIPIDUS: CONTRAINDICATION TO OR UNABLE TO SWALLOW DESMOPRESSIN TABLETS.

Created: 05/26
Effective: 06/19/26 Client Approval: 05/26 P&T Approval: 04/26

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DEUTETRABENAZINE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DEUTETRABENAZINE	AUSTEDO, AUSTEDO XR	44192		GPI-10 (6238003000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chorea associated with Huntington's disease (ICD-10 G10) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist or movement disorder specialist

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of tardive dyskinesia (ICD-10 G24.01) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist, movement disorder specialist, or psychiatrist
   - The patient has a history of using agents that cause tardive dyskinesia (e.g., Haldol [haloperidol], Abilify [aripiprazole])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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DEUTETRABENAZINE (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DEUTETRABENAZINE (Austedo, Austedo XR)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Chorea (involuntary movements) associated with Huntington's disease (a type of brain disorder)
   2. Tardive dyskinesia (uncontrolled body movements)

B. If you have chorea associated with Huntington's disease, approval also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor) or movement disorder specialist

C. If you have tardive dyskinesia, approval also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor), movement disorder specialist, or psychiatrist (mental health doctor)
   3. You have a history of using medications (such as Haldol [haloperidol], Abilify [aripiprazole]) that cause tardive dyskinesia (uncontrolled body movements)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the prescribing information and/or drug monograph for Austedo, Austedo XR.

REFERENCES

Austedo, Austedo XR [Prescribing Information]. Parsippany, NJ: Teva Pharmaceuticals, Inc.; September 2023.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DEUTETRABENAZINE (PART D)

For Part D use only:

DEUTETRABENAZINE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	HUNTINGTON DISEASE: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST OR MOVEMENT DISORDER SPECIALIST. TARDIVE DYSKINESIA: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST, PSYCHIATRIST, OR MOVEMENT DISORDER SPECIALIST.
Coverage Duration	12 MONTHS
Other Criteria	TARDIVE DYSKINESIA: HISTORY OF USING AGENTS THAT CAUSE TARDIVE DYSKINESIA.

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25 Created: 04/17
Commercial Effective: N/A Client Approval: 06/24 P&T Approval: 05/18

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DEXMEDETOMIDINE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DEXMEDETOMIDINE HCL	IGALMI	20971		GPI-10 (6020603010)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

************Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for the treatment of acute agitation associated with schizophrenia or bipolar I or II disorder (ICD-10 R45.1, F31.81) and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a psychiatrist
   - The patient had a trial and failure of or contraindication to TWO antipsychotics (e.g., olanzapine, haloperidol, ziprasidone)

   If yes, **approve for 1 month by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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DEXMEDETOMIDINE (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DEXMEDETOMIDINE (Igalmi)** requires the following rule(s) be met for approval:

A. The request is for the treatment of acute (short-term) agitation associated with schizophrenia (a type of mental health disorder) or bipolar I or II disorder (a type of mood disorder)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a psychiatrist (type of mental health doctor)
D. You have tried and failed or have a contraindication to (harmful for you to use) TWO antipsychotics (such as olanzapine, haloperidol, ziprasidone)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DEXMEDETOMIDINE (PART D)

RENEWAL CRITERIA

1. Is the request for treatment of acute agitation associated with schizophrenia or bipolar I or II disorder (ICD-10 R45.1, F31.81)?

   If yes, continue to #2.
   If no, do no approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the patient's maintenance therapy for the underlying psychiatric disorder currently being adjusted or optimized to reduce or eliminate the need for continued PRN medications for acute agitation?

   If yes, **approve for 3 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Have attempts to adjust medications been exhausted **AND** the physician has determined that chronic PRN medications are required for the continued safety of the patient or caregivers?

   If yes, **approve for 6 months HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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DEXMEDETOMIDINE (PART D)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DEXMEDETOMIDINE (Igalmi)** requires the following rule(s) be met for renewal:

A. The request is for the treatment of acute (short-term) agitation associated with schizophrenia (a type of mental health disorder) or bipolar I or II disorder (a type of mood disorder)
B. You meet ONE of the following:
    1. Your maintenance therapy for your underlying psychiatric (mental) disorder is currently being adjusted or optimized to reduce or eliminate the need for continued PRN (as needed) medications for acute agitation
    2. Attempts to adjust medications have been exhausted AND your doctor has determined that chronic PRN (long-term as needed) medications are required for the continued safety of you or your caregivers

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Igalmi.

REFERENCES

Igalmi [Prescribing Information]. New Haven, CT: BioXcel Therapeutics, Inc.; April 2022.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DEXMEDETOMIDINE (PART D)

For Part D use only:

DEXMEDETOMIDINE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	ACUTE AGITATION: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A PSYCHIATRIST.
Coverage Duration	INITIAL: 1 MO. RENEWAL: SEE OTHER CRITERIA.
Other Criteria	ACUTE AGITATION: INITIAL: TRIAL AND FAILURE OF OR CONTRAINDICATION TO TWO ANTIPSYCHOTICS. RENEWAL: 1) MAINTENANCE THERAPY FOR UNDERLYING PSYCHIATRIC DISORDER IS CURRENTLY ADJUSTED/OPTIMIZED TO REDUCE/ELIMINATE THE NEED FOR CONTINUED PRN MEDICATIONS: 3 MONTHS, OR 2) ATTEMPTS TO ADJUST MEDICATIONS HAVE BEEN EXHAUSTED AND PHYSICIAN DETERMINED THAT CHRONIC PRN MEDICATIONS ARE REQUIRED FOR THE CONTINUED SAFETY OF PATIENT OR CAREGIVERS: 6 MONTHS.

Created: 03/23
Effective: 01/01/26 Client Approval: 01/26 P&T Approval: 10/21

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DEXTROMETHORPHAN/QUINIDINE TIRF (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DEXTROMETHORPHAN HBR/QUINIDINE	NUEDEXTA	37278		GPI-10 (6260990230)	

These are TIRF-Like drugs requiring a payment determination for 'Part D' or 'Non-Part D'.

PAYMENT DETERMINATION CRITERIA

1. Does the patient have a diagnosis of pseudobulbar affect (PBA) (ICD-10 F48.2)?

   If yes, **set MCARE_DRUG_DETERM_OVR to 'Y' and approve for 12 months by HICL or GPI-10. Document in the PA comments: Part D Determination Override and diagnosis.**

   If no, **do not enter an MCARE override.**
   CSR Note:
   - If the caller is a physician, member, and/or AOR, please initiate a verbal PA intake request in MR4.
   - If the caller is a pharmacy, please advise the pharmacy to contact the provider or memberto pursue a payment determination and document diagnosis provided in MedAccess.

   Please follow the clinical authorization process within the HQ notes.

   RPH Note:
   - Review for both FDA and Part D compendial supported off-label indications.
   - If the provided diagnosis is not FDA approved or compendial supported off-label use, **set MCARE_DRUG_DETERM_OVR to 'N' and enter override within the denied PA for 12 months by HICL or GPI-10.**
   - If the diagnosis is UNKNOWN do not enter an MCARE override; follow the criteria for any additional UM and decision the case accordingly. Provide the following PAC instruction: '**PAC: do not enter an MCARE override**.'

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DEXTROMETHORPHAN/QUINIDINE (Nuedexta)** requires the following rule(s) be met for approval:
   A. You have pseudobulbar affect (PBA: uncontrollable, inappropriate laughing and/or crying due to a nervous system disorder)

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DEXTROMETHORPHAN/QUINIDINE TIRF (PART D)

RATIONALE

Prior authorization on Nuedexta is required due to a high potential for non-Part D use. Nuedexta should NOT be used for non-medically accepted indications as defined in section 1860D-2(e)(4) of the Act. For further information, please refer to the prescribing information and/or Drug Monograph for Nuedexta.

REFERENCES

Announcement of Calendar Year (CY) 2015 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. April 7, 2014. Section III – Part D: Appropriate Utilization of Prior Authorization Requirements to Determine Part D Drug Status. Page 112 – 114.

Nuedexta [Prescribing Information]. Rockville, MD: Otsuka America Pharmaceuticals, Inc.; December 2022.

For Part D use only:

DEXTROMETHORPHAN QUINIDINE (PART D)	
Covered Uses	ALL MEDICALLY-ACCEPTED INDICATIONS.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 05/18
Effective: 03/09/26 Client Approval: 03/26 P&T Approval: 05/20

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DIAZOXIDE CHOLINE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DIAZOXIDE CHOLINE	VYKAT XR	50391		GPI-10 (3090283020)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hyperphagia (ICD-10 R63.2) and meet **ALL** of the following criteria?
   - The patient is 4 years of age or older
   - The patient has a genetically confirmed Prader-Willi syndrome (PWS)
   - Therapy is prescribed by or in consultation with an endocrinologist, geneticist, or neurologist

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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DIAZOXIDE CHOLINE (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DIAZOXIDE CHOLINE (Vykat XR)** requires the following rule(s) be met for approval:

A. You have hyperphagia (extreme hunger)
B. You are 4 years of age or older
C. You have genetically confirmed Prader-Willi syndrome (PWS: a type of generic disorder)
D. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor), geneticist (doctor who treats gene disorders), or neurologist (a type of brain and nervous system doctor)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DIAZOXIDE CHOLINE (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hyperphagia (ICD-10 R63.2) and meet **ALL** of the following criteria?
   - The patient's hyperphagia is associated with Prader-Willi syndrome (PWS)
   - The patient has had clinical improvement

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DIAZOXIDE CHOLINE (Vykat XR)** requires the following rule(s) be met for renewal:
   A. You have hyperphagia (extreme hunger)
   B. Your hyperphagia is associated with Prader-Willi syndrome (PWS: a type of generic disorder)
   C. You have had clinical improvement

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vykat XR.

REFERENCES

Vykat XR [Prescribing Information]. Redwood City, CA: Soleno Therapeutics, Inc.; March 2025.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DIAZOXIDE CHOLINE (PART D)

For Part D use only:

DIAZOXIDE CHOLINE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	HYPERPHAGIA ASSOCIATED WITH PRADER-WILLI SYNDROME (PWS): INITIAL: GENETICALLY CONFIRMED PWS.
Age Restrictions	N/A
Prescriber Restrictions	HYPERPHAGIA ASSOCIATED WITH PWS: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST, GENETICIST, OR NEUROLOGIST.
Coverage Duration	HYPERPHAGIA ASSOCIATED WITH PWS: INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	HYPERPHAGIA ASSOCIATED WITH PWS: RENEWAL: CLINICAL IMPROVEMENT WHILE ON THERAPY.

Created: 04/25
Effective: 05/05/25 Client Approval: 04/25 P&T Approval: 01/25

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DICHLORPHENAMIDE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DICHLORPHENAMIDE	KEVEYIS, ORMALVI, DICHLORPHENAMIDE	03642		GPI-10 (3710002000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of primary hyperkalemic periodic paralysis, primary hypokalemic periodic paralysis, or related variants (ICD-10 G72.3), and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient does NOT have hepatic insufficiency, pulmonary obstruction, or a health condition that warrants concurrent use with high-dose aspirin

   If yes, **approve for 2 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DICHLORPHENAMIDE (Keveyis, Ormalvi)** requires the following rule(s) be met for approval:
   A. You have primary hyperkalemic periodic paralysis (extreme muscle weakness with high potassium levels in your blood), primary hypokalemic periodic paralysis (extreme muscle weakness with low potassium levels in your blood), or related variants
   (Initial denial text continued on next page)

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DICHLORPHENAMIDE (PART D)

INITIAL CRITERIA (CONTINUED)

B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
D. You do NOT have hepatic insufficiency (liver failure), pulmonary obstruction (difficulty breathing due to blockage of airflow), or a health condition that requires you to use high-dose aspirin

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DICHLORPHENAMIDE (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of primary hyperkalemic periodic paralysis, primary hypokalemic periodic paralysis, or related variants (ICD-10 G72.3) **AND** meet the following criterion?
   - The patient continues to benefit from the medication

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DICHLORPHENAMIDE (Keveyis, Ormalvi)** requires the following rule(s) be met for renewal:
   A. You have primary hyperkalemic periodic paralysis (extreme muscle weakness with high potassium levels in your blood), primary hypokalemic periodic paralysis (extreme muscle weakness with low potassium levels in your blood), or related variants
   B. You continue to benefit from the medication

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the prescribing information and/or drug monograph for Keveyis or Ormalvi.

REFERENCES
Keveyis [Prescribing Information]. Chicago, IL: Xeris Pharmaceuticals, Inc.; January 2024.
Ormalvi [Prescribing Information]. Cambridge, UK: Cycle Pharmaceuticals Ltd.; February 2024.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DICHLORPHENAMIDE (PART D)

For Part D use only:

DICHLORPHENAMIDE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	PRIMARY HYPERKALEMIC PERIODIC PARALYSIS, PRIMARY HYPOKALEMIC PERIODIC PARALYSIS, OR RELATED VARIANTS: INITIAL: 18 YEARS OF AGE OR OLDER.
Prescriber Restrictions	PRIMARY HYPERKALEMIC PERIODIC PARALYSIS, PRIMARY HYPOKALEMIC PERIODIC PARALYSIS, OR RELATED VARIANTS: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST.
Coverage Duration	INITIAL: 2 MONTHS, RENEWAL: 12 MONTHS.
Other Criteria	PRIMARY HYPERKALEMIC PERIODIC PARALYSIS, PRIMARY HYPOKALEMIC PERIODIC PARALYSIS, OR RELATED VARIANTS: INITIAL: DOES NOT HAVE HEPATIC INSUFFICIENCY, PULMONARY OBSTRUCTION, OR A HEALTH CONDITION THAT WARRANTS CONCURRENT USE OF HIGH-DOSE ASPIRIN. RENEWAL: CONTINUES TO BENEFIT FROM THE MEDICATION.

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25 Created: 09/2015
Commercial Effective: N/A Client Approval: 08/24 P&T Approval: 11/16

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DICLOFENAC TOPICAL SOLUTION (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DICLOFENAC SODIUM	PENNSAID, DICLOFENAC SODIUM		35936	GPI-14 (90210030302030)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
Yes	No	No	Yes	No	No	Yes	No	No	Yes	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of osteoarthritis of the knee(s) (ICD-10 Group M17) **AND** meet the following criterion?
   - The patient had a trial of or contraindication to a formulary version of diclofenac sodium 1.5% topical drops

   If yes, **approve for 6 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DICLOFENAC TOPICAL SOLUTION (Pennsaid)** requires the following rules be met for approval:
   A. You have osteoarthritis (bone and joint pain) of the knee(s)
   B. You have tried or have a contraindication to (harmful for you to use) a formulary version of diclofenac sodium 1.5% topical drops

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DICLOFENAC TOPICAL SOLUTION (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Pennsaid.

REFERENCES

Pennsaid [Prescribing Information]. Deerfield, IL: Horizon Pharma USA Inc.; November 2024.

For Part D use only:

DICLOFENAC TOPICAL SOLUTION (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Medical Required Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 MONTHS
Other Criteria	OSTEOARTHRITIS OF THE KNEE: TRIAL OF OR CONTRAINDICATION TO A FORMULARY VERSION OF DICLOFENAC SODIUM 1.5% TOPICAL DROPS.

Created: 09/22
Effective: 01/01/26 Client Approval: 12/25 P&T Approval: 10/21

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DICLOFENAC-FLECTOR TIRF (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DICLOFENAC EPOLAMINE	FLECTOR, DICLOFENAC EPOLAMINE		97958	GPI-14 (90210030205920)	

These are TIRF-Like drugs requiring a payment determination for 'Part D' or 'Non-Part D'.

PAYMENT DETERMINATION CRITERIA

1. Does the patient have a diagnosis of acute pain due to minor strains, sprains, or contusions (ICD-10 G89.11) **AND** meet the following criterion?
   - The patient is 6 years of age or older

   If yes, **set MCARE_DRUG_DETERM_OVR to 'Y' and approve for 12 months by GPID or GPI-14. Document in the PA comments: Part D Determination Override and diagnosis.**

   If no, **do not enter an MCARE override. Then, process as follows:**
   CSR Note:
   - If the caller is a physician, member, and/or AOR, please initiate a verbal PA intake request in MR4.
   - If the caller is a pharmacy, please advise the pharmacy to contact the provider or memberto pursue a payment determination and document the diagnosis provided in MedAccess.

   Please follow the clinical authorization process within the HQ notes.

   RPH Note:
   - Review for both FDA and Part D compendial supported off-label indications.
   - If the provided diagnosis is not FDA approved or compendial supported off-label use **set MCARE_DRUG_DETERM_OVR to 'N', and enter override within the denied PA for12 months by GPID or GPI-14.**
   - If the diagnosis is UNKNOWN do not enter an MCARE override; follow the criteria for any additional UM and decision the case accordingly. Provide the following PAC instruction: '**PAC: do not enter an MCARE override**.'

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DICLOFENAC-FLECTOR** requires the following rule(s) be met for approval:
   A. You have acute (short-term) pain due to minor strains, sprains, or contusions (bruises)
   B. You are 6 years of age or older

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DICLOFENAC-FLECTOR TIRF (PART D)

RATIONALE

Prior authorization on Flector is required due to a high potential for non-Part D use (D vs. E payment determination only). Flector should NOT be used for non-medically accepted indications as defined in section 1860D-2(e)(4) of the Act. For further information, please refer to the Prescribing Information and/or Drug Monograph for Flector patch.

REFERENCES

Flector [Prescribing Information]. Parsippany, NJ: IBSA Pharma Inc.; April 2021.

Announcement of Calendar Year (CY) 2015 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. April 7, 2014. Section III – Part D: Appropriate Utilization of Prior Authorization Requirements to Determine Part D Drug Status. Page 112 – 114.

For Part D use only:

DICLOFENAC-FLECTOR (PART D)	
Covered Uses	ALL MEDICALLY-ACCEPTED INDICATIONS.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 10/14
Effective: 03/09/26 Client Approval: 03/26 P&T Approval: 07/20

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DICLOFENAC-LICART TIRF (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DICLOFENAC EPOLAMINE	LICART		45883	GPI-14 (90210030208520)	

These are TIRF-Like drugs requiring a payment determination for 'Part D' or 'Non-Part D'.

PAYMENT DETERMINATION CRITERIA

1. Does the patient have a diagnosis of acute pain due to minor strains, sprains, or contusions (ICD-10 G89.11)?

   If yes, **set MCARE_DRUG_DETERM_OVR to 'Y' and approve for 12 months by GPID or GPI-14. Document in the PA comments: Part D Determination Override and diagnosis.**

   If no, **do not enter an MCARE override. Then, process as follows:**
   CSR Note:
   - If the caller is a physician, member, and/or AOR, please initiate a verbal PA intake request in MR3.
   - If the caller is a pharmacy, please advise the pharmacy to contact the provider or memberto pursue a payment determination and document the diagnosis provided in MedAccess.

   Please follow the clinical authorization process within the HQ notes.

   RPH Note:
   - Review for both FDA and Part D compendial supported off-label indications.
   - If the provided diagnosis is not FDA approved or compendial supported off-label use, **set MCARE_DRUG_DETERM_OVR to 'N' and enter override within the denied PA for 12 months by GPID or GPI-14.**
   - If the diagnosis is UNKNOWN do not enter an MCARE override; follow the criteria for any additional UM and decision the case accordingly. Provide the following PAC instruction: '**PAC: do not enter an MCARE override**.'

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DICLOFENAC-LICART TIRF (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the request for the treatment of acute pain due to minor strains, sprains, or contusions (ICD-10 G89.11) and the patient meets **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - The patient has tried generic Flector (diclofenac epolamine) patch

   If yes, **approve for 12 months by GPID or GPI-14. NOTE: If the claim rejects for payment determination after analyzing, then follow the above TIRF-Like determination criteria.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   If not a Part D indication: Set MCARE_DRUG_DETERM_OVR to 'N' and enter override within the denied PA for 12 months by GPID or GPI-14.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DICLOFENAC-LICART** requires the following rule(s) be met for approval:
   A. Licart will be used for the treatment of acute (short-term) pain due to minor strains, sprains, or contusions (bruises)
   B. You are 6 years of age or older
   C. You have tried generic Flector (diclofenac epolamine) patch

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DICLOFENAC-LICART TIRF (PART D)

RATIONALE

Prior authorization on Licart is required due to a high potential for non-Part D use (D vs. E payment determination only). Licart should NOT be used for non-medically accepted indications as defined in section 1860D-2(e)(4) of the Act. For further information, please refer to the Prescribing Information and/or Drug Monograph for Licart patch.

REFERENCES

Licart [Prescribing Information]. Parsippany, NJ: IBSA Pharma Inc.; March 2026.

Announcement of Calendar Year (CY) 2015 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. April 7, 2014. Section III – Part D: Appropriate Utilization of Prior Authorization Requirements to Determine Part D Drug Status. Page 112 – 114.

For Part D use only:

DICLOFENAC-LICART (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	ACUTE PAIN DUE TO MINOR STRAINS, SPRAINS, OR CONTUSIONS: TRIAL OF GENERIC FLECTOR PATCH.

Created: 08/20
Effective: 05/09/26 Client Approval: 05/26 P&T Approval: 07/20

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DIFELIKEFALIN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DIFELIKEFALIN ACETATE	KORSUVA	47561		GPI-10 (9969002010)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of moderate to severe pruritus associated with chronic kidney disease (ICD-10 Group N18 and Group L29) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is undergoing hemodialysis (HD)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DIFELIKEFALIN (Korsuva)** requires the following rule(s) be met for approval:
   A. You have moderate to severe pruritus (itching) associated with chronic (long-term) kidney disease
   B. You are 18 years of age or older
   C. You are undergoing hemodialysis (HD: a process of removing excess water and toxins from the blood)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DIFELIKEFALIN (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Korsuva.

REFERENCES
Korsuva [Prescribing Information]. Stamford, CT: Cara Therapeutics, Inc., August 2021.

For Part D use only:

DIFELIKEFALIN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 03/25
Effective: 03/17/25 Client Approval: 03/25 P&T Approval: 04/22

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DIMETHYL FUMARATE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DIMETHYL FUMARATE	TECFIDERA, DIMETHYL FUMARATE	40168		GPI-10 (6240552500)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), including clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease, **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: **Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DIMETHYL FUMARATE (Tecfidera)** requires the following rule(s) be met for approval:
   A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease returns and goes away), or active secondary progressive disease (advanced disease)
   B. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DIMETHYL FUMARATE (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tecfidera.

REFERENCES

Tecfidera [Prescribing Information]. Cambridge, MA: Biogen Inc.; March 2024.

For Part D use only:

DIMETHYL FUMARATE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 11/07
Client Approval: 06/24
P&T Approval: 05/19

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DINUTUXIMAB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DINUTUXIMAB	UNITUXIN	42038		GPI-10 (2135602800)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of high-risk neuroblastoma (HRNB) and meet **ALL** of the following criteria?
   - Unituxin will be used in combination with a granulocyte-macrophage colony-stimulating factor (GM-CSF), interleukin-2 (IL-2), and 13-cis-retinoic acid (RA)
   - The patient has achieved a partial response to prior first-line multi-agent, multimodal therapy (e.g., chemotherapy, surgery, radiation, and transplant)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline for **DINUTUXIMAB (Unituxin)** requires the following rule(s) be met for approval:
   A. You have high-risk neuroblastoma (HRNB: a type of rare cancer)
   B. Unituxin will be used together with a granulocyte-macrophage colony-stimulating factor (GM-CSF), interleukin-2 (IL-2), and 13-cis-retinoic acid (RA)
   C. You have shown a partial response (the cancer partly responded to treatment, but still did not go away) to prior first-line multi-agent, multimodal therapy (therapy that has many drugs and ways to treat your condition, such as chemotherapy, surgery, radiation, and transplant)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DINUTUXIMAB (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Unituxin.

REFERENCES

Unituxin [Prescribing Information]. Research Triangle Park, NC: United Therapeutics Corp.; September 2020.

Part D use only:

DINUTUXIMAB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 07/15
Effective: 01/01/26 Client Approval: 01/26 P&T Approval: 08/15

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DIROXIMEL FUMARATE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DIROXIMEL FUMARATE	VUMERITY	46164		GPI-10 (6240553000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), to include clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease, and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DIROXIMEL FUMARATE (Vumerity)** requires the following rule(s) be met for approval:
   A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease goes away and returns), or active secondary progressive disease (advanced disease)
   B. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DIROXIMEL FUMARATE (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vumerity.

REFERENCES

Vumerity [Prescribing Information]. Cambridge, MA: Biogen Inc.; March 2024.

For Part D use only:

DIROXIMEL FUMARATE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 11/19
Client Approval: 06/24
P&T Approval: 10/19

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DONEPEZIL (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DONEPEZIL HCL	ADLARITY		52053 52054	GPI-14 (62051025108820), (62051025108830)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of dementia associated with Alzheimer's disease (ICD-10 Group G30) and meet **ALL** of the following criteria?
   - The patient had a trial of or contraindication to one generic oral acetylcholinesterase inhibitor (e.g., donepezil, galantamine)
   - The patient had a trial of or contraindication to one generic acetylcholinesterase inhibitor patch (e.g., rivastigmine)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DONEPEZIL (Adlarity)** requires the following rule(s) be met for approval:
   A. You have dementia (a type of memory disorder) associated with Alzheimer's disease (a progressive brain disorder that slowly destroys memory and thinking skills)
   B. You have tried or have a contraindication to (harmful for you to use) one generic oral acetylcholinesterase inhibitor (such as donepezil, galantamine)
   C. You have tried or have a contraindication to (harmful for you to use) one generic acetylcholine inhibitor patch (such as rivastigmine)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DONEPEZIL (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Adlarity.

REFERENCES
Adlarity [Prescribing Information]. Grand Rapids, MI: Astellas Corium, Inc.; March 2022.

For Part D use only:

DONEPEZIL (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	DEMENTIA ASSOCIATED WITH ALZHEIMER'S DISEASE: 1) TRIAL OF OR CONTRAINDICATION TO ONE GENERIC ORAL ACETYLCHOLINESTERASE INHIBITOR, AND 2) TRIAL OF OR CONTRAINDICATION TO ONE GENERIC ACETYLCHOLINESTERASE INHIBITOR PATCH.

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25 Created: 06/22
Commercial Effective: N/A Client Approval: 08/24 P&T Approval: 01/22

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DONIDALORSEN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DONIDALORSEN SODIUM	DAWNZERA	50832		GPI-10 (8547002070)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hereditary angioedema (HAE) (ICD-10 D84.1) and meet **ALL** of the following criteria?
- The patient is 12 years of age or older
- Dawnzera will be used for prophylaxis against HAE attacks
- Therapy is prescribed by or in consultation with an allergist, immunologist, hematologist, or pulmonologist
- Dawnzera will NOT be used concurrently with an alternative prophylactic agent for HAE attacks (e.g., Takhzyro [lanadelumab-flyo], Haegarda [C1 esterase inhibitor], Cinryze [C1 esterase inhibitor], Orladeyo [berotralstat], danazol, Andembry [garadacimab-gxii])
- The patient had a trial of or contraindication to ONE of the following preferred agents: Cinryze (C1 esterase inhibitor), Haegarda (C1 esterase inhibitor), Takhzyro (lanadelumab-flyo)

  If yes, continue to #2.
  If no, do not approve.
  DENIAL TEXT: See the initial denial text at the end of the guideline.

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DONIDALORSEN (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient meet **ONE** of the following criteria?
   - The patient has Type I or II HAE, as confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q
   - The patient has Type III HAE

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DONIDALORSEN (Dawnzera)** requires the following rule(s) be met for approval:
   A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
   B. You are 12 years of age or older
   C. Dawnzera will be used for the prevention of hereditary angioedema attacks
   D. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), immunologist (a type of immune system doctor), hematologist (a type of blood doctor), or pulmonologist (lung/breathing doctor)
   E. You will NOT use Dawnzera concurrently (at the same time) with an alternative preventive medication for HAE attacks (such as Takhzyro [lanadelumab-flyo], Haegarda [C1 esterase inhibitor], Cinryze [C1 esterase inhibitor], Orladeyo [berotralstat], danazol, Andembry [garadacimab-gxii])
   F. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Cinryze (C1 esterase inhibitor), Haegarda (C1 esterase inhibitor), Takhzyro (lanadelumab-flyo)
   G. You meet ONE of the following:
      1. You have Type I or II hereditary angioedema (a type of gene condition with severe body swelling), as confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q (types of lab tests)
      2. You have Type III hereditary angioedema (a type of gene condition with severe body swelling)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DONIDALORSEN (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary angioedema (HAE) (ICD-10 D84.1) **AND** meet the following criterion?
   - Dawnzera will NOT be used concurrently with an alternative prophylactic agent for HAE attacks (e.g., Takhzyro [lanadelumab-flyo], Haegarda [C1 esterase inhibitor], Cinryze [C1 esterase inhibitor], Orladeyo [berotralstat], danazol, Andembry [garadacimab-gxii])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DONIDALORSEN (Dawnzera)** requires the following rule(s) be met for renewal:
   A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
   B. You will NOT use Dawnzera concurrently (at the same time) with an alternative preventive medication for HAE attacks (such as Takhzyro [lanadelumab-flyo], Haegarda [C1 esterase inhibitor], Cinryze [C1 esterase inhibitor], Orladeyo [berotralstat], danazol, Andembry [garadacimab-gxii])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Dawnzera.

REFERENCES
Dawnzera [Prescribing Information]. Carlsbad, CA: Ionis Pharmaceuticals Inc.; September 2025.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DONIDALORSEN (PART D)

For Part D use only:

DONIDALORSEN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	HEREDITARY ANGIOEDEMA (HAE): INITIAL: 1) TYPE III HAE, OR 2) TYPE I OR II HAE CONFIRMED BY ONE OF THE FOLLOWING COMPLEMENT TESTS: C1-INH PROTEIN LEVELS, C4 PROTEIN LEVELS, C1-INH FUNCTIONAL LEVELS, C1Q.
Age Restrictions	N/A
Prescriber Restrictions	HAE: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH AN ALLERGIST, IMMUNOLOGIST, HEMATOLOGIST OR PULMONOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS
Other Criteria	HAE: INITIAL: 1) NOT ON CONCURRENT TREATMENT WITH ALTERNATIVE PROPHYLACTIC AGENT FOR HAE ATTACKS, AND 2) TRIAL OF OR CONTRAINDICATION TO ONE OF THE FOLLOWING PREFERRED AGENTS: CINRYZE, HAEGARDA, TAKHZYRO. RENEWAL: NOT ON CONCURRENT TREATMENT WITH ALTERNATIVE PROPHYLACTIC AGENT FOR HAE ATTACKS.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DORDAVIPRONE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DORDAVIPRONE HCL	MODEYSO	50809		GPI-10 (2158001520)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of diffuse midline glioma (ICD-10 C71.9) and meet **ALL** ofthe following criteria?
   - The patient is 1 year of age or older
   - The patient's tumor has an H3 K27M mutation
   - The patient's disease had progressed following prior therapy (e.g., temozolomide, radiation therapy)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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DORDAVIPRONE (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DORDAVIPRONE (Modeyso)** requires the following rule(s) be met for approval:

A. You have diffuse midline glioma (a type of brain cancer/tumor)
B. You are 1 year of age or older
C. Your tumor has an H3 K27M mutation (abnormal change in a type of gene)
D. Your disease has progressed (worsened) following prior therapy (such astemozolomide, radiation therapy)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Modeyso.

REFERENCES

Modeyso [Prescribing Information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; August 2025.

For Part D use only:

DORDAVIPRONE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 08/25
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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DOSTARLIMAB-GXLY (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DOSTARLIMAB-GXLY	JEMPERLI	47318		GPI-10 (2135792830)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of recurrent or advanced endometrial cancer (EC) (ICD-10 C54.1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer has mismatch repair deficient (dMMR) biomarkers, as determined by an FDA-approved test
   - The patient's cancer has progressed on or following prior treatment with a platinum-containing regimen (e.g., carboplatin)
   - The patient is not a candidate for curative surgery or radiation

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of primary advanced or recurrent endometrial cancer (EC) (ICD-10 C54.1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Jemperli will be used as a single agent OR in combination with carboplatin and paclitaxel

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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DOSTARLIMAB-GXLY (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of recurrent or advanced solid tumor and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's tumor has mismatch repair deficient (dMMR) biomarkers, as determined by an FDA-approved test
   - The patient's tumor has progressed on or following prior treatment (e.g., carboplatin, oxaliplatin, irinotecan)
   - The patient has no satisfactory alternative treatment options

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DOSTARLIMAB-GXLY (Jemperli)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Recurrent or advanced endometrial cancer (EC: cancer that starts in the lining of the uterus that has returned or has spread from the original site)
      2. Primary advanced or recurrent endometrial cancer
      3. Recurrent or advanced solid tumor

   B. If you have recurrent or advanced endometrial cancer, approval also requires:
      1. You are 18 years of age or older
      2. Your cancer has mismatch repair deficient (dMMR: a type of gene mutation) biomarkers, as determined by a Food and Drug Administration (FDA)-approved test
      3. Your cancer has progressed on or following previous treatment with a platinum-containing regimen (such as carboplatin)
      4. You are not a candidate for curative surgery (cure the disease) or radiation

   C. If you have primary advanced or recurrent endometrial cancer, approval also requires:
      1. You are 18 years of age or older
      2. Jemperli will be used as a single agent OR in combination with carboplatin and paclitaxel

   (Denial text continued on next page)

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DOSTARLIMAB-GXLY (PART D)

GUIDELINES FOR USE (CONTINUED)

D. If you have a recurrent or advanced solid tumor, approval also requires:

1. You are 18 years of age or older
2. Your tumor has mismatch repair deficient (dMMR: a type of gene mutation) biomarkers, as determined by a Food and Drug Administration (FDA)-approved test
3. Your tumor has progressed on or following prior treatment (such as carboplatin, oxaliplatin, irinotecan)
4. You have no satisfactory alternative treatment options

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Jemperli.

REFERENCES

Jemperli [Prescribing Information]. Philadelphia, PA: GlaxoSmithSkline LLC., August 2024.

For Part D use only:

DOSTARLIMAB-GXLY (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 05/21
Client Approval: 08/24
P&T Approval: 10/24

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DOXECITINE-DOXRIBTIMINE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DOXECITINE/ DOXRIBTIMINE	KYGEVVI	50999		GPI-10 (3090990220)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of thymidine kinase 2 deficiency (TK2d) **AND** meet the following criterion?
   - The patient's age at symptom onset for thymidine kinase 2 deficiency (TK2d) is 12 years or younger

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DOXECITINE-DOXRIBTIMINE (Kygevvi)** requires the following rule(s) be met for approval:
   A. You have thymidine kinase 2 deficiency (TK2d: a type of genetic disorder)
   B. Your age at symptom onset for thymidine kinase 2 deficiency (TK2d: a type of genetic disorder) is 12 years or younger

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DOXECITINE-DOXRIBTIMINE (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Kygevvi.

REFERENCES
Kygevvi [Prescribing Information]. Smyrna, GA: UCB, Inc.; November 2025.

For Part D use only:

DOXECITINE-DOXRIBTIMINE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 05/26
Effective: 06/19/26 Client Approval: 05/26 P&T Approval: 04/26

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DOXEPIN TOPICAL (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DOXEPIN HCL	PRUDOXIN, ZONALON, DOXEPIN HCL		21210	GPI-10 (9022001510)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of moderate pruritus (ICD-10 L29) associated with atopic dermatitis (ICD-10 Group L20) or lichen simplex chronicus (ICD-10 L28.0) and meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The requested medication will be used as short-term (up to 8 days) management of moderate pruritus

   If yes, **approve for 1 month by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DOXEPIN TOPICAL (Prudoxin, Zonalon)** requires the following rule(s) be met for approval:
   A. You have moderate pruritus (itching) associated with atopic dermatitis (type of red itchy skin condition) or lichen simplex chronicus (thickened skin from rubbing or scratching)
   B. You are 18 years of age or older
   C. The requested medication will be used as short-term (up to 8 days) management of moderate pruritus (itching)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DOXEPIN TOPICAL (PART D)

RATIONALE

For further information, please refer to the prescribing information and or drug monograph for Doxepin cream.

REFERENCES

Zonalon cream [Prescribing Information]. Morgantown, WV: Mylan Pharmaceuticals Inc.; June 2017.

Prudoxin cream [Prescribing Information]. Morgantown, WV: Mylan Pharmaceuticals Inc.; June 2017.

Doxepin HCl 5% cream [Prescribing Information]. Morgantown, WV: Mylan Pharmaceuticals Inc.; May 2017.

For Part D use only:

DOXEPIN TOPICAL (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 MONTH
Other Criteria	N/A

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25 Created: 05/18
Commercial Effective: N/A Client Approval: 08/24 P&T Approval: 10/18

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DRONABINOL CAPSULE BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DRONABINOL	MARINOL, DRONABINOL	01955		GPI-10 (5030003000)	

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding for the indication of nausea and vomiting associated with cancer chemotherapy.

1. Is the prescription written for greater than a 2-day (48-hours) supply?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D. (Populate the B vs. D field with a 'D' in the PA override field)**

   If no, continue to #2.

2. Is the prescription written for a full therapeutic replacement for an intravenous anti-emetic drug as part of a cancer chemotherapeutic regimen and is for use within 48 hours of the patient receiving cancer treatment?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B. (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field)**

   If no, **approve for 12 months by HICL or GPI-10 under Part D. (Populate the B vs. D field with a'D' in the PA override field)**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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DRONABINOL CAPSULE BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of anorexia (ICD-10 R63.0) or weight loss (ICD-10 R63.4) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has acquired immunodeficiency syndrome (AIDS)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of nausea and vomiting (ICD-10 Group R11) associated with cancer chemotherapy and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to ONE antiemetic therapy (e.g.,ondansetron, steroids indicated for emesis, aprepitant)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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DRONABINOL CAPSULE BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **DRONABINOL CAPSULE (Marinol)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Anorexia (loss of appetite) or weight loss
   2. Nausea and vomiting caused by cancer chemotherapy (medications used to treat cancer)

B. If you have anorexia or weight loss, approval also requires:
   1. You are 18 years of age or older
   2. You have acquired immunodeficiency syndrome (AIDS: a type of immune system disorder caused by a virus infection)

C. If you have nausea and vomiting caused by cancer chemotherapy, approval also requires:
   1. You are 18 years of age or older
   2. You have tried or have a contraindication to (harmful for you to use) ONE antiemetic therapy (medications used to treat nausea and vomiting, such as ondansetron, steroids indicated for emesis [vomiting], aprepitant)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Marinol.

Ensure that any use as a full therapeutic replacement for an intravenous anti-emetic drug as part of a cancer chemotherapeutic regimen within 48 hours of the patient receiving cancer treatment is billed under Part B. The assumption is that any prescription that exceeds a 2 day supply is by default not intended to specifically comply with the Medicare Part B requirement for Part B coverage of antiemetics, and therefore should be covered under Part D, irrespective of the timing relative to chemo (i.e. even if the prescription is filled within 48 hours of chemo).

REFERENCES

Marinol [Prescribing Information]. Parsippany, NJ: ThePharmaNetwork, LLC; January 2023.
Medicare Prescription Drug Benefit Manual Chapter 6 – Part D Drugs and Formulary Requirements, Appendix C- Summary of Coverage Policy, Medicare Part B Versus Part D Coverage Issues. Rev 18, 07-12-24. Available at: http://www.cms.gov/PrescriptionDrugCovContra/12_PartDManuals.asp. [Accessed April 9, 2025].

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DRONABINOL CAPSULE BvD (PART D)

For Part D use only:

DRONABINOL CAPSULE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 MONTHS
Other Criteria	NAUSEA AND VOMITING ASSOCIATED WITH CANCER CHEMOTHERAPY: TRIAL OF OR CONTRAINDICATION TO ONE ANTIEMETIC THERAPY.

Created: 11/15
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 05/20

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DROXIDOPA (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DROXIDOPA	NORTHERA, DROXIDOPA	40936		GPI-10 (3870003000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of neurogenic orthostatic hypotension (NOH) (ICD-10 G90.3) and meet **ALL** of the following criteria?
   - The patient's NOH is caused by ONE of the following: primary autonomic failure (Parkinson's disease, multiple system atrophy, or pure autonomic failure), dopamine beta-hydroxylase deficiency, or non-diabetic autonomic neuropathy
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist or cardiologist
   - The prescriber performed baseline blood pressure readings while the patient is sitting and also within 3 minutes of standing from a supine (lying face up) position
   - The patient has a decrease of at least 20 mmHg in systolic blood pressure or 10 mmHg diastolic blood pressure within three minutes after standing from a sitting position
   - The patient has symptoms of orthostatic dizziness, lightheadedness, or the 'feeling that you are about to black out'

   If yes, **approve for 3 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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DROXIDOPA (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DROXIDOPA (Northera)** requires the following rule(s) be met for approval:

A. You have neurogenic orthostatic hypotension (a type of low blood pressure) caused by ONE of the following:
   1. Primary autonomic failure (Parkinson's disease [a type of movement disorder], multiple system atrophy [a type of nervous system disorder], or pure autonomic failure [a type of nervous system disorder])
   2. Dopamine beta-hydroxylase deficiency (missing a type of enzyme)
   3. Non-diabetic autonomic neuropathy (a type of nerve disorder)

B. B. You are 18 years of age or older

C. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor) or cardiologist (a type of heart doctor)

D. Your doctor performed baseline blood pressure readings while you are sitting and also within 3 minutes of standing from a supine (lying face up) position

E. You have a decrease of at least 20 mmHg in systolic blood pressure or 10 mmHg diastolic blood pressure within three minutes after standing from a sitting position

F. You have symptoms of orthostatic dizziness, lightheadedness, or the feeling that you are about to 'black out'

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DROXIDOPA (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of neurogenic orthostatic hypotension (NOH) (ICD-10 G90.3) **AND** meet the following criterion?
   - The patient continues to benefit from the medication

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DROXIDOPA (Northera)** requires the following rule(s) be met for renewal:
   A. You have neurogenic orthostatic hypotension (a type of low blood pressure)
   B. You continue to benefit from the medication

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Northera.

REFERENCES

Northera [Prescribing Information]. Deerfield, IL: Lundbeck Pharmaceuticals LLC; July 2019.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DROXIDOPA (PART D)

For Part D use only:

DROXIDOPA (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	NEUROGENIC ORTHOSTATIC HYPOTENSION (NOH): INITIAL: 1) BASELINE BLOOD PRESSURE READINGS WHILE THE PATIENT IS SITTING AND ALSO WITHIN 3 MINUTES OF STANDING FROM A SUPINE POSITION. 2) A DECREASE OF AT LEAST 20 MMHG IN SYSTOLIC BLOOD PRESSURE OR 10 MMHG DIASTOLIC BLOOD PRESSURE WITHIN THREE MINUTES AFTER STANDING FROM A SITTING POSITION.
Age Restrictions	N/A
Prescriber Restrictions	NOH: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST OR CARDIOLOGIST.
Coverage Duration	NOH: INITIAL: 3 MONTHS RENEWAL: 12 MONTHS
Other Criteria	NOH: RENEWAL: CONTINUES TO BENEFIT FROM THE MEDICATION.

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25 Created: 05/14
Commercial Effective: N/A Client Approval: 08/24 P&T Approval: 11/16

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DUPILUMAB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DUPILUMAB	DUPIXENT	44180		GPI-10 (9027302000)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe atopic dermatitis (AD) (ICD-10 Group L20) and meet **ALL** of the following criteria?
   - The patient is 6 months of age or older
   - Therapy is prescribed by or in consultation with a dermatologist, allergist, or immunologist
   - Dupixent will NOT be used concurrently with another systemic biologic (e.g., Adbry [tralokinumab-ldrm]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Eucrisa (crisaborole)]) for the treatment of AD

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient have a trial of or contraindication to **ONE** of the following?
   - Topical corticosteroid (e.g., hydrocortisone, clobetasol propionate, halobetasol propionate)
   - Topical calcineurin inhibitor (e.g., Protopic [tacrolimus], Elidel [pimecrolimus])
   - Topical PDE-4 inhibitor (e.g., Eucrisa [crisaborole], Adquey [difamilast], Zoryve [roflumilast])
   - Topical AhR agonist (e.g., Vtama [tapinarof])
   - Topical JAK inhibitor (e.g., Opzelura [ruxolitinib])

   If yes, **approve for 6 months by HICL or GPI-10.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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DUPILUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of moderate to severe asthma with an eosinophilic phenotype (ICD-10 J82.83) and meet **ALL** of the following criteria?
   - The patient has a blood eosinophil level of 150 to 1500 cells/mcL within the past 12 months
   - Dupixent will NOT be used concurrently with another systemic biologic (e.g., Nucala [mepolizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of eosinophilic phenotype asthma

   If yes, continue to #5.
   If no, continue to #4.

4. Does the patient have a diagnosis of moderate to severe oral corticosteroid-dependent asthma (ICD-10 J45.909) **AND** meet the following criteria?
   - Dupixent will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of oral corticosteroid-dependent asthma

   If yes, continue to #5.
   If no, continue to #8.

5. Does the patient meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a physician specializing in pulmonary or allergy medicine
   - Dupixent will be used in combination with a medium, high-dose, or maximally-tolerated dose of an inhaled corticosteroid (e.g., beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (e.g., a long-acting inhaled beta2-agonist [e.g., salmeterol, formoterol], a long-acting muscarinic antagonist [e.g., Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [e.g., montelukast, zafirlukast, zileuton], theophylline)

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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DUPILUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

6. Does the patient meet **ONE** of the following criteria?
   - The patient has experienced at least ONE asthma exacerbation requiring systemic corticosteroid (e.g., prednisone) burst lasting at least 3 days within the past 12 months
   - The patient has experienced at least ONE serious asthma exacerbation requiring hospitalization or an ER visit within the past 12 months

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #7.

7. Does the patient have poor symptom control despite current therapy as evidenced by at least **THREE** of the following within the past 4 weeks?
   - Daytime asthma symptoms more than twice per week
   - Any night waking due to asthma
   - Use of a short-acting inhaled beta2-agonist (SABA) reliever (e.g., albuterol) for symptoms more than twice per week
   - Any activity limitation due to asthma

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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DUPILUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

8. Does the patient have a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) (ICD-10 Groups J32 and J33) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Dupixent will be used as add-on maintenance treatment
   - Therapy is prescribed by or in consultation with an otolaryngologist, allergist, or immunologist
   - There is evidence of nasal polyps by direct examination, endoscopy, or sinus CT scan
   - The patient has inadequately controlled disease
   - The patient had a 56-day trial of ONE intranasal corticosteroid (e.g., mometasone, fluticasone, beclomethasone)
   - Dupixent will NOT be used concurrently with another systemic biologic (e.g., Nucala [mepolizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CRSwNP

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, continue to #9.

9. Does the patient have a diagnosis of eosinophilic esophagitis (EoE) (ICD-10 K20.0) and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - The patient weighs at least 15 kg (33 lbs)
   - Therapy is prescribed by or in consultation with a gastroenterologist, allergist, or immunologist
   - The patient's diagnosis is confirmed by an esophagogastroduodenoscopy (EGD) with biopsy
   - Dupixent will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of EoE

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, continue to #10.

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DUPILUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

10. Does the patient have a diagnosis of prurigo nodularis (PN) (ICD-10 L28.1) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Therapy is prescribed by or in consultation with a dermatologist, immunologist, or allergist
    - The patient has chronic pruritus (itch lasting longer than 6 weeks), multiple pruriginous lesions (localized or general), and a history or sign of a prolonged scratching behavior
    - Dupixent will NOT be used concurrently with another systemic biologic (e.g., Nemluvio [nemolizumab-ilto]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) forthe treatment of PN

    If yes, **approve for 6 months by HICL or GPI-10.**
    If no, continue to #11.

11. Does the patient have a diagnosis of chronic obstructive pulmonary disease (COPD) (ICD-10 Group J44 except for ICD-10 J44.0 and ICD-10 J44.81) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - The patient has an eosinophilic phenotype COPD
    - Therapy is prescribed by or in consultation with a pulmonologist
    - Dupixent will be used in combination with a long-acting muscarinic antagonist (LAMA)/long-acting beta-2-agonist (LABA)/inhaled corticosteroid (ICS) (e.g., Trelegy Ellipta, Breztri Aerosphere, Spiriva with Symbicort)
    - Dupixent will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAKinhibitor, PDE-4 inhibitor [e.g., Daliresp (roflumilast)]) for the treatment of eosinophilic phenotype COPD

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #12.

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DUPILUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

12. Does the patient have a diagnosis of chronic spontaneous urticaria (CSU; also called chronic idiopathic urticaria [CIU]) (ICD-10 L50.1, L50.8, L50.9) and meet **ALL** of the following criteria?
    - The patient is 2 years of age or older
    - Therapy is prescribed by or in consultation with an allergist, dermatologist, or immunologist
    - The patient still experiences hives or angioedema on most days of the week for at least 6 weeks
    - The patient had a trial of and is maintained on, OR has a contraindication to, a second generation H1 anti-histamine (e.g., Clarinex [desloratadine], Xyzal [levocetirizine])
    - Dupixent will NOT be used concurrently with another systemic biologic (e.g., Xolair [omalizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of chronic spontaneous urticaria (chronic idiopathic urticaria)

    If yes, **approve for 6 months by HICL or GPI-10.**
    If no, continue to #13.

13. Does the patient have a diagnosis of bullous pemphigoid (BP) (ICD-10 L12.0) **AND** meet the following criterion?
    - The patient is 18 years of age or older

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #14.

14. Does the patient have a diagnosis of allergic fungal rhinosinusitis (AFRS) (ICD-10 J30.89) and meet **ALL** of the following criteria?
    - The patient is 6 years of age or older
    - The patient has a history of sino-nasal surgery

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, do not approve.
    DENIAL TEXT: See the initial denial text at the end of the guideline.

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DUPILUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: Our guideline named **DUPILUMAB (Dupixent)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe atopic dermatitis (AD: a type of skin condition)
   2. Moderate to severe asthma (a type of lung condition)
   3. Chronic rhinosinusitis with nasal polyps (CRSwNP: inflammation of nasal and sinus ways with small growths in the nose)
   4. Eosinophilic esophagitis (EoE: a type of immune system disorder)
   5. Prurigo nodularis (PN: a type of skin condition)
   6. Chronic obstructive pulmonary disease (COPD: a type of long-term lung condition)
   7. Chronic spontaneous urticaria (CSU: also called chronic idiopathic urticaria)[severe itching with unknown cause]
   8. Bullous pemphigoid (BP: a type of skin condition)
   9. Allergic fungal rhinosinusitis (AFRS: inflammation of nasal and sinus ways due to an allergic reaction to fungi)

B. If you have moderate to severe atopic dermatitis, approval also requires:
   1. You are 6 months of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
   3. You will NOT use Dupixent concurrently (at the same time) with another systemic biologic (such as Adbry [tralokinumab-ldrm]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Eucrisa (crisaborole)]) for the treatment of atopic dermatitis
   4. You have tried or have a contraindication to (harmful for you to use) ONE of the following: topical corticosteroid (such as hydrocortisone, clobetasol propionate, halobetasol propionate), topical calcineurin inhibitor (such as Protopic [tacrolimus], Elidel [pimecrolimus]), topical phosphodiesterase-4 inhibitor (such as Eucrisa [crisaborole]), Adquey [difamilast], Zoryve [roflumilast]), topical aryl hydrocarbon receptor (AhR) agonist (such as Vtama [tapinarof]), or topical JAK inhibitor (such as Opzelura [ruxolitinib])

(Initial denial text continued on next page)

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DUPILUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

C. If you have moderate to severe asthma, approval also requires:

1. You are 6 years of age or older
2. Therapy is prescribed by or in consultation with a doctor specializing in pulmonary (lung/breathing) or allergy medicine
3. You meet ONE of the following:
   a. You have an eosinophilic phenotype asthma (a type of inflammatory asthma) and meet all of the following:
      i. You have a blood eosinophil level (a type of lab test) of 150 to 1500 cells/mcL within the past 12 months
      ii. You will NOT use Dupixent concurrently (at the same time) with another systemic biologic (such as Nucala [mepolizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic phenotype asthma
   b. You have oral corticosteroid-dependent asthma, AND you will NOT use Dupixent concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of oral corticosteroid-dependent asthma
4. Dupixent will be used in combination with a medium, high-dose, or maximally-tolerated dose of an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis) such as a long-acting inhaled beta2-agonist (such as salmeterol, formoterol), a long-acting muscarinic antagonist (such as Tudorza (aclidinium)], Spiriva (tiotropium), Incruse Ellipta (umeclidinium), a leukotriene receptor antagonist (such as montelukast, zafirlukast, zileuton), theophylline
5. You meet ONE of the following:
   a. You have experienced at least ONE asthma exacerbation (worsening of symptoms) requiring systemic corticosteroid (such as prednisone) burst lasting at least 3 days within the past 12 months
   b. You have experienced at least ONE serious asthma exacerbation requiring hospitalization or an emergency room visit within the past 12 months
   c. You have poor symptom control despite current therapy as shown by at least THREE of the following within the past 4 weeks:
      i. Daytime asthma symptoms more than twice per week
      ii. Any night waking due to asthma
      iii. Use of a short-acting inhaled beta2-agonist reliever (such as albuterol) for symptoms more than twice per week
      iv. Any activity limitation due to asthma

(Initial denial text continued on next page)

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DUPILUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

D. If you have chronic rhinosinusitis with nasal polyps, approval also requires:
1. You are 12 years of age or older
2. Dupixent will be used as add-on maintenance treatment (taken on a regular basis)
3. Therapy is prescribed by or in consultation with an otolaryngologist (ear, nose, and throat doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
4. There is evidence of nasal polyps (non-cancerous growths) by direct examination, endoscopy (using a small camera), or sinus computed tomography (CT) scan (a type of imaging test)
5. You have inadequately controlled disease
6. You had a 56-day trial of ONE intranasal corticosteroid (such as mometasone, fluticasone, beclomethasone)
7. You will NOT use Dupixent concurrently (at the same time) with another systemic biologic (such as Nucala [mepolizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic rhinosinusitis with nasal polyps

E. If you have eosinophilic esophagitis, approval also requires:
1. You are 1 year of age or older
2. You weigh at least 15 kilograms (33 pounds)
3. Therapy is prescribed by or in consultation with a gastroenterologist (a type of doctor who treats digestive conditions), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
4. Your diagnosis is confirmed by an esophagogastroduodenoscopy (EGD) with biopsy (a test to look at the lining of the food pipe, stomach, and small intestine)
5. You will NOT use Dupixent concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic esophagitis

F. If you have prurigo nodularis, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor), immunologist (a type of immune system doctor), or allergist (a type of allergy doctor)
3. You have chronic pruritus (itch lasting longer than 6 weeks), multiple pruriginous lesions (wounds), and a history or sign of a prolonged scratching behavior
4. You will NOT use Dupixent concurrently (at the same time) with another systemic biologic (such as Nemluvio [nemolizumab-ilto]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of prurigo nodularis

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DUPILUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

G. If you have chronic obstructive pulmonary disease, approval also requires:
1. You are 18 years of age or older
2. You have an eosinophilic phenotype chronic obstructive pulmonary disease (COPD)(a type of inflammatory long-term lung condition)
3. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor)
4. Dupixent will be used in combination with a long-acting muscarinic antagonist (LAMA)/long-acting beta-2-agonist (LABA)/inhaled corticosteroid (ICS) (such as Trelegy Ellipta, Breztri Aerosphere, Spiriva with Symbicort)
5. You will NOT use Dupixent concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Daliresp (roflumilast)]) for the treatment of eosinophilic phenotype COPD

H. If you have chronic spontaneous urticaria (chronic idiopathic urticaria), approval also requires:
1. You are 2 years of age or older
2. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
3. You still experience hives or angioedema (a type of swelling) on most days of the week for at least 6 weeks
4. You have tried and are maintained on, OR you have a contraindication to (harmful for you to use), a second generation H1 anti-histamine (type of allergy medication, such as Clarinex [desloratadine], Xyzal [levocetirizine])
5. You will NOT use Dupixent concurrently (at the same time) with another systemic biologic (such as Xolair [omalizumab]) or targeted small molecules (such as JAK[Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic spontaneous urticaria (chronic idiopathic urticaria)

I. If you have bullous pemphigoid, approval also requires:
1. You are 18 years of age or older

J. If you have allergic fungal rhinosinusitis, approval also requires:
1. You are 6 years of age or older
2. You have a history of sino-nasal surgery (a type of surgery)

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DUPILUMAB (PART D)

RENEWAL CRITERIA

NOTE: For the diagnoses of bullous pemphigoid (BP) and allergic fungal rhinosinusitis (AFRS), please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of moderate to severe atopic dermatitis (AD) (ICD-10 Group L20) and meet **ALL** of the following criteria?
   - The patient has shown improvement while on Dupixent
   - Dupixent will NOT be used concurrently with another systemic biologic (e.g., Adbry [tralokinumab-ldrm]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Eucrisa (crisaborole)]) for the treatment of AD

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe asthma with an eosinophilic phenotype (ICD-10 J82.83) and meet **ALL** of the following criteria?
   - The patient continues to use an inhaled corticosteroid (e.g., beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (e.g., a long-acting inhaled beta2-agonist [e.g., salmeterol, formoterol], a long-acting muscarinic antagonist [e.g., Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [e.g., montelukast, zafirlukast, zileuton], theophylline)
   - Dupixent will NOT be used concurrently with another systemic biologic (e.g., Nucala [mepolizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of eosinophilic phenotype asthma

   If yes, continue to #4.
   If no, continue to #3.

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DUPILUMAB (PART D)

RENEWAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of moderate to severe oral corticosteroid-dependent asthma (ICD-10 J45.909) and meet **ALL** of the following criteria?
   - The patient continues to use an inhaled corticosteroid (e.g., beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (e.g., a long-acting inhaled beta2-agonist [e.g., salmeterol, formoterol], a long-acting muscarinic antagonist [e.g., Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [e.g., montelukast, zafirlukast, zileuton], theophylline)
   - Dupixent will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of oral corticosteroid-dependent asthma

   If yes, continue to #4.
   If no, continue to #5.

4. Has the patient shown a clinical response as evidenced by **ONE** of the following criteria?
   - Reduction in asthma exacerbations from baseline
   - Decreased utilization of rescue medications (e.g., albuterol)
   - Increase in percent predicted FEV1 from pretreatment baseline
   - Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

5. Does the patient have a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) (ICD-10 Groups J32 and J33) and meet **ALL** of the following criteria?
   - The patient has shown improvement on Dupixent
   - Dupixent will NOT be used concurrently with another systemic biologic (e.g., Nucala [mepolizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CRSwNP

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #6.

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DUPILUMAB (PART D)

RENEWAL CRITERIA (CONTINUED)

6. Does the patient have a diagnosis of eosinophilic esophagitis (EoE) (ICD-10 K20.0) and meet **ALL** of the following criteria?
- The patient has shown improvement while on Dupixent (e.g., symptom improvement or achieving histological remission defined as peak esophageal intraepithelial eosinophil count of 6 eos/hpf or less)
- Dupixent will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of EoE

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #7.

7. Does the patient have a diagnosis of prurigo nodularis (PN) (ICD-10 L28.1) and meet **ALL** of the following criteria?
- The patient has had improvement (reduction) of pruritus or pruriginous lesions
- Dupixent will NOT be used concurrently with another systemic biologic (e.g., Nemluvio [nemolizumab-ilto]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of PN

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #8.

8. Does the patient have a diagnosis of chronic obstructive pulmonary disease (COPD) (ICD-10 Group J44 except for ICD-10 J44.0 and ICD-10 J44.81) and meet **ALL** of the following criteria?
- The patient has an eosinophilic phenotype COPD
- Dupixent will be used in combination with a long-acting muscarinic antagonist (LAMA)/long-acting beta-2-agonist (LABA)/inhaled corticosteroid (ICS) (e.g., Trelegy Ellipta, Breztri Aerosphere, Spiriva with Symbicort)
- Dupixent will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Daliresp (roflumilast)]) for the treatment of eosinophilic phenotype COPD

If yes, continue to #9.
If no, continue to #10.

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DUPILUMAB (PART D)

RENEWAL CRITERIA (CONTINUED)

9. Has the patient shown a clinical response as evidenced by **ONE** of the following criteria?
   - The patient has a reduction in COPD exacerbations from baseline
   - The patient has a reduction in severity or frequency of COPD-related symptoms (e.g., wheezing, shortness of breath, coughing, sputum production)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

10. Does the patient have a diagnosis of chronic spontaneous urticaria (CSU; also called chronic idiopathic urticaria [CIU]) (ICD-10 L50.1, L50.8, L50.9) and meet **ALL** of the following criteria?
    - Therapy is prescribed by or in consultation with an allergist, dermatologist, or immunologist
    - The patient is maintained on, OR has a contraindication to, a second generation H1 anti-histamine (e.g., Clarinex [desloratadine], Xyzal [levocetirizine])
    - Dupixent will NOT be used concurrently with another systemic biologic (e.g., Xolair [omalizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of chronic spontaneous urticaria (chronic idiopathic urticaria)

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, do not approve.

    RENEWAL DENIAL TEXT: Our guideline named **DUPILUMAB (Dupixent)** requires the following rule(s) be met for renewal:
    A. You have ONE of the following:
       1. Moderate to severe atopic dermatitis (AD: a type of skin condition)
       2. Moderate to severe asthma (a type of lung condition)
       3. Chronic rhinosinusitis with nasal polyps (CRSwNP: inflammation of nasal and sinus ways with small growths in the nose)
       4. Eosinophilic esophagitis (EoE: a type of immune system disorder)
       5. Prurigo nodularis (PN: a type of skin condition)
       6. Chronic obstructive pulmonary disease (COPD: a type of long-term lung condition)
       7. Chronic spontaneous urticaria (CSU: also called chronic idiopathic urticaria) [severe itching with unknown cause]

    B. If you have moderate to severe atopic dermatitis, renewal also requires:
       1. You have shown improvement on Dupixent
       2. You will NOT use Dupixent concurrently (at the same time) with another systemic biologic (such as Adbry [tralokinumab-ldrm]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Eucrisa (crisaborole)]) for the treatment of atopic dermatitis

    (Renewal denial text continued on next page)

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DUPILUMAB (PART D)

RENEWAL CRITERIA (CONTINUED)

C. If you have moderate to severe asthma, renewal also requires:
1. You meet ONE of the following:
   a. You have an eosinophilic phenotype asthma (a type of inflammatory asthma), AND you will NOT use Dupixent concurrently (at the same time) with another systemic biologic (such as Nucala [mepolizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic phenotype asthma
   b. You have oral corticosteroid-dependent asthma, AND you will NOT use Dupixent concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of oral corticosteroid-dependent asthma
2. You will continue to use an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis) such as a long-acting inhaled beta2-agonist (such as salmeterol, formoterol), a long-acting muscarinic antagonist [such as Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [such as montelukast, zafirlukast, zileuton], theophylline)
3. You have shown a clinical response as evidenced by ONE the following:
   a. You have experienced a reduction (decrease) in asthma exacerbations (worsening of symptoms) from baseline (before treatment)
   b. You have decreased your use of rescue medications (such as albuterol)
   c. Your percent predicted FEV1 (amount of air exhaled in one second) has increased from pretreatment baseline (before starting Dupixent)
   d. You have experienced a reduction in severity or frequency of asthma-related symptoms (such as wheezing, shortness of breath, coughing)

D. If you have chronic rhinosinusitis with nasal polyps, renewal also requires:
1. You have shown improvement on Dupixent
2. You will NOT use Dupixent concurrently (at the same time) with another systemic biologic (such as Nucala [mepolizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic rhinosinusitis with nasal polyps

E. If you have eosinophilic esophagitis, renewal also requires:
1. You have shown improvement while on Dupixent (such as symptom improvement or achieving histological remission defined as peak esophageal intraepithelial eosinophil count of 6 eos/hpf or less [a type of test that evaluates disease status])
2. You will NOT use Dupixent concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic esophagitis

(Renewal denial text continued on next page)

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DUPILUMAB (PART D)

RENEWAL CRITERIA (CONTINUED)

F. If you have prurigo nodularis, renewal also requires:
1. You have experienced improvement or reduction of pruritus (itching) or pruriginous lesions (wounds)
2. You will NOT use Dupixent concurrently (at the same time) with another systemic biologic (such as Nemluvio [nemolizumab-ilto]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of prurigo nodularis

G. If you have chronic obstructive pulmonary disease, renewal also requires:
1. You have an eosinophilic phenotype chronic obstructive pulmonary disease (COPD) (a type of inflammatory long-term lung condition)
2. Dupixent will be used in combination with a long-acting muscarinic antagonist (LAMA)/long-acting beta-2-agonist (LABA)/inhaled corticosteroid (ICS) (such as Trelegy Ellipta, Breztri Aerosphere, Spiriva with Symbicort)
3. You will NOT use Dupixent concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Daliresp (roflumilast)]) for the treatment of eosinophilic phenotype COPD
4. You have shown a clinical response as evidenced by ONE the following:
   a. You have a reduction (decrease) in COPD exacerbations (worsening of symptoms) from baseline (before starting Dupixent)
   b. You have a reduction in severity or frequency of COPD-related symptoms (such as wheezing, shortness of breath, coughing, sputum [mucus] production)

H. If you have chronic spontaneous urticaria (chronic idiopathic urticaria), renewal also requires:
1. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
2. You are maintained on, OR you have a contraindication to (harmful for you to use), a second generation H1 antihistamine (type of allergy medication, such as Clarinex [desloratadine], Xyzal [levocetirizine])
3. You will NOT use Dupixent concurrently (at the same time) with another systemic biologic (such as Xolair [omalizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic spontaneous urticaria (chronic idiopathic urticaria)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Dupixent.

REFERENCES

- Dupixent [Prescribing Information]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; February 2026.

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DUPILUMAB (PART D)

For Part D use only:

DUPILUMAB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	INITIAL: EOSINOPHILIC ASTHMA: BLOOD EOSINOPHIL LEVEL OF 150 TO 1500 CELLS/MCL WITHIN THE PAST 12 MONTHS. EOSINOPHILIC ESOPHAGITIS (EOE): DIAGNOSIS CONFIRMED BY ESOPHAGOGASTRODUODENOSCOPY (EGD) WITH BIOPSY.
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: AD, PN, CSU: PRESCRIBED OR IN CONSULTATION WITH A DERMATOLOGIST, ALLERGIST OR IMMUNOLOGIST. ASTHMA: PRESCRIBED OR IN CONSULTATION WITH ALLERGIST OR PULMONOLOGIST. CRSWNP: PRESCRIBED OR IN CONSULTATION WITH OTOLARYNGOLOGIST, ALLERGIST OR IMMUNOLOGIST. EOE: PRESCRIBED OR IN CONSULTATION WITH GASTROENTEROLOGIST, ALLERGIST, OR IMMUNOLOGIST. COPD: PRESCRIBED OR IN CONSULTATION WITH PULMONOLOGIST. RENEWAL: CSU: PRESCRIBED OR IN CONSULTATION WITH ALLERGIST, DERMATOLOGIST, OR IMMUNOLOGIST.
Coverage Duration	BP, AFRS: 12 MO. AD/CRSWNP/EOE/PN/CSU: INITIAL/RENEWAL: 6 MO/12 MO. ASTHMA/COPD: INIT/RENEW: 12 MO.
Other Criteria	INITIAL: AD: TRIAL OF OR CONTRAINDICATION TO ONE TOPICAL (CORTICOSTEROID, CALCINEURIN INHIBITOR, PDE4 INHIBITOR, AHR AGONIST OR JAK INHIBITOR). ASTHMA: 1) CONCURRENT THERAPY WITH A MEDIUM, HIGH-DOSE OR MAXIMALLY-TOLERATED DOSE OF AN INHALED CORTICOSTEROID (ICS) AND ONE OTHER MAINTENANCE MEDICATION, AND 2) ONE ASTHMA EXACERBATION REQUIRING SYSTEMIC CORTICOSTEROID BURST LASTING AT LEAST 3 DAYS WITHIN THE PAST 12 MONTHS, OR ONE SERIOUS EXACERBATION REQUIRING HOSPITALIZATION OR ER VISIT WITHIN THE PAST 12 MONTHS, OR POOR SYMPTOM CONTROL DESPITE CURRENT THERAPY AS EVIDENCED BY AT LEAST THREE OF THE FOLLOWING WITHIN THE PAST 4 WEEKS: (A) DAYTIME ASTHMA SYMPTOMS MORE THAN TWICE/WEEK, (B) ANY NIGHT WAKING DUE TO ASTHMA, (C) SABA RELIEVER FOR SYMPTOMS MORE THAN TWICE/WEEK, (D) ANY ACTIVITY LIMITATION DUE TO ASTHMA. CHRONIC RHINOSINUSITIS WITH NASAL POLYPS (CRSWNP): 1) A 56 DAY TRIAL OF ONE TOPICAL NASAL CORTICOSTEROID, 2)

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	EVIDENCE OF NASAL POLYPS BY DIRECT EXAMINATION, ENDOSCOPY, OR SINUS CT SCAN, AND 3) INADEQUATELY CONTROLLED DISEASE. PRURIGO NODULARIS (PN): CHRONIC PRURITUS (ITCH MORE THAN 6 WEEKS), MULTIPLE PRURIGINOUS LESIONS, AND HISTORY OR SIGN OF A PROLONGED SCRATCHING BEHAVIOR. EOSINOPHILIC COPD: USED IN COMBINATION WITH A LAMA/LABA/ICS. CHRONIC SPONTANEOUS URTICARIA (CSU): 1) TRIAL OF AND MAINTAINED ON, OR CONTRAINDICATION TO A SECOND GENERATION H1 ANTI-HISTAMINE AND 2) STILL EXPERIENCES HIVES OR ANGIOEDEMA MOST DAYS OF THE WEEK FOR AT LEAST 6 WEEKS. INITIAL/RENEWAL : ALL INDICATIONS EXCEPT BULLOUS PEMPHIGOID (BP): NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION. RENEWAL: AD, CRSWNP, EOE: IMPROVEMENT WHILE ON THERAPY. ASTHMA: 1) CONTINUED USE OF ICS AND ONE OTHER MAINTENANCE MEDICATION, AND 2) CLINICAL RESPONSE AS EVIDENCED BY: (A) REDUCTION IN ASTHMA EXACERBATIONS FROM BASELINE, (B) DECREASED UTILIZATION OF RESCUE MEDICATIONS, (C) INCREASE IN PERCENT PREDICTED FEV1 FROM PRETREATMENT BASELINE, OR (D) REDUCTION IN SEVERITY OR FREQUENCY OF ASTHMA-RELATED SYMPTOMS. PN: IMPROVEMENT OR REDUCTION OF PRURITUS OR PRURIGINOUS LESIONS. EOSINOPHILIC COPD: 1) USED IN COMBINATION WITH A LAMA/LABA/ICS, AND 2) CLINICAL RESPONSE AS EVIDENCED BY ONE OF THE FOLLOWING: (A) REDUCTION IN COPD EXACERBATIONS FROM BASELINE, OR (B) REDUCTION IN SEVERITY OR FREQUENCY OF COPD-RELATED SYMPTOMS. CSU: MAINTAINED ON OR CONTRAINDICATION TO A SECOND GENERATION H1 ANTI-HISTAMINE.

Created: 01/17
Effective: 08/01/26 Client Approval: 07/26 DMC Approval: 06/30/26

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DURVALUMAB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DURVALUMAB	IMFINZI	44230		GPI-10 (2135822900)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of non-small cell lung cancer (NSCLC) (ICD-10 Group C34) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, continue to #5.

2. Does the patient have resectable (node positive or tumors are at least 4 cm) cancer and meet **ALL** of the following criteria?
   - The patient has no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements
   - Imfinzi will be used in combination with platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin) as neoadjuvant treatment, OR as a single agent as adjuvant treatment after surgery and prior use in combination with platinum-containing chemotherapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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DURVALUMAB (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have unresectable Stage III cancer **AND** meet the following criterion?
   - The patient's disease has NOT progressed following concurrent platinum-based chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin) and radiation therapy (cCRT)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

4. Does the patient have metastatic cancer and meet **ALL** of the following criteria?
   - The patient does NOT have sensitizing epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) genomic tumor aberrations
   - Imfinzi will be used in combination with Imjudo (tremelimumab-actl) and platinum-based chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Does the patient have a diagnosis of small cell lung cancer (SCLC) (ICD-10 Group C34) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #6.
   If no, continue to #8.

6. Does the patient have limited-stage (LS) cancer **AND** meet the following criterion?
   - The patient's disease has NOT progressed following concurrent platinum-based chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin) and radiation therapy (cCRT)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #7.

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DURVALUMAB (PART D)

GUIDELINES FOR USE (CONTINUED)

7. Does the patient have extensive-stage (ES) cancer **AND** meet the following criterion?
   - Imfinzi will be used in combination with etoposide, AND either carboplatin or cisplatin

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

8. Does the patient have a diagnosis of locally advanced or metastatic biliary tract cancer (BTC) (ICD-10 Group C24) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Imfinzi will be used in combination with gemcitabine and cisplatin

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #9.

9. Does the patient have a diagnosis of unresectable hepatocellular carcinoma (uHCC) (ICD-10 C22.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Imfinzi will be used in combination with Imjudo (tremelimumab-actl)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #10.

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DURVALUMAB (PART D)

GUIDELINES FOR USE (CONTINUED)

10. Does the patient have a diagnosis of primary advanced or recurrent endometrial cancer (ICD-10 C54.1) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - The patient's cancer is mismatch repair deficient (dMMR), as determined by an FDA-approved test
    - Imfinzi will be used in combination with carboplatin and paclitaxel, OR as a single agent after prior use in combination with carboplatin and paclitaxel

    If yes, **approve for 12 months by HICL or GPI-10.**
    APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

    If no, continue to #11.

11. Does the patient have a diagnosis of high-risk non-muscle invasive bladder cancer (NMIBC) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - The patient is Bacillus Calmette-Guerin (BCG) naive
    - Imfinzi will be used in combination with Bacillus Calmette-Guerin (BCG)

    If yes, **approve for 12 months by HICL or GPI-10.**
    APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

    If no, continue to #12.

12. Does the patient have a diagnosis of muscle invasive bladder cancer (MIBC) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Imfinzi will be used in combination with gemcitabine and cisplatin as neoadjuvant treatment, OR as a single agent as adjuvant treatment following radical cystectomy and prior use in combination with gemcitabine and cisplatin

    If yes, **approve for 12 months by HICL or GPI-10.**
    APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

    If no, continue to #13.

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DURVALUMAB (PART D)

GUIDELINES FOR USE (CONTINUED)

13. Does the patient have a diagnosis of resectable gastric or gastroesophageal junction adenocarcinoma (GC/GEJC) (ICD-10 Group C16) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Imfinzi will be used in combination with fluorouracil, leucovorin, oxaliplatin and docetaxel (FLOT) as neoadjuvant and adjuvant treatment, OR as a single-agent after prior use in combination with FLOT

    If yes, **approve for 12 months by HICL or GPI-10.**
    APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

    If no, do not approve.

    DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

    Our guideline named **DURVALUMAB (Imfinzi)** requires the following rule(s) be met for approval:

    A. You have ONE of the following:
        1. Non-small cell lung cancer (NSCLC: a type of lung cancer)
        2. Small cell lung cancer (SCLC: a type of lung cancer)
        3. Locally advanced or metastatic biliary tract cancer (a type of biliary tract cancer that has spread from where it started to nearby tissue or lymph nodes or has spread to other parts of the body)
        4. Unresectable hepatocellular carcinoma (a type of liver cancer that cannot be completely removed by surgery)
        5. Primary advanced or recurrent endometrial cancer (a type of uterus cancer that has spread or has returned after treatment)
        6. High-risk non-muscle invasive bladder cancer (NMIBC: bladder cancer that has not spread to the muscles)
        7. Muscle invasive bladder cancer (MIBC: bladder cancer that has spread to the muscles)
        8. Resectable gastric or gastroesophageal junction adenocarcinoma (GC/GEJC) (a type of digestive system cancer that can be removed by surgery)

    (Denial text continued on next page)

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DURVALUMAB (PART D)

GUIDELINES FOR USE (CONTINUED)

B. If you have non-small cell lung cancer, approval also requires:
1. You are 18 years of age or older
2. You meet ONE of the following:
   a. Your cancer is resectable (can be removed by surgery) (node positive [has spread to the lymph nodes] or tumors are at least 4 cm); you have no known epidermal growth factor receptor (EGFR: a type of protein) mutations (abnormal change in a type of gene) or anaplastic lymphoma kinase (ALK: a type of enzyme) rearrangements; and Imfinzi will be used in combination with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin) as neoadjuvant treatment (given before main treatment), OR as a single agent as adjuvant treatment (additional treatment) after surgery and previous use in combination with platinum-containing chemotherapy
   b. Your cancer is Stage III and unresectable (cannot be completely removed by surgery); and your disease has NOT progressed (worsened) after using concurrent (at the same time) platinum-based chemotherapy (such as cisplatin, carboplatin, oxaliplatin) and radiation therapy (cCRT: concurrent chemoradiotherapy)
   c. Your cancer is metastatic (cancer that has spread to other parts of the body); you do NOT have sensitizing epidermal growth factor receptor (EGFR: a type of protein) mutations (abnormal change in a type of gene) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations (a type of abnormal gene); and Imfinzi will be used in combination with Imjudo (tremelimumab-actl) and platinum-based chemotherapy (such as cisplatin, carboplatin, oxaliplatin)

C. If you have small cell lung cancer, approval also requires:
1. You are 18 years of age or older
2. You meet ONE of the following:
   a. You have limited-stage cancer (LS: cancer that is contained in a single area on one side of the chest) AND your disease has NOT progressed (worsened) following concurrent (at the same time) platinum-based chemotherapy (such as cisplatin, carboplatin, oxaliplatin) and radiation therapy (cCRT: concurrent chemoradiotherapy)
   b. You have extensive-stage cancer (ES: cancer that has spread widely throughout the lungs or other parts of the body) and Imfinzi will be used in combination with etoposide, AND either carboplatin or cisplatin

D. If you have locally advanced or metastatic biliary tract cancer, approval also requires:
1. You are 18 years of age or older
2. Imfinzi will be used in combination with gemcitabine and cisplatin

E. If you have unresectable hepatocellular carcinoma, approval also requires:
1. You are 18 years of age or older
2. Imfinzi will be used in combination with Imjudo (tremelimumab-actl)

(Denial text continued on next page)

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DURVALUMAB (PART D)

GUIDELINES FOR USE (CONTINUED)

F. If you have primary advanced or recurrent endometrial cancer, approval also requires:
1. You are 18 years of age or older
2. Your cancer is mismatch repair deficient (dMMR: a type of gene mutation [abnormal change]), as determined by a Food and Drug Administration (FDA)-approved test
3. Imfinzi will be used in combination with carboplatin and paclitaxel, OR as a single agent after previous use in combination with carboplatin and paclitaxel

G. If you have high-risk non-muscle invasive bladder cancer, approval also requires:
1. You are 18 years of age or older
2. You are Bacillus Calmette-Guerin (BCG: a type of bladder cancer treatment) naive (have not previously used BCG)
3. You will use Imfinzi in combination with Bacillus Calmette-Guerin (BCG)

H. If you have muscle invasive bladder cancer, approval also requires:
1. You are 18 years of age or older
2. Imfinzi will be used in combination with gemcitabine and cisplatin as neoadjuvant treatment (given before main treatment), OR as a single agent as adjuvant treatment (additional treatment) following radical cystectomy (bladder removal surgery) and previous use in combination with gemcitabine and cisplatin

I. If you have resectable gastric or gastroesophageal junction adenocarcinoma, approval also requires:
1. You are 18 years of age or older
2. Imfinzi will be used in combination with fluorouracil, leucovorin, oxaliplatin and docetaxel (FLOT) as neoadjuvant (given before main treatment) and adjuvant (add-on) treatment, OR as a single-agent after prior use in combination with FLOT

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DURVALUMAB (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Imfinzi.

REFERENCES

Imfinzi [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; May 2026.

For Part D use only:

DURVALUMAB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 05/17
Effective: 06/17/26 Client Approval: 06/26 P&T Approval: 01/26

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COSRE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DUVELISIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DUVELISIB	COPIKTRA	45269		GPI-10 (2153803000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory chronic lymphocytic leukemia (CLL) (ICD-10 Group C91.1) or small lymphocytic lymphoma (SLL) (ICD-10 Group C83.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received at least two prior therapies for CLL or SLL

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DUVELISIB (Copiktra)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Relapsed or refractory chronic lymphocytic leukemia (CLL: a type of blood cancer that has returned after treatment or did not fully respond to treatment)
      2. Small lymphocytic lymphoma (SLL: a type of blood cancer)
   B. You are 18 years of age or older
   C. You have received at least two prior therapies for chronic lymphocytic leukemia or small lymphocytic lymphoma

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DUVELISIB (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Copiktra.

REFERENCES
Copiktra [Prescribing Information]. Verastem, Inc.: Needham, MA; December 2021.

For Part D use only:

DUVELISIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25 Created: 10/18
Commercial Effective: N/A Client Approval: 08/24 P&T Approval: 10/18

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ECALLANTIDE BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ECALLANTIDE	KALBITOR	36797		GPI-10 (8584003000)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	Yes	No	No	Yes	No	No	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #5.

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ECALLANTIDE BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

If yes, **Refer to plan. (The health plan makes the final payment determination decision)**

- **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
- **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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ECALLANTIDE BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hereditary angioedema (HAE) (ICD-10 D84.1) and meet **ALL** of the following criteria?
- The patient is 12 years of age or older
- Kalbitor will be used for the treatment of acute HAE attacks
- Therapy is prescribed by or in consultation with an allergist, immunologist, hematologist, or pulmonologist
- Kalbitor will be administered by a healthcare professional with appropriate medical supportto manage anaphylaxis and/or angioedema
- Kalbitor will NOT be used concurrently with other agents used for the treatment of acute HAE attacks (e.g., Ruconest [C1 esterase inhibitor], Firazyr [icatibant], Berinert [C1 esterase inhibitor])

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
- The patient has Type I or II HAE, as confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q
- The patient has Type III HAE

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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ECALLANTIDE BvD (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ECALLANTIDE (Kalbitor)** requires the following rule(s) be met for approval:

A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
B. You are 12 years of age or older
C. Kalbitor will be used for the treatment of acute (sudden and severe) hereditary angioedema attacks
D. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), immunologist (a type of immune system doctor), hematologist (a type of blood doctor), or pulmonologist (lung/breathing doctor)
E. Kalbitor will be administered by a healthcare professional with appropriate medical support to manage anaphylaxis (severe allergic reaction) and/or angioedema (a type of swelling)
F. You will NOT use Kalbitor concurrently (at the same time) with other medications used for the treatment of acute (sudden and severe) HAE attacks (such as Ruconest [C1 esterase inhibitor], Firazyr [icatibant], Berinert [C1 esterase inhibitor])
G. You meet ONE of the following:
    1. You have Type I or II hereditary angioedema (a type of gene condition with severe body swelling), as confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q (types of lab tests)
    2. You have Type III hereditary angioedema (a type of gene condition with severe body swelling)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ECALLANTIDE BvD (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary angioedema (HAE) (ICD-10 D84.1) **AND** meet the following criterion?
   - Kalbitor will NOT be used concurrently with other agents used for the treatment of acute HAE attacks (e.g., Ruconest [C1 esterase inhibitor], Firazyr [icatibant], Berinert [C1 esterase inhibitor])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ECALLANTIDE (Kalbitor)** requires the following rule(s) be met for renewal:
   A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
   B. You will NOT use Kalbitor concurrently (at the same time) with other medications used for the treatment of acute (sudden and severe) HAE attacks (such as Ruconest [C1 esterase inhibitor], Firazyr [icatibant], Berinert [C1 esterase inhibitor])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ECALLANTIDE BvD (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kalbitor. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Kalbitor [Prescribing Information]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; June 2025.

Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed February 3, 2026].

For Part D use only:

ECALLANTIDE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	HEREDITARY ANGIOEDEMA (HAE): INITIAL: 1) TYPE III HAE, OR 2) TYPE I OR II HAE CONFIRMED BY ONE OF THE FOLLOWING COMPLEMENT TESTS: C1-INH PROTEIN LEVELS, C4 PROTEIN LEVELS, C1-INH FUNCTIONAL LEVELS, C1Q.
Age Restrictions	N/A
Prescriber Restrictions	HAE: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH AN ALLERGIST, IMMUNOLOGIST, HEMATOLOGIST, OR PULMONOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	HAE: INITIAL: KALBITOR WILL BE ADMINISTERED BY A HEALTHCARE PROFESSIONAL WITH APPROPRIATE MEDICAL SUPPORT TO MANAGE ANAPHYLAXIS AND/OR ANGIOEDEMA. INITIAL/RENEWAL: NO CONCURRENT USE WITH OTHER MEDICATIONS FOR TREATMENT OF ACUTE HAE ATTACKS.

Created: 10/19
Effective: 03/01/26 Client Approval: 02/26 P&T Approval: 04/25

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ECULIZUMAB BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ECULIZUMAB	SOLIRIS	34618		GPI-10 (8580505000)	

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**
   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**
   If no continue to #5.

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override)**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.
Guideline interpretation beyond this point requires Clinical/Technician review.

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ECULIZUMAB BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS) (ICD-10 D59.31)?

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.
   If no, continue to #2.

2. Does the patient have a diagnosis of atypical hemolytic uremic syndrome (aHUS) (ICD-10 D59.32, D59.39)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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ECULIZUMAB BvD (PART D)

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) (ICD-10 D59.5) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a hematologist
   - The patient's diagnosis is confirmed by flow cytometry that shows PNH granulocyte clone size of at least 10% AND at least 2 different GPI-protein deficiencies (e.g., CD55, CD59) on at least 2 cell lineages (e.g., erythrocytes, granulocytes)
   - Soliris will NOT be used concurrently with another C5 complement inhibitor therapy (e.g., Ultomiris [ravulizumab-cwvz], Piasky [crovalimab-akkz]), C3 complement inhibitor (e.g., Empaveli [pegcetacoplan]), or factor B inhibitor (e.g., Fabhalta [iptacopan])
   - The patient has tried and failed (as evidenced by hemoglobin levels less than 10.5 g/dL directly following at least 3 months of stable dosing) OR has a contraindication to Fabhalta (iptacopan) or Ultomiris (ravulizumab-cwvz)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

4. Does the patient have a diagnosis of generalized myasthenia gravis (gMG) (ICD-10 Group G70.0) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - The patient is anti-acetylcholine receptor (AchR) antibody positive
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient is in Myasthenia Gravis Foundation of America class II, III, or IV
   - The patient had a trial of or contraindication to ONE corticosteroid (e.g., prednisone)
   - The patient had a trial of or contraindication to ONE non-steroidal immunosuppressive therapy (e.g., azathioprine, cyclophosphamide, methotrexate)
   - Soliris will NOT be used concurrently with another neonatal Fc receptor blocker (e.g., Rystiggo [rozanolixizumab-noli], Vyvgart [efgartigimod alfa-fcab]) or complement inhibitor (e.g., Ultomiris [ravulizumab-cwvz], Zilbrysq [zilucoplan]) for the treatment of gMG

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

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ECULIZUMAB BvD (PART D)

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of neuromyelitis optica spectrum disorder (NMOSD) (ICD-10 G36.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist or ophthalmologist
   - The patient has a positive serologic test for anti-aquaporin-4 (AQP4) antibodies
   - Soliris will NOT be used concurrently with another NMOSD agent (e.g., Rituxan [rituximab], Uplizna [inebilizumab-cdon], Enspryng [satralizumab-mwge], Ultomiris [ravulizumab-cwvz])
   - The patient had a trial of or contraindication to the preferred C5 inhibitor: Ultomiris (ravulizumab-cwvz)

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

6. Does the patient have at least **ONE** of the following core clinical characteristics?
   - Optic neuritis
   - Acute myelitis
   - Area postrema syndrome
   - Acute brainstem syndrome
   - Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions
   - Symptomatic cerebral syndrome with NMOSD-typical brain lesions

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ECULIZUMAB (Soliris)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Atypical hemolytic uremic syndrome (aHUS: a rare blood disorder)
      2. Paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
      3. Generalized myasthenia gravis (gMG: a chronic autoimmune disorder)
      4. Neuromyelitis optica spectrum disorder (NMOSD: a type of brain disorder)

   (Initial denial text continued on next page)

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ECULIZUMAB BvD (PART D)

INITIAL CRITERIA (CONTINUED)

B. Soliris is NOT being used for hemolytic uremic syndrome related to Shiga toxin E. coli (a type of bacteria causing small blood vessels in the kidneys to become damaged and inflamed)

C. If you have paroxysmal nocturnal hemoglobinuria, approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
3. Your PNH diagnosis is confirmed by ALL of the following through flow cytometry (test to measure characteristics of cells):
   a. You have at least 2 different GPI-protein deficiencies (missing a certain type of protein, such as CD55, CD59) on at least 2 cell lineages (types of cells such as erythrocytes [red blood cells], granulocytes [a type of white blood cell])
   b. PNH granulocyte clone size is at least 10%
4. You will NOT use Soliris concurrently (at the same time) with another C5 complement inhibitor therapy (such as Ultomiris [ravulizumab-cwvz], Piasky [crovalimab-akkz]), C3 complement inhibitor (such as Empaveli [pegcetacoplan]), or factor B inhibitor (such as Fabhalta [iptacopan])
5. You meet ONE of the following:
   a. You have tried and failed (drug did not work) Fabhalta (iptacopan) or Ultomiris (ravulizumab-cwvz), as shown by hemoglobin (a type of protein in red blood cells) levels less than 10.5 g/dL directly following at least 3 months of stable dosing
   b. You have a contraindication to (harmful for you to use) Fabhalta (iptacopan) or Ultomiris (ravulizumab-cwvz)

D. If you have generalized myasthenia gravis, approval also requires:

1. You are 6 years of age or older
2. You are anti-acetylcholine receptor (AchR) antibody positive (an indicator of disease)
3. Therapy is prescribed by or in consultation with a neurologist (type of brain and nervous system doctor)
4. You are in Myasthenia Gravis Foundation of America class II, III, or IV (indicates severity of disease)
5. You have tried or have a contraindication to (harmful for you to use) ONE corticosteroid (such as prednisone)
6. You have tried or have a contraindication to (harmful for you to use) ONE non-steroidal immunosuppressive therapy (treatment that lowers the body's immune system activity, such as azathioprine, cyclophosphamide, methotrexate)
7. You will NOT use Soliris concurrently (at the same time) with another neonatal Fc receptor blocker (such as Rystiggo [rozanolixizumab-noli], Vyvgart [efgartigimod alfa-fcab]) or complement inhibitor (such as Ultomiris [ravulizumab-cwvz], Zilbrysq [zilucoplan]) for the treatment of generalized myasthenia gravis

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ECULIZUMAB BvD (PART D)

INITIAL CRITERIA (CONTINUED)

E. If you have neuromyelitis optica spectrum disorder, approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor) or ophthalmologist (a type of eye doctor)
3. You have a positive serologic (blood) test for anti-aquaporin-4 (AQP4: type of protein) antibodies
4. You will NOT use Soliris concurrently (at the same time) with another neuromyelitis optica spectrum disorder (NMOSD) medication (such as Rituxan [rituximab], Uplizna [inebilizumab-cdon], Enspryng [satralizumab-mwge], Ultomiris [ravulizumab-cwvz])
5. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Ultomiris (ravulizumab-cwvz)
6. You have at least ONE of the following core clinical characteristics:
   a. Optic neuritis (inflammation that damages eye nerve)
   b. Acute myelitis (sudden and severe spinal cord inflammation)
   c. Area postrema syndrome (attacks of uncontrollable nausea, vomiting, or hiccups for several days)
   d. Acute brainstem syndrome (problems with vision, hearing, swallowing and muscle weakness in the head)
   e. Symptomatic narcolepsy (sudden sleepiness) or acute diencephalic clinical syndrome (tumor in a part of brain) with NMOSD-typical diencephalic magnetic resonance imaging (MRI: a type of imaging lab) lesions (affected areas)
   f. Symptomatic cerebral syndrome with NMOSD-typical brain lesions

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ECULIZUMAB BvD (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS) (ICD-10 D59.31)?

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.
   If no, continue to #2.

2. Does the patient have a diagnosis of atypical hemolytic uremic syndrome (aHUS) (ICD-10 D59.32, D59.39)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Does the patient have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) (ICD-10 D59.5) and meet **ALL** of the following criteria?
   - The patient has had clinical benefit (e.g., reduction in number of blood transfusions, improvement/stabilization of lactate dehydrogenase and hemoglobin levels) compared to baseline
   - Soliris will NOT be used concurrently with another C5 complement inhibitor therapy (e.g., Ultomiris [ravulizumab-cwvz], Piasky [crovalimab-akkz]), C3 complement inhibitor (e.g., Empaveli [pegcetacoplan]), or factor B inhibitor (e.g., Fabhalta [iptacopan])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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ECULIZUMAB BvD (PART D)

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of generalized myasthenia gravis (gMG) (ICD-10 Group G70.0) and meet **ALL** of the following criteria?
   - The patient has had clinical benefit compared to baseline (e.g., Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool)
   - Soliris will NOT be used concurrently with another neonatal Fc receptor blocker (e.g., Rystiggo [rozanolixizumab-noli], Vyvgart [efgartigimod alfa-fcab]) or complement inhibitor (e.g., Ultomiris [ravulizumab-cwvz], Zilbrysq [zilucoplan]) for the treatment of gMG

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Does the patient have a diagnosis of neuromyelitis optica spectrum disorder (NMOSD) (ICD-10 G36.0) and meet **ALL** of the following criteria?
   - The patient has had clinical benefit compared to baseline (e.g., reduction in relapse frequency)
   - Soliris will NOT be used concurrently with another NMOSD agent (e.g., Rituxan [rituximab], Uplizna [inebilizumab-cdon], Enspryng [satralizumab-mwge], Ultomiris [ravulizumab-cwvz])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ECULIZUMAB (Soliris)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
      2. Atypical hemolytic uremic syndrome (aHUS: a rare blood disorder)
      3. Generalized myasthenia gravis (gMG: a chronic autoimmune disorder)
      4. Neuromyelitis optica spectrum disorder (NMOSD: a type of brain disorder)

   (Renewal denial text continued on next page)

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ECULIZUMAB BvD (PART D)

RENEWAL CRITERIA (CONTINUED)

B. Soliris is NOT being used for hemolytic uremic syndrome related to Shiga toxin E. coli (a type of bacteria causing small blood vessels in the kidneys to become damaged and inflamed)

C. If you have paroxysmal nocturnal hemoglobinuria, renewal also requires:
1. You have had clinical benefit (such as reduction in number of blood transfusions [adding blood to the body], improvement/stabilization of lactate dehydrogenase [an enzyme] and hemoglobin [a type of protein in red blood cells] levels) compared to baseline (before treatment)
2. You will NOT use Soliris concurrently (at the same time) with another C5 complement inhibitor therapy (such as Ultomiris [ravulizumab-cwvz], Piasky [crovalimab-akkz]), C3 complement inhibitor (such as Empaveli [pegcetacoplan]), or factor B inhibitor (such as Fabhalta [iptacopan])

D. If you have generalized myasthenia gravis, renewal also requires:
1. You have had clinical benefit compared to baseline (such as shown by the Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool)
2. You will NOT use Soliris concurrently (at the same time) with another neonatal Fc receptor blocker (such as Rystiggo [rozanolixizumab-noli], Vyvgart [efgartigimod alfa-fcab]) or complement inhibitor (such as Ultomiris [ravulizumab-cwvz], Zilbrysq [zilucoplan]) for the treatment of generalized myasthenia gravis

E. If you have neuromyelitis optica spectrum disorder, renewal also requires:
1. You have had clinical benefit compared to baseline (before treatment) (such as a reduction in relapse frequency)
2. You will NOT use Soliris concurrently (at the same time) with another neuromyelitis optical spectrum disorder (NMOSD) medication (such as Rituxan [rituximab], Uplizna [inebilizumab-cdon], Enspryng [satralizumab-mwge], Ultomiris [ravulizumab-cwvz])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ECULIZUMAB BvD (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Review for Soliris.

The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Soliris [Prescribing Information]. Boston, MA: Alexion Pharmaceuticals, Inc.; February 2025.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed July 3, 2024].

For Part D use only:

ECULIZUMAB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	INITIAL/RENEWAL: SHIGA TOXIN E. COLI RELATED HEMOLYTIC UREMIC SYNDROME (STEC-HUS).
Required Medical Information	INITIAL: PAROXYSMAL NOCTURNAL HEMOGLOBINURIA (PNH): DIAGNOSIS CONFIRMED VIA FLOW CYTOMETRY: 1) AT LEAST TWO DIFFERENT GPI PROTEIN DEFICIENCIES ON AT LEAST TWO CELL LINEAGES, AND 2) PNH GRANULOCYTE CLONE SIZE OF AT LEAST 10 PERCENT.
Age Restrictions	INITIAL: PNH: 18 YEARS OF AGE OR OLDER.
Prescriber Restrictions	INITIAL: PNH: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST. GENERALIZED MYASTHENIA GRAVIS (GMG): PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST. NEUROMYELITIS OPTICA SPECTRUM DISORDER (NMOSD): PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST OR OPHTHALMOLOGIST.
Coverage Duration	INITIAL: AHUS, NMOSD: 12 MONTHS. PNH, GMG: 6 MONTHS. RENEWAL (ALL INDICATIONS): 12 MONTHS.
Other Criteria	INITIAL: PNH: 1) NO CONCURRENT USE WITH ANOTHER C5 COMPLEMENT INHIBITOR THERAPY, C3 COMPLEMENT INHIBITOR, OR FACTOR B INHIBITOR, AND 2) TRIAL AND FAILURE OF (AS EVIDENCED BY HEMOGLOBIN LEVELS LESS THAN 10.5 G/DL DIRECTLY FOLLOWING AT LEAST 3 MONTHS OF STABLE DOSING) OR CONTRAINDICATION TO FABHALTA OR ULTOMIRIS. GMG: 1) MYASTHENIA GRAVIS FOUNDATION OF AMERICA CLASS II, III, OR IV, 2) TRIAL OF OR CONTRAINDICATION TO ONE CORTICOSTEROID, 3) TRIAL OF OR CONTRAINDICATION TO ONE NON-STEROIDAL

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	IMMUNOSUPPRESSIVE THERAPY, AND 4) NO CONCURRENT USE WITH ANOTHER NEONATAL FC RECEPTOR BLOCKER OR COMPLEMENT INHIBITOR FOR GMG. NMOSD: 1) HAS ONE CORE CLINICAL CHARACTERISTIC: OPTIC NEURITIS, ACUTE MYELITIS, AREA POSTREMA SYNDROME, ACUTE BRAINSTEM SYNDROME, SYMPTOMATIC NARCOLEPSY OR ACUTE DIENCEPHALIC CLINICAL SYNDROME WITH NMOSD-TYPICAL DIENCEPHALIC MRI LESIONS, OR SYMPTOMATIC CEREBRAL SYNDROME WITH NMOSD-TYPICAL BRAIN LESIONS, 2) NO CONCURRENT USE WITH ANOTHER NMOSD AGENT, AND 3) TRIAL OF OR CONTRAINDICATION TO THE PREFERRED C5 INHIBITOR: ULTOMIRIS. RENEWAL: PNH: 1) CLINICAL BENEFIT COMPARED TO BASELINE, AND 2) NO CONCURRENT USE WITH ANOTHER C5 COMPLEMENT INHIBITOR THERAPY, C3 COMPLEMENT INHIBITOR, OR FACTOR B INHIBITOR. GMG: 1) CLINICAL BENEFIT COMPARED TO BASELINE, AND 2) NO CONCURRENT USE WITH ANOTHER NEONATAL FC RECEPTOR BLOCKER OR COMPLEMENT INHIBITOR FOR GMG. NMOSD: 1) CLINICAL BENEFIT COMPARED TO BASELINE, AND 2) NO CONCURRENT USE WITH ANOTHER NMOSD AGENT.

Created: 10/19
Effective: 01/01/26 Client Approval: 11/25 P&T Approval: 04/25

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ECULIZUMAB-AAGH BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ECULIZUMAB-AAGH	EPYSQLI	49759		GPI-10 (8580505002)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	Yes	No	No	Yes	No	No	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #5.

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ECULIZUMAB-AAGH BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override)**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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ECULIZUMAB-AAGH BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS) (ICD-10 D59.31)?

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of atypical hemolytic uremic syndrome (aHUS) (ICD-10 D59.32, D59.39)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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ECULIZUMAB-AAGH BvD (PART D)

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) (ICD-10 D59.5) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a hematologist
   - The patient's diagnosis is confirmed by flow cytometry that shows PNH granulocyte clone size of at least 10% AND at least 2 different GPI-protein deficiencies (e.g., CD55, CD59) on at least 2 cell lineages (e.g., erythrocytes, granulocytes)
   - Epysqli will NOT be used concurrently with another C5 complement inhibitor therapy (e.g., Ultomiris [ravulizumab-cwvz], Piasky [crovalimab-akkz]), C3 complement inhibitor (e.g., Empaveli [pegcetacoplan]), or Factor B inhibitor (e.g., Fabhalta [iptacopan])
   - The patient has tried and failed (as evidenced by hemoglobin levels less than 10.5 g/dL directly following at least 3 months of stable dosing) OR has a contraindication to Fabhalta (iptacopan) or Ultomiris (ravulizumab-cwvz)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

4. Does the patient have a diagnosis of generalized myasthenia gravis (gMG) (ICD-10 Group G70.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is anti-acetylcholine receptor (AchR) antibody positive
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient is in Myasthenia Gravis Foundation of America class II, III, or IV
   - The patient had a trial of or contraindication to ONE corticosteroid (e.g., prednisone)
   - The patient had a trial of or contraindication to ONE non-steroidal immunosuppressive therapy (e.g., azathioprine, cyclophosphamide, methotrexate)
   - Epysqli will NOT be used concurrently with another neonatal Fc receptor blocker (e.g., Rystiggo [rozanolixizumab-noli], Vyvgart [efgartigimod alfa-fcab]) or complement inhibitor (e.g., Ultomiris [ravulizumab-cwvz], Zilbrysq [zilucoplan]) for the treatment of gMG

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ECULIZUMAB-AAGH BvD (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ECULIZUMAB-AAGH (Epysqli)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Atypical hemolytic uremic syndrome (aHUS: a rare blood disorder)
   2. Paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
   3. Generalized myasthenia gravis (gMG: a chronic autoimmune disorder)

B. Epysqli will NOT be used for hemolytic uremic syndrome related to Shiga toxin E. coli (STEC-HUS: a type of bacteria causing small blood vessels in the kidneys to become damaged and inflamed)

C. If you have paroxysmal nocturnal hemoglobinuria, approval also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
   3. Your PNH diagnosis is confirmed by ALL of the following through flow cytometry (test to measure characteristics of cells):
      a. You have at least 2 different GPI-protein deficiencies (missing a certain type of protein, such as CD55, CD59) on at least 2 cell lineages (types of cells such as erythrocytes [red blood cells], granulocytes [a type of white blood cell])
      b. PNH granulocyte clone size is at least 10%
   4. You will NOT use Epysqli concurrently (at the same time) with another C5 complement inhibitor therapy (such as Ultomiris [ravulizumab-cwvz], Piasky [crovalimab-akkz]), C3 complement inhibitor (such as Empaveli [pegcetacoplan]), or Factor B inhibitor (such as Fabhalta [iptacopan])
   5. You meet ONE of the following:
      a. You have tried and failed (drug did not work) Fabhalta (iptacopan) or Ultomiris (ravulizumab-cwvz), as shown by hemoglobin (a type of protein in red blood cells) levels less than 10.5 g/dL directly following at least 3 months of stable dosing
      b. You have a contraindication to (harmful for you to use) Fabhalta (iptacopan) or Ultomiris (ravulizumab-cwvz)

(Initial denial text continued on next page)

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ECULIZUMAB-AAGH BvD (PART D)

INITIAL CRITERIA (CONTINUED)

D. If you have generalized myasthenia gravis, approval also requires:

1. You are 18 years of age or older
2. You are anti-acetylcholine receptor (AchR) antibody positive (an indicator of disease)
3. Therapy is prescribed by or in consultation with a neurologist (type of brain and nervous system doctor)
4. You are in Myasthenia Gravis Foundation of America class II, III, or IV (indicates severity of disease)
5. You have tried or have a contraindication to (harmful for you to use) ONE corticosteroid (such as prednisone)
6. You have tried or have a contraindication to (harmful for you to use) ONE non-steroidal immunosuppressive therapy (treatment that lowers the body's immune system activity, such as azathioprine, cyclophosphamide, methotrexate)
7. You will NOT use Epysqli concurrently (at the same time) with another neonatal Fc receptor blocker (such as Rystiggo [rozanolixizumab-noli], Vyvgart [efgartigimod alfa-fcab]) or complement inhibitor (such as Ultomiris [ravulizumab-cwvz], Zilbrysq [zilucoplan]) for the treatment of generalized myasthenia gravis

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ECULIZUMAB-AAGH BvD (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS) (ICD-10 D59.31)?

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of atypical hemolytic uremic syndrome (aHUS) (ICD-10 D59.32, D59.39)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Does the patient have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) (ICD-10 D59.5) and meet **ALL** of the following criteria?
   - The patient has had clinical benefit (e.g., reduction in number of blood transfusions, improvement/stabilization of lactate dehydrogenase [LDH] and hemoglobin levels) compared to baseline
   - Epysqli will NOT be used concurrently with another C5 complement inhibitor therapy (e.g., Ultomiris [ravulizumab-cwvz], Piasky [crovalimab-akkz]), C3 complement inhibitor (e.g., Empaveli [pegcetacoplan]), or Factor B inhibitor (e.g., Fabhalta [iptacopan])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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ECULIZUMAB-AAGH BvD (PART D)

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of generalized myasthenia gravis (gMG) (ICD-10 Group G70.0) and meet **ALL** of the following criteria?
   - The patient has had clinical benefit compared to baseline (e.g., Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool)
   - Epysqli will NOT be used concurrently with another neonatal Fc receptor blocker (e.g., Rystiggo [rozanolixizumab-noli], Vyvgart [efgartigimod alfa-fcab]) or complement inhibitor (e.g., Ultomiris [ravulizumab-cwvz], Zilbrysq [zilucoplan]) for the treatment of gMG

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ECULIZUMAB-AAGH (Epysqli)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Atypical hemolytic uremic syndrome (aHUS: a rare blood disorder)
      2. Paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
      3. Generalized myasthenia gravis (gMG: a chronic autoimmune disorder)
   B. Epysqli will NOT be used for hemolytic uremic syndrome related to Shiga toxin E. coli (STEC-HUS: a type of bacteria causing small blood vessels in the kidneys to become damaged and inflamed)
   C. If you have paroxysmal nocturnal hemoglobinuria, renewal also requires:
      1. You have had clinical benefit (such as reduction in number of blood transfusions [adding blood to the body], improvement/stabilization of lactate dehydrogenase [an enzyme] and hemoglobin [a type of protein in red blood cells] levels) compared to baseline (before treatment)
      2. You will NOT use Epysqli concurrently (at the same time) with another C5 complement inhibitor therapy (such as Ultomiris [ravulizumab-cwvz], Piasky [crovalimab-akkz]), C3 complement inhibitor (such as Empaveli [pegcetacoplan]), or Factor B inhibitor (such as Fabhalta [iptacopan])

   (Renewal denial text continued on next page)

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ECULIZUMAB-AAGH BvD (PART D)

RENEWAL CRITERIA (CONTINUED)

D. If you have generalized myasthenia gravis, renewal also requires:

1. You have had clinical benefit compared to baseline (such as shown by the Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool)
2. You will NOT use Epysqli concurrently (at the same time) with another neonatal Fc receptor blocker (such as Rystiggo [rozanolixizumab-noli], Vyvgart [efgartigimod alfa-fcab]) or complement inhibitor (such as Ultomiris [ravulizumab-cwvz], Zilbrysq [zilucoplan]) for the treatment of generalized myasthenia gravis

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Review for Epysqli.

The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Epysqli [Prescribing Information]. Incheon, South Korea: Samsung Bioepis Co.; April 2025.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed March 14, 2025].

For Part D use only:

ECULIZUMAB-AAGH (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	INITIAL/RENEWAL: SHIGA TOXIN E. COLI RELATED HEMOLYTIC UREMIC SYNDROME (STEC-HUS).
Required Medical Information	INITIAL: PAROXYSMAL NOCTURNAL HEMOGLOBINURIA (PNH): DIAGNOSIS CONFIRMED VIA FLOW CYTOMETRY: 1) AT LEAST TWO DIFFERENT GPI PROTEIN DEFICIENCIES ON AT LEAST TWO CELL LINEAGES, AND 2) PNH GRANULOCYTE CLONE SIZE OF AT LEAST 10 PERCENT.
Age Restrictions	INITIAL: PNH: 18 YEARS OF AGE OR OLDER.
Prescriber Restrictions	INITIAL: PNH: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST. GENERALIZED MYASTHENIA GRAVIS

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	(GMG): PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST.
Coverage Duration	INITIAL: AHUS: 12 MONTHS. PNH, GMG: 6 MONTHS. RENEWAL: ALL INDICATIONS: 12 MONTHS.
Other Criteria	INITIAL/RENEWAL: PNH: NO CONCURRENT USE WITH ANOTHER C5 COMPLEMENT INHIBITOR THERAPY (E.G., ULTOMIRIS, PIASKY), C3 COMPLEMENT INHIBITOR (E.G., EMPAVELI), OR FACTOR B INHIBITOR (E.G., FABHALTA). GMG: NO CONCURRENT USE WITH ANOTHER NEONATAL FC RECEPTOR BLOCKER (E.G., RYSTIGGO, VYVGART) OR COMPLEMENT INHIBITOR (E.G., ULTOMIRIS, ZILBRYSQ) FOR GMG. INITIAL: PNH: TRIAL AND FAILURE OF (AS EVIDENCED BY HEMOGLOBIN LEVELS LESS THAN 10.5 G/DL DIRECTLY FOLLOWING AT LEAST 3 MONTHS OF STABLE DOSING) OR CONTRAINDICATION TO FABHALTA OR ULTOMIRIS. GMG: 1) MYASTHENIA GRAVIS FOUNDATION OF AMERICA CLASS II, III, OR IV, 2) TRIAL OF OR CONTRAINDICATION TO ONE CORTICOSTEROID, AND 3) TRIAL OF OR CONTRAINDICATION TO ONE NON-STEROIDAL IMMUNOSUPPRESSIVE THERAPY. RENEWAL: PNH, GMG: CLINICAL BENEFIT COMPARED TO BASELINE.

Created: 03/25
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 04/25

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ECULIZUMAB-AEEB BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ECULIZUMAB-AEEB	BKEMV	49642		GPI-10 (8580505001)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	Yes	No	No	Yes	No	No	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #5.

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ECULIZUMAB-AEEB BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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ECULIZUMAB-AEEB BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS) (ICD-10 D59.31)?

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of atypical hemolytic uremic syndrome (aHUS) (ICD-10 D59.32, D59.39)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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ECULIZUMAB-AEEB BvD (PART D)

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) (ICD-10 D59.5) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a hematologist
   - The patient's diagnosis is confirmed by flow cytometry that shows PNH granulocyte clone size of at least 10% AND at least 2 different GPI-protein deficiencies (e.g., CD55, CD59) on at least 2 cell lineages (e.g., erythrocytes, granulocytes)
   - Bkemv will NOT be used concurrently with another C5 complement inhibitor therapy (e.g., Ultomiris [ravulizumab-cwvz], Piasky [crovalimab-akkz]), C3 complement inhibitor (e.g., Empaveli [pegcetacoplan]), or Factor B inhibitor (e.g., Fabhalta [iptacopan])
   - The patient has tried and failed (as evidenced by hemoglobin levels less than 10.5 g/dL directly following at least 3 months of stable dosing) OR has a contraindication to Fabhalta (iptacopan) or Ultomiris (ravulizumab-cwvz)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

4. Does the patient have a diagnosis of generalized myasthenia gravis (gMG) (ICD-10 Group G70.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is anti-acetylcholine receptor (AchR) antibody positive
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient is in Myasthenia Gravis Foundation of America class II, III, or IV
   - The patient had a trial of or contraindication to ONE corticosteroid (e.g., prednisone)
   - The patient had a trial of or contraindication to ONE non-steroidal immunosuppressive therapy (e.g., azathioprine, cyclophosphamide, methotrexate)
   - Bkemv will NOT be used concurrently with another neonatal Fc receptor blocker (e.g., Rystiggo [rozanolixizumab-noli], Vyvgart [efgartigimod alfa-fcab]) or complement inhibitor (e.g., Ultomiris [ravulizumab-cwvz], Zilbrysq [zilucoplan]) for the treatment of gMG

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ECULIZUMAB-AEEB BvD (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ECULIZUMAB-AEEB (Bkemv)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Atypical hemolytic uremic syndrome (aHUS: a rare blood disorder)
   2. Paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
   3. Generalized myasthenia gravis (gMG: a chronic [long-term] autoimmune disorder)

B. Bkemv will NOT be used for hemolytic uremic syndrome related to Shiga toxin E. coli (STEC-HUS: a type of bacteria causing small blood vessels in the kidneys to become damaged and inflamed)

C. If you have paroxysmal nocturnal hemoglobinuria, approval also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
   3. Your PNH diagnosis is confirmed by ALL of the following through flow cytometry (test to measure characteristics of cells):
      a. You have at least 2 different GPI-protein deficiencies (missing a certain type of protein, such as CD55, CD59) on at least 2 cell lineages (types of cells such as erythrocytes [red blood cells], granulocytes [a type of white blood cell])
      b. PNH granulocyte clone size is at least 10%
   4. You will NOT use Bkemv concurrently (at the same time) with another C5 complement inhibitor therapy (such as Ultomiris [ravulizumab-cwvz], Piasky [crovalimab-akkz]), C3 complement inhibitor (such as Empaveli [pegcetacoplan]), or Factor B inhibitor (such as Fabhalta [iptacopan])
   5. You meet ONE of the following:
      a. You have tried and failed (drug did not work) Fabhalta (iptacopan) or Ultomiris (ravulizumab-cwvz), as shown by hemoglobin (a type of protein in red blood cells) levels less than 10.5 g/dL directly following at least 3 months of stable dosing
      b. You have a contraindication to (harmful for you to use) Fabhalta (iptacopan) or Ultomiris (ravulizumab-cwvz)

(Initial denial text continued on next page)

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ECULIZUMAB-AEEB BvD (PART D)

INITIAL CRITERIA (CONTINUED)

D. If you have generalized myasthenia gravis, approval also requires:

1. You are 18 years of age or older
2. You are anti-acetylcholine receptor (AchR) antibody positive (an indicator of disease)
3. Therapy is prescribed by or in consultation with a neurologist (type of brain and nervous system doctor)
4. You are in Myasthenia Gravis Foundation of America class II, III, or IV (indicates severity of disease)
5. You have tried or have a contraindication to (harmful for you to use) ONE corticosteroid (such as prednisone)
6. You have tried or have a contraindication to (harmful for you to use) ONE non-steroidal immunosuppressive therapy (treatment that lowers the body's immune system activity, such as azathioprine, cyclophosphamide, methotrexate)
7. You will NOT use Bkemv concurrently (at the same time) with another neonatal Fc receptor blocker (such as Rystiggo [rozanolixizumab-noli], Vyvgart [efgartigimod alfa-fcab]) or complement inhibitor (such as Ultomiris [ravulizumab-cwvz], Zilbrysq [zilucoplan]) for the treatment of generalized myasthenia gravis

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ECULIZUMAB-AEEB BvD (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS) (ICD-10 D59.31)?

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.
   If no, continue to #2.

2. Does the patient have a diagnosis of atypical hemolytic uremic syndrome (aHUS) (ICD-10 D59.32, D59.39)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Does the patient have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) (ICD-10 D59.5) and meet **ALL** of the following criteria?
   - The patient has had clinical benefit (e.g., reduction in number of blood transfusions, improvement/stabilization of lactate dehydrogenase and hemoglobin levels) compared to baseline
   - Bkemv will NOT be used concurrently with another C5 complement inhibitor therapy (e.g., Ultomiris [ravulizumab-cwvz], Piasky [crovalimab-akkz]), C3 complement inhibitor (e.g., Empaveli [pegcetacoplan]), or Factor B inhibitor (e.g., Fabhalta [iptacopan])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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ECULIZUMAB-AEEB BvD (PART D)

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of generalized myasthenia gravis (gMG) (ICD-10 Group G70.0) and meet **ALL** of the following criteria?
   - The patient has had clinical benefit compared to baseline (e.g., Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool)
   - Bkemv will NOT be used concurrently with another neonatal Fc receptor blocker (e.g., Rystiggo [rozanolixizumab-noli], Vyvgart [efgartigimod alfa-fcab]) or complement inhibitor (e.g., Ultomiris [ravulizumab-cwvz], Zilbrysq [zilucoplan]) for the treatment of gMG

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ECULIZUMAB-AEEB (Bkemv)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Atypical hemolytic uremic syndrome (aHUS: a rare blood disorder)
      2. Paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
      3. Generalized myasthenia gravis (gMG: a chronic autoimmune disorder)
   B. Bkemv will NOT be used for hemolytic uremic syndrome related to Shiga toxin E. coli (STEC-HUS: a type of bacteria causing small blood vessels in the kidneys to become damaged and inflamed)
   C. If you have paroxysmal nocturnal hemoglobinuria, renewal also requires:
      1. You have had clinical benefit (such as reduction in number of blood transfusions [adding blood to the body], improvement/stabilization of lactate dehydrogenase [an enzyme] and hemoglobin [a type of protein in red blood cells] levels) compared to baseline (before treatment)
      2. You will NOT use Bkemv concurrently (at the same time) with another C5 complement inhibitor therapy (such as Ultomiris [ravulizumab-cwvz], Piasky [crovalimab-akkz]), C3 complement inhibitor (such as Empaveli [pegcetacoplan]), or Factor B inhibitor (such as Fabhalta [iptacopan])

   (Renewal denial text continued on next page)

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ECULIZUMAB-AEEB BvD (PART D)

RENEWAL CRITERIA (CONTINUED)

D. If you have generalized myasthenia gravis, renewal also requires:

1. You have had clinical benefit compared to baseline (such as shown by the Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool)
2. You will NOT use Bkemv concurrently (at the same time) with another neonatal Fc receptor blocker (such as Rystiggo [rozanolixizumab-noli], Vyvgart [efgartigimod alfa-fcab]) or complement inhibitor (such as Ultomiris [ravulizumab-cwvz], Zilbrysq [zilucoplan]) for the treatment of generalized myasthenia gravis

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Review for Bkemv.

The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Bkemv [Prescribing Information]. Thousand Oaks, CA: Amgen; October 2024.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed March 10 2025].

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ECULIZUMAB-AEEB BvD (PART D)

For Part D use only:

ECULIZUMAB-AEEB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	INITIAL/RENEWAL: SHIGA TOXIN E. COLI RELATED HEMOLYTIC UREMIC SYNDROME (STEC-HUS).
Required Medical Information	INITIAL: PAROXYSMAL NOCTURNAL HEMOGLOBINURIA (PNH): DIAGNOSIS CONFIRMED VIA FLOW CYTOMETRY: 1) AT LEAST TWO DIFFERENT GPI PROTEIN DEFICIENCIES ON AT LEAST TWO CELL LINEAGES, AND 2) PNH GRANULOCYTE CLONE SIZE OF AT LEAST 10 PERCENT.
Age Restrictions	INITIAL: PNH: 18 YEARS OF AGE OR OLDER.
Prescriber Restrictions	INITIAL: PNH: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST. GENERALIZED MYASTHENIA GRAVIS (GMG): PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST.
Coverage Duration	INITIAL: AHUS: 12 MONTHS. PNH, GMG: 6 MONTHS. RENEWAL: ALL INDICATIONS: 12 MONTHS.
Other Criteria	INITIAL/RENEWAL: PNH: NO CONCURRENT USE WITH ANOTHER C5 COMPLEMENT INHIBITOR THERAPY (E.G., ULTOMIRIS, PIASKY), C3 COMPLEMENT INHIBITOR (E.G., EMPAVELI), OR FACTOR B INHIBITOR (E.G., FABHALTA). GMG: NO CONCURRENT USE WITH ANOTHER NEONATAL FC RECEPTOR BLOCKER (E.G., RYSTIGGO, VYVGART) OR COMPLEMENT INHIBITOR (E.G., ULTOMIRIS, ZILBRYSQ) FOR GMG. INITIAL: PNH: TRIAL AND FAILURE OF (AS EVIDENCED BY HEMOGLOBIN LEVELS LESS THAN 10.5 G/DL DIRECTLY FOLLOWING AT LEAST 3 MONTHS OF STABLE DOSING) OR CONTRAINDICATION TO FABHALTA OR ULTOMIRIS. GMG: 1) MYASTHENIA GRAVIS FOUNDATION OF AMERICA CLASS II, III, OR IV, 2) TRIAL OF OR CONTRAINDICATION TO ONE CORTICOSTEROID, AND 3) TRIAL OF OR CONTRAINDICATION TO ONE NON-STEROIDAL IMMUNOSUPPRESSIVE THERAPY. RENEWAL: PNH, GMG: CLINICAL BENEFIT COMPARED TO BASELINE.

Created: 03/25
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 04/25

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EDARAVONE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EDARAVONE	RADICAVA, EDARAVONE	44252		GPI-10 (7450903000)	ROUTE = INTRAVEN.

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of amyotrophic lateral sclerosis (ALS) (ICD-10 G12.21) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a neurologist or ALS specialist at an ALS Specialty Center or Care Clinic
   - The patient's duration of disease (from onset of symptoms) is 2 years or less
   - The patient has normal respiratory function (e.g., Forced Vital Capacity [FVC] of at least 80 percent)
   - The patient has mild to moderate ALS with a score of 2 or higher in all of the following 12 items of the Amyotrophic Lateral Sclerosis Functional Rating Scale-Revised (ALSFRS-R): speech, salivation, swallowing, handwriting, cutting food, dressing and hygiene, turning in bed, walking, climbing stairs, dyspnea, orthopnea, respiratory insufficiency
   - The patient has tried riluzole tablet OR is currently taking riluzole tablet

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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EDARAVONE (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **EDARAVONE (Radicava)** requires the following rule(s) be met for approval:

A. You have amyotrophic lateral sclerosis (ALS: a type of brain and nerve condition)
B. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor) or ALS specialist at an ALS Specialty Center or Care Clinic
C. You have had the disease (from onset of symptoms) for 2 years or less
D. You have normal respiratory (breathing) function (such as Forced Vital Capacity [FVC: a type of lung test] of at least 80 percent)
E. You have mild to moderate ALS with a score of 2 or higher in all of the following 12 items of the Amyotrophic Lateral Sclerosis Functional Rating Scale-Revised (ALSFRS-R: a tool for evaluating functional status): speech, salivation, swallowing, handwriting, cutting food, dressing and hygiene, turning in bed, walking, climbing stairs, dyspnea (difficulty breathing), orthopnea (shortness of breath while lying down), respiratory insufficiency (a type of breathing condition)
F. You have tried riluzole tablet OR are currently taking riluzole tablet

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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EDARAVONE (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of amyotrophic lateral sclerosis (ALS) (ICD-10 G12.21) and meet **ALL** of the following criteria?
   - The patient does not require invasive ventilation
   - The patient has improved baseline functional ability OR the patient has maintained a score of 2 or greater in all 12 items of the Amyotrophic Lateral Sclerosis Functional Rating Scale-Revised (ALSFRS-R)

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EDARAVONE (Radicava)** requires the following rule(s) be met for renewal:
   A. You have amyotrophic lateral sclerosis (ALS: a type of brain and nerve condition)
   B. You do not require invasive ventilation (inserting a breathing tube into your throat)
   C. You have improved baseline functional ability OR you have maintained a score of 2 or greater in all 12 items of the Amyotrophic Lateral Sclerosis Functional Rating Scale-Revised (ALSFRS-R)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Radicava.

REFERENCES

Radicava [prescribing information]. Jersey City, NJ: Mitsubishi Tanabe Pharma America, Inc.; November 2022.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EDARAVONE (PART D)

For Part D use only:

EDARAVONE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	AMYOTROPHIC LATERAL SCLEROSIS (ALS): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST OR ALS SPECIALIST AT AN ALS SPECIALTY CENTER OR CARE CLINIC.
Coverage Duration	ALS: INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS
Other Criteria	ALS: INITIAL: 1) DURATION OF DISEASE (FROM ONSET OF SYMPTOMS) IS LESS THAN OR EQUAL TO 2 YEARS, 2) NORMAL RESPIRATORY FUNCTION, 3) HAS MILD TO MODERATE ALS WITH A SCORE OF 2 OR HIGHER IN ALL OF THE FOLLOWING 12 ITEMS OF THE AMYOTROPHIC LATERAL SCLEROSIS FUNCTIONAL RATING SCALE REVISED (ALSFRS-R): SPEECH, SALIVATION, SWALLOWING, HANDWRITING, CUTTING FOOD, DRESSING AND HYGIENE, TURNING IN BED, WALKING, CLIMBING STAIRS, DYSPNEA, ORTHOPNEA, RESPIRATORY INSUFFICIENCY, AND 4) TRIAL OF RILUZOLE TABLET OR CURRENTLY TAKING RILUZOLE TABLET. RENEWAL: 1) DOES NOT REQUIRE INVASIVE VENTILATION, AND 2) HAS IMPROVED BASELINE FUNCTIONAL ABILITY OR HAS MAINTAINED A SCORE OF 2 OR HIGHER IN ALL 12 ITEMS OF THE ALSFRS-R.

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25 Created: 05/17
Commercial Effective: N/A Client Approval: 08/24 P&T Approval: 04/22

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EDARAVONE ORAL (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EDARAVONE	RADICAVA ORS		52318	GPI-14 (74509030001820)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of amyotrophic lateral sclerosis (ALS) (ICD-10 G12.21) and meet **ALL** the following?
   - Therapy is prescribed by or in consultation with a neurologist or ALS specialist at an ALS Specialty Center or Care Clinic
   - The duration of patient's disease (from onset of symptoms) is 3 years or less
   - The patient has a forced vital capacity (FVC) greater than 70 percent
   - The patient has mild to moderate ALS with a score of 2 or higher in all of the following 12 items of the Amyotrophic Lateral Sclerosis Functional Rating Scale Revised (ALSFRS-R): speech, salivation, swallowing, handwriting, cutting food, dressing and hygiene, turning in bed, walking, climbing stairs, dyspnea, orthopnea, respiratory insufficiency
   - The patient has tried riluzole tablet OR is currently taking riluzole tablet

   If yes, **approve for 6 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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EDARAVONE ORAL (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **EDARAVONE ORAL (Radicava ORS)** requires the following rule(s) be met for approval:

A. You have amyotrophic lateral sclerosis (ALS: a type of brain and nerve condition)
B. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor) or ALS specialist at an ALS Specialty Center or Care Clinic
C. You have had ALS (from onset of symptoms) for 3 years or less
D. You have a forced vital capacity (FVC: amount of air exhaled from lungs) of greater than 70 percent
E. You have mild to moderate ALS with a score of 2 or higher in all of the following 12 items of the Amyotrophic Lateral Sclerosis Functional Rating Scale Revised (ALSFRS-R: a tool for evaluating functional status): speech, salivation, swallowing, handwriting, cutting food, dressing and hygiene, turning in bed, walking, climbing stairs, dyspnea (difficulty breathing), orthopnea (shortness of breath while lying down), respiratory insufficiency (a type of breathing condition)
F. You have tried riluzole tablet OR are currently taking riluzole tablet

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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EDARAVONE ORAL (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of amyotrophic lateral sclerosis (ALS) (ICD-10 G12.21) and meet **ALL** of the following criteria?
   - The patient does not require invasive ventilation
   - The patient has improved baseline functional ability OR the patient has maintained a score of 2 or greater in all 12 items of the ALSFRS-R

   If yes, **approve for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EDARAVONE ORAL (Radicava ORS)** requires the following rule(s) be met for renewal:
   A. You have amyotrophic lateral sclerosis (ALS: a type of brain and nerve condition)
   B. You do not require invasive ventilation (inserting a breathing tube into your throat)
   C. You have improved baseline functional ability OR you have maintained a score of 2 or greater in all 12 items of the Amyotrophic Lateral Sclerosis Functional Rating Scale Revised (ALSFRS-R)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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EDARAVONE ORAL (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Radicava ORS.

REFERENCES

Radicava ORS [Prescribing Information].]. Jersey City, NJ: Mitsubishi Tanabe Pharma America, Inc.; May 2022.

For Part D use only:

EDARAVONE ORAL (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	AMYOTROPHIC LATERAL SCLEROSIS (ALS): INITIAL: FORCED VITAL CAPACITY IS GREATER THAN 70 PERCENT
Age Restrictions	N/A
Prescriber Restrictions	ALS: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST OR ALS SPECIALIST AT AN ALS SPECIALTY CENTER OR CARE CLINIC.
Coverage Duration	INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS.
Other Criteria	ALS: INITIAL: 1) DURATION OF DISEASE (FROM ONSET OF SYMPTOMS) IS 3 YEARS OR LESS, 2) HAS MILD TO MODERATE ALS WITH A SCORE OF 2 OR HIGHER IN ALL OF THE FOLLOWING 12 ITEMS OF THE AMYOTROPHIC LATERAL SCLEROSIS FUNCTIONAL RATING SCALE REVISED (ALSFRS-R): SPEECH, SALIVATION, SWALLOWING, HANDWRITING, CUTTING FOOD, DRESSING AND HYGIENE, TURNING IN BED, WALKING, CLIMBING STAIRS, DYSPNEA, ORTHOPNEA, RESPIRATORY INSUFFICIENCY, AND 3) TRIAL OF RILUZOLE TABLET OR CURRENTLY TAKING RILUZOLE TABLET. RENEWAL: 1) DOES NOT REQUIRE INVASIVE VENTILATION, AND 2) IMPROVED BASELINE FUNCTIONAL ABILITY OR HAS MAINTAINED A SCORE OF 2 OR HIGHER IN ALL 12 ITEMS OF THE ALSFRS-R.

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25 Created: 11/22
Commercial Effective: N/A Client Approval: 08/24 P&T Approval: 04/22

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EFBEMALENOGRASTIM ALFA-VUXW (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EFBEMALENOGRASTIM ALFA-VUXW	RYZNEUTA	49318		GPI-10 (8240151680)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the patient receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia and meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a non-myeloid malignancy
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred agent: Nyvepria (pegfilgrastim-apgf)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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EFBEMALENOGRASTIM ALFA-VUXW (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **EFBEMALENOGRASTIM ALFA-VUXW (Ryzneuta)** requires the following rule(s) be met for approval:

A. You are receiving myelosuppressive anti-cancer medications (medications that decrease bone marrow activity) associated with a clinically significant incidence of febrile neutropenia (a type of blood condition with fever)
B. You are 18 years of age or older
C. You have a non-myeloid malignancy (cancer not affecting bone marrow)
D. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
E. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Nyvepria (pegfilgrastim-apgf)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ryzneuta.

REFERENCES

Ryzneuta [Prescribing Information]. East Windsor, NJ: Acrotech Biopharma Inc; November 2024.

For Part D use only:

EFBEMALENOGRASTIM ALFA-VUXW (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR ONCOLOGIST.
Coverage Duration	12 MONTHS
Other Criteria	TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT NYVEPRIA, WHERE INDICATIONS ALIGN.

Created: 05/25
Effective: 06/01/25 Client Approval: 05/25 P&T Approval: 01/22

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EFGARTIGIMOD ALFA-FCAB BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EFGARTIGIMOD ALFA-FCAB	VYVGART	47735		GPI-10 (9939822530)	

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #5.

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EFGARTIGIMOD ALFA-FCAB BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override)**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EFGARTIGIMOD ALFA-FCAB BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of generalized myasthenia gravis (gMG) (ICD-10 Group G70.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient is Myasthenia Gravis Foundation of America class II, III, or IV
   - The patient had a trial of or contraindication to ONE corticosteroid (e.g., prednisone)
   - The patient had a trial of or contraindication to ONE non-steroidal immunosuppressive therapy (e.g., azathioprine, cyclophosphamide, methotrexate)
   - Vyvgart will NOT be used concurrently with another neonatal Fc receptor blocker (e.g., Rystiggo [rozanolixizumab-noli]) or complement inhibitor (e.g., Ultomiris [ravulizumab-cwvz], Zilbrysq [zilucoplan]) for the treatment of gMG

     If yes, **approve for 6 months by HICL or GPI-10.**
     APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

     If no, do not approve.
     DENIAL TEXT: See the initial denial text at the end of the guideline.

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EFGARTIGIMOD ALFA-FCAB BvD (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **EFGARTIGIMOD ALFA-FCAB (Vyvgart)** requires the following rule(s) be met for approval:

A. You have generalized myasthenia gravis (gMG: a chronic autoimmune disorder)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a neurologist (type of brain doctor)
D. You have Myasthenia Gravis Foundation of America class II, III, or IV (indicates severity of disease)
E. You had a trial of or contraindication to (harmful for you to use) ONE corticosteroid (such as prednisone)
F. You had a trial of or contraindication to (harmful for you to use) ONE non-steroidal immunosuppressive therapy (such as azathioprine, cyclophosphamide, methotrexate)
G. You will NOT use Vyvgart concurrently (at the same time) with another neonatal Fc receptor blocker (such as Rystiggo [rozanolixizumab-noli]) or complement inhibitor (such as Ultomiris [ravulizumab-cwvz], Zilbrysq [zilucoplan]) for the treatment of generalized myasthenia gravis

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EFGARTIGIMOD ALFA-FCAB BvD (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of generalized myasthenia gravis (gMG) (ICD-10 Group G70.0) and meet **ALL** of the following criteria?
   - The patient had clinical benefit compared to baseline (e.g., Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool)
   - Vyvgart will NOT be used concurrently with another neonatal Fc receptor blocker (e.g., Rystiggo [rozanolixizumab-noli]) or complement inhibitor (e.g., Ultomiris [ravulizumab-cwvz], Zilbrysq [zilucoplan]) for the treatment of gMG

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EFGARTIGIMOD ALFA-FCAB (Vyvgart)** requires the following rule(s) be met for renewal:
   A. You have generalized myasthenia gravis (gMG: chronic autoimmune disorder)
   B. You have had clinical benefit compared to baseline (for example, as shown by the Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool)
   C. You will NOT use Vyvgart concurrently (at the same time) with another neonatal Fc receptor blocker (such as Rystiggo [rozanolixizumab-noli]) or complement inhibitor (such as Ultomiris [ravulizumab-cwvz], Zilbrysq [zilucoplan]) for the treatment of generalized myasthenia gravis

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EFGARTIGIMOD ALFA-FCAB BvD (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vyvgart. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Vyvgart [Prescribing Information]. Zwijnaarde, Belgium: Argenx BV; May 2026.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: hhttps://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed May 29, 2026].

For Part D use only:

EFGARTIGIMOD ALFA-FCAB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	GENERALIZED MYASTHENIA GRAVIS (GMG): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST.
Coverage Duration	GMG: INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS
Other Criteria	GMG: INITIAL: 1) FOR MYASTHENIA GRAVIS FOUNDATION OF AMERICA CLASS II, III, OR IV, 2) TRIAL OF OR CONTRAINDICATION TO ONE CORTICOSTEROID, 3) TRIAL OF OR CONTRAINDICATION TO ONE NON-STEROIDAL IMMUNOSUPPRESSIVE THERAPY, AND 4) NO CONCURRENT USE WITH ANOTHER NEONATAL FC RECEPTOR BLOCKER OR COMPLEMENT INHIBITOR FOR GMG. RENEWAL: 1) CLINICAL BENEFIT COMPARED TO BASELINE, AND 2) NO CONCURRENT USE WITH ANOTHER NEONATAL FC RECEPTOR BLOCKER OR COMPLEMENT INHIBITOR FOR GMG.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EFGARTIGIMOD-HYALURONIDASE-QVFC BVD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EFGARTIGIMOD-HYALURONIDAS-QVFC	VYVGART HYTRULO	49016		GPI-10 (9939990215)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	Yes	No	No	Yes	No	No	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #5.

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EFGARTIGIMOD-HYALURONIDASE-QVFC BVD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override)**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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EFGARTIGIMOD-HYALURONIDASE-QVFC BVD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of generalized myasthenia gravis (gMG) (ICD-10 Group G70.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient is Myasthenia Gravis Foundation of America class II, III, or IV
   - The patient had a trial of or contraindication to ONE corticosteroid (e.g., prednisone)
   - The patient had a trial of or contraindication to ONE non-steroidal immunosuppressive therapy (e.g., azathioprine, cyclophosphamide, methotrexate)
   - Vyvgart Hytrulo will NOT be used concurrently with another neonatal Fc receptor blocker (e.g., Rystiggo [rozanolixizumab-noli]) or complement inhibitor (e.g., Ultomiris [ravulizumab-cwvz], Zilbrysq [zilucoplan]) for the treatment of gMG

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

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EFGARTIGIMOD-HYALURONIDASE-QVFC BVD (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of chronic inflammatory demyelinating polyneuropathy (CIDP) (ICD-10 G61.81) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EFGARTIGIMOD-HYALURONIDASE-QVFC (Vyvgart Hytrulo)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Generalized myasthenia gravis (gMG: a chronic autoimmune disorder)
      2. Chronic inflammatory demyelinating polyneuropathy (CIDP: a type of nerve disorder)
   B. If you have generalized myasthenia gravis, approval also requires:
      1. You are 18 years of age or older
      2. Therapy is prescribed by or in consultation with a neurologist (type of brain doctor)
      3. You have Myasthenia Gravis Foundation of America class II, III, or IV (indicates severity of disease)
      4. You have tried or have a contraindication to (harmful for you to use) ONE corticosteroid (such as prednisone)
      5. You have tried or have a contraindication to (harmful for you to use) ONE non-steroidal immunosuppressive therapy (such as azathioprine, cyclophosphamide, methotrexate)
      6. You will NOT use Vyvgart Hytrulo concurrently (at the same time) with another neonatal Fc receptor blocker (such as Rystiggo [rozanolixizumab-noli]) or complement inhibitor (such as Ultomiris [ravulizumab-cwvz], Zilbrysq [zilucoplan]) for the treatment of generalized myasthenia gravis
   C. If you have chronic inflammatory demyelinating polyneuropathy, approval also requires:
      1. You are 18 years of age or older

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EFGARTIGIMOD-HYALURONIDASE-QVFC BVD (PART D)

RENEWAL CRITERIA

NOTE: For the diagnosis of chronic inflammatory demyelinating polyneuropathy (CIDP), please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of generalized myasthenia gravis (gMG) (ICD-10 Group G70.0) and meet **ALL** of the following criteria?
   - The patient had clinical benefit compared to baseline (e.g., Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool)
   - Vyvgart Hytrulo will NOT be used concurrently with another neonatal Fc receptor blocker (e.g., Rystiggo [rozanolixizumab-noli]) or complement inhibitor (e.g., Ultomiris [ravulizumab-cwvz], Zilbrysq [zilucoplan]) for the treatment of gMG

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EFGARTIGIMOD-HYALURONIDASE-QVFC (Vyvgart Hytrulo)** requires the following rule(s) be met for renewal:
   A. You have generalized myasthenia gravis (gMG: chronic autoimmune disorder)
   B. You have had clinical benefit compared to baseline (for example, as shown by the Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool)
   C. You will NOT use Vyvgart Hytrulo concurrently (at the same time) with another neonatal Fc receptor blocker (such as Rystiggo [rozanolixizumab-noli]) or complement inhibitor (such as Ultomiris [ravulizumab-cwvz], Zilbrysq [zilucoplan]) for the treatment of generalized myasthenia gravis

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EFGARTIGIMOD-HYALURONIDASE-QVFC BVD (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vyvgart Hytrulo. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Vyvgart Hytrulo [Prescribing Information]. San Diego, CA: Halozyme Therapeutics, Inc.; May 2026.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed July 2, 2024].

For Part D use only:

EFGARTIGIMOD-HYALURONIDASE-QVFC (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	GENERALIZED MYASTHENIA GRAVIS (GMG): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST.
Coverage Duration	GMG: INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS. CIDP: 12 MONTHS.
Other Criteria	GMG: INITIAL: 1) MYASTHENIA GRAVIS FOUNDATION OF AMERICA CLASS II, III, OR IV, 2) TRIAL OF OR CONTRAINDICATION TO ONE CORTICOSTEROID, 3) TRIAL OF OR CONTRAINDICATION TO ONE NON-STEROIDAL IMMUNOSUPPRESSIVE THERAPY, AND 4) NO CONCURRENT USE WITH ANOTHER NEONATAL FC RECEPTOR BLOCKER OR COMPLEMENT INHIBITOR FOR GMG. RENEWAL: 1) CLINICAL BENEFIT COMPARED TO BASELINE, AND 2) NO CONCURRENT USE WITH ANOTHER NEONATAL FC RECEPTOR BLOCKER OR COMPLEMENT INHIBITOR FOR GMG.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EFINACONAZOLE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EFINACONAZOLE	JUBLIA	41184		GPI-10 (9015403700)	

Do not review Part D guideline with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of onychomycosis (fungal infection) of the toenail(s) (ICD-10 B35.1)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have onychomycosis due to trichophyton rubrum **AND** meet the following criterion?
   - The patient had a trial of or contraindication to ciclopirox topical solution AND either oral terbinafine or oral itraconazole

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Does the patient have onychomycosis due to trichophyton mentagrophytes **AND** meet the following criterion?
   - The patient had a trial of or contraindication to oral terbinafine OR oral itraconazole

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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EFINACONAZOLE (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **EFINACONAZOLE (Jublia)** requires the following rule(s) be met for approval:

A. You have onychomycosis of the toenail(s) (toenail fungus infection)

B. If you have onychomycosis due to trichophyton rubrum (a type of fungus), approval also requires:
   1. You have tried or have a contraindication to (harmful for you to use) ciclopirox topical solution AND either oral terbinafine or oral itraconazole

C. If you have onychomycosis due to trichophyton mentagrophytes (a type of fungus), approval also requires:
   1. You have tried or have a contraindication to (harmful for you to use) oral terbinafine OR oral itraconazole

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Jublia.

REFERENCES

Jublia [Prescribing Information]. Bridgewater, NJ: Valeant Pharmaceuticals; March 2022.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EFINACONAZOLE (PART D)

For Part D use only:

EFINACONAZOLE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	ONYCHOMYCOSIS DUE TO TRICHOPHYTON RUBRUM: TRIAL OF OR CONTRAINDICATION TO 1) CICLOPIROX TOPICAL SOLUTION AND 2) ORAL TERBINAFINE OR ORAL ITRACONAZOLE. ONYCHOMYCOSIS DUE TO TRICHOPHYTON MENTAGROPHYTES: TRIAL OF OR CONTRAINDICATION TO ORAL TERBINAFINE OR ORAL ITRACONAZOLE.

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25 Created: 11/16
Commercial Effective: N/A Client Approval: 08/24 P&T Approval: 11/16

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EFLAPEGRASTIM-XNST (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EFLAPEGRASTIM-XNST	ROLVEDON	48301		GPI-10 (8240151880)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a non-myeloid malignancy and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient is receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia
   - The patient had a trial of or contraindication to the preferred agent: Nyvepria (pegfilgrastim-apgf)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EFLAPEGRASTIM-XNST (Rolvedon)** requires the following rule(s) be met for approval:
   A. You have a non-myeloid malignancy (cancer not affecting bone marrow)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
   D. You are receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia (medications that affect the bone marrow and cause low levels of a type of white blood cell with fever)

   (Denial text continued on next page)

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EFLAPEGRASTIM-XNST (PART D)

GUIDELINES FOR USE (CONTINUED)

E. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Nyvepria (pegfilgrastim-apgf)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rolvedon.

REFERENCES

Rolvedon [Prescribing Information]. Irvine, CA: Spectrum Pharmaceuticals, Inc.; June 2023.

For Part D use only:

EFLAPEGRASTIM-XNST (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	NON MYELOID MALIGNANCY: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR ONCOLOGIST.
Coverage Duration	12 MONTHS
Other Criteria	NON MYELOID MALIGNANCY: TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT: NYVEPRIA.

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 01/23
Client Approval: 08/24
P&T Approval: 04/22

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EFLORNITHINE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EFLORNITHINE	IWILFIN	21417		GPI-10 (2175722030)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of high-risk neuroblastoma (HRNB) **AND** meet the following criterion?
   - The patient has demonstrated a partial response to prior therapy, including anti-GD2 immunotherapy (e.g., Unituxin [dinutuximab])

   If yes, **approve for 24 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EFLORNITHINE (Iwilfin)** requires the following rule(s) be met for approval:
   A. You have high-risk neuroblastoma (HRNB: a type of rare cancer)
   B. You have shown a partial response (the cancer partly responded to treatment, but still did not go away) to prior therapy, including anti-GD2 immunotherapy (such as Unituxin [dinutuximab])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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EFLORNITHINE (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Iwilfin.

REFERENCES
Iwilfin [Prescribing Information]. Louisville, KY: US WorldMeds, LLC.; December 2023.

For Part D use only:

EFLORNITHINE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	24 MONTHS
Other Criteria	N/A

Part D Effective: 01/01/25 Created: 02/24
Commercial Effective: N/A Client Approval: 08/24 P&T Approval: 01/24

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELACESTRANT (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ELACESTRANT HCL	ORSERDU	48658		GPI-10 (2140372010)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced or metastatic breast cancer (ICD-10 Group C50) and meet **ALL** of the following criteria?
   - The patient's breast cancer is estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative with estrogen receptor 1 gene (ESR1) mutation(s)
   - The patient has disease progression following endocrine therapy (e.g., Faslodex [fulvestrant], anastrozole, letrozole)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ELACESTRANT (Orserdu)** requires the following rule(s) be met for approval:
   A. You have advanced or metastatic breast cancer (breast cancer that has spread to other parts of the body)
   B. Your breast cancer is estrogen receptor (ER: type of protein)-positive, human epidermal growth factor receptor 2 (HER2: type of protein)-negative with estrogen receptor 1 (ESR1: type of gene)-mutation(s)
   C. You have disease progression following endocrine-based regimen (disease has worsened after using a type of hormone therapy such as Faslodex [fulvestrant], anastrozole, letrozole)

   (Denial text continued on the next page)

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ELACESTRANT (PART D)

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Orserdu.

REFERENCES

Orserdu [Prescribing Information]. New York, NY: Stemline Therapeutics, Inc.; November 2023.

For Part D use only:

ELACESTRANT (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 02/23
Effective: 07/01/25 Client Approval: 05/25 P&T Approval: 04/23

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PLUS CLOSED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELAFIBRANOR (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ELAFIBRANOR	IQIRVO	49672		GPI-10 (5278002000)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	Yes	No	No	No	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of primary biliary cholangitis (PBC) (ICD-10 K74.3) as confirmed by at least **TWO** of the following criteria?
   - The patient has an elevated alkaline phosphatase (ALP) level
   - The patient has the presence of antimitochondrial antibodies (AMA) OR other PBC-specific autoantibodies, including sp100 or gp210, if AMA is negative
   - The patient has histologic evidence (obtained by liver biopsy) of non-suppurative destructive cholangitis and destruction of interlobular bile ducts

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ELAFIBRANOR (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist or hepatologist
   - The patient does not have decompensated cirrhosis (Child-Pugh B or C)
   - Iqirvo will NOT be used concurrently with any other second-line PBC treatment (i.e., Ocaliva [obeticholic acid], Livdelzi [seladelpar])

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - Iqirvo will be used as monotherapy in a patient who is unable to tolerate ursodiol (UDCA)
   - Iqirvo will be used in combination with ursodiol (UDCA) in a patient who had an inadequate response to at least 1 year of treatment with ursodiol (UDCA) monotherapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ELAFIBRANOR (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ELAFIBRANOR (Iqirvo)** requires the following rule(s) be met for approval:

A. You have primary biliary cholangitis (PBC: a type of immune system disorder that destroys the bile duct), as confirmed by TWO of the following:
   1. You have an elevated (high) alkaline phosphatase (ALP) level (a type of lab test)
   2. You have the presence of antimitochondrial antibodies (AMA: indicator of the body attacking its own cells) or other PBC-specific autoantibodies (indicator of the body attacking its own cells), including sp100 or gp210, if AMA is negative
   3. You have histologic evidence (lab data obtained by liver biopsy [removal of cells or tissue from the liver for examination]) of non-suppurative destructive cholangitis and destruction of interlobular bile ducts (symptoms of liver disease)

B. You are 18 years of age or older

C. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions) or hepatologist (a type of liver doctor)

D. You do not have decompensated cirrhosis (a condition where there is liver damage and scarring with major symptoms) (Child-Pugh B or C: a score that evaluates the severity of liver damage)

E. You will NOT use Iqirvo concurrently (at the same time) with any other second-line therapy for PBC (Ocaliva [obeticholic acid], Livdelzi [seladelpar])

F. You meet ONE of the following:
   1. Iqirvo will be used as monotherapy (one drug treatment) if you are unable to tolerate ursodiol (UDCA)
   2. Iqirvo will be used in combination (together) with ursodiol (UDCA) if you had an inadequate (poor) response to at least 1 year of treatment with ursodiol (UDCA) monotherapy (one drug treatment)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ELAFIBRANOR (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of primary biliary cholangitis (PBC) (ICD-10 K74.3) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Iqirvo will NOT be used concurrently with any other second-line PBC treatment (i.e., Ocaliva [obeticholic acid], Livdelzi [seladelpar])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ELAFIBRANOR (Iqirvo)** requires the following rule(s) be met for renewal:
   A. You have primary biliary cholangitis (PBC: a type of immune system disorder that destroys the bile duct)
   B. You continue to benefit from the medication
   C. You will NOT use Iqirvo concurrently (at the same time) with any other second-line therapy for PBC (Ocaliva [obeticholic acid], Livdelzi [seladelpar])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ELAFIBRANOR (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Iqirvo.

REFERENCES
Iqirvo [Prescribing Information]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.; June 2024.

For Part D use only:

ELAFIBRANOR (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	PRIMARY BILIARY CHOLANGITIS (PBC): INITIAL: DIAGNOSIS CONFIRMED BY TWO OF THE FOLLOWING: 1) ELEVATED ALKALINE PHOSPHATASE LEVEL, 2) PRESENCE OF ANTIMITOCHONDRIAL ANTIBODIES OR OTHER PBC-SPECIFIC AUTOANTIBODIES, INCLUDING SP100 OR GP210, IF AMA IS NEGATIVE, OR 3) HISTOLOGIC EVIDENCE (OBTAINED BY LIVER BIOPSY) OF NON-SUPPURATIVE DESTRUCTIVE CHOLANGITIS AND DESTRUCTION OF INTERLOBULAR BILE DUCTS.
Age Restrictions	N/A
Prescriber Restrictions	PBC: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST OR HEPATOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS
Other Criteria	PBC: INITIAL: 1) NO CONCURRENT USE WITH ANOTHER SECOND-LINE THERAPY FOR PBC, 2) USED IN COMBINATION WITH URSODIOL IF INADEQUATE RESPONSE AFTER TREATMENT WITH URSODIOL MONOTHERAPY FOR AT LEAST 1 YEAR, OR USED AS MONOTHERAPY IF UNABLE TO TOLERATE URSODIOL, AND 3) DOES NOT HAVE DECOMPENSATED CIRRHOSIS (CHILD-PUGH B OR C). RENEWAL: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SECOND-LINE THERAPY FOR PBC.

Part D Effective: 01/01/25 Created: 06/24
Commercial Effective: N/A Client Approval: 11/24 P&T Approval: 04/24

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ADVANTAGE AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELAGOLIX (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ELAGOLIX SODIUM	ORILISSA	45108		GPI-10 (3009003010)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe pain associated with endometriosis (ICD-10 R52 and Group N80) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an obstetrician, or gynecologist
   - The patient had a trial of or contraindication to a nonsteroidal anti-inflammatory drug (NSAID) AND a progestin-containing preparation (e.g., combination hormonal contraceptive preparation, progestin-only therapy)
   - Orilissa will NOT be used concurrently with another GnRH-modulating agent (e.g., Lupron Depot [leuprolide], Synarel [nafarelin], Zoladex [goserelin])

   If yes, **approve for 6 months by HICL or GPI-10.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ELAGOLIX (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT:

Our guideline named **ELAGOLIX (Orilissa)** requires the following rule(s) be met for approval:

A. You have moderate to severe pain associated with endometriosis (a condition affecting the uterus)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with an obstetrician or gynecologist (a type of women's health doctor)
D. You have tried or have a contraindication to (harmful for you to use) a nonsteroidal anti-inflammatory drug (NSAID such as ibuprofen, meloxicam, naproxen) AND a progestin-containing preparation (such as combination hormonal contraceptive preparation, progestin-only therapy)
E. Orilissa will NOT be used at the same time with another GnRH-modulating agent (such as Lupron Depot [leuprolide], Synarel [nafarelin], Zoladex [goserelin])

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ELAGOLIX (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe pain associated with endometriosis (ICD-10 R52 and Group N80) and meet **ALL** of the following criteria?
   - The patient has had improvement in pain associated with endometriosis while on Orilissa therapy
   - Orilissa will NOT be used concurrently with another GnRH-modulating agent (e.g., Lupron Depot [leuprolide], Synarel [nafarelin], Zoladex [goserelin])

   If yes, **approve for 12 months by HICL or GPI-10.**

   If no, do not approve.

   RENEWAL DENIAL TEXT:

   Our guideline named **ELAGOLIX (Orilissa)** requires the following rule(s) be met for renewal:
   A. You have moderate to severe pain associated with endometriosis (a condition affecting the uterus)
   B. You have had improvement in pain related to endometriosis while on Orilissa therapy
   C. Orilissa will NOT be used at the same time with another GnRH-modulating agent (such as Lupron Depot [leuprolide], Synarel [nafarelin], Zoladex [goserelin])

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Orilissa.

REFERENCES
Orilissa [Prescribing Information]. North Chicago, IL: AbbVie Inc.; December 2025.

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ADVANTAGE AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELAGOLIX (PART D)

For Part D use only:

ELAGOLIX (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	MODERATE TO SEVERE PAIN ASSOCIATED WITH ENDOMETRIOSIS: INITIAL: 18 YEARS OF AGE OR OLDER.
Prescriber Restrictions	MODERATE TO SEVERE PAIN ASSOCIATED WITH ENDOMETRIOSIS: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH AN OBSTETRICIAN/GYNECOLOGIST.
Coverage Duration	INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS
Other Criteria	MODERATE TO SEVERE PAIN ASSOCIATED WITH ENDOMETRIOSIS: INITIAL: 1) NO CONCURRENT USE WITH ANOTHER GNRH-MODULATING AGENT, AND 2) TRIAL OF OR CONTRAINDICATION TO AN NSAID AND A PROGESTIN-CONTAINING PREPARATION. RENEWAL: 1) IMPROVEMENT IN PAIN ASSOCIATED WITH ENDOMETRIOSIS WHILE ON THERAPY, AND 2) NO CONCURRENT USE WITH ANOTHER GNRH-MODULATING AGENT

Created: 08/18
Effective: 09/01/26 Client Approval: 08/26 DMC Approval: 08/04/26

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELAGOLIX/ESTRADIOL/NORETHINDRONE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ELAGOLIX/ESTRADIOL/ NORETHINDRONE	ORIAHNN	46577		GPI-10 (2499350340)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Has the patient received a total of 24 months cumulative treatment with Oriahnn?

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, continue to #2.

2. Is the request for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) (ICD-10 Group D25) and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is a premenopausal woman
   - Therapy is prescribed by or in consultation with an obstetrician or gynecologist (OB/GYN)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ELAGOLIX/ESTRADIOL/NORETHINDRONE (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ELAGOLIX/ESTRADIOL/NORETHINDRONE (Oriahnn)** requires the following rule(s) be met for approval:

A. The request is for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids: non-cancerous growths in the uterus)
B. You are 18 years of age or older
C. You are a premenopausal woman
D. Therapy is prescribed by or in consultation with an obstetrician or gynecologist (OB/GYN: doctor who specializes in women's reproductive system)
E. You have not received a total of 24 months cumulative treatment with Oriahnn

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ELAGOLIX/ESTRADIOL/NORETHINDRONE (PART D)

RENEWAL CRITERIA

1. Has the patient received a total of 24 months cumulative treatment with Oriahnn?

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, continue to #2.

2. Is the request for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) (ICD-10 Group D25) **AND** the patient meets the following criterion?
   - The patient has had improvement of heavy menstrual bleeding

   If yes, **approve for 18 months (or up to 24 months cumulative lifetime treatment duration) by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ELAGOLIX/ESTRADIOL/NORETHINDRONE (Oriahnn)** requires the following rule(s) be met for renewal:
   A. The request is for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids: non-cancerous growths in the uterus)
   B. You have had improvement of heavy menstrual bleeding on therapy
   C. You have not received a total of 24 months cumulative treatment with Oriahnn

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Oriahnn.

REFERENCES

Oriahnn [Prescribing Information]. North Chicago, IL: AbbVie Inc., June 2023.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELAGOLIX/ESTRADIOL/NORETHINDRONE (PART D)

For Part D use only:

ELAGOLIX/ESTRADIOL/NORETHINDRONE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	HEAVY MENSTRUAL BLEEDING ASSOCIATED WITH UTERINE LEIOMYOMAS: INITIAL: 18 YEARS OR OLDER
Prescriber Restrictions	HEAVY MENSTRUAL BLEEDING ASSOCIATED WITH UTERINE LEIOMYOMAS: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH AN OBSTETRICIAN/GYNECOLOGIST.
Coverage Duration	INITIAL: 6 MOS. RENEWAL: 18 MOS OR UP TO 24 MOS CUMULATIVE LIFETIME TREATMENT DURATION
Other Criteria	HEAVY MENSTRUAL BLEEDING ASSOCIATED WITH UTERINE LEIOMYOMAS: INITIAL: HAS NOT RECEIVED A TOTAL OF 24 MONTHS CUMULATIVE TREATMENT WITH ORIAHNN. RENEWAL: 1) IMPROVEMENT OF HEAVY MENSTRUAL BLEEDING AND 2) HAS NOT RECEIVED A TOTAL OF 24 MONTHS CUMULATIVE TREATMENT WITH ORIAHNN.

Created: 06/20
Effective: 07/01/25 Client Approval: 05/25 P&T Approval: 07/20

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELAMIPRETIDE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ELAMIPRETIDE HCL	FORZINITY	50903		GPI-10 (3090833020)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Barth syndrome (ICD-10 E78.71) **AND** meet the following criterion?
   - The patient weighs at least 30 kg (66 lbs)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ELAMIPRETIDE (Forzinity)** requires the following rule(s) be met for approval:
   A. You have Barth syndrome (a rare genetic condition)
   B. You weigh at least 30 kilograms (66 pounds)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELAMIPRETIDE (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Forzinity.

REFERENCES

Forzinity [Prescribing Information]. Needham, MA: Stealth BioTherapeutics Inc.; September 2025.

For Part D use only:

ELAMIPRETIDE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 01/26
Effective: 01/26/26 Client Approval: 01/26 P&T Approval: 01/26

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELAPEGADEMASE-LVLR (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ELAPEGADEMASE-LVLR	REVCOVI	45340		GPI-10 (3090203020)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of adenosine deaminase severe combined immune deficiency (ADA-SCID) (ICD-10 D81.31) as manifested by **ONE** of the following criteria?
   - The patient has a confirmatory genetic test
   - The patient has suggestive laboratory findings (e.g., elevated deoxyadenosine nucleotide [dAXP] levels, lymphopenia) AND hallmark signs/symptoms (e.g., recurrent infections, failure to thrive, persistent diarrhea)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is therapy prescribed by or in consultation with an immunologist, hematologist-oncologist, or physician specializing in inherited metabolic disorders?

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ELAPEGADEMASE-LVLR (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ELAPEGADEMASE-LVLR (Revcovi)** requires the following rule(s) be met for approval:

A. You have adenosine deaminase severe combined immune deficiency (ADA-SCID: an inherited disorder that damages the immune system) as shown by ONE of the following:
   1. A confirmatory genetic test (a type of lab test)
   2. Suggestive laboratory findings (such as elevated deoxyadenosine nucleotide [dAXP] levels, lymphopenia [low amount of a type of white blood cell]) and hallmark signs/symptoms (such as recurrent infections, failure to thrive, persistent diarrhea)

B. Therapy is prescribed by or in consultation with an immunologist (a type of immune system doctor), hematologist-oncologist (a type of blood-cancer doctor), or physician (doctor) specializing in inherited metabolic disorders

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ELAPEGADEMASE-LVLR (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of adenosine deaminase severe combined immune deficiency (ADA-SCID) (ICD-10 D81.31) and meet **ALL** of the following criteria?
   - The patient has improvement or maintenance of immune function from baseline (e.g., decrease in number and severity of infections)
   - The patient has not received a successful hematopoietic cell transplantation (HCT) or gene therapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ELAPEGADEMASE-LVLR (Revcovi)** requires the following rule(s) be met for renewal:
   A. You have adenosine deaminase severe combined immune deficiency (ADA-SCID: inherited disorder that damages the immune system)
   B. You have improvement or maintenance of immune function from baseline (such as a decrease in number and severity of infections)
   C. You have not received successful hematopoietic cell transplantation (HCT: type of bone marrow transplant) or gene therapy

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Revcovi.

REFERENCES
Revcovi [Prescribing Information]. Cary, NC: Chiesi USA, Inc.; August 2022.

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ELAPEGADEMASE-LVLR (PART D)

For Part D use only:

ELAPEGADEMASE-LVLR (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	ADENOSINE DEAMINASE SEVERE COMBINED IMMUNE DEFICIENCY (ADA-SCID): INITIAL: ADA-SCID AS MANIFESTED BY: 1) CONFIRMATORY GENETIC TEST, OR 2) SUGGESTIVE LABORATORY FINDINGS (E.G., ELEVATED DEOXYADENOSINE NUCLEOTIDE [DAXP] LEVELS, LYMPHOPENIA) AND HALLMARK SIGNS/SYMPTOMS (E.G., RECURRENT INFECTIONS, FAILURE TO THRIVE, PERSISTENT DIARRHEA).
Age Restrictions	N/A
Prescriber Restrictions	ADA-SCID: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH IMMUNOLOGIST, HEMATOLOGIST/ONCOLOGIST, OR PHYSICIAN SPECIALIZING IN INHERITED METABOLIC DISORDERS.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	ADA-SCID: RENEWAL: 1) IMPROVEMENT OR MAINTENANCE OF IMMUNE FUNCTION FROM BASELINE, AND 2) HAS NOT RECEIVED SUCCESSFUL HCT OR GENE THERAPY.

Created: 11/18
Effective: 01/01/26 Client Approval: 01/26 P&T Approval: 05/20

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELBASVIR/GRAZOPREVIR (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ELBASVIR/ GRAZOPREVIR	ZEPATIER	43030		GPI-10 (1235990230)	

Do not review this guideline with physicians; if the caller wishes to initiate a request, then a MRF must be completed (see the MedImpact Standard MRF for HepC).

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic hepatitis C virus (HCV) (ICD-10 B18.2) and meet **ALL** of the following criteria?
- The patient is 12 years of age or older OR weighs at least 30 kg (66 lbs)
- The patient has genotype 1 or 4 infection

If yes, continue to #2.
If no, continue to #11.

2. Does the patient have an HCV RNA level within the past 6 months?

If yes, continue to #3.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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ELBASVIR/GRAZOPREVIR (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient meet **ANY** of the following criteria?
   - The patient has moderate or severe hepatic impairment (decompensated cirrhosis; Child-Pugh B or C)
   - Zepatier will be used concurrently with any of the following medications: phenytoin, carbamazepine, rifampin, efavirenz (e.g., Atripla, Sustiva), atazanavir (e.g., Evotaz, Reyataz), darunavir (e.g., Prezcobix, Prezista), lopinavir, saquinavir, Aptivus (tipranavir), cyclosporine, nafcillin, ketoconazole, modafinil, bosentan, etravirine, elvitegravir/cobicistat/emtricitabine/tenofovir (e.g., Stribild, Genvoya), atorvastatin at doses greater than 20 mg daily, rosuvastatin at doses greater than 10 mg daily, Sovaldi (sofosbuvir), Epclusa (velpatasvir/sofosbuvir), Harvoni (ledipasvir/sofosbuvir), Mavyret (pibrentasvir/glecaprevir), Vosevi (velpatasvir/sofosbuvir/voxilaprevir)

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #4.

4. Is the patient treatment-naïve **AND** meets the following criterion?
   - The patient has an intolerance or contraindication to ONE of the following preferred agents: Epclusa, Harvoni

   If yes, continue to #5.
   If no, continue to #7.

5. Does the patient meet **ONE** of the following criteria?
   - The patient has genotype 1a infection AND does not have baseline NS5A polymorphisms
   - The patient has genotype 1b infection
   - The patient has genotype 4 infection
   - The patient is post-kidney transplant AND does not have baseline NS5A RAS polymorphisms

   If yes, **approve for 12 weeks by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #6.

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ELBASVIR/GRAZOPREVIR (PART D)

GUIDELINES FOR USE (CONTINUED)

6. Does the patient meet **ALL** of the following criteria?
   - The patient has genotype 1a infection
   - The patient has baseline NS5A polymorphisms
   - Zepatier will be used with ribavirin

   If yes, **approve for 16 weeks by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #7.

7. Is the patient treatment-experienced **AND** meets the following criterion?
   - The patient has an intolerance or contraindication to ONE of the following preferred agents: Epclusa, Harvoni

   If yes, continue to #8.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

8. Does the patient have genotype 1 infection and meet **ONE** of the following criteria?
   - The patient has genotype 1a infection, without baseline NS5A polymorphisms, AND failed prior treatment with peginterferon/ribavirin
   - The patient has genotype 1b infection AND failed prior treatment with peginterferon/ribavirin
   - The patient failed prior treatment with a peginterferon/ribavirin/protease inhibitor triple regimen AND Zepatier will be used with ribavirin

   If yes, **approve for 12 weeks by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #9.

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ELBASVIR/GRAZOPREVIR (PART D)

GUIDELINES FOR USE (CONTINUED)

9. Does the patient meet **ONE** of the following criteria?
   - The patient has genotype 1a infection with baseline NS5A polymorphisms, failed priortreatment with peginterferon/ribavirin, AND Zepatier will be used with ribavirin
   - The patient has genotype 4 infection, failed prior treatment with peginterferon/ribavirin, AND Zepatier will be used with ribavirin

   If yes, **approve for 16 weeks by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #10.

10. Is the patient post-kidney transplant and meets **ALL** of the following criteria?
    - The patient failed prior treatment with a non-direct acting antiviral agent (e.g., interferon)
    - The patient does not have baseline NS5A RAS polymorphisms

    If yes, **approve for 12 weeks by HICL or GPI-10.**
    APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

    If no, continue to #11.

11. Is the requested regimen recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment?

    If yes, **approve as indicated per guidance in AASLD/IDSA.**
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

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ELBASVIR/GRAZOPREVIR (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ELBASVIR/GRAZOPREVIR (Zepatier)** requires the following rule(s) be met for approval:

A. You have chronic hepatitis C virus (HCV: liver inflammation caused by a type of virus)
B. You are 12 years of age or older OR weigh at least 30 kilograms (66 pounds)
C. You have genotype 1 or 4 hepatitis C infection (types of hepatitis C virus)
D. You have an HCV RNA level (a measure of the amount of hepatitis C virus in the blood) within the past 6 months
E. You do NOT have moderate or severe liver impairment (decompensated cirrhosis [a condition where there is liver damage and scarring with major symptoms]; Child-Pugh B or C: [a score that evaluates the severity of liver damage])
F. You will NOT use Zepatier concurrently (at the same time) with any of the following medications: phenytoin, carbamazepine, rifampin, efavirenz (such as Atripla, Sustiva), atazanavir (such as Evotaz, Reyataz), darunavir (such as Prezcobix, Prezista), lopinavir, saquinavir, Aptivus (tipranavir), cyclosporine, nafcillin, ketoconazole, modafinil, bosentan, etravirine, elvitegravir/cobicistat/emtricitabine/tenofovir (such as Stribild, Genvoya), atorvastatin at doses greater than 20mg daily, rosuvastatin at doses greater than 10mg daily, Sovaldi (sofosbuvir), Epclusa (velpatasvir/sofosbuvir), Harvoni (ledipasvir/sofosbuvir), Mavyret (pibrentasvir/glecaprevir), Vosevi (velpatasvir/sofosbuvir/voxilaprevir)
G. You have an intolerance (side effect) or contraindication to (harmful for you to use) ONE of the following preferred medications: Epclusa, Harvoni
H. If you are treatment-naive (no prior treatment), approval also requires ONE of the following:
    1. You have genotype 1a infection AND you do not have baseline NS5A polymorphisms (variations in a type of hepatitis C virus protein)
    2. You have genotype 1b infection
    3. You have genotype 4 infection
    4. You received a kidney transplant (replaced your kidney) AND you do not have baseline NS5A resistance-associated substitution (RAS) polymorphisms (variations in a type of hepatitis C virus protein)
    5. You have genotype 1a infection, with baseline NS5A polymorphisms, AND Zepatier will be used with ribavirin

(Denial text continued on next page)

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ELBASVIR/GRAZOPREVIR (PART D)

GUIDELINES FOR USE (CONTINUED)

I. **If you are treatment-experienced (failed prior treatment), approval also requires ONE of the following:**
   1. You have genotype 1a infection, without baseline NS5A polymorphisms (variations in a type of hepatitis C virus protein), AND were previously treated with peginterferon/ribavirin
   2. You have genotype 1b infection AND were previously treated with peginterferon/ribavirin
   3. You have genotype 1 infection, were previously treated with a peginterferon/ribavirin/protease inhibitor triple regimen, AND Zepatier will be used with ribavirin
   4. You have genotype 1a infection with baseline NS5A polymorphisms, were previously treated with peginterferon/ribavirin, AND Zepatier will be used with ribavirin
   5. You have genotype 4 infection, were previously treated with peginterferon/ribavirin, AND Zepatier will be used with ribavirin
   6. You received a kidney transplant (replaced your kidney), were previously treated with a non-direct acting antiviral (such as interferon), AND you do not have baseline NS5A resistance-associated substitution (RAS) polymorphisms (variations in a type of hepatitis C virus protein)

J. Zepatier will also be approved for any other regimen/condition not listed above that is recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zepatier.

REFERENCES

Zepatier [Prescribing Information]. Kenilworth, NJ: Merck; May 2022.
Guidance from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) Recommendations for Testing, Managing, and Treating hepatitis C. Available online at http://www.hcvguidelines.org/full-report-view Accessed January 31, 2024.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELBASVIR/GRAZOPREVIR (PART D)

For Part D use only:

ELBASVIR/GRAZOPREVIR (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	HCV RNA LEVEL WITHIN PAST 6 MONTHS.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	CRITERIA WILL BE APPLIED CONSISTENT WITH CURRENT AASLD/IDSA GUIDANCE.
Other Criteria	1) CRITERIA WILL BE APPLIED CONSISTENT WITH CURRENT AASLD/IDSA GUIDANCE, 2) INTOLERANCE OR CONTRAINDICATION TO ONE OF THE PREFERRED FORMULARY AGENTS: HARVONI OR EPCLUSA, WHEN THESE AGENTS ARE CONSIDERED ACCEPTABLE FOR TREATMENT OF THE SPECIFIC GENOTYPE PER AASLD/IDSA GUIDANCE, 3) NO CONCURRENT USE WITH THE FOLLOWING AGENTS: PHENYTOIN, CARBAMAZEPINE, RIFAMPIN, EFAVIRENZ, ATAZANAVIR, DARUNAVIR, LOPINAVIR, SAQUINAVIR, TIPRANAVIR, CYCLOSPORINE, NAFCILLIN, KETOCONAZOLE, MODAFINIL, BOSENTAN, ETRAVIRINE, ELVITEGRAVIR/COBICISTAT/EMTRICITABINE/TENOFOVIR, ATORVASTATIN AT DOSES GREATER THAN 20MG PER DAY, ROSUVASTATIN AT DOSES GREATER THAN 10MG PER DAY, SOVALDI, EPCLUSA, HARVONI, MAVYRET, VOSEVI, AND 4) DOES NOT HAVE MODERATE OR SEVERE LIVER IMPAIRMENT (CHILD PUGH B OR C).

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Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 04/24

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELEXACAFTOR-TEZACAFTOR-IVACAFTOR (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ELEXACAFTOR/ TEZACAFTOR/ IVACAFTOR	TRIKAFTA	46112		GPI-10 (4530990340)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of cystic fibrosis (CF) (ICD-10 Group E84) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a pulmonologist or cystic fibrosis expert
   - Trikafta will NOT be used concurrently with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (e.g., medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)
   - The patient has at least ONE variant in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is either responsive to Trikafta based on clinical or in vitro data or that results in the production of CFTR protein

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ELEXACAFTOR-TEZACAFTOR-IVACAFTOR (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ELEXACAFTOR-TEZACAFTOR-IVACAFTOR (Trikafta)** requires the following rule(s) be met for approval:

A. You have cystic fibrosis (CF: a type of lung disorder)
B. You are 2 years of age or older
C. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or cystic fibrosis expert
D. You will NOT use Trikafta concurrently (at the same time) with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (such as medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)
E. You have at least ONE variant in the cystic fibrosis transmembrane conductance regulator (CFTR) gene (a type of gene) that is either responsive to Trikafta based on clinical or in vitro data (testing outside of the body in a tube) or that results in the production of CFTR protein

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ELEXACAFTOR-TEZACAFTOR-IVACAFTOR (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of cystic fibrosis (CF) (ICD-10 Group E84) and meet **ALL** of the following criteria?
   - The patient has experienced an improvement in clinical status
   - Trikafta will NOT be used concurrently with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (e.g., medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)

   If yes, **approve for lifetime by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ELEXACAFTOR-TEZACAFTOR-IVACAFTOR (Trikafta)** requires the following rule(s) be met for renewal:
   A. You have cystic fibrosis (CF: a type of lung disorder)
   B. You have experienced an improvement in your clinical status
   C. You will NOT use Trikafta concurrently (at the same time) with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (such as medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Trikafta.

REFERENCES

Trikafta [Prescribing Information]. Boston, MA: Vertex Pharmaceuticals Inc.; March 2026.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELEXACAFTOR-TEZACAFTOR-IVACAFTOR (PART D)

For Part D use only:

ELEXACAFTOR-TEZACAFTOR-IVACAFTOR (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	CYSTIC FIBROSIS (CF): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A PULMONOLOGIST OR CYSTIC FIBROSIS EXPERT.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: LIFETIME.
Other Criteria	CF: INITIAL: NO CONCURRENT USE WITH ANOTHER CYSTIC FIBROSIS TRANSMEMBRANE CONDUCTANCE REGULATOR (CFTR) MODULATOR. RENEWAL: 1) IMPROVEMENT IN CLINICAL STATUS, AND 2) NO CONCURRENT USE WITH ANOTHER CFTR MODULATOR.

Created: 10/19
Effective: 05/09/26 Client Approval: 05/26 P&T Approval: 01/25

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELIGLUSTAT (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ELIGLUSTAT TARTRATE	CERDELGA	41346		GPI-10 (8270004060)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of type 1 (non-neuronopathic) Gaucher disease (ICD-10 E75.22) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is a CYP2D6 extensive metabolizer (EM), intermediate metabolizer (IM), or poor metabolizer (PM) as detected by an FDA-cleared test

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ELIGLUSTAT (Cerdelga)** requires the following rule(s) be met for approval:
   A. You have type 1 non-neuronopathic Gaucher disease (a type of genetic disorder)
   B. You are 18 years of age or older
   C. You are a CYP2D6 (cytochrome P450 2D6: a type of liver enzyme) extensive metabolizer (normal breakdown of drugs in the body), intermediate metabolizer (slower than normal breakdown of drugs in the body), or poor metabolizer (slow breakdown of drugs in the body) as detected by a Food and Drug Administration (FDA)-cleared test

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELIGLUSTAT (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Cerdelga.

REFERENCES
Cerdelga [Prescribing Information]. Waterford, Ireland: Genzyme; July 2021.

For Part D use only:

ELIGLUSTAT (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELINZANETANT (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ELINZANETANT	LYNKUET	50837		GPI-10 (3060631500)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe menopausal vasomotor symptoms (VMS) (ICD-10 N95.1) and meet **ALL** of the following criteria?
   - The patient experiences at least 7 hot flashes per day
   - Lynkuet will NOT be used concurrently with another hormonal (e.g., Prempro [conjugated estrogen/medroxyprogesterone]) or non-hormonal (e.g., Veozah [fezolinetant], Brisdelle [paroxetine mesylate]) agent for VMS
   - The patient had a trial of or contraindication to the clinical standard of care agent: hormonal therapy (e.g., estradiol transdermal patch [e.g., Minivelle, Climara], oral conjugated estrogens [e.g., Premarin])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   INITIAL DENIAL TEXT: See the initial denial text at the end of the guideline.

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ELINZANETANT

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ELINZANETANT (Lynkuet)** requires the following rule(s) be met for approval:

A. You have moderate to severe menopausal vasomotor symptoms (VMS: symptoms related to menopause)
B. You experience at least 7 hot flashes per day
C. You will NOT use Lynkuet concurrently (at the same time) with another hormonal (such as Prempro [conjugated estrogen/medroxyprogesterone]) or non-hormonal (such as Veozah [fezolinetant], Brisdelle [paroxetine mesylate]) medication for vasomotor symptoms (symptoms related to menopause)
D. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: hormonal therapy (such as estradiol transdermal patch [such as Minivelle, Climara], oral conjugated estrogens [such as Premarin])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ELINZANETANT

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe menopausal vasomotor symptoms (VMS) (ICD-10 N95.1) and meet **ALL** of the following criteria?
   - The patient has a continued need for VMS treatment (persistently symptomatic with hot flashes)
   - The patient has had a reduction in VMS frequency or severity due to Lynkuet treatment
   - Lynkuet will NOT be used concurrently with another hormonal (e.g., Prempro [conjugated estrogen/medroxyprogesterone]) or non-hormonal (e.g., Veozah [fezolinetant], Brisdelle [paroxetine mesylate]) agent for VMS

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ELINZANETANT (Lynkuet)** requires the following rule(s) be met for renewal:
   A. You have moderate to severe menopausal vasomotor symptoms (VMS: symptoms related to menopause)
   B. You have a continued need for vasomotor symptoms (symptoms related to menopause) treatment (persistently symptomatic with hot flashes)
   C. You have had a reduction in vasomotor symptoms (symptoms related to menopause) frequency or severity due to Lynkuet treatment
   D. You will NOT use Lynkuet concurrently (at the same time) with another hormonal (such as Prempro [conjugated estrogen/medroxyprogesterone]) or non-hormonal (such as Veozah [fezolinetant], Brisdelle [paroxetine mesylate]) medication for vasomotor symptoms (symptoms related to menopause)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ELINZANETANT

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lynkuet.

REFERENCES

Lynkuet [Prescribing Information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; October 2025.

For Part D use only:

ELINZANETANT (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS
Other Criteria	MENOPAUSAL VASOMOTOR SYMPTOMS (VMS): INITIAL: 1) EXPERIENCES AT LEAST 7 HOT FLASHES PER DAY, AND 2) TRIAL OF OR CONTRAINDICATION TO THE CLINICAL STANDARD OF CARE AGENT: HORMONAL THERAPY (E.G., ESTRADIOL TRANSDERMAL PATCH, ORAL CONJUGATED ESTROGENS). INITIAL/RENEWAL: NO CONCURRENT USE WITH ANOTHER HORMONAL (E.G., PREMPRO) OR NON-HORMONAL (E.G., VEOZAH, BRISDELLE) AGENT FOR VMS. RENEWAL: 1) CONTINUED NEED FOR VMS TREATMENT (PERSISTENT HOT FLASHES), AND 2) REDUCTION IN VMS FREQUENCY OR SEVERITY WITH THERAPY.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELOSULFASE ALFA (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ELOSULFASE ALFA	VIMIZIM	40929		GPI-10 (3090703005)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of mucopolysaccharidosis type IVA (MPS IVA; Morquio A syndrome) (ICD-10 E76.210)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   The guideline named **ELOSULFASE ALFA (Vimizim)** requires the following rule(s) be met for approval:
   A. You have mucopolysaccharidosis type IVA (MPS IVA; Morquio A syndrome) (a condition that mainly affects the metabolism and skeleton)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Vimizim.

REFERENCES
Vimizim [Prescribing Information]. Novato, CA: Biomarin Pharmaceutical Inc; December 2019.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELOSULFASE ALFA (PART D)

For Part D use only:

ELOSULFASE ALFA (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELOTUZUMAB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ELOTUZUMAB	EMPLICITI	42842		GPI-10 (2135903000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of multiple myeloma (ICD-10 Group C90.0) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has received one to three prior therapies for the treatment of multiple myeloma (e.g., Velcade [bortezomib], Thalomid [thalidomide], Revlimid [lenalidomide], Alkeran [melphalan], stem cell transplantation) AND Empliciti will be used in combination with Revlimid (lenalidomide) and dexamethasone
   - The patient has received at least two prior therapies including Revlimid (lenalidomide) and a proteasome inhibitor (e.g., Velcade [bortezomib], Kyprolis [carfilzomib], Ninlaro [ixazomib])AND Empliciti will be used in combination with pomalidomide and dexamethasone

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELOTUZUMAB (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ELOTUZUMAB (Empliciti)** requires the following rule(s) be met for approval:

A. You have multiple myeloma (plasma cell cancer)
B. You are 18 years of age or older
C. You meet ONE of the following:
   1. You have received one to three prior therapies for the treatment of multiple myeloma (such as Velcade [bortezomib], Thalomid [thalidomide], Revlimid [lenalidomide], Alkeran [melphalan], stem cell transplantation) AND Empliciti will be used in combination with Revlimid (lenalidomide) and dexamethasone
   2. You have received at least two prior therapies including Revlimid (lenalidomide) and a proteasome inhibitor (such Velcade [bortezomib], Kyprolis [carfilzomib], Ninlaro [ixazomib]) AND Empliciti will be used in combination with pomalidomide and dexamethasone

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information,please refer to the Prescribing Information and/or Drug Monograph for Empliciti.

REFERENCES

Empliciti [Prescribing Information]. Princeton, NJ: Bristol-Myers Squibb Company; October 2019.

Part D use only:

ELOTUZUMAB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELRANATAMAB-BCMM BVD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ELRANATAMAB-BCMM	ELREXFIO	49146		GPI-10 (2135202815)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	Yes	No	Yes	Yes	No	Yes	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #5.

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ELRANATAMAB-BCMM BVD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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ELRANATAMAB-BCMM BVD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of relapsed or refractory multiple myeloma (ICD-10 Group C90.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received at least four prior lines of therapy, including a proteasome inhibitor (e.g., Velcade [bortezomib], Kyprolis [carfilzomib]), an immunomodulatory agent (e.g., Revlimid [lenalidomide], Pomalyst [pomalidomide]), and an anti-CD38 monoclonal antibody (e.g., Darzalex [daratumumab])

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ELRANATAMAB-BCMM (Elrexfio)** requires the following rule(s) be met for approval:
   A. You have relapsed or refractory multiple myeloma (a type of blood cancer that has returned or did not respond to treatment)
   B. You are 18 years of age or older
   C. You have received at least four prior lines of therapy, including a proteasome inhibitor (such as Velcade [bortezomib], Kyprolis [carfilzomib]), an immunomodulatory agent (such as Revlimid [lenalidomide], Pomalyst [pomalidomide]), and an anti-CD38 monoclonal antibody (such as Darzalex [daratumumab])
   (Initial denial text continued on next page)

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ELRANATAMAB-BCMM BVD (PART D)

INITIAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ELRANATAMAB-BCMM BVD (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of relapsed or refractory multiple myeloma (ICD-10 Group C90.0) and meet **ALL** of the following criteria?
   - The patient has received at least 24 weeks of treatment with Elrexfio
   - The patient has responded to treatment (partial response [PR] or better), and has maintained this response for at least 2 months

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ELRANATAMAB-BCMM (Elrexfio)** requires the following rule(s) be met for renewal:
   A. You have relapsed or refractory multiple myeloma (a type of blood cancer that has returned or did not respond to treatment)
   B. You have received at least 24 weeks of treatment with Elrexfio
   C. You have responded to treatment (partial response [PR] or better), and have maintained this response for at least 2 months

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Elrexfio. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Elrexfio [Prescribing Information]. New York, NY: Pfizer Inc.; August 2023.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed July 3, 2024].

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELRANATAMAB-BCMM BVD (PART D)

For Part D use only:

ELRANATAMAB-BCMM (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	RELAPSED OR REFRACTORY MULTIPLE MYELOMA: RENEWAL: 1) HAS RECEIVED AT LEAST 24 WEEKS OF TREATMENT WITH ELREXFIO, AND 2) HAS RESPONDED TO TREATMENT (PARTIAL RESPONSE OR BETTER), AND HAS MAINTAINED THIS RESPONSE FOR AT LEAST 2 MONTHS.

Created: 08/23
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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELTROMBOPAG - ALVAIZ (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ELTROMBOPAG CHOLINE	ALVAIZ	49330		GPI-10 (8240503005)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of persistent or chronic immune (idiopathic) thrombocytopenia (ITP) (ICD-10 D69.3) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a hematologist or immunologist
   - The patient had a trial of or contraindication to one corticosteroid or immunoglobulin, or had an insufficient response to a splenectomy
   - Alvaiz will NOT be used concurrently with other thrombopoietin receptor agonists (TPO-RAs) (e.g., Promacta [eltrombopag], Doptelet [avatrombopag], Nplate [romiplostim])

     If yes, continue to #2.
     If no, continue to #3.

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ELTROMBOPAG - ALVAIZ (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient meet **ONE** of the following criteria?
   - The patient has a platelet count of less than 30 x 10^9/L
   - The patient has a platelet count of less than 50 x 10^9/L AND a prior bleeding event

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient have a diagnosis of thrombocytopenia due to chronic hepatitis C and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's thrombocytopenia prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

4. Does the patient have a diagnosis of severe aplastic anemia (ICD-10 D61.9) and meet **ALL** ofthe following criteria?
   - The patient is 18 years of age or older
   - The patient had an insufficient response to immunosuppressive therapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ELTROMBOPAG - ALVAIZ (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ELTROMBOPAG - ALVAIZ** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Persistent or chronic immune (idiopathic) thrombocytopenia (ITP: a type of blood disorder)
   2. Thrombocytopenia (a type of blood disorder) due to chronic hepatitis C (a type of liver infection)
   3. Severe aplastic anemia (a type of blood disorder)

B. If you have persistent or chronic immune (idiopathic) thrombocytopenia, approval also requires:
   1. You are 6 years of age and older
   2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or immunologist (a type of immune system doctor)
   3. You have tried or have a contraindication to (harmful for you to use) one corticosteroid or immunoglobulin, or you did not have a good enough response to a splenectomy (spleen removal)
   4. You will NOT use Alvaiz concurrently (at the same time) with other thrombopoietin receptor agonists (TPO-RAs, such as Promacta [eltrombopag], Doptelet [avatrombopag], Nplate [romiplostim])
   5. You meet ONE of the following:
      a. You have a platelet (a type of blood cell) count of less than 30 x 10^9/L
      b. You have a platelet (a type of blood cell) count of less than 50 x 10^9/L AND a prior bleeding event

C. If you have thrombocytopenia due to chronic hepatitis C, approval also requires:
   1. You are 18 years of age or older
   2. Your thrombocytopenia does not allow you to start interferon-based therapy (a type of drug for hepatitis) or limits your ability to maintain interferon-based therapy

D. If you have severe aplastic anemia, approval also requires:
   1. You are 18 years of age or older
   2. You did not have a good enough response to immunosuppressive therapy (treatment that lowers the activity of the body's immune system)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ELTROMBOPAG - ALVAIZ (PART D)

RENEWAL CRITERIA

NOTE: For the diagnoses of thrombocytopenia due to chronic hepatitis C or severe aplastic anemia, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of persistent or chronic immune (idiopathic) thrombocytopenia (ITP) (ICD-10 D69.3) and meet **ALL** of the following criteria?
   - The patient has shown a clinical response to therapy, defined as having an improvementin platelet count from baseline OR a reduction in bleeding events
   - Alvaiz will NOT be used concurrently with other thrombopoietin receptor agonists (TPO-RAs) (e.g., Promacta [eltrombopag], Doptelet [avatrombopag], Nplate [romiplostim])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ELTROMBOPAG - ALVAIZ** requires the following rules be met for renewal:
   A. You have persistent or chronic immune (idiopathic) thrombocytopenia (ITP: a type of blood disorder)
   B. You have shown a clinical response to therapy, defined as having an improvement in platelet (a type of blood cell) count from baseline (before starting Alvaiz) OR a decreasein bleeding events
   C. You will NOT use Alvaiz concurrently (at the same time) with other thrombopoietin receptor agonists (TPO-RAs, such as Promacta [eltrombopag], Doptelet [avatrombopag], Nplate [romiplostim])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ELTROMBOPAG - ALVAIZ (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Alvaiz.

REFERENCES
Alvaiz [Prescribing Information]. Parsippany, NJ: Teva Pharmaceuticals; November 2023.

For Part D use only:

ELTROMBOPAG - ALVAIZ (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	PERSISTENT OR CHRONIC IMMUNE THROMBOCYTOPENIA (ITP): INITIAL: 1) PLATELET COUNT IS LESS THAN 30 X 10^9/L, OR 2) PLATELET COUNT IS LESS THAN 50 X 10^9/L AND HAD A PRIOR BLEEDING EVENT.
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: ITP: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR IMMUNOLOGIST.
Coverage Duration	ITP: INITIAL: 6 MO, RENEWAL: 12 MO. HEPATITIS C, SEVERE APLASTIC ANEMIA: 12 MO.
Other Criteria	INITIAL: ITP: 1) TRIAL OF OR CONTRAINDICATION TO ONE CORTICOSTEROID OR IMMUNOGLOBULIN, OR AN INSUFFICIENT RESPONSE TO SPLENECTOMY, AND 2) NO CONCURRENT USE WITH OTHER THROMBOPOIETIN RECEPTOR AGONISTS (TPO-RAS). RENEWAL: ITP: 1) IMPROVEMENT IN PLATELET COUNT FROM BASELINE OR REDUCTION IN BLEEDING EVENTS, AND 2) NO CONCURRENT USE WITH OTHER TPO-RAS.

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Effective: 09/01/25 Client Approval: 08/25 P&T Approval: 07/25

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELTROMBOPAG - PROMACTA (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ELTROMBOPAG OLAMINE	PROMACTA, ELTROMBOPAG OLAMINE	35989		GPI-10 (8240503010)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
Yes	No	No	Yes	No	No	Yes	No	No	Yes	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of persistent or chronic immune thrombocytopenia (ITP) (ICD-10 D69.3) and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - Therapy is prescribed by or in consultation with a hematologist or immunologist
   - The patient had a trial of or contraindication to one corticosteroid (e.g., prednisone) or immunoglobulin (e.g., Panzyga [immune globulin]), OR had an insufficient response to a splenectomy
   - The requested drug will NOT be used concurrently with other thrombopoietin receptor agonists (TPO-RAs) (e.g., Nplate [romiplostim], Doptelet [avatrombopag])

   If yes, continue to #2.
   If no, continue to #4.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has a platelet count of less than 30 x10^9/L
   - The patient has a platelet count of less than 50 x 10^9/L AND a prior bleeding event

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ELTROMBOPAG - PROMACTA (PART D)

INITIAL CRITERIA (CONTINUED)

3. Is the request for Promacta (eltrombopag) oral suspension packets and the patient meets **ONE** of the following criteria?
   - The patient had a trial of Promacta (eltrombopag) tablet
   - The patient is unable to tolerate the tablet formulation

   If yes, **approve for 6 months by GPID or GPI-14 for all of the following strengths:**
   - **12.5mg packets.**
   - **25mg packets.**

   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, **approve for 6 months by GPID or GPI-14 for all of the following strengths:**
   - **12.5mg tablet.**
   - **25mg tablet.**
   - **50mg tablet.**
   - **75mg tablet.**

   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

4. Does the patient have a diagnosis of thrombocytopenia due to chronic hepatitis C **AND** meet the following criterion?
   - The patient's thrombocytopenia prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy

   If yes, continue to #6.
   If no, continue to #5.

5. Does the patient have a diagnosis of severe aplastic anemia (ICD-10 D61.9) and meet **ONE** ofthe following criteria?
   - The patient is 2 years of age or olderAND the requested drug will be used in combination with standard immunosuppressive therapy as first-line treatment
   - The patient had an insufficient response to immunosuppressive therapy

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ELTROMBOPAG - PROMACTA (PART D)

INITIAL CRITERIA (CONTINUED)

6. Is the request for Promacta (eltrombopag) oral suspension packets and the patient meets **ONE** of the following criteria?
   - The patient had a trial of Promacta (eltrombopag) tablet
   - The patient is unable to tolerate the tablet formulation

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following strengths:**
   - **12.5mg packets.**
   - **25mg packets.**

   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, **approve for 12 months by GPID or GPI-14 for all of the following strengths:**
   - **12.5mg tablet.**
   - **25mg tablet.**
   - **50mg tablet.**
   - **75mg tablet.**

   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ELTROMBOPAG - PROMACTA** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Persistent or chronic immune thrombocytopenia (a type of blood disorder)
      2. Thrombocytopenia (a type of blood disorder) due to chronic hepatitis C (a type of liver infection)
      3. Severe aplastic anemia (type of blood condition)

   (Initial denial text continued on next page)

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ELTROMBOPAG - PROMACTA (PART D)

INITIAL CRITERIA (CONTINUED)

B. If you have persistent or chronic immune thrombocytopenia, approval also requires:
1. You are 1 year of age or older
2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or immunologist (a type of immune system doctor)
3. You have tried or have a contraindication to (harmful for you to use) one corticosteroid (such as prednisone) or immunoglobulin (such as Panzyga [immune globulin]), OR you had an insufficient response to splenectomy (surgical removal of spleen did not work)
4. You meet ONE of the following:
   a. You have a platelet (a type of blood cell) count of less than 30 x 10^9/L
   b. You have a platelet (a type of blood cell) count of less than 50 x 10^9/L AND had a prior bleeding event
5. You will NOT use the requested drug concurrently (at the same time) with other thrombopoietin receptor agonists (TPO-Ras, such as Nplate [romiplostim], Doptelet [avatrombopag])

C. If you have thrombocytopenia due to chronic hepatitis C, approval also requires:
1. Your thrombocytopenia does not allow you to start interferon-based therapy (type of drug for hepatitis) or limits your ability to maintain interferon-based therapy

D. If you have severe aplastic anemia, approval also requires ONE of the following:
1. You are 2 years of age or older AND the requested drug will be used in combination with standard immunosuppressive therapy (treatment that lowers the activity of the body's immune system) as first-line treatment
2. You did not have a good enough response to immunosuppressive therapy

E. If the request is for Promacta (eltrombopag) oral suspension packets (for any indication), approval also requires:
1. You had a trial of Promacta (eltrombopag) tablet OR you are unable to tolerate the tablet formulation

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ELTROMBOPAG - PROMACTA (PART D)

RENEWAL CRITERIA

NOTE: For the diagnoses of thrombocytopenia due to chronic hepatitis C or severe aplastic anemia, please refer to the initial criteria section.

1. Does the patient have a diagnosis of persistent or chronic immune thrombocytopenia (ITP) (ICD-10 D69.3) and meet **ALL** of the following criteria?
   - The patient has improvement in platelet counts from baseline or reduction in bleeding events
   - The requested drug will NOT be used concurrently with other thrombopoietin receptor agonists (TPO-RAs) (e.g., Nplate [romiplostim], Doptelet [avatrombopag])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ELTROMBOPAG - PROMACTA** requires the following rule(s) be met for renewal:
   A. You have persistent or chronic immune thrombocytopenia (a type of blood disorder)
   B. You have improvement in platelet (a type of blood cell) counts from baseline or reduction in bleeding events
   C. You will NOT use the requested drug concurrently (at the same time) with other thrombopoietin receptor agonists (TPO-RAs, such as Nplate [romiplostim], Doptelet [avatrombopag])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the prescribing information and/or Drug Monograph for Promacta.

REFERENCES

Promacta [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2023.

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ELTROMBOPAG - PROMACTA (PART D)

For Part D use only:

ELTROMBOPAG - PROMACTA (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	PERSISTENT OR CHRONIC IMMUNE THROMBOCYTOPENIA (ITP): INITIAL: 1) PLATELET COUNT OF LESS THAN 30 X 10^9/L, OR 2) PLATELET COUNT OF LESS THAN 50 X 10^9/L AND A PRIOR BLEEDING EVENT.
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: ITP: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR IMMUNOLOGIST.
Coverage Duration	ITP: INITIAL: 6 MO, RENEWAL: 12 MO. HEPATITIS C, SEVERE APLASTIC ANEMIA: 12 MO.
Other Criteria	INITIAL: ITP: 1) TRIAL OF OR CONTRAINDICATION TO ONE CORTICOSTEROID OR IMMUNOGLOBULIN, OR HAD AN INSUFFICIENT RESPONSE TO SPLENECTOMY, AND 2) NO CONCURRENT USE WITH OTHER THROMBOPOIETIN RECEPTOR AGONISTS (TPO-RAS). ALL INDICATIONS: ELTROMBOPAG ORAL SUSPENSION PACKETS: TRIAL OF A FORMULARY VERSION OF ELTROMBOPAG TABLET OR PATIENT IS UNABLE TO TOLERATE TABLET FORMULATION. RENEWAL: ITP: 1) IMPROVEMENT IN PLATELET COUNTS FROM BASELINE OR REDUCTION IN BLEEDING EVENTS, AND 2) NO CONCURRENT USE WITH OTHER TPO-RAS.

Created: 11/07
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 07/25

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELUXADOLINE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ELUXADOLINE	VIBERZI	42445		GPI-10 (5255802000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of irritable bowel syndrome with diarrhea (IBS-D) (ICD-10 K58.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - The patient had a trial of or contraindication to dicyclomine AND the preferred agent: Xifaxan (rifaximin)

   If yes, **approve for 3 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ELUXADOLINE (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ELUXADOLINE (Viberzi)** requires the following rule(s) be met for approval:

A. You have irritable bowel syndrome with diarrhea (a type of bowel disease)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
D. You have tried or have a contraindication to (harmful for you to use) dicyclomine AND the preferred medication: Xifaxan (rifaximin)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELUXADOLINE (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of irritable bowel syndrome with diarrhea (IBS-D) (ICD-10 K58.0) **AND** meet the following criterion?
   - The patient continues to benefit from the medication

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ELUXADOLINE (Viberzi)** requires the following rule(s) be met for renewal:
   A. You have irritable bowel syndrome with diarrhea (a type of bowel disease)
   B. You continue to benefit from the medication

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Viberzi.

REFERENCES

Viberzi [Prescribing Information]. Madison, NJ: Allergan USA, Inc; June 2020.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELUXADOLINE (PART D)

For Part D use only:

ELUXADOLINE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	IRRITABLE BOWEL SYNDROME WITH DIARRHEA (IBS-D): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST.
Coverage Duration	INITIAL: 3 MONTHS, RENEWAL: 12 MONTHS.
Other Criteria	IBS-D: INITIAL: TRIAL OF OR CONTRAINDICATION TO DICYCLOMINE AND THE PREFRRED AGENT: XIFAXAN. RENEWAL: CONTINUES TO BENEFIT FROM THE MEDICATION.

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25 Created: 11/21
Commercial Effective: N/A Client Approval: 08/24 P&T Approval: 02/16

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EMAPALUMAB-LZSG (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EMAPALUMAB-LZSG	GAMIFANT	45503		GPI-10 (9940503540)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of primary (familial) hemophagocytic lymphohistiocytosis (HLH) (ICD-10 D76.1) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an immunologist, hematologist, or oncologist
   - Gamifant will be used concurrently with dexamethasone
   - The patient has refractory, recurrent, or progressive disease OR the patient had a trial of or intolerance to conventional HLH therapy (chemotherapy, steroids, immunotherapy)

   If yes, continue to #2.
   If no, continue to #3.

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EMAPALUMAB-LZSG (PART D)

INITIAL CRITERIA (CONTINUED)

2. Is the patient's primary HLH diagnosis confirmed by **ONE** of the following criteria?
   - The patient has undergone a genetic test identifying HLH-associated gene mutation (e.g., PRF1, UNC13D)
   - The patient has at least five of the following eight diagnostic criteria for HLH: fever; splenomegaly; cytopenias (affecting at least 2 of 3 cell lineages); hypertriglyceridemia and/or hypofibrinogenemia; hemophagocytosis in bone marrow or spleen or lymph nodes, and no evidence of malignancy; low or absent natural killer-cell activity; ferritin level of at least 500 mcg/L; soluble CD25 level of at least 2,400 U/mL

   If yes, **approve for 8 weeks by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient have a diagnosis of hemophagocytic lymphohistiocytosis (HLH)/macrophage activation syndrome (MAS) (ICD-10 D76.1) and meet **ALL** of the following criteria?
   - The patient has known or suspected Still's disease or systemic juvenile idiopathic arthritis (sJIA)
   - The patient had an inadequate response or intolerance to glucocorticoids OR has a recurrent MAS

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EMAPALUMAB-LZSG (Gamifant)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Primary (familial) hemophagocytic lymphohistiocytosis (HLH: a type of genetic immune disorder)
      2. Hemophagocytic lymphohistiocytosis (HLH)/macrophage activation syndrome (MAS) (a type of immune disorder)

   (Initial denial text continued on next page)

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EMAPALUMAB-LZSG (PART D)

INITIAL CRITERIA (CONTINUED)

B. If you have primary hemophagocytic lymphohistiocytosis, approval also requires:
1. Therapy is prescribed by or in consultation with an immunologist (doctor who specializes in immune disorders), hematologist (a type of blood doctor), or oncologist (a type of cancer doctor)
2. Gamifant will be used at the same time with dexamethasone
3. You have refractory, recurrent, or progressive disease (disease does not respond to treatment, returns, or is getting worse) OR you have tried or had an intolerance (side effect) to conventional hemophagocytic lymphohistiocytosis therapy (chemotherapy, steroids, immunotherapy)
4. Your diagnosis is confirmed by ONE of the following:
   a. You have undergone a genetic test identifying a HLH-associated gene mutation (such as PRF1 [type of gene], UNC13D [type of gene])
   b. You have at least five of the following eight diagnostic criteria for HLH: fever; splenomegaly (enlarged spleen); cytopenias (low number of a type of blood cell affecting at least 2 of 3 cell lineages); hypertriglyceridemia (high level of triglycerides, a type of fat in the blood) and/or hypofibrinogenemia (low level of fibrinogen, a type of protein in the blood); hemophagocytosis (destruction of certain types of cells) in bone marrow or spleen or lymph nodes, and no evidence of malignancy (cancer); low or absent natural killer-cell (white blood cells) activity; ferritin level (a type of lab test) of at least 500 mcg/L; soluble CD25 level (a type of lab test) of at least 2,400 U/mL

C. If you have hemophagocytic lymphohistiocytosis/macrophage activation syndrome, approval also requires:
1. You have known or suspected Still's disease (an autoinflammatory disease) or systemic juvenile idiopathic arthritis (sJIA: a type of joint condition)
2. You had an inadequate response (treatment did not work) or intolerance (side effect) to glucocorticoids OR you have a recurrent (disease has returned) macrophage activation syndrome (MAS: a type of immune disorder)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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EMAPALUMAB-LZSG (PART D)

RENEWAL CRITERIA

NOTE: For the diagnosis of hemophagocytic lymphohistiocytosis (HLH)/macrophage activation syndrome (MAS), please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of primary (familial) hemophagocytic lymphohistiocytosis (HLH) (ICD-10 D76.1) and meet **ALL** of the following criteria?
   - The patient has not received a successful hematopoietic stem cell transplantation
   - The patient has demonstrated improved immune system response from baseline (e.g., resolution of fever, decreased splenomegaly, improvement in CNS symptoms, improved CBC, increased fibrinogen levels, reduced D-dimer, reduced ferritin, reduced soluble CD25 levels)

   If yes, **approve for 8 weeks by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EMAPALUMAB-LZSG (Gamifant)** requires the following rule(s) be met for renewal:
   A. You have primary (familial) hemophagocytic lymphohistiocytosis (HLH: a type of genetic immune disorder)
   B. You have not received a successful hematopoietic stem cell transplantation (bone marrow transplant)
   C. You have demonstrated improved immune system response from baseline (for example, your fever has gone away, decreased splenomegaly [spleen size has gotten smaller], improvement in central nervous system symptoms, improved complete blood count, increased fibrinogen levels, or reduced D-dimer, ferritin, or soluble CD25 [types of proteins] levels)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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EMAPALUMAB-LZSG (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Gamifant.

REFERENCES

Gamifant [Prescribing Information]. Waltham, MA: Sobi Inc.; June 2025.

For Part D use only:

EMAPALUMAB-LZSG (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	HEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS (HLH): INITIAL: 1) A GENETIC TEST IDENTIFYING HLH-ASSOCIATED GENE MUTATION (E.G., PRF1, UNC13D), OR 2) HAS AT LEAST FIVE OF THE FOLLOWING EIGHT DIAGNOSTIC CRITERIA FOR HLH: (A) FEVER, (B) SPLENOMEGALY, (C) CYTOPENIAS (AFFECTING AT LEAST 2 OF 3 CELL LINEAGES), (D) HYPERTRIGLYCERIDEMIA OR HYPOFIBRINOGENEMIA, (E) HEMOPHAGOCYTOSIS IN BONE MARROW OR SPLEEN OR LYMPH NODES AND NO EVIDENCE OF MALIGNANCY, (F) LOW OR ABSENT NATURAL KILLER-CELL ACTIVITY, (G) FERRITIN LEVEL OF 500 MCG/L OR GREATER, (H) SOLUBLE CD25 LEVEL OF 2,400 U/ML OR GREATER.
Age Restrictions	N/A
Prescriber Restrictions	HLH: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH AN IMMUNOLOGIST, HEMATOLOGIST, OR ONCOLOGIST.
Coverage Duration	HLH: INITIAL/RENEWAL: 8 WEEKS. HLH/MACROPHAGE ACTIVATION SYNDROME (MAS): 12 MONTHS.
Other Criteria	HLH: INITIAL: 1) CONCURRENT THERAPY WITH DEXAMETHASONE, AND 2) ONE OF THE FOLLOWING: (A) HAS REFRACTORY, RECURRENT, OR PROGRESSIVE DISEASE, OR (B) HAD A TRIAL OF OR INTOLERANCE TO CONVENTIONAL HLH THERAPY (I.E., CHEMOTHERAPY, STEROIDS, IMMUNOTHERAPY). RENEWAL: 1) HAS NOT RECEIVED SUCCESSFUL HEMATOPOIETIC STEM CELL TRANSPLANTATION, AND 2) DEMONSTRATED IMPROVED IMMUNE SYSTEM RESPONSE FROM BASELINE (E.G., RESOLUTION OF FEVER, DECREASED SPLENOMEGALY, IMPROVEMENT IN CNS SYMPTOMS, IMPROVED CBC, INCREASED FIBRINOGEN LEVELS, REDUCED D-DIMER, REDUCED FERRITIN, REDUCED SOLUBLE CD25 LEVELS.)

Created: 02/21
Effective: 01/01/26 Client Approval: 12/25 P&T Approval: 10/25

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ENASIDENIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ENASIDENIB MESYLATE	IDHIFA	44450		GPI-10 (2153503020)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory acute myeloid leukemia (AML) (ICD-10 C92.02, C92.00) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is isocitrate dehydrogenase-2 (IDH2) mutation positive, as detected by an FDA-approved diagnostic test

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ENASIDENIB (Idhifa)** requires the following rule(s) be met for approval:
   A. You have relapsed or refractory acute myeloid leukemia (AML: a type of blood and bone marrow cancer that has returned or did not respond to treatment)
   B. You are 18 years of age or older
   C. You are isocitrate dehydrogenase-2 (IDH2: a type of enzyme) mutation positive, as detected by a Food and Drug Administration (FDA)-approved diagnostic test

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ENASIDENIB (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Idhifa.

REFERENCES

Idhifa [Prescribing Information]. Summit, NJ: Celgene Corporation; November 2020.

For Part D use only:

ENASIDENIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25 Created: 08/17
Commercial Effective: N/A Client Approval: 08/24 P&T Approval: 10/17

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ENCORAFENIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ENCORAFENIB	BRAFTOVI	45039		GPI-10 (2153204000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic melanoma (ICD-10 Group C43) and meet **ALL** of the following criteria?
   - The patient has a BRAF V600E or V600K mutation, as detected by an FDA-approved test
   - Braftovi will be used in combination with Mektovi (binimetinib)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of metastatic colorectal cancer (mCRC) (ICD-10 C19) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a BRAF V600E mutation, as detected by an FDA-approved test
   - Braftovi will be used in combination with Erbitux (cetuximab) and fluorouracil-based chemotherapy (e.g. mFOLFOX6, FOLFIRI), OR Braftovi will be used in combination with Erbitux (cetuximab) and the patient has received prior therapy (e.g., irinotecan)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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ENCORAFENIB (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a BRAF V600E mutation, as detected by an FDA-approved test
   - Braftovi will be used in combination with Mektovi (binimetinib)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ENCORAFENIB (Braftovi)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Unresectable or metastatic melanoma (a type of skin cancer that cannot be completely removed with surgery or has spread to other parts of the body)
      2. Metastatic colorectal cancer (mCRC: a type of digestive cancer that has spread to other parts of the body)
      3. Metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of the body)

   B. If you have unresectable or metastatic melanoma, approval also requires:
      1. You have a BRAF V600E or V600K mutation (abnormal change in types of genes), as detected by a Food and Drug Administration (FDA)-approved test
      2. Braftovi will be used in combination with Mektovi (binimetinib)

   (Denial text continued on next page)

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ENCORAFENIB (PART D)

GUIDELINES FOR USE (CONTINUED)

C. If you have metastatic colorectal cancer, approval also requires:
1. You are 18 years of age or older
2. You have a BRAF V600E mutation (abnormal change in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test
3. You meet ONE of the following:
   a. Braftovi will be used in combination with Erbitux (cetuximab) and fluorouracil-based chemotherapy (such as mFOLFOX6 [fluorouracil, leucovorin and oxaliplatin], FOLFIRI [fluorouracil, leucovorin, and irinotecan])
   b. Braftovi will be used in combination with Erbitux (cetuximab), and you have previously received treatment (such as irinotecan)

D. If you have metastatic non-small cell lung cancer, approval also requires:
1. You are 18 years of age or older
2. You have a BRAF V600E mutation (abnormal change in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test
3. Braftovi will be used in combination with Mektovi (binimetinib)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Braftovi.

REFERENCES
Braftovi [Prescribing Information]. Boulder, CO: Array BioPharma Inc.; February 2026.

For Part D use only:

ENCORAFENIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 07/18
Effective: 03/11/26 Client Approval: 03/26 P&T Approval: 01/25

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ENFORTUMAB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ENFORTUMAB VEDOTIN-EJFV	PADCEV	46257		GPI-10 (2135702620)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced or metastatic urothelial cancer (mUC) (ICD-10 Groups C65, C66, C67, C68) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, continue to #4.

2. Will Padcev be used as a single agent and the patient meets **ONE** of the following criteria?
   - The patient has previously received a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor and platinum (e.g., cisplatin, carboplatin)-containing chemotherapy
   - The patient is ineligible for cisplatin-containing chemotherapy AND has previously received one or more prior lines of therapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

3. Will Padcev be used in combination with Keytruda (pembrolizumab) or Keytruda Qlex (pembrolizumab and berahyaluronidase alfa-pmph)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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ENFORTUMAB (PART D)

GUIDELINES FOR USE (CONTINUED)

4. Does the patient have a diagnosis of bladder cancer (ICD-10 Group C67) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has muscle invasive bladder cancer (MIBC)
   - Padcev will be used in combination with Keytruda (pembrolizumab) or Keytruda Qlex (pembrolizumab and berahyaluronidase alfa-pmph) as neoadjuvant treatment and then continued after cystectomy as adjuvant treatment

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ENFORTUMAB (Padcev)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Locally advanced or metastatic urothelial cancer (mUC: a type of urinary system cancer that has spread to nearby tissue or lymph nodes or to other parts of the body)
      2. Bladder cancer

   B. If you have locally advanced or metastatic urothelial cancer, approval also requires:
      1. You are 18 years of age or older
      2. You meet ONE of the following:
         a. Padcev will be used as a single agent, and you meet ONE of the following:
            i. You have previously received a medication that works against a type of protein called programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) AND you have previously received a platinum (such as cisplatin, carboplatin)-containing chemotherapy (type of cancer medication)
            ii. You are not eligible for cisplatin-containing chemotherapy and have previously received one or more prior lines of therapy
         b. Padcev will be used in combination with Keytruda (pembrolizumab) or Keytruda Qlex (pembrolizumab and berahyaluronidase alfa-pmph)

   C. If you have bladder cancer, approval also requires:
      1. You are 18 years of age or older
      2. You have muscle invasive bladder cancer (MIBC: bladder cancer that has grown into the muscle wall)
      3. Padcev will be used in combination with Keytruda (pembrolizumab) or Keytruda Qlex (pembrolizumab and berahyaluronidase alfa-pmph) as neoadjuvant treatment (given before main treatment), and then continued after cystectomy (bladder removal surgery) as adjuvant treatment (additional treatment)

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ENFORTUMAB (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Padcev.

REFERENCES

Padcev [Prescribing Information]. Northbrook, IL: Astellas Pharma US, Inc., July 2026.

For Part D use only:

ENFORTUMAB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 12/19
Effective: 07/29/26 Client Approval: 07/26 DMC Approval: 07/26

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ENSARTINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ENSARTINIB HYDROCHLORIDE	ENSACOVE	50112		GPI-10 (2153301520)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's tumors are anaplastic lymphoma kinase (ALK)-positive
   - The patient has NOT previously received an ALK-inhibitor (e.g., Xalkori [crizotinib], Alecensa [alectinib])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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ENSARTINIB (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ENSARTINIB (Ensacove)** requires the following rule(s) be met for approval:

A. You have locally advanced or metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread from where it started to nearby tissue/lymph nodes or other parts of the body)
B. You are 18 years of age or older
C. Your tumors are anaplastic lymphoma kinase (ALK: a type of enzyme)-positive
D. You have NOT previously received an ALK-inhibitor (such as Xalkori [crizotinib], Alecensa [alectinib])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ensacove.

REFERENCES

Ensacove [Prescribing Information]. Miami, FL: Xcovery Holdings, Inc.; January 2026.

For Part D use only:

ENSARTINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ENSIFENTRINE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ENSIFENTRINE	OHTUVAYRE	49726		GPI-10 (4443002000)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	Yes	No	No	Yes	No	No	Yes	No	Yes	Yes

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

This is an inhalation drug that normally requires a nebulizer. If Payment Determination has not been assessed and/or is being contested, please reanalyze or refer to the NEBULIZER BVD DETERMINATION guideline in the library.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of chronic obstructive pulmonary disease (COPD) (ICD-10 Group J44 except for ICD-10 J44.0 and ICD-10 J44.81) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Ohtuvayre will be used as maintenance treatment
   - Therapy is prescribed by or in consultation with a pulmonologist

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient have a blood eosinophil level of 100 cells/microliter or greater?

   If yes, continue to #3.
   If no, continue to #4.

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ENSIFENTRINE (PART D)

INITIAL CRITERIA (CONTINUED)

3. Has the patient had a history of and will continue on, or has a contraindication or failure to, the following standard of care therapy?
   - LAMA (long-acting antimuscarinic)/LABA (long-acting beta-2-agonist)/ICS (inhaled corticosteroid) combination drug (e.g., Trelegy Ellipta, Breztri Aerosphere)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Has the patient had a history of and will continue on, or has a contraindication or failure to, the following standard of care therapy?
   - LAMA (long-acting antimuscarinic)/LABA (long-acting beta-2-agonist) combination drug (e.g., Stiolto Respimat, Anoro Ellipta)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ENSIFENTRINE (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ENSIFENTRINE (Ohtuvayre)** requires the following rule(s) be met for approval:

A. You have chronic obstructive pulmonary disease (COPD: a type of long-term lung condition)
B. You are 18 years of age or older
C. Ohtuvayre will be used as maintenance treatment (taken on a regular basis)
D. Therapy is prescribed by or in consultation with a pulmonologist (a type of lung/breathing doctor)
E. You have a history of and will continue on, or you had a contraindication (harmful for you to use) or failure (drug did not work) to, ONE of the following standard of care therapies:
    1. LAMA (long-acting antimuscarinic)/LABA (long-acting beta-2-agonist) combination drug (such as Stiolto Respimat, Anoro Ellipta)
    2. LAMA/LABA/ICS (inhaled corticosteroid) combination drug (such as Trelegy Ellipta, Breztri Aerosphere) if you have a blood eosinophil level of 100 cells/microliter or greater

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ENSIFENTRINE (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of chronic obstructive pulmonary disease (COPD) (ICD-10 Group J44 except for ICD-10 J44.0 and ICD-10 J44.81)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient have a blood eosinophil level of 100 cells/microliter or greater?

   If yes, continue to #3.
   If no, continue to #4.

3. Has the patient had a history of and will continue on, or has a contraindication or failure to, the following standard of care therapy?
   - LAMA (long-acting antimuscarinic)/LABA (long-acting beta-2-agonist)/ICS (inhaled corticosteroid) combination drug (e.g., Trelegy Ellipta, Breztri Aerosphere)

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Has the patient had a history of and will continue on, or has a contraindication or failure to, the following standard of care therapy?
   - LAMA (long-acting antimuscarinic)/LABA (long-acting beta-2-agonist) combination drug (e.g., Stiolto Respimat, Anoro Ellipta)

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

5. Has the patient shown a clinical response as evidenced by **ONE** of the following criteria?
   - The patient has a reduction in COPD exacerbations from baseline
   - The patient has a reduction in severity or frequency of COPD-related symptoms (e.g., wheezing, shortness of breath, coughing, sputum production, etc.)
   - The patient has an increase in FEV1 by at least 5 percent from pretreatment baseline

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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ENSIFENTRINE (PART D)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ENSIFENTRINE (Ohtuvayre)** requires the following rule(s) be met for renewal:

A. You have chronic obstructive pulmonary disease (COPD: a type of long-term lung condition)
B. You have a history of and will continue on, or you had a contraindication (harmful for you to use) or failure (drug did not work) to ONE of the following standard of care therapies:
    1. LAMA (long-acting antimuscarinic)/LABA (long-acting beta-2-agonist) combination drug (such as Stiolto Respimat, Anoro Ellipta)
    2. LAMA/LABA/ICS (inhaled corticosteroid) combination drug (such as Trelegy Ellipta, Breztri Aerosphere) if you have a blood eosinophil level of 100 cells/microliter or greater
C. You have shown a clinical response as evidenced by ONE of the following:
    1. You have a reduction (decrease) in COPD exacerbations (worsening of symptoms) from baseline (before starting Ohtuvayre)
    2. You have a reduction in severity or frequency of COPD-related symptoms (such as wheezing, shortness of breath, coughing, sputum (mucus) production, etc.)
    3. You have an increase in FEV1 (a type of lung test) by at least 5 percent from pretreatment baseline (before starting Ohtuvayre)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

This drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination.
50.16.2 – Inhalation Durable Medical Equipment (DME) Supply Drugs (Rev. 18, 09-17-18)
Medicare Part B covers certain inhalation drugs, such as Albuterol and Levalbuterol nebulizer solutions, as supplies under the DME benefit. The DME benefit, however, is not available to beneficiaries residing in long-term care facilities (i.e. Nursing Facilities and Intermediate Care Facilities for Individuals with Intellectual Disabilities). Consequently, if the beneficiary is not on a Part A stay in one of these facilities, these inhalation drugs can be covered under Medicare Part D. CMS permits Part D sponsors to rely on a patient residence code of “3” or “9” on a pharmacy claim for determining when such inhalation drugs may be covered under Part D. Moreover, we expect that sponsors will only pay claims for these products when the pharmacy claim includes these specified patient residence codes regardless of any prior coverage determination based upon a prescriber statement indicating that the beneficiary resides in a long-term care facility (i.e. the prescriber statement and patient residence code must be aligned). For further information, please refer to the Prescribing Information and/or Drug Monograph for Ohtuvayre.

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ENSIFENTRINE (PART D)

REFERENCES

Ohtuvayre [Prescribing Information]. Raleigh, NC: Verona Pharma, Inc.; June 2024.
Medicare Prescription Drug Benefit Manual Chapter 6 – Part D Drugs and Formulary Requirements, Appendix C- Summary of Coverage Policy Medicare Part B Versus Part D Coverage Issues. Rev 10, 02-19-10. Available at: http://www.cms.gov/PrescriptionDrugCovContra/12_PartDManuals.asp. [Accessed July 9, 2024].

For Part D use only:

ENSIFENTRINE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A PULMONOLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	COPD: INITIAL: HISTORY OF AND CONTINUATION ON, OR CONTRAINDICATION/FAILURE TO, STANDARD OF CARE THERAPY: LAMA/LABA COMBINATION THERAPY OR LAMA/LABA/ICS COMBINATION THERAPY IF BLOOD EOSINOPHIL LEVEL IS GREATER THAN OR EQUAL TO 100 CELLS/MICROLITER. RENEWAL: 1) HISTORY OF AND CONTINUATION ON, OR CONTRAINDICATION/FAILURE TO, STANDARD OF CARE THERAPY: LAMA/LABA COMBINATION THERAPY OR LAMA/LABA/ICS COMBINATION THERAPY IF BLOOD EOSINOPHIL LEVEL IS GREATER THAN OR EQUAL TO 100 CELLS/MICROLITER, AND 2) CLINICAL RESPONSE AS EVIDENCED BY ONE OF THE FOLLOWING: (A) REDUCTION IN COPD EXACERBATIONS FROM BASELINE, (B) REDUCTION IN SEVERITY OR FREQUENCY OF COPD-RELATED SYMPTOMS, OR (C) INCREASE IN FEV1 BY AT LEAST 5 PERCENT FROM PRETREATMENT BASELINE. THIS DRUG MAY BE COVERED UNDER MEDICARE PART B OR D DEPENDING UPON THE CIRCUMSTANCES.

Part D Effective: 08/01/24 Created: 07/24
Commercial Effective: N/A Client Approval: 07/24 P&T Approval: 04/24

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ENTRECTINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ENTRECTINIB	ROZLYTREK	45952		GPI-10 (2153382000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's tumor is *ROS1*-positive, as detected by an FDA-approved test

   If yes, continue to #3.
   If no, continue to #2.

2. Does the patient have a diagnosis of a solid tumor and meet **ALL** of the following criteria?
   - The patient is 1 month of age or older
   - The tumor has a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation, as detected by an FDA-approved test
   - The tumor is metastatic, or surgical resection is likely to result in severe morbidity
   - The patient has progressed following treatment or there are no satisfactory alternative treatments

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Is the request for Rozlytrek (100mg or 200mg) capsules?

   If yes, **approve both 100mg and 200mg capsules for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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ENTRECTINIB (PART D)

GUIDELINES FOR USE

4. Is the request for Rozlytrek 50mg pellets and the patient meets **ALL** of the following criteria?
   - The patient had a trial of or contraindication to Rozlytrek capsules made into an oral suspension
   - The patient has difficulty or is unable to swallow capsules

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ENTRECTINIB (Rozlytrek)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of the body)
      2. Solid tumor (an abnormal mass)
   B. If you have metastatic non-small cell lung cancer, approval also requires:
      1. You are 18 years of age or older
      2. Your tumor is *ROS1*-positive (abnormal change in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test
   C. If you have a solid tumor, approval also requires:
      1. You are 1 month of age or older
      2. The tumor has a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation (an abnormal change in a type of gene that does not have any known resistance), as detected by a Food and Drug Administration (FDA)-approved test
      3. Your tumor is metastatic (has spread to other parts of the body), or surgical resection (removal) is likely to result in severe morbidity (disease)
      4. You have progressed (gotten worse) after treatment or there are no satisfactory alternative treatments
   D. If the request is for Rozlytrek 50mg pellets, approval also requires:
      1. You have tried or have a contraindication to (harmful for you to use) Rozlytrek capsules that are used to make an oral suspension
      2. You have difficulty or are not able to swallow capsules

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ENTRECTINIB (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rozlytrek.

REFERENCES

Rozlytrek [Prescribing Information]. South San Francisco, CA: Genentech USA, Inc.; January 2024.

For Part D use only:

ENTRECTINIB CAPSULES (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

ENTRECTINIB PELLETS (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC), SOLID TUMORS: 1) TRIAL OF OR CONTRAINDICATION TO ROZLYTREK CAPSULES MADE INTO AN ORAL SUSPENSION, AND 2) DIFFICULTY OR UNABLE TO SWALLOW CAPSULES.

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 08/19
Client Approval: 06/24
P&T Approval: 01/24

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ENZALUTAMIDE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ENZALUTAMIDE	XTANDI	39580		GPI-10 (2140243000)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have **ONE** of the following diagnoses?
   - Metastatic castration-sensitive prostate cancer (mCSPC) (ICD-10 Z19.1, C61)
   - Metastatic castration-resistant prostate cancer (mCRPC) (ICD-10 Z19.2, C61)
   - Non-metastatic castration-resistant prostate cancer (nmCRPC) (ICD-10 Z19.2, C61)

   If yes, continue to #3.
   If no, continue to #2.

2. Does the patient have a diagnosis of non-metastatic castration-sensitive prostate cancer (nmCSPC) (ICD-10 Z19.1, C61) **AND** meet the following criterion?
   - The patient is at high risk for metastasis (i.e., prostate specific antigen [PSA] doubling time of 9 months or less)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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ENZALUTAMIDE (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient meet **ONE** of the following criteria?
   - The patient has received a bilateral orchiectomy
   - The patient has a castrate level of testosterone (i.e., less than 50 ng/dL)
   - Xtandi will be used concurrently with a gonadotropin releasing hormone (GnRH) analog (e.g., Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ENZALUTAMIDE (Xtandi)** requires the following rules be met for approval:

   A. You have ONE of the following:
      1. Metastatic castration-resistant prostate cancer (mCRPC: cancer that has spread after treatment with hormone therapy)
      2. Metastatic castration-sensitive prostate cancer (mCSPC: cancer that had spread beyond the prostate and responds to hormone therapy)
      3. Non-metastatic castration-resistant prostate cancer (nmCRPC: prostate cancer that has not spread to other parts of the body and does not respond to hormone therapy)
      4. Non-metastatic castration-sensitive prostate cancer (nmCSPC: prostate cancer that has not spread to other parts of the body and responds to hormone therapy)

   B. If you have metastatic castration-resistant prostate cancer, metastatic castration-sensitive prostate cancer, or non-metastatic castration-resistant prostate cancer, approval also requires ONE of the following:
      1. You have received a bilateral orchiectomy (surgical removal of both testicles)
      2. You have a castrate level of testosterone (blood testosterone levels are less than 50 ng/dL)
      3. Xtandi will be used concurrently (at the same time) with a gonadotropin releasing hormone agonist or antagonist (such as Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

   (Denial text continued on next page)

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ENZALUTAMIDE (PART D)

GUIDELINES FOR (CONTINUED)

C. If you have non-metastatic castration-sensitive prostate cancer, approval also requires:

1. You are at high risk for metastasis (prostate specific antigen [PSA] level has doubled over 9 months or less)
2. You meet ONE of the following:
   a. You have received a bilateral orchiectomy (surgical removal of both testicles)
   b. You have a castrate level of testosterone (blood testosterone levels are less than 50 ng/dL)
   c. Xtandi will be used concurrently (at the same time) with a gonadotropin releasing hormone agonist or antagonist (such as Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xtandi.

REFERENCES

Xtandi [Prescribing Information]. Northbrook, IL: Astellas Pharma US, Inc.; March 2025.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ENZALUTAMIDE (PART D)

For Part D use only:

ENZALUTAMIDE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	NON-METASTATIC CASTRATION-SENSITIVE PROSTATE CANCER (NMCSPC): HIGH RISK FOR METASTASIS (I.E. PSA DOUBLING TIME OF 9 MONTHS OR LESS). METASTATIC CASTRATION-RESISTANT PROSTATE CANCER (MCRPC), NON-METASTATIC CRPC (NMCRPC), METASTATIC CSPC (MCSPC), NMCSPC: 1) RECEIVED A BILATERAL ORCHIECTOMY, 2) CASTRATE LEVEL OF TESTOSTERONE (I.E., LESS THAN 50 NG/DL), OR 3) CONCURRENT USE WITH A GONADOTROPIN RELEASING HORMONE (GNRH) ANALOG.

Created: 11/07
Effective: 01/01/26 Client Approval: 12/25 P&T Approval: 01/24

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EPCORITAMAB-BYSP BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EPCORITAMAB-BYSP	EPKINLY	48945		GPI-10 (2135203120)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	Yes	No	Yes	Yes	No	Yes	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit).**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #5.

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EPCORITAMAB-BYSP BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override)**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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EPCORITAMAB-BYSP BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory diffuse large B-cell lymphoma (DLBCL) (ICD-10 Group C83.3), including DLBCL arising from indolent lymphoma, or high-grade B-cell lymphoma, and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient previously received at least two lines of systemic therapy (e.g., R-CHOP [rituximab, cyclophosphamide, doxorubicin, vincristine and prednisone], GemOx [gemcitabine, oxaliplatin])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of relapsed or refractory follicular lymphoma (FL) (ICD-10 Group C82) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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EPCORITAMAB-BYSP BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient meet **ONE** of the following criteria?
   - Epkinly will be used in combination with lenalidomide (Revlimid) and rituximab
   - Epkinly will be used as monotherapy after receiving at least two lines of systemic therapy (e.g., Gazyva [obinutuzumab], bendamustine, rituximab, Revlimid [lenalidomide])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EPCORITAMAB-BYSP (Epkinly)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Relapsed or refractory diffuse large B-cell lymphoma (DLBCL: a type of blood cancer that has returned or is not responding to treatment), including DLBCL arising from indolent (slow growing) lymphoma (a type of blood cancer), or high-grade B-cell lymphoma (a type of blood cancer)
      2. Relapsed or refractory follicular lymphoma (FL: a type of blood cancer that has returned or is not responding to treatment)

   B. If you have diffuse large B-cell lymphoma or high-grade B-cell lymphoma, approval also requires:
      1. You are 18 years of age or older
      2. You previously received at least two lines of systemic therapy (treatment that travels throughout the body) (such as R-CHOP [rituximab, cyclophosphamide, doxorubicin, vincristine and prednisone], GemOx [gemcitabine, oxaliplatin])

   C. If you have follicular lymphoma, approval also requires:
      1. You are 18 years of age or older
      2. You meet ONE of the following:
         a. Epkinly will be used in combination with lenalidomide (Revlimid) and rituximab
         b. Epkinly will be used as monotherapy (one medication treatment) after receiving at least two lines of systemic therapy (treatment that travels throughout the body) (such as Gazyva [obinutuzumab], bendamustine, rituximab, Revlimid [lenalidomide])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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EPCORITAMAB-BYSP BvD (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Epkinly. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Epkinly [Prescribing Information]. Plainsboro, NJ: Genmab US, Inc.; November 2025.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed July 2, 2024].

For Part D use only:

EPCORITAMAB-BYSP (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EPLONTERSEN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EPLONTERSEN SODIUM	WAINUA		55135	GPI-14 (6270102510D520)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hereditary transthyretin-mediated amyloidosis with polyneuropathy (hATTR-PN) (ICD-10 E85.1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist, cardiologist, physician at an amyloidosis treatment center, or medical geneticist
   - The patient is ambulatory (i.e., Familial Amyloid Polyneuropathy [FAP] stage 1 - 2 or Polyneuropathy Disability [PND] Stage I - IIIb polyneuropathy)
   - Wainua will NOT be used concurrently with other hATTR-PN agents (e.g. Tegsedi [inotersen], Amvuttra [vutrisiran], Onpattro [patisiran])

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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EPLONTERSEN (PART D)

INITIAL CRITERIA (CONTINUED)

2. Is the hATTR diagnosis confirmed by **ONE** of the following?
   - Biopsy of tissue/organ to confirm amyloid presence AND chemical typing to confirm the presence of TTR (transthyretin) protein
   - DNA genetic sequencing to confirm hATTR mutation

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EPLONTERSEN (Wainua)** requires the following rule(s) be met for approval:
   A. You have hereditary transthyretin-mediated amyloidosis with polyneuropathy (hATTR-PN: a rare genetic disorder with widespread nerve damage/pain)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nerve doctor), cardiologist (a type of heart doctor), physician at an amyloidosis treatment center, or medical geneticist (doctor who treats gene disorders)
   D. You are ambulatory (able to walk) (you have Familial Amyloid Polyneuropathy [FAP: a tool used to evaluate disease severity] stage 1 to 2 or Polyneuropathy Disability [PND: a tool used to evaluate disease severity] Stage I to IIIb polyneuropathy)
   E. You will NOT use Wainua concurrently (at the same time) with other hATTR-PN medications (such as Tegsedi [inotersen], Amvuttra [vutrisiran], Onpattro [patisiran])
   F. Your diagnosis is confirmed by ONE of the following:
      1. Biopsy (removal of cells from the body for examination) of tissue/organ to confirm amyloid (a type of abnormal protein) presence AND chemical typing to confirm the presence of TTR (transthyretin) protein
      2. DNA genetic sequencing (a type of lab test) to confirm hATTR mutation (a type of abnormal gene)

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EPLONTERSEN (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary transthyretin-mediated amyloidosis with polyneuropathy (hATTR-PN) (ICD-10 E85.1) and meet **ALL** of the following criteria?
   - The patient has not progressed to Familial Amyloid Polyneuropathy (FAP) stage 3 or Polyneuropathy Disability (PND) Stage 4 polyneuropathy as evidenced by functional decline (e.g., wheelchair-bound, bedridden)
   - Wainua will NOT be used concurrently with other hATTR-PN agents (e.g. Tegsedi [inotersen], Amvuttra [vutrisiran], Onpattro [patisiran])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EPLONTERSEN (Wainua)** requires the following rule(s) be met for renewal:
   A. You have hereditary transthyretin-mediated amyloidosis with polyneuropathy (hATTR-PN: a rare genetic disorder with widespread nerve pain/damage)
   B. You have not progressed to Familial Amyloid Polyneuropathy (FAP: a tool used to evaluate disease severity) stage 3 or Polyneuropathy Disability (PND: a tool used to evaluate disease severity) stage 4 polyneuropathy as shown by functional decline (such as being wheelchair-bound or bedridden)
   C. You will NOT use Wainua concurrently (at the same time) with other hATTR-PN medications (such as Tegsedi [inotersen], Amvuttra [vutrisiran], Onpattro [patisiran])

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Wainua.

REFERENCES
Wainua [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; December 2023.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EPLONTERSEN (PART D)

For Part D use only:

EPLONTERSEN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	HEREDITARY TRANSTHYRETIN-MEDIATED AMYLOIDOSIS WITH POLYNEUROPATHY (HATTR-PN): INITIAL: DIAGNOSIS CONFIRMED BY: 1) BIOPSY OF TISSUE/ORGAN TO CONFIRM AMYLOID PRESENCE AND CHEMICAL TYPING TO CONFIRM PRESENCE OF TTR PROTEIN, OR 2) DNA GENETIC SEQUENCING TO CONFIRM HATTR MUTATION.
Age Restrictions	N/A
Prescriber Restrictions	HATTR-PN: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST, CARDIOLOGIST, PHYSICIAN AT AN AMYLOIDOSIS TREATMENT CENTER, OR MEDICAL GENETICIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	HATTR-PN: INITIAL: 1) FAMILIAL AMYLOID POLYNEUROPATHY (FAP) STAGE 1 OR 2, OR UP TO POLYNEUROPATHY DISABILITY (PND) STAGE IIIB POLYNEUROPATHY, AND 2) NO CONCURRENT USE WITH OTHER HATTR-PN AGENTS. RENEWAL: 1) NOT PROGRESSED TO FAP STAGE 3 OR PND STAGE 4 POLYNEUROPATHY AS EVIDENCED BY FUNCTIONAL DECLINE, AND 2) NO CONCURRENT USE WITH OTHER HATTR-PN AGENTS.

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PLUS CLOSED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EPLONTERSEN SYRINGE BVD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EPLONTERSEN SODIUM	WAINUA		59052	GPI-14 (6270102510E520)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	Yes	No	No	Yes	No	Yes	Yes	No	No	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #5.

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EPLONTERSEN SYRINGE BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override)**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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PLUS CLOSED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EPLONTERSEN SYRINGE BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hereditary transthyretin-mediated amyloidosis with polyneuropathy (hATTR-PN) (ICD-10 E85.1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist, cardiologist, physician at an amyloidosis treatment center, or medical geneticist
   - The patient is ambulatory (i.e., Familial Amyloid Polyneuropathy [FAP] stage 1 - 2 or Polyneuropathy Disability [PND] Stage I - IIIb polyneuropathy)
   - Wainua will NOT be used concurrently with other hATTR-PN agents (e.g. Tegsedi [inotersen], Amvuttra [vutrisiran], Onpattro [patisiran])

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the hATTR diagnosis confirmed by **ONE** of the following?
   - Biopsy of tissue/organ to confirm amyloid presence AND chemical typing to confirm the presence of TTR (transthyretin) protein
   - DNA genetic sequencing to confirm hATTR mutation

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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EPLONTERSEN SYRINGE BvD (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **EPLONTERSEN SYRINGE (Wainua)** requires the following rule(s) be met for approval:

A. You have hereditary transthyretin-mediated amyloidosis with polyneuropathy (hATTR-PN: a rare genetic disorder with widespread nerve damage/pain)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nerve doctor), cardiologist (a type of heart doctor), physician at an amyloidosis treatment center, or medical geneticist (doctor who treats gene disorders)
D. You are ambulatory (able to walk) (you have Familial Amyloid Polyneuropathy [FAP: a tool used to evaluate disease severity] stage 1 to 2 or Polyneuropathy Disability [PND: a tool used to evaluate disease severity] Stage I to IIIb polyneuropathy)
E. You will NOT use Wainua concurrently (at the same time) with other hATTR-PN medications (such as Tegsedi [inotersen], Amvuttra [vutrisiran], Onpattro [patisiran])
F. Your diagnosis is confirmed by ONE of the following:
    1. Biopsy (removal of cells from the body for examination) of tissue/organ to confirm amyloid (a type of abnormal protein) presence AND chemical typing to confirm the presence of TTR (transthyretin) protein
    2. DNA genetic sequencing (a type of lab test) to confirm hATTR mutation (a type of abnormal gene)

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EPLONTERSEN SYRINGE BvD (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary transthyretin-mediated amyloidosis with polyneuropathy (hATTR-PN) (ICD-10 E85.1) and meet **ALL** of the following criteria?
   - The patient has not progressed to Familial Amyloid Polyneuropathy (FAP) stage 3 or Polyneuropathy Disability (PND) Stage 4 polyneuropathy as evidenced by functional decline (e.g., wheelchair-bound, bedridden)
   - Wainua will NOT be used concurrently with other hATTR-PN agents (e.g. Tegsedi [inotersen], Amvuttra [vutrisiran], Onpattro [patisiran])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EPLONTERSEN SYRINGE (Wainua)** requires the following rule(s) be met for renewal:
   A. You have hereditary transthyretin-mediated amyloidosis with polyneuropathy (hATTR-PN: a rare genetic disorder with widespread nerve pain/damage)
   B. You have not progressed to Familial Amyloid Polyneuropathy (FAP: a tool used to evaluate disease severity) stage 3 or Polyneuropathy Disability (PND: a tool used to evaluate disease severity) stage 4 polyneuropathy as shown by functional decline (such as being wheelchair-bound or bedridden)
   C. You will NOT use Wainua concurrently (at the same time) with other hATTR-PN medications (such as Tegsedi [inotersen], Amvuttra [vutrisiran], Onpattro [patisiran])

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Wainua. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Wainua [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; December 2023.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug/Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed May 12, 2026].

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PLUS CLOSED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EPLONTERSEN SYRINGE BvD (PART D)

For Part D use only:

EPLONTERSEN SYRINGE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	HEREDITARY TRANSTHYRETIN-MEDIATED AMYLOIDOSIS WITH POLYNEUROPATHY (HATTR-PN): INITIAL: DIAGNOSIS CONFIRMED BY: 1) BIOPSY OF TISSUE/ORGAN TO CONFIRM AMYLOID PRESENCE AND CHEMICAL TYPING TO CONFIRM PRESENCE OF TTR PROTEIN, OR 2) DNA GENETIC SEQUENCING TO CONFIRM HATTR MUTATION.
Age Restrictions	N/A
Prescriber Restrictions	HATTR-PN: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST, CARDIOLOGIST, PHYSICIAN AT AN AMYLOIDOSIS TREATMENT CENTER, OR MEDICAL GENETICIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	HATTR-PN: INITIAL: 1) FAMILIAL AMYLOID POLYNEUROPATHY (FAP) STAGE 1 OR 2, OR UP TO POLYNEUROPATHY DISABILITY (PND) STAGE IIIB POLYNEUROPATHY, AND 2) NO CONCURRENT USE WITH OTHER HATTR-PN AGENTS. RENEWAL: 1) NOT PROGRESSED TO FAP STAGE 3 OR PND STAGE 4 POLYNEUROPATHY AS EVIDENCED BY FUNCTIONAL DECLINE, AND 2) NO CONCURRENT USE WITH OTHER HATTR-PN AGENTS.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EPOETIN ALFA (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EPOETIN ALFA	EPOGEN, PROCRIT	04553		GPI-10 (8240102000)	

PAYMENT DETERMINATION CRITERIA

1. Does the patient have a diagnosis of end stage renal disease (ESRD) and is on dialysis (ICD-10 N18.6)?

   If yes, **do NOT approve under Part D. Finalize as follows:**

   PAC NOTE: Please defer to a pharmacist for denial.

   CLINICAL SPECIALIST NOTE: This medication is included in the bundled dialysis facility payment which is paid under Medicare Part B and is not a Part D eligible drug. Please follow your internal procedures for denial.

   If no, review the clinical criteria for Part D coverage below if applicable. (**NOTE:** If the ESRD_Dialysis attribute is present, select the 'ESRD' Override Type within the PA, which is available in the 'Additional Overrides' section.)

   Guideline interpretation beyond this point requires Clinical/Technician review.

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EPOETIN ALFA (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of anemia due to chronic kidney disease (CKD) (ICD-10 D63.1) and meet **ALL** of the following criteria?
   - The patient had a trial of or contraindication to the preferred agent: Retacrit (epoetin alfa-epbx)
   - The patient's hemoglobin level is less than 10 g/dL

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of anemia related to zidovudine (Retrovir) therapy and meet **ALL** of the following criteria?
   - The patient had a trial of or contraindication to the preferred agent: Retacrit (epoetin alfa-epbx)
   - The patient's hemoglobin level is less than 10 g/dL

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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EPOETIN ALFA (PART D)

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of anemia due to the effects of concomitantly administered cancer chemotherapy (ICD-10 D64.81) and meet **ALL** of the following criteria?
   - The patient had a trial of or contraindication to the preferred agent: Retacrit (epoetin alfa-epbx)
   - The patient's hemoglobin level is less than 10 g/dL

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

4. Is the patient undergoing elective, noncardiac, nonvascular surgery and meet **ALL** of the following criteria?
   - The patient had a trial of or contraindication to the preferred agent: Retacrit (epoetin alfa-epbx)
   - The patient's hemoglobin level is less than 13 g/dL

   If yes, **approve for 1 month by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EPOETIN ALFA (Procrit, Epogen)** requires the following rule(s) be met for approval:
   A. The request is for ONE of the following:
      1. Anemia (low amount of healthy red blood cells) due to chronic kidney disease (CKD)
      2. Anemia related to zidovudine (Retrovir) therapy (type of drug to treat human immunodeficiency virus)
      3. Anemia due to the effects of concomitantly administered (given at the same time) cancer chemotherapy
      4. You are undergoing elective, noncardiac, nonvascular surgery (surgery not relating to the heart of blood vessels)

   B. If you have anemia due to chronic kidney disease, approval also requires:
      1. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Retacrit (epoetin alfa-epbx)
      2. Your hemoglobin level (type of blood test) is less than 10 g/dL

   (Initial denial text continued on next page)

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EPOETIN ALFA (PART D)

INITIAL CRITERIA (CONTINUED)

C. If you have anemia related to zidovudine (Retrovir) therapy, approval also requires:
1. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Retacrit (epoetin alfa-epbx)
2. Your hemoglobin level (type of blood test) is less than 10 g/dL

D. If you have anemia due to the effects of concomitantly administered cancer chemotherapy, approval also requires:
1. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Retacrit (epoetin alfa-epbx)
2. Your hemoglobin level (type of blood test) is less than 10 g/dL

E. If you are undergoing elective, noncardiac, nonvascular surgery, approval also requires:
1. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Retacrit (epoetin alfa-epbx)
2. Your hemoglobin level (type of blood test) is less than 13 g/dL

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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EPOETIN ALFA (PART D)

RENEWAL CRITERIA

NOTE: For the indication of elective, noncardiac, nonvascular surgery, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of anemia due to chronic kidney disease (CKD) (ICD-10 D63.1) **AND** meet the following criterion?
   - The patient is NOT receiving dialysis treatment
     [Note: If the patient is currently receiving dialysis treatment, the requested medication is included in the bundle dialysis facility payment which is paid under Medicare Part B]. Please refer to CRITERIA FOR PART B vs PART D DETERMINATION above.

     If yes, continue to #2.
     If no, continue to #4.

2. Is the patient an adult (18 years of age or older) and meets **ONE** of the following criteria?
   - The patient's hemoglobin level is less than 10 g/dL
   - The patient's hemoglobin level has reached 10 g/dL and the dose is being or has been reduced/interrupted to decrease the need for blood transfusions

     If yes, **approve for 12 months by HICL or GPI-10.**
     APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

     If no, continue to #3.

3. Is the request for a pediatric (less than 18 years of age) patient and meets **ONE** of the following criteria?
   - The patient's hemoglobin level is less than 10 g/dL
   - The patient's hemoglobin level has approached or exceeds 12 g/dL and the dose is being or has been reduced/interrupted to decrease the need for blood transfusions

     If yes, **approve for 12 months by HICL or GPI-10.**
     APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.
     If no, do not approve.
     DENIAL TEXT: See the renewal denial text at the end of the guideline.

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EPOETIN ALFA (PART D)

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of anemia related to zidovudine (Retrovir) therapy **AND** meet the following criterion?
   - The patient's hemoglobin level is between 10g/dL and 12g/dL

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Does the patient have a diagnosis of anemia due to the effects of concomitantly administered cancer chemotherapy (ICD-10 D64.81) and meet **ONE** of the following criteria?
   - The patient's hemoglobin level is less than 10 g/dL
   - The patient's hemoglobin level does not exceed a level needed to avoid red blood cell (RBC) transfusion

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EPOETIN ALFA (Procrit, Epogen)** requires the following rules be met for renewal:
   A. The request is for ONE of the following:
      1. Anemia (low amount of healthy red blood cells) due to chronic kidney disease (CKD)
      2. Anemia related to zidovudine (Retrovir) therapy (type of drug to treat human immunodeficiency virus)
      3. Anemia due to the effects of concomitantly administered (given at the same time) cancer chemotherapy

   (Renewal denial text continued on next page)

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EPOETIN ALFA (PART D)

RENEWAL CRITERIA (CONTINUED)

B. If you are an adult with anemia due to chronic kidney disease, renewal also requires:
1. You are NOT receiving dialysis treatment (process of removing excess water, toxins from the blood)
2. Your hemoglobin level (type of blood test) is less than 10 g/dL OR has reached 10 g/dL and your dose is being or has been reduced/interrupted to decrease the need for blood transfusions

C. If you are a pediatric patient with anemia due to chronic kidney disease, renewal also requires:
1. You are NOT receiving dialysis treatment (process of removing excess water, toxins from the blood)
2. Your hemoglobin level (a type of blood test) is less than 10 g/dL OR has approached or exceeds 12 g/dL and your dose is being or has been reduced/interrupted to decrease the need for blood transfusions

D. If you have anemia related to zidovudine (Retrovir) therapy, renewal also requires:
1. Your hemoglobin level (type of blood test) is between 10 g/dL and 12 g/dL

E. If you have anemia due to the effects of concomitantly administered cancer chemotherapy, renewal also requires ONE of the following:
1. Your hemoglobin level (type of blood test) is less than 10 g/dL
2. Your hemoglobin level does not exceed a level needed to avoid red blood cell (RBC) transfusion

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Patients identified as Part D End Stage Renal Disease (ESRD) undergoing dialysis will be directed to a dialysis treatment center and have their ESRD treatment related drug included in the bundled dialysis facility payment which is paid under Medicare Part B.

For further information, please refer to the Prescribing Information and/or Drug Monograph for Procrit or Epogen.

REFERENCES

Procrit [Prescribing Information]. Thousand Oaks, CA: Amgen; February 2019.
Epogen [Prescribing Information]. Thousand Oaks, CA: Amgen; July 2018.

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EPOETIN ALFA (PART D)

For Part D use only:

EPOETIN ALFA (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	INITIAL: CHRONIC KIDNEY DISEASE (CKD), ANEMIA RELATED TO ZIDOVUDINE OR CANCER CHEMOTHERAPY: HEMOGLOBIN LEVEL IS LESS THAN 10G/DL. ELECTIVE, NON-CARDIAC, NON-VASCULAR SURGERY: HEMOGLOBIN LEVEL IS LESS THAN 13G/DL. RENEWAL: 1) CKD IN ADULTS NOT ON DIALYSIS: (A) HEMOGLOBIN LEVEL IS LESS THAN 10G/DL, OR (B) HEMOGLOBIN LEVEL HAS REACHED 10G/DL AND THE DOSE IS BEING OR HAS BEEN REDUCED/INTERRUPTED TO DECREASE THE NEED FOR BLOOD TRANSFUSIONS. 2) CKD IN PEDIATRIC PATIENTS: (A) HEMOGLOBIN LEVEL IS LESS THAN 10G/DL, OR (B) HEMOGLOBIN LEVEL HAS APPROACHED OR EXCEEDS 12G/DL AND THE DOSE IS BEING OR HAS BEEN REDUCED/INTERRUPTED TO DECREASE THE NEED FOR BLOOD TRANSFUSIONS. 3) ANEMIA RELATED TO ZIDOVUDINE: HEMOGLOBIN LEVEL BETWEEN 10G/DL AND 12G/DL. 4) CANCER CHEMOTHERAPY: (A) HEMOGLOBIN LEVEL IS LESS THAN 10 G/DL, OR (B) HEMOGLOBIN LEVEL DOES NOT EXCEED A LEVEL NEEDED TO AVOID RBC TRANSFUSION.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	ANEMIA FROM CHEMO/CKD WITHOUT DIALYSIS/ZIDOVUDINE: INITIAL/RENEWAL: 12 MONTHS. SURGERY: 1 MONTH.
Other Criteria	INITIAL: CKD, ANEMIA RELATED TO ZIDOVUDINE OR CANCER CHEMOTHERAPY, OR ELECTIVE, NON-CARDIAC, NON-VASCULAR SURGERY: TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT RETACRIT. RENEWAL: CKD: NOT RECEIVING DIALYSIS TREATMENT. THIS DRUG MAY BE EITHER BUNDLED WITH AND COVERED UNDER END STAGE RENAL DISEASE DIALYSIS RELATED SERVICES OR COVERED UNDER MEDICARE D DEPENDING UPON THE CIRCUMSTANCES.

Created: 11/19
Effective: 05/12/25 Client Approval: 04/25 P&T Approval: 10/23

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EPOETIN ALFA-EPBX (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EPOETIN ALFA-EPBX	RETACRIT	44931		GPI-10 (8240102004)	

PAYMENT DETERMINATION CRITERIA

1. Does the patient have a diagnosis of end stage renal disease (ESRD) and is on dialysis (ICD-10 N18.6)?

   If yes, **do NOT approve under Part D. Finalize as follows:**

   PAC NOTE: Please defer to a pharmacist for denial.

   CLINICAL SPECIALIST NOTE: This medication is included in the bundled dialysis facility payment which is paid under Medicare Part B and is not a Part D eligible drug. Please follow your internal procedures for denial.

   If no, review the clinical criteria for Part D coverage below if applicable. (**NOTE:** If the ESRD_Dialysis attribute is present, select the 'ESRD' Override Type within the PA, which is available in the 'Additional Overrides' section.)

   Guideline interpretation beyond this point requires Clinical/Technician review.

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EPOETIN ALFA-EPBX (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of anemia due to chronic kidney disease (CKD) (ICD-10 D63.1) **AND** meet the following criterion?
   - The patient's hemoglobin level is less than 10g/dL

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of anemia related to zidovudine (Retrovir) therapy **AND** meet the following criterion?
   - The patient's hemoglobin level is less than 10g/dL

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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EPOETIN ALFA-EPBX (PART D)

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of anemia due to the effects of concomitantly administered cancer chemotherapy (ICD-10 D64.81) **AND** meet the following criterion?
   - The patient's hemoglobin level is less than 10g/dL

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

4. Is the patient undergoing elective, noncardiac, nonvascular surgery **AND** meet the following criterion?
   - The patient's hemoglobin level is 13g/dL or less

   If yes, **approve for 1 month by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EPOETIN ALFA-EPBX (Retacrit)** requires the following rule(s) be met for approval:

   A. The request is for ONE of the following:
      1. Anemia (low amount of healthy red blood cells) due to chronic kidney disease (CKD)
      2. Anemia related to zidovudine (Retrovir) therapy (type of drug to treat human immunodeficiency virus)
      3. Anemia due to the effects of concomitantly administered (given at the same time) cancer chemotherapy
      4. You are undergoing elective, noncardiac, nonvascular surgery (surgery not relating to the heart or blood vessels)

   B. If you have anemia due to chronic kidney disease, approval also requires:
      1. Your hemoglobin level (type of blood test) is less than 10g/dL

   C. If you have anemia related to zidovudine (Retrovir) therapy, approval also requires:
      1. Your hemoglobin level (type of blood test) is less than 10g/dL

   (Initial denial text continued on next page)

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EPOETIN ALFA-EPBX (PART D)

INITIAL CRITERIA (CONTINUED)

D. If you have anemia due to the effects of concomitantly administered cancer chemotherapy, approval also requires:
1. Your hemoglobin level (type of blood test) is less than 10g/dL

E. If you are undergoing elective, noncardiac, nonvascular surgery, approval also requires:
1. Your hemoglobin level (type of blood test) is 13g/dL or less

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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EPOETIN ALFA-EPBX (PART D)

RENEWAL CRITERIA

NOTE: For the indication of elective, noncardiac, nonvascular surgery, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of anemia due to chronic kidney disease (CKD) (ICD-10 D63.1) **AND** meet the following criterion?
   - The patient is NOT receiving dialysis treatment:
     [Note: If the patient is currently receiving dialysis treatment, the requested medication is included in the bundle dialysis facility payment which is paid under Medicare Part B]. Please refer to CRITERIA FOR PART B vs PART D DETERMINATION above.

     If yes, continue to #2.
     If no, continue to #4.

2. Is the patient an adult (18 years of age or older) and meets **ONE** of the following criteria?
   - The patient's hemoglobin level is less than 10g/dL
   - The patient's hemoglobin level has reached 10g/dL and the dose is being or has been reduced/interrupted to decrease the need for blood transfusions

     If yes, **approve for 12 months by HICL or GPI-10.**
     APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

     If no, continue to #3.

3. Is the request for a pediatric (less than 18 years of age) patient and meets **ONE** of the following criteria?
   - The patient's hemoglobin level is less than 10g/dL
   - The patient's hemoglobin level has approached or exceeds 12g/dL and the dose is being or has been reduced/interrupted to decrease the need for blood transfusions

     If yes, **approve for 12 months by HICL or GPI-10.**
     APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

     If no, do not approve.
     DENIAL TEXT: See the renewal denial text at the end of the guideline.

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EPOETIN ALFA-EPBX (PART D)

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of anemia related to zidovudine (Retrovir) therapy **AND** meet the following criterion?
   - The patient's hemoglobin level is between 10g/dL and 12g/dL

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Does the patient have a diagnosis of anemia due to the effects of concomitantly administered cancer chemotherapy (ICD-10 D64.81) and meet **ONE** of the following criteria?
   - The patient's hemoglobin level is less than 10g/dL
   - The patient's hemoglobin level does not exceed a level needed to avoid red blood cell (RBC) transfusion

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EPOETIN ALFA-EPBX (Retacrit)** requires that the following rule(s) be met for renewal:

   A. The request is for ONE of the following:
      1. Anemia (low amount of healthy red blood cells) due to chronic kidney disease (CKD)
      2. Anemia related to zidovudine (Retrovir) therapy (type of drug to treat human immunodeficiency virus)
      3. Anemia due to the effects of concomitantly administered (given at the same time) cancer chemotherapy

   B. If you are an adult with anemia due to chronic kidney disease, renewal also requires:
      1. You are NOT receiving dialysis treatment (process of removing excess water, toxins from the blood)
      2. Your hemoglobin level (type of blood test) is less than 10g/dL OR has reached 10g/dL and your dose is being or has been reduced/interrupted to decrease the need for blood transfusions

   (Renewal denial text continued on next page)

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EPOETIN ALFA-EPBX (PART D)

RENEWAL CRITERIA (CONTINUED)

C. If you are a pediatric patient with anemia due to chronic kidney disease, renewal also requires:
1. You are NOT receiving dialysis treatment (process of removing excess water, toxins from the blood)
2. Your hemoglobin level (a type of blood test) is less than 10g/dL OR has approached or exceeds 12g/dL and your dose is being or has been reduced/interrupted to decrease the need for blood transfusions

D. If you have anemia related to zidovudine (Retrovir) therapy, renewal also requires:
1. Your hemoglobin level (type of blood test) is between 10g/dL and 12g/dL

E. If you have anemia due to the effects of concomitantly administered cancer chemotherapy, renewal also requires ONE of the following:
1. Your hemoglobin level (type of blood test) is less than 10g/dL
2. Your hemoglobin level does not exceed a level needed to avoid red blood cell (RBC) transfusion

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Patients identified as Part D End Stage Renal Disease (ESRD) undergoing dialysis will be directed to a dialysis treatment center and have their ESRD treatment related drug included in the bundled dialysis facility payment which is paid under Medicare Part B.

For further information, please refer to the Prescribing Information and/or Drug Monograph for Retacrit.

REFERENCES

Retacrit [Prescribing Information]. New York, NY: Pfizer Inc.; June 2024.

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EPOETIN ALFA-EPBX (PART D)

For Part D use only:

EPOETIN ALFA-EPBX (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	INITIAL: CHRONIC KIDNEY DISEASE (CKD), ANEMIA RELATED TO ZIDOVUDINE, OR CANCER CHEMOTHERAPY: HEMOGLOBIN LEVEL IS LESS THAN 10G/DL. ELECTIVE, NON-CARDIAC, NON-VASCULAR SURGERY: HEMOGLOBIN LEVEL IS 13G/DL OR LESS. RENEWAL: 1) CKD IN ADULTS NOT ON DIALYSIS: (A) HEMOGLOBIN LEVEL IS LESS THAN 10G/DL, OR (B) HEMOGLOBIN LEVEL HAS REACHED 10G/DL AND THE DOSE IS BEING OR HAS BEEN REDUCED/INTERRUPTED TO DECREASE THE NEED FOR BLOOD TRANSFUSIONS. 2) CKD IN PEDIATRIC PATIENTS: (A) HEMOGLOBIN LEVEL IS LESS THAN 10G/DL, OR (B) HEMOGLOBIN LEVEL HAS APPROACHED OR EXCEEDS 12G/DL AND THE DOSE IS BEING OR HAS BEEN REDUCED/INTERRUPTED TO DECREASE THE NEED FOR BLOOD TRANSFUSIONS. 3) ANEMIA RELATED TO ZIDOVUDINE: HEMOGLOBIN LEVEL BETWEEN 10G/DL AND 12G/DL. 4) CANCER CHEMOTHERAPY: (A) HEMOGLOBIN LEVEL IS LESS THAN 10 G/DL, OR (B) HEMOGLOBIN LEVEL DOES NOT EXCEED A LEVEL NEEDED TO AVOID RBC TRANSFUSION.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	ANEMIA FROM CHEMO/CKD WITHOUT DIALYSIS/ZIDOVUDINE: INITIAL/RENEWAL: 12 MONTHS. SURGERY: 1 MONTH.
Other Criteria	RENEWAL: CKD: NOT RECEIVING DIALYSIS TREATMENT. THIS DRUG MAY BE EITHER BUNDLED WITH AND COVERED UNDER END STAGE RENAL DISEASE DIALYSIS RELATED SERVICES OR COVERED UNDER MEDICARE D DEPENDING UPON THE CIRCUMSTANCES.

Created: 08/18
Effective: 01/01/26 Client Approval: 12/25 P&T Approval: 10/23

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EPOPROSTENOL IV BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EPOPROSTENOL SODIUM	VELETRI, EPOPROSTENOL SODIUM	37762		GPI-10 (4017004010)	
EPOPROSTENOL SODIUM (GLYCINE)	FLOLAN	07323			

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, continue to #6.
   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, continue to #6.
   If no, continue to #5.

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EPOPROSTENOL IV BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enterany override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL for Flolan and Veletri or by GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

6. Is the drug administered via an implantable pump?

   If yes, **approve for 12 months by HICL for Flolan and Veletri or by GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, continue to #7.

7. Is the drug administered using an external pump?

   If yes, continue to #8.
   If no, **approve for 12 months by HICL for Flolan and Veletri or by GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

8. Is the drug specifically infused through an external infusion pump covered by Medicare?

   If yes, **approve for 12 months by HICL for Flolan and Veletri or by GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, **approve for 12 months by HICL for Flolan and Veletri or by GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EPOPROSTENOL IV BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of 15 mmHg or less
   - Pulmonary vascular resistance (PVR) greater than 2 Wood units

   If yes, **approve for 12 months by HICL for Flolan and Veletri or by GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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EPOPROSTENOL IV BvD (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **EPOPROSTENOL IV (Veletri, Flolan)** requires the following rule(s) be met for approval:

A. You have pulmonary arterial hypertension (PAH: a type of lung and heart condition) (World Health Organization Group 1: a way to classify the severity of disease)
B. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
C. Your pulmonary arterial hypertension diagnosis is confirmed by right heart catheterization (a test used to measure how well the heart is pumping) with ALL of the following lab values:
    1. Mean pulmonary artery pressure (PAP: a type of measurement for pulmonary arterial hypertension) greater than 20 mmHg
    2. Pulmonary capillary wedge pressure (PCWP: a type of measurement for pulmonary arterial hypertension) of 15 mmHg or less
    3. Pulmonary vascular resistance (PVR: a type of measurement for pulmonary arterial hypertension) greater than 2 Wood units

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EPOPROSTENOL IV BvD (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2)?

   If yes**, approve for 12 months by HICL for Flolan and Veletri or by GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EPOPROSTENOL IV (Veletri, Flolan)** requires the following rule(s) be met for renewal:
   A. You have pulmonary arterial hypertension (PAH: a type of lung and heart condition) (World Health Organization Group 1: a way to classify the severity of disease)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monographs for Flolan and Veletri.

The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B. Drugs administered by an implantable pump are covered under Part B. Drugs administered via an external pump are covered under Part B if they are included under the local coverage policy of the applicable Medicare coverage policies (National and/or Local Coverage Policies). Drugs administered via an external pump that are not included under the applicable Medicare coverage policies are covered under Part D. A CMS website to assist with National and Local Coverage Determination for BvD review is http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx

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EPOPROSTENOL IV BvD (PART D)

REFERENCES

Flolan [Prescribing Information]. Research Triangle Park, NC: GlaxoSmithKline; August 2021.
Veletri [Prescribing Information]. Titusville, NJ: Actelion Pharmaceuticals US, Inc.; July 2022.
Medicare Prescription Drug Benefit Manual Chapter 6 – Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed July 3, 2024].

For Part D use only:

EPOPROSTENOL IV (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	PULMONARY ARTERIAL HYPERTENSION (PAH): INITIAL: DIAGNOSIS CONFIRMED BY RIGHT HEART CATHETERIZATION WITH THE FOLLOWING PARAMETERS: 1) MEAN PULMONARY ARTERY PRESSURE (PAP) GREATER THAN 20 MMHG, 2) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF 15 MMHG OR LESS, AND 3) PULMONARY VASCULAR RESISTANCE (PVR) GREATER THAN 2 WOOD UNITS.
Age Restrictions	N/A
Prescriber Restrictions	PAH: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST.
Coverage Duration	INITIAL AND RENEWAL: 12 MONTHS
Other Criteria	N/A

Created: 11/16
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 01/24

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EPTINEZUMAB-JJMR (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EPTINEZUMAB-JJMR	VYEPTI	46372		GPI-10 (6770201520)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for the preventive treatment of migraines (ICD-10 Group G43) and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Vyepti will NOT be used concurrently with other CGRP inhibitors (e.g., Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm]) for migraine prevention
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Emgality (galcanezumab-gnlm), Ajovy (fremanezumab-vfrm), Nurtec ODT (rimegepant), Qulipta (atogepant)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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EPTINEZUMAB-JJMR (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **EPTINEZUMAB-JJMR (Vyepti)** requires the following rule(s) be met for approval:

A. The request is for the preventative treatment of migraines (a type of headache)
B. You are 18 years of age or older
C. You will NOT use Vyepti concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm]) for migraine prevention
D. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Emgality (galcanezumab-gnlm), Ajovy (fremanezumab-vfrm), Nurtec ODT (rimegepant), Qulipta (atogepant)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EPTINEZUMAB-JJMR (PART D)

RENEWAL CRITERIA

1. Is the request for the preventive treatment of migraines (ICD-10 Group G43) **AND** the patient meets the following criterion?
   - Vyepti will NOT be used concurrently with other CGRP inhibitors (e.g., Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm]) for migraine prevention

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has experienced a reduction in migraine or headache frequency with therapy
   - The patient has experienced a reduction in migraine severity with therapy
   - The patient has experienced a reduction in migraine duration with therapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EPTINEZUMAB-JJMR (Vyepti)** requires the following rule(s) be met for renewal:
   A. The request is for the preventive treatment of migraines (a type of headache)
   B. You will NOT use Vyepti concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm]) for migraine prevention
   C. You meet ONE of the following:
      1. You have experienced a reduction in migraine or headache frequency with therapy
      2. You have experienced a reduction in migraine severity with therapy
      3. You have experienced a reduction in migraine duration with therapy

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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EPTINEZUMAB-JJMR (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vyepti.

REFERENCE

Vyepti [Prescribing Information]. Bothell, WA: Lundbeck Seattle BioPharmaceuticals, Inc.; March 2025.

For Part D use only:

EPTINEZUMAB-JJMR (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS.
Other Criteria	MIGRAINE PREVENTION: INITIAL: TRIAL OF OR CONTRAINDICATION TO ONE OF THE FOLLOWING PREFERRED AGENTS: EMGALITY, AJOVY, NURTEC ODT, QULIPTA. INITIAL/RENEWAL: NO CONCURRENT USE WITH OTHER CGRP INHIBITORS FOR MIGRAINE PREVENTION. RENEWAL: REDUCTION IN MIGRAINE OR HEADACHE FREQUENCY, MIGRAINE SEVERITY, OR MIGRAINE DURATION WITH THERAPY.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ERDAFITINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ERDAFITINIB	BALVERSA	45687		GPI-10 (2153222500)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced or metastatic urothelial carcinoma (ICD-10 Groups C65, C66, C67, C68) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a susceptible FGFR3 genetic alteration, as detected by an FDA-approved companion diagnostic test
   - The patient has disease progression on or after at least one line of prior systemic therapy (e.g., cisplatin, Keytruda [pembrolizumab])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ERDAFITINIB (Balversa)** requires the following rule(s) be met for approval:
   A. You have locally advanced or metastatic urothelial carcinoma (a type of bladder cancer that has spread to nearby tissue or other parts of the body)
   B. You are 18 years of age or older
   C. You have a susceptible (can be treated with the drug) fibroblast growth factor receptor 3 (FGFR3: a type of protein) genetic alteration (mutation), as detected by a Food and Drug Administration (FDA)-approved companion diagnostic test
   D. You have disease progression (condition has worsened) on or after at least one line of prior systemic therapy (treatment that targets the entire body, such as cisplatin, Keytruda [pembrolizumab])

   (Denial text continued on next page)

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ERDAFITINIB (PART D)

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Balversa.

REFERENCES

Balversa [Prescribing Information]. Horsham, PA: Janssen Products, LP; January 2024.

For Part D use only:

ERDAFITINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 04/19
Client Approval: 08/24
P&T Approval: 04/24

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ERENUMAB-AOOE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ERENUMAB-AOOE	AIMOVIG	44923		GPI-10 (6770202010)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for the preventive treatment of migraines (ICD-10 Group G43) and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Aimovig will NOT be used concurrently with other CGRP inhibitors (e.g.,Ajovy [fremanezumab-vfrm], Emgality [galcanezumab-gnlm], Nurtec ODT [rimegepant]) for migraine prevention

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ERENUMAB-AOOE (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ERENUMAB-AOOE (Aimovig)** requires the following rule(s) be met for approval:

A. The request is for the preventive treatment of migraines (a type of headache)
B. You are 18 years of age or older
C. You will NOT use Aimovig concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Emgality [galcanezumab-gnlm], Nurtec ODT [rimegepant]) for migraine prevention

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ERENUMAB-AOOE (PART D)

RENEWAL CRITERIA

1. Is the request for the preventive treatment of migraines (ICD-10 Group G43) **AND** the patient meets the following criterion?
   - Aimovig will NOT be used concurrently with other CGRP inhibitors (e.g., Ajovy [fremanezumab-vfrm], Emgality [galcanezumab-gnlm], Nurtec ODT [rimegepant]) for migraine prevention

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has experienced a reduction in migraine or headache frequency with therapy
   - The patient has experienced a reduction in migraine severity with therapy
   - The patient has experienced a reduction in migraine duration with therapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ERENUMAB-AOOE (Aimovig)** requires the following rule(s) be met for renewal:
   A. The request is for the preventive treatment of migraines (a type of headache)
   B. You will NOT use Aimovig concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Emgality [galcanezumab-gnlm], Nurtec ODT [rimegepant]) for migraine prevention
   C. You meet ONE of the following:
      1. You have experienced a reduction in migraines or headache frequency with therapy
      2. You have experienced a reduction in migraine severity with therapy
      3. You have experienced a reduction in migraine duration with therapy

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ERENUMAB-AOOE (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Aimovig.

REFERENCE
Aimovig [Prescribing Information]. Thousand Oaks, CA: Amgen/Novartis; March 2025.

For Part D use only:

ERENUMAB-AOOE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	MIGRAINE PREVENTION: INITIAL/RENEWAL: NO CONCURRENT USE WITH OTHER CGRP INHIBITORS FOR MIGRAINE PREVENTION. RENEWAL: REDUCTION IN MIGRAINE OR HEADACHE FREQUENCY, MIGRAINE SEVERITY, OR MIGRAINE DURATION WITH THERAPY.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ERIBULIN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ERIBULIN MESYLATE	HALAVEN, ERIBULIN MESYLATE	37256		GPI-10 (2150000920)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic breast cancer (ICD-10 Group C50) **AND** meet the following criterion?
   - The patient has tried at least TWO chemotherapeutic regimens in the adjuvant or metastatic setting, which include one agent from EACH of the following drug classes: an anthracycline (e.g., daunorubicin, doxorubicin, epirubicin), a taxane (e.g., docetaxel, paclitaxel)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of unresectable or metastatic liposarcoma (ICD-10 Groups C49, C48) **AND** meet the following criterion?
   - The patient has tried an anthracycline-containing regimen (e.g., daunorubicin, doxorubicin, epirubicin)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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ERIBULIN (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ERIBULIN (Halaven)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Metastatic breast cancer (a type of cancer that has spread to other parts of the body)
   2. Unresectable or metastatic liposarcoma (a type of cancer that begins in the fat cells that cannot be completely removed with surgery or has spread to other parts of the body)

B. If you have metastatic breast cancer, approval also requires:
   1. You have tried at least TWO chemotherapeutic regimens (drugs used to treat cancer) in the adjuvant (add on treatment) or metastatic setting, which include one medication from EACH of the following drug classes:
      a. An anthracycline (a type of cancer treatment such as daunorubicin, doxorubicin, epirubicin)
      b. A taxane (a type of cancer treatment such as docetaxel, paclitaxel)

C. If you have unresectable or metastatic liposarcoma, approval also requires:
   1. You have tried an anthracycline-containing regimen (a type of cancer treatment such as daunorubicin, doxorubicin, epirubicin)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Halaven.

REFERENCES

Halaven [Prescribing Information]. Nutley, NJ: Eisai Inc.; April 2024.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ERIBULIN (PART D)

For Part D use only:

ERIBULIN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 11/07
Effective: 07/01/25 Client Approval: 05/25 P&T Approval: 05/15

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ERLOTINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ERLOTINIB HCL	TARCEVA, ERLOTINIB HCL	26745		GPI-10 (2136002510)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient's tumor has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test
   - The requested medication will NOT be used concurrently with an EGFR tyrosine kinase inhibitor (e.g., Gilotrif [afatinib], Iressa [gefitinib], Vizimpro [dacomitinib], Tagrisso [osimertinib])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of locally advanced, unresectable, or metastatic pancreatic cancer (ICD-10 Group C25) **AND** meet the following criterion?
   - The requested medication will be used in combination with gemcitabine

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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ERLOTINIB (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ERLOTINIB (Tarceva)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Metastatic non-small cell lung cancer (type of lung cancer that has spread to other parts of the body)
   2. Locally advanced, unresectable, or metastatic pancreatic cancer (pancreas cancer that has spread to other parts of the body or cannot be completely removed by surgery)

B. If you have metastatic non-small cell lung cancer, approval also requires:
   1. Your tumor has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations (abnormal changes in a type of gene) as detected by a Food and Drug Administration (FDA)-approved test
   2. You will NOT use the requested medication concurrently (at the same time) with an EGFR tyrosine kinase inhibitor (such as Gilotrif [afatinib], Iressa [afatinib], Vizimpro [dacomitinib], Tagrisso [Osimertinib])

C. If you have locally advanced, unresectable, or metastatic pancreatic cancer, approval also requires:
   1. The requested medication will be used in combination with gemcitabine

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tarceva.

REFERENCES

Tarceva [Prescribing Information]. Northbrook, IL. Astellas Pharma US, Inc. October 2016.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ERLOTINIB (PART D)

For Part D use only:

ERLOTINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) WITH EGFR MUTATION: NOT ON CONCURRENT THERAPY WITH AN EGFR TYROSINE KINASE INHIBITOR.

Created: 11/10
Effective: 07/01/25 Client Approval: 05/25 P&T Approval: 04/22

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ESKETAMINE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ESKETAMINE HCL	SPRAVATO	41003		GPI-10 (5811002010)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of treatment-resistant depression (TRD) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a psychiatrist or other Risk Evaluation and Mitigation Strategy (REMS)-certified provider
   - The patient has non-psychotic, unipolar depression
   - The patient does NOT have active substance abuse

   (**NOTE:** Treatment resistant depression is defined as a treatment failure after trial of two or more antidepressant medications of adequate dose and duration.)

   If yes, **approve for 3 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

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ESKETAMINE (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of major depressive disorder (MDD) (ICD-10 Groups F32, F33) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Spravato will be used in combination with an oral antidepressant (e.g., Zoloft [sertraline], Cymbalta [duloxetine])
   - The patient has acute suicidal ideation or behavior
   - Therapy is prescribed by or in consultation with a psychiatrist or other Risk Evaluation and Mitigation Strategy (REMS)-certified provider
   - The patient has non-psychotic, unipolar depression
   - The patient does NOT have active substance abuse

   If yes, **approve for 4 weeks by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ESKETAMINE (Spravato)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Treatment-resistant depression (TRD: depressive symptoms are not responding to treatment)
      2. Major depressive disorder (MDD: a type of mental illness)

   B. If you have treatment-resistant depression, approval also requires:
      1. You are 18 years of age or older
      2. Therapy is prescribed by or in consultation with a psychiatrist (a type of mental health doctor) or other Risk Evaluation and Mitigation Strategy (REMS)-certified provider (a doctor that is authorized to prescribe the requested medication)
      3. You have non-psychotic, unipolar depression (you have no other mental health conditions except depression)
      4. You do NOT have active substance (drug) abuse

   (Initial denial text continued on next page)

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ESKETAMINE (PART D)

INITIAL CRITERIA (CONTINUED)

C. If you have major depressive disorder, approval also requires:

1. You are 18 years of age or older
2. Spravato will be used in combination with an oral antidepressant (such as Zoloft [sertraline], Cymbalta [duloxetine])
3. You have acute (short-term) suicidal ideation or behavior (thoughts of killing yourself)
4. Therapy is prescribed by or in consultation with a psychiatrist (a type of mental health doctor) or other Risk Evaluation and Mitigation Strategy (REMS)-certified provider (a doctor that is authorized to prescribe the requested medication)
5. You have non-psychotic, unipolar depression (you have no other mental health conditions except depression)
6. You do NOT have active substance (drug) abuse

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ESKETAMINE (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of treatment-resistant depression (TRD) **AND** meet the following criterion?
   - The patient has demonstrated clinical benefit (improvement in depression) compared to baseline

   (**NOTE:** Treatment resistant depression is defined as a treatment failure after trial of two or more antidepressant medications of adequate dose and duration.)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [xx] per [xx] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of major depressive disorder (MDD) (ICD-10 Groups F32, F33) **AND** meet the following criterion?
   - The patient has demonstrated clinical benefit (improvement in depression) compared to baseline

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [xx] per [xx] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ESKETAMINE (Spravato)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Treatment-resistant depression (TRD: depressive symptoms are not responding to treatment)
      2. Major depressive disorder (MDD: a type of mental illness)
   B. You have demonstrated clinical benefit (improvement in depression) compared to baseline (before treatment)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ESKETAMINE (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Spravato.

REFERENCE
Spravato [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc., January 2025.

For Part D use only:

ESKETAMINE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: TREATMENT-RESISTANT DEPRESSION (TRD), MAJOR DEPRESSIVE DISORDER (MDD): PRESCRIBED BY OR IN CONSULTATION WITH A PSYCHIATRIST OR OTHER REMS-CERTIFIED PROVIDER.
Coverage Duration	INITIAL: TRD: 3 MONTHS. MDD: 4 WEEKS. RENEWAL: TRD, MDD: 12 MONTHS.
Other Criteria	INITIAL: TRD, MDD: 1) NON-PSYCHOTIC, UNIPOLAR DEPRESSION, AND 2) NO ACTIVE SUBSTANCE ABUSE. RENEWAL: TRD, MDD: DEMONSTRATED CLINICAL BENEFIT (IMPROVEMENT IN DEPRESSION) COMPARED TO BASELINE.

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Effective: 01/01/26 Client Approval: 12/25 P&T Approval: 10/25

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ESRD BVD DETERMINATION (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CALCITONIN, SALMON, SYNTHETIC	CALCITONIN-SALMON, MIACALCIN	02859		GPI-10 (3004302000)	
CALCITRIOL	CALCITRIOL, ROCALTROL	00999		GPI-10 (3090503000)	GCN ≠ 13015
CALCIUM ACETATE	CALCIUM ACETATE, PHOSLYRA	04884		GPI-10 (5280002010)	
CALCIUM GLUCONATE	CALCIUM GLUCONATE	00585		GPI-10 (7910003000)	GCN ≠ 3850
CALCIUM GLUC IN NACL, ISO-OSM	CALCIUM GLUCONATE-NACL	45482		GPI-10 (7910990219)	
CINACALCET HCL	SENSIPAR, CINACALCET HCL	25998		GPI-10 (3090522510)	
DAPRODUSTAT	JESDUVROQ	48668		GPI-10 (8240252000)	
DOXERCALCIFEROL	HECTOROL, DOXERCALCIFEROL	20533		GPI-10 (3090504000)	GCN ≠ 31684
ETELCALCETIDE HYDROCHLORIDE	PARSABIV	44093		GPI-10 (3090523010)	
HEPARIN SODIUM,PORCINE, HEPARIN SODIUM,PORCINE/ PF	HEPARIN SODIUM	02810		GPI-10 (8310002020)	FDB: BRAND ≠ HEPARIN LOCK, HEPARIN FLUSH GPID ≠ 28669 MEDI-SPAN: GPI-14 ≠ 83100020202026
HEPARIN (PORCINE) IN SODIUM CHLORIDE	HEPARIN (PORCINE) IN NACL			GPI-14 (83100020222033)	
HEPARIN SODIUM,PORCINE/ PF	HEPARIN SODIUM		42638 29477 26429	GPI-14 (83100020202034, 83100020202013)	
IBANDRONATE SODIUM	BONIVA, IBANDRONATE SODIUM		36226	GPI-14 (30042048102030)	

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LANTHANUM CARBONATE	FOSRENOL, LANTHANUM CARBONATE	26756		GPI-10 (5280004520)	
LEVOCARNITINE	CARNITOR SF, LEVOCARNITINE SF LEVOCARNITINE	00859		GPI-10 (3090304510)	GCN ≠ 70382
LEVOCARNITINE (WITH SUCROSE)	CARNITOR, LEVOCARNITINE	34794			
LIDOCAINE HCL	LIDOCAINE HCL, XYLOCAINE		11830 11852 11854 11857	GPI-10 (6910004010)	
LIDOCAINE HCL/PF	LIDOCAINE HCL, XYLOCAINE-MPF		26151 26877 26879 26884 26885 26886 26888		
LIDOCAINE/ TETRACAINE	SYNERA, PLIAGLIS, LIDOCAINE/TETRACAINE	33008		GPI-10 (9085990284)	
PAMIDRONATE DISODIUM	PAMIDRONATE DISODIUM	06250		GPI-10 (3004206010)	FDB: GCN ≠ 85999 MEDI-SPAN: GPI-14 ≠ 30042060102012
PARICALCITOL	ZEMPLAR, PARICALCITOL	18250		GPI-10 (3090507000)	
PROTAMINE SULFATE	PROTAMINE SULFATE		25860	GPI-10 (8550001010)	
SEVELAMER CARBONATE	RENVELA, SEVELAMER CARBONATE	35262		GPI-10 (5280007005)	
SEVELAMER HCL	RENAGEL, SEVELAMER HCL	18832		GPI-10 (5280007010)	
SUCROFERRIC OXYHYDROXIDE	VELPHORO	40909		GPI-10 (5280008010)	
TETRACAINE HCL	PONTOCAINE		30561		
TENAPANOR HCL	XPHOZAH		54891 54892	GPI-10 (3090326060)	
VADADUSTAT	VAFSEO	49335		GPI-10 (8240258000)	

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ZOLEDRONIC ACID	ZOMETA, ZOLEDRONIC ACID	21845		GPI-10 (3004209000)	
ZOLEDRONIC ACID/MANNITOL--WATER, ZOLEDRONIC AC/MANNITOL/0.9 NACL	ZOMETA, RECLAST, ZOLENDRONIC ACID	34717 44040			
IRON DEXTRAN COMPLEX	INFED	00733			
SODIUM FERRIC GLUCONAT/ SUCROSE	FERRLECIT, SOD FERRIC GLUCONATE COMPLEX	19948			
FERRIC CARBOXYMALTOSE	INJECTAFER, FERRIC CARBOXYMALTOSE	35687		GPI-10 (8230006200)	
IRON SUCROSE COMPLEX	VENOFER, IRON SUCROSE	21773		GPI-10 (8230004800)	
HYDROXOCOBALAMIN	HYDROXOCOBALAMIN		94601		
FERUMOXYTOL	FERAHEME, FERUMOXYTOL, FERABRIGHT	36439			
DALTEPARIN SODIUM,PORCINE	FRAGMIN	07429			
ENOXAPARIN SODIUM	LOVENOX, ENOXAPARIN SODIUM	07878		GPI-10 (8310102010)	BRAND ≠ ENOXILUV
ARGATROBAN	ARGATROBAN	21768		GPI-10 (8333701500)	
ARGATROBAN IN 0.9 % SOD CHLOR	ARGATROBAN-0.9% NACL	37600			
BIVALIRUDIN	ANGIOMAX, BIVALIRUDIN	21872			
RETEPLASE	RETAVASE	12650			
ALTEPLASE	CATHFLO ACTIVASE, ACTIVASE	02803			
CYANOCOBALAMIN	CYANOCOBALAMIN			GPI-10 (8210001000)	

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ESRD BVD DETERMINATION (PART D)

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

NOTE: This PA is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of end stage renal disease (ESRD) and is on dialysis (ICD-10 N18.6)?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Does the physician indicate that the patient is no longer on dialysis?

   If yes, **approve the requested drug for 12 months by HICL or GPI-10 under Part D.** (**NOTE**: If the ESRD_Dialysis attribute is present, select the 'ESRD' Override Type within the PA, which is available in the 'Additional Overrides' section.)

   If no, continue to #3.

3. Does the physician attest that the requested medication is being used for an indication that is unrelated to dialysis?

   If yes, **approve the requested drug for 12 months by HICL or GPI-10 under Part D.** (**NOTE:** If the ESRD_Dialysis attribute is present, select the 'ESRD' Override Type within the PA, which is available in the 'Additional Overrides' section.)

   If no, **do NOT approve under Part D. Finalize as follows:**

   PAC NOTE: Please defer to a pharmacist for denial.

   CLINICAL SPECIALIST NOTE: This medication is included in the bundled dialysis facility payment which is paid under Medicare Part B and is not a Part D eligible drug. Please follow your internal procedures for denial.

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ESRD BVD DETERMINATION (PART D)

RATIONALE

Patients identified as Part D End Stage Renal Disease (ESRD) undergoing dialysis will be directed to a dialysis treatment center and have their ESRD treatment related drug included in the bundled dialysis facility payment. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination.

REFERENCES

ESRD PPS Consolidated Billing. https://www.cms.gov/medicare/payment/prospective-payment-systems/end-stage-renal-disease-esrd/esrd-pps-consolidated-billing. Accessed January 6th, 2026.

CMS Memo: Announcement of Calendar Year (CY) 2014 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. April 2013. Available at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2014.pdf. Accessed January 21, 2026.

For Part D use only:

ESRD BVD DETERMINATION (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	THIS DRUG MAY BE EITHER BUNDLED WITH AND COVERED UNDER END STAGE RENAL DISEASE DIALYSIS RELATED SERVICES OR COVERED UNDER MEDICARE D DEPENDING UPON THE CIRCUMSTANCES. INFORMATION MAY NEED TO BE SUBMITTED DESCRIBING THE USE AND SETTING OF THE DRUG TO MAKE THE DETERMINATION.

Created: 02/11
Effective: 07/11/26 Client Approval: 07/26 P&T Approval: 11/14

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ETANERCEPT (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ETANERCEPT	ENBREL	18830		GPI-10 (6629003000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient had a trial of or contraindication to 3 months of treatment with ONE conventional synthetic DMARD (disease-modifying antirheumatic drug) (e.g., methotrexate at a dose of at least 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, sulfasalazine)
   - Enbrel will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

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ETANERCEPT (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (pJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Enbrel will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of pJIA

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   - Enbrel will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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ETANERCEPT (PART D)

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Enbrel will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS
   - The patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient is 4 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist
   - The patient has psoriasis covering 3% or more of body surface area (BSA) OR psoriatic lesions affecting the hands, feet, face, scalp, or genital area
   - Enbrel will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ETANERCEPT (PART D)

INITIAL CRITERIA (CONTINUED)

6. Does the patient meet **ONE** of the following criteria?
   - The patient has had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy)
   - The patient has a contraindication or intolerance to both immunosuppressant and PUVA (phototherapy)
   - The patient is switching from a different biologic (e.g., Humira [adalimumab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ETANERCEPT (Enbrel)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
      2. Psoriatic arthritis (PsA: a type of skin and joint condition)
      3. Moderate to severe polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition in children)
      4. Ankylosing spondylitis (AS: a type of joint condition)
      5. Moderate to severe plaque psoriasis (PsO: a type of skin condition)

   B. If you have moderate to severe rheumatoid arthritis, approval also requires:
      1. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
      2. You have tried 3 months of or have a contraindication to (harmful for you to use) ONE conventional synthetic DMARD (disease-modifying antirheumatic drug, such as methotrexate at a dose of at least 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, sulfasalazine)
      3. You will NOT use Enbrel concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis

   (Initial denial text continued on next page)

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ETANERCEPT (PART D)

INITIAL CRITERIA (CONTINUED)

C. If you have moderate to severe polyarticular juvenile idiopathic arthritis, approval also requires:
1. You are 2 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You will NOT use Enbrel concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis

D. If you have psoriatic arthritis, approval also requires:
1. You are 2 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
3. You will NOT use Enbrel concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

E. If you have ankylosing spondylitis, approval also requires:
1. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
2. You will NOT use Enbrel concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis
3. You have tried or have a contraindication to (harmful for you to use) an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)

(Initial denial text continued on next page)

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ETANERCEPT (PART D)

INITIAL CRITERIA (CONTINUED)

F. If you have moderate to severe plaque psoriasis, approval also requires:

1. You are 4 years of age or older
2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
3. You have psoriasis covering 3 percent or more of body surface area (BSA) OR psoriatic lesions (patches) affecting the hands, feet, face, scalp, or genital area
4. You will NOT use Enbrel concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis
5. You meet ONE of the following:
   a. You have had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy)
   b. You have a contraindication (harmful for you to use) or intolerance (side effect) to both immunosuppressant (a type of drug that decreases the body's immune response) and PUVA (phototherapy)
   c. You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ETANERCEPT (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) **AND** meet the following criterion?
   - The patient continues to benefit from the medication
   - Enbrel will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (pJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Enbrel will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of pJIA

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Enbrel will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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ETANERCEPT (PART D)

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Enbrel will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Enbrel will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ETANERCEPT (Enbrel)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
      2. Moderate to severe polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition in children)
      3. Psoriatic arthritis (PsA: a type of skin and joint condition)
      4. Ankylosing spondylitis (AS: a type of joint condition)
      5. Moderate to severe plaque psoriasis (PsO: a type of skin condition)

   (Renewal denial text continued on next page)

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ETANERCEPT (PART D)

RENEWAL CRITERIA (CONTINUED)

B. If you have moderate to severe rheumatoid arthritis, renewal also requires:
1. You continue to benefit from the medication
2. You will NOT use Enbrel concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis

C. If you have moderate to severe polyarticular juvenile idiopathic arthritis, renewal also requires:
1. You continue to benefit from the medication
2. You will NOT use Enbrel concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis

D. If you have psoriatic arthritis, renewal also requires:
1. You continue to benefit from the medication
2. You will NOT use Enbrel concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

E. If you have ankylosing spondylitis, renewal also requires:
1. You continue to benefit from the medication
2. You will NOT use Enbrel concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis

F. If you have moderate to severe plaque psoriasis, renewal also requires:
1. You continue to benefit from the medication
2. You will NOT use Enbrel concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ETANERCEPT (PART D)

RATIONALE
For further information, please refer to the prescribing information and/or Drug Monograph for Enbrel.

REFERENCES
Enbrel [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; October 2024.

For Part D use only:

ETANERCEPT (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	INITIAL: PLAQUE PSORIASIS (PSO): PSORIASIS COVERING 3 PERCENT OR MORE OF BODY SURFACE AREA OR PSORIATIC LESIONS AFFECTING THE HANDS, FEET, FACE, SCALP, OR GENITAL AREA.
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: RHEUMATOID ARTHRITIS (RA), POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA), ANKYLOSING SPONDYLITIS (AS): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST. PSO: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: RA: TRIAL OF OR CONTRAINDICATION TO 3 MONTHS OF TREATMENT WITH ONE CONVENTIONAL SYNTHETIC DMARD (DISEASE-MODIFYING ANTIRHEUMATIC DRUG) - IF PATIENT TRIED METHOTREXATE, THEN TRIAL AT A DOSE OF AT LEAST 20 MG PER WEEK OR MAXIMALLY TOLERATED DOSE IS REQUIRED. AS: TRIAL OF OR CONTRAINDICATION TO AN NSAID. PSO: 1) AT LEAST A 3 MONTH TRIAL OF ONE ORAL IMMUNOSUPPRESSANT (CYCLOSPORINE, METHOTREXATE, TACROLIMUS) OR PUVA (PHOTOTHERAPY), 2) CONTRAINDICATION OR INTOLERANCE TO BOTH IMMUNOSUPPRESSANT AND PUVA, OR 3) PATIENT IS SWITCHING FROM A DIFFERENT BIOLOGIC, PDE-4 INHIBITOR, OR JAK INHIBITOR FOR THE SAME INDICATION. INITIAL/RENEWAL: ALL INDICATIONS: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION. RENEWAL: ALL INDICATIONS: CONTINUES TO BENEFIT FROM THE MEDICATION.

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ETANERCEPT (PART D)

Created: 11/07
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 10/24

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ETEPLIRSEN BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ETEPLIRSEN	EXONDYS-51	43770		GPI-10 (7460003500)	

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, continue to #6.
   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, continue to #6.
   If no, continue to #5.

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

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ETEPLIRSEN BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

6. Is the drug administered via an implantable pump?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, continue to #7.

7. Is the drug administered via an external pump?

   If yes, continue to #8.
   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

8. Is the drug specifically infused through an external infusion pump covered by Medicare?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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ETEPLIRSEN BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Duchenne muscular dystrophy (DMD) (ICD-10 G71.01) and meets **ALL** of the following criteria?
   - The patient has a confirmed mutation of the DMD gene that is amenable to exon 51 skipping therapy
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient is ambulatory
   - The patient is currently receiving treatment with or has a contraindication to corticosteroids (e.g., prednisone, prednisolone)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ETEPLIRSEN BvD (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ETEPLIRSEN (Exondys 51)** requires the following rule(s) be met for approval:

A. You have Duchenne muscular dystrophy (DMD: a type of inherited muscle disorder)
B. You have a confirmed mutation in the DMD gene that will respond to exon 51 skipping therapy (a process that allows a protein to still function with sections of faulty genetic code)
C. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor)
D. You are ambulatory (able to walk)
E. You are currently receiving treatment with or you have a contraindication to (harmful for you to use) corticosteroids (such as prednisone, prednisolone)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ETEPLIRSEN BvD (PART D)

RENEWAL CRITERIA

1. Does the patient meet **ONE** of the following criteria?
   - The patient has maintained or demonstrated a less than expected decline in ambulatory ability based on muscle function assessments (e.g., 6-minute walk test)
   - The patient has maintained or demonstrated a less than expected decline in other muscle function (i.e., pulmonary or cardiac function)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ETEPLIRSEN (Exondys 51)** requires ONE of the following rules be met for renewal:
   A. You have maintained or demonstrated a less than expected decline in ambulatory ability (ability to walk) based on muscle function assessments (such as the 6-minute walk test)
   B. You have maintained or demonstrated a less than expected decline in other muscle function (pulmonary [lung] or cardiac [heart] function)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monographs for Exondys 51.

The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B. Drugs administered by an implantable pump are covered under Part B. Drugs administered via an external pump are covered under Part B if they are included under the local coverage policy of the applicable Medicare coverage policies (National and/or Local Coverage Policies). Drugs administered via an external pump that are not included under the applicable Medicare coverage policies are covered under Part D. A CMS website to assist with National and Local Coverage Determination for B versus D review is http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ETEPLIRSEN BvD (PART D)

REFERENCES

Exondys 51 [Prescribing Information]. Cambridge, MA: Sarepta Therapeutics, Inc.; January 2022.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed July 2, 2024].

For Part D use only:

ETEPLIRSEN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	DUCHENNE MUSCULAR DYSTROPHY (DMD): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST.
Coverage Duration	INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS.
Other Criteria	DMD: INITIAL: PATIENT IS AMBULATORY AND CURRENTLY RECEIVING TREATMENT WITH OR HAS A CONTRAINDICATION TO CORTICOSTEROIDS. RENEWAL: MAINTAINED OR DEMONSTRATED A LESS THAN EXPECTED DECLINE IN AMBULATORY ABILITY IN MUSCLE FUNCTION ASSESSMENTS OR OTHER MUSCLE FUNCTION (I.E., PULMONARY OR CARDIAC FUNCTION).

Created: 01/16
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 10/20

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ETRASIMOD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ETRASIMOD ARGININE	VELSIPITY	49267		GPI-10 (5250452510)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Velsipity will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Selarsdi /Yesintek/ustekinumab-aauz
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Skyrizi (risankizumab-rzaa)
     - Tremfya (guselkumab)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ETRASIMOD (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ETRASIMOD (Velsipity)** requires the following rule(s) be met for approval:

A. You have moderate to severe ulcerative colitis (UC: a type of digestive disorder)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
D. You will NOT use Velsipity concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis
E. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
    1. Selarsdi/Yesintek/ustekinumab-aauz
    2. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
    3. Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
    4. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
    5. Skyrizi (risankizumab-rzaa)
    6. Tremfya (guselkumab)

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ETRASIMOD (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) **AND** meet the following criterion?
   - Velsipity will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

     If yes, **approve for 12 months by HICL or GPI-10.**
     APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

     If no, do not approve.

     RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

     Our guideline named **ETRASIMOD (Velsipity)** requires the following rule(s) be met for renewal:
     A. You have moderate to severe ulcerative colitis (UC: a type of digestive disorder)
     B. You will NOT use Velsipity concurrently (at the same time) with anothersystemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

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RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Velsipity.

REFERENCES
Velsipity [Prescribing Information]. New York, NY: Pfizer, Inc.; August 2025.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ETRASIMOD (PART D)

For Part D use only:

ETRASIMOD (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	ULCERATIVE COLITIS (UC): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	UC: INITIAL: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: SELARSDI/YESINTEK/USTEKINUMAB-AAUZ, XELJANZ, HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, RINVOQ, SKYRIZI, TREMFYA. INITIAL/RENEWAL: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION.

Created: 11/23
Effective: 05/01/26 Client Approval: 04/26 P&T Approval: 10/24

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EVEROLIMUS-AFINITOR (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EVEROLIMUS	AFINITOR, TORPENZ, EVEROLIMUS		20784 20844 28783 31396	GPI-14 (21532530000330, 21532530000310, 21532530000320, 21532530000325)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced breast cancer (ICD-10 Group C50) and meet **ALL** of the following criteria?
   - The patient is a postmenopausal woman
   - The patient's breast cancer is hormone receptor (HR)-positive, HER2-negative
   - The requested medication will be used in combination with Aromasin (exemestane)
   - The patient has failed treatment with Femara (letrozole) or Arimidex (anastrozole)

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of progressive, neuroendocrine tumors (NET) with unresectable, locally advanced or metastatic disease (ICD-10 Group C7A) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #3.
   If no, continue to #4.

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EVEROLIMUS-AFINITOR (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient meet **ONE** of the following criteria?
   - The patient has neuroendocrine tumors of pancreatic origin (PNET)
   - The patient has well-differentiated, non-functional neuroendocrine tumors (NET) of gastrointestinal (GI) or lung origin

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC) (ICD-10 Groups C64, C65) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Does the patient have a diagnosis of tuberous sclerosis complex (TSC)-associated renal angiomyolipoma (ICD-10 Q85.1, D17.71) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient does not require immediate surgery

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #6.

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EVEROLIMUS-AFINITOR (PART D)

GUIDELINES FOR USE (CONTINUED)

6. Does the patient have a diagnosis of tuberous sclerosis complex (TSC)-associated subependymal giant cell astrocytoma (SEGA) (ICD-10 Q85.1, D43.2) and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - The patient's diagnosis requires therapeutic intervention but cannot be curatively resected

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EVEROLIMUS-AFINITOR (Afinitor, Torpenz)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Advanced breast cancer
      2. Progressive, neuroendocrine tumors (NET: a rare type of tumor) with unresectable (unable to remove by surgery), locally advanced (cancer that has spread from where it started to nearby tissue or lymph nodes) or metastatic disease (cancer that has spread to other parts of the body)
      3. Advanced renal cell carcinoma (RCC: type of kidney cancer)
      4. Tuberous sclerosis complex (TSC: a rare type of tumor disorder)-associated renal angiomyolipoma (type of kidney tumor)
      5. Tuberous sclerosis complex (TSC: a rare type of tumor disorder)-associated subependymal giant cell astrocytoma (SEGA: a type of brain tumor)

   B. If you have advanced breast cancer, approval also requires:
      1. You are a postmenopausal woman
      2. Your breast cancer is hormone receptor-positive (HR: a type of protein), human epidermal growth factor receptor 2 (HER2: a type of protein)-negative
      3. The requested medication will be used in combination with Aromasin (exemestane)
      4. You have failed treatment with Femara (letrozole) or Arimidex (anastrozole)

   C. If you have progressive, neuroendocrine tumors with unresectable, locally advanced or metastatic disease, approval also requires:
      1. You are 18 years of age or older
      2. You meet ONE of the following:
         a. You have neuroendocrine tumors of pancreatic origin (PNET: tumor in the pancreas)
         b. You have well-differentiated, non-functional neuroendocrine tumors (NET) of gastrointestinal (GI: relating to the digestive system) or lung origin

   (Denial text continued on next page)

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EVEROLIMUS-AFINITOR (PART D)

GUIDELINES FOR USE (CONTINUED)

D. If you have advanced renal cell carcinoma, approval also requires:
1. You are 18 years of age or older

E. If you have tuberous sclerosis complex-associated renal angiomyolipoma, approval also requires:
1. You are 18 years of age or older
2. You do NOT require immediate surgery

F. If you have tuberous sclerosis complex-associated subependymal giant cell astrocytoma, approval also requires:
1. You are 1 year of age or older
2. Your diagnosis requires therapeutic intervention but cannot be curatively resected (completely removed with surgery)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Afinitor/Torpenz.

REFERENCES

Afinitor/Afinitor Disperz [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; February 2022.
Torpenz [Prescribing Information]. Maple Grove, MN: Upsher-Smith Laboratories, LLC; June 2024.

For Part D use only:

EVEROLIMUS-AFINITOR (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 07/23
Effective: 07/01/25 Client Approval: 05/25 P&T Approval: 04/18

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EVEROLIMUS-AFINITOR DISPERZ (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EVEROLIMUS	AFINITOR DISPERZ, EVEROLIMUS		34589 34590 34592	GPI-14 (21532530007310), (21532530007320), (21532530007340)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

AFINITOR DISPERZ

1. Does the patient have a diagnosis of tuberous sclerosis complex (TSC)-associated subependymal giant cell astrocytoma (SEGA) (ICD-10 Q85.1, D43.2) and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - The patient's diagnosis requires therapeutic intervention but cannot be curatively resected

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of tuberous sclerosis complex (TSC)-associated partial-onset seizures (ICD-10 Q85.1, Groups G40.1, G40.2) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - The requested medication will be used as adjunctive treatment

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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EVEROLIMUS-AFINITOR DISPERZ (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **EVEROLIMUS-AFINITOR DISPERZ** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Tuberous sclerosis complex (TSC: a rare type of tumor disorder)-associated subependymal giant cell astrocytoma (SEGA: a type of brain tumor)
   2. Tuberous sclerosis complex (TSC: a rare type of tumor disorder)-associated partial-onset seizures

B. If you have tuberous sclerosis complex-associated subependymal giant cell astrocytoma, approval also requires:
   1. You are 1 year of age or older
   2. Your diagnosis requires therapeutic intervention but cannot be curatively resected (completely removed with surgery)

C. If you have tuberous sclerosis complex-associated partial-onset seizures, approval also requires:
   1. You are 2 years of age or older
   2. The requested medication will be used as adjunctive (add-on) treatment

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Afinitor Disperz.

REFERENCES

Afinitor/Afinitor Disperz [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; February 2022.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EVEROLIMUS-AFINITOR DISPERZ (PART D)

For Part D use only:

EVEROLIMUS-AFINITOR DISPERZ (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 03/23
Effective: 07/01/25 Client Approval: 05/25 P&T Approval: 04/18

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EVINACUMAB-DGNB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EVINACUMAB-DGNB	EVKEEZA	47113		GPI-10 (3939203020)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of homozygous familial hypercholesterolemia (HoFH) (ICD-10 E78.01) and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - Evkeeza will be used as an adjunct to other low-density lipoprotein-cholesterol (LDL-C) lowering therapies (e.g., statins [such as Lipitor (atorvastatin)], PCSK9 inhibitors [such as Repatha (evolocumab)], Zetia [ezetimibe], Juxtapid [lomitapide], lipoprotein apheresis)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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EVINACUMAB-DGNB (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **EVINACUMAB-DGNB (Evkeeza)** requires the following rule(s) be met for approval:

A. You have homozygous familial hypercholesterolemia (HoFH: a type of inherited high cholesterol)
B. You are 1 year of age or older
C. Evkeeza will be used as an adjunct (add-on) to other low-density lipoprotein-cholesterol (LDL-C) lowering therapies (such as statins [such as Lipitor (atorvastatin)], PCSK9 inhibitors [such as Repatha (evolocumab)], Zetia [ezetimibe], Juxtapid [lomitapide], lipoprotein apheresis [procedure that removes bad cholesterol from the blood])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Evkeeza.

REFERENCES

Evkeeza [Prescribing Information]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; September 2025.

For Part D use only:

EVINACUMAB-DGNB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 02/21
Effective: 10/20/25 Client Approval: 10/25 P&T Approval: 10/25

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FAM-TRASTUZUMAB DERUXTECAN-NXKI (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FAM-TRASTUZUMAB DERUXTECAN-NXKI	ENHERTU	46262		GPI-10 (2135507055)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of breast cancer (ICD-10 Group C50) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, continue to #8.

2. Is the patient's cancer unresectable or metastatic?

   If yes, continue to #3.
   If no, continue to #6.

3. Is the patient's cancer HER2-positive (IHC 3+ or ISH positive) and the patient meets **ONE** of the following criteria?
   - The patient has received a prior anti-HER2-based regimen (e.g., Herceptin [trastuzumab], Kadcyla [ado-trastuzumab emastine]) in the metastatic setting
   - The patient has received a prior anti-HER2-based regimen (e.g., Herceptin [trastuzumab], Kadcyla [ado-trastuzumab emastine]) in the neoadjuvant or adjuvant setting AND has developed disease recurrence during or within 6 months of completing therapy
   - Enhertu will be used in combination with pertuzumab (Perjeta), when cancer is determined by an FDA-authorized test

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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FAM-TRASTUZUMAB DERUXTECAN-NXKI (PART D)

GUIDELINES FOR USE (CONTINUED)

4. Is the patient's cancer HR-positive, HER2-low (IHC 1+ or IHC 2+/ISH-) or HER2-ultralow (IHC 0 with membrane staining), as determined by an FDA-authorized test, **AND** the patient meets the following criterion?
   - The patient's disease has progressed on at least one endocrine therapy (e.g., letrozole, anastrozole, tamoxifen) in the metastatic setting

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Is the patient's cancer HER2-low (IHC 1+ or IHC 2+/ISH-), as determined by an FDA-authorized test, and the patient meets **ONE** of the following criteria?
   - The patient has received a prior chemotherapy in the metastatic setting
   - The patient has developed disease recurrence during or within 6 months of completing adjuvant chemotherapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

6. Is the patient's cancer in early Stage II or III and meets **ALL** of the following criteria?
   - The patient's cancer is HER2-positive (IHC3+ or ISH+), as determined by an FDA-authorized test
   - Enhertu will be used as a neodjuvant treatment and followed by a taxane (e.g., paclitaxel), trastuzumab, and pertuzumab (THP)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #7.

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FAM-TRASTUZUMAB DERUXTECAN-NXKI (PART D)

GUIDELINES FOR USE (CONTINUED)

7. Is the patient's cancer in early stage and meets **ALL** of the following criteria?
   - The patient's cancer is HER2-positive (IHC3+ or ISH+)
   - Enhertu will be used as adjuvant treatment
   - The patient has residual invasive disease following neoadjuvant trastuzumab and taxane-based treatment

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

8. Does the patient have unresectable or metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's tumors have activating HER2 (ERBB2) mutations, as detected by an FDA-authorized test
   - The patient has received a prior systemic therapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #9.

9. Does the patient have a diagnosis of locally advanced or metastatic gastric OR gastroesophageal junction (GEJ) adenocarcinoma (ICD-10 Group C16) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer is HER2-positive (IHC 3+ or IHC 2+/ISH positive)
   - The patient has received a prior trastuzumab-based regimen

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #10.

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FAM-TRASTUZUMAB DERUXTECAN-NXKI (PART D)

GUIDELINES FOR USE (CONTINUED)

10. Does the patient have a diagnosis of unresectable or metastatic solid tumors and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - The patient's cancer is HER2-positive (IHC 3+)
    - The patient has received prior systemic treatment and has no satisfactory alternative treatment options

    If yes, **approve for 12 months by HICL or GPI-10.**
    APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

    If no, do not approve.

    DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

    Our guideline named **FAM-TRASTUZUMAB DERUXTECAN-NXKI (Enhertu)** requires the following rule(s) be met for approval:

    A. You have ONE of the following:
        1. Unresectable or metastatic breast cancer (a type of breast cancer that cannot be removed by surgery or has spread to other parts of the body)
        2. Early breast cancer
        3. Unresectable or metastatic non-small cell lung cancer (NSCLC) (a type of lung cancer that cannot be removed by surgery or has spread to other parts of the body)
        4. Locally advanced or metastatic gastric OR gastroesophageal junction (GEJ) adenocarcinoma (a type of digestive system cancer that has spread to nearby tissue or lymph nodes, or has spread to other parts of the body)
        5. Unresectable or metastatic solid tumors (a type of abnormal mass that cannot be removed by surgery or has spread to other parts of the body)

    (Denial text continued on next page)

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FAM-TRASTUZUMAB DERUXTECAN-NXKI (PART D)

GUIDELINES FOR USE (CONTINUED)

B. If you have unresectable or metastatic breast cancer, approval also requires:
1. You are 18 years of age or older
2. If your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive (IHC 3+ or ISH positive), approval also requires you meet ONE of the following:
   a. You have received a prior anti-HER2-based regimen (type of medication such as Herceptin [trastuzumab], Kadcyla [ado-trastuzumab emastine]) in the metastatic setting (cancer has spread to other parts of the body)
   b. You have received a prior anti-HER2-based regimen (such as Herceptin [trastuzumab], Kadcyla [ado-trastuzumab emastine]) in the neoadjuvant (given before main treatment) or adjuvant (additional treatment) setting AND the disease has returned during or within 6 months of completing therapy
   c. You will use Enhertu in combination with pertuzumab (Perjeta), when your cancer is determined by a Food and Drug Administration (FDA)-authorized test
3. If your cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-low (IHC 1+ or IHC 2+/ISH-) or HER2-ultralow (IHC 0 with membrane staining), as determined by a Food and Drug Administration (FDA)-authorized test, approval also requires that your disease has progressed while on at least one endocrine therapies (such as letrozole, anastrozole, tamoxifen) in the metastatic setting (cancer has spread to other parts of the body)
4. If your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-low (IHC 1+ or IHC 2+/ISH-), as determined by a Food and Drug Administration (FDA)-authorized test, approval also requires you meet ONE of the following:
   a. You have received a prior chemotherapy (a type of cancer treatment) in the metastatic setting (cancer has spread to other parts of the body)
   b. You have developed disease recurrence (disease has returned) during or within 6 months of completing adjuvant (additional) chemotherapy

C. If you have early breast cancer, approval also requires:
1. You are 18 years of age or older
2. You meet ONE of the following:
   a. Your cancer is early Stage II or III; your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive (IHC 3+ or ISH positive), as determined by a Food and Drug Administration (FDA)-authorized test; AND Enhertu will be used as a neoadjuvant treatment (given before main treatment) and followed by a taxane (such as paclitaxel), trastuzumab, and pertuzumab (THP)
   b. Your cancer is in early stage; your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive (IHC 3+ or ISH positive); Enhertu will be used as adjuvant treatment (additional treatment); and you have residual invasive disease (remaining disease that has spread) following neoadjuvant (given before main treatment) trastuzumab and taxane-based treatment

(Denial text continued on next page)

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FAM-TRASTUZUMAB DERUXTECAN-NXKI (PART D)

GUIDELINES FOR USE (CONTINUED)

D. If you have unresectable or metastatic non-small cell lung cancer, approval also requires:
1. You are 18 years of age or older
2. Your tumors have activating HER2 (ERBB2) mutations (abnormal change in a type of gene), as detected by a Food and Drug Administration (FDA)-authorized test
3. You have received a prior systemic therapy (treatment that targets the entire body)

E. If you have locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:
1. You are 18 years of age or older
2. Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive (IHC 3+ or IHC 2+/ISH positive)
3. You have received a prior trastuzumab-based (type of medication) regimen

F. If you have unresectable or metastatic solid tumors, approval also requires:
1. You are 18 years of age or older
2. Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive (IHC 3+)
3. You have received previous systemic treatment (therapy that targets the entire body) and have no other satisfactory treatment options

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Enhertu.

REFERENCES
Enhertu [Prescribing Information]. Basking Ridge, NJ: Daiichi Sankyo, Inc.; May 2026.

For Part D use only:

FAM-TRASTUZUMAB DERUXTECAN-NXKI (PART D)	
Covered uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FECAL MICROBIOTA CAPSULE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FECAL MICROBIO SPORE, LIVE-BRPK	VOWST	48888		GPI-10 (5252202010)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the request for the prevention of recurrent *Clostridioides difficile* infection (CDI) (ICD-10 A04.71) **AND** the patient meets the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient previously received Vowst?

   If yes, continue to #4.
   If no, continue to #3.

3. Has the patient completed antibiotic treatment (e.g., vancomycin [Vancocin], fidaxomicin [Dificid]) for recurrent CDI (defined as at least 3 CDI episodes)?

   If yes, **approve for 30 days by HICL or GPI-10 for 1 fill.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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FECAL MICROBIOTA CAPSULE (PART D)

GUIDELINES FOR USE (CONTINUED)

4. Does the patient meet **ALL** of the following criteria?
   - The patient had treatment failure, defined as the presence of CDI diarrhea within 8 weeks of the first dose of Vowst AND a positive stool test for *C. difficile*
   - The patient has not previously received more than one treatment course of Vowst AND the start of that treatment course was at least 12 days and not more than 8 weeks prior

   If yes, **approve for 30 days by HICL or GPI-10 for 1 fill.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FECAL MICROBIOTA CAPSULE (Vowst)** requires the following rule(s) be met for approval:
   A. You will use Vowst for the prevention of recurrent *Clostridioides difficile* infection (CDI: a bacterial infection)
   B. You are 18 years of age or older
   C. If you have NOT previously received Vowst, approval also requires:
      1. You have completed antibiotic (such as vancomycin [Vancocin], fidaxomicin [Dificid]) treatment for recurrent CDI (defined as at least 3 CDI episodes)
   D. If you have been previously treated with Vowst, approval also requires:
      1. You had treatment failure, defined as the presence of CDI diarrhea within 8 weeks of the first dose of Vowst AND a positive stool test for *C. difficile*
      2. You have not previously received more than one treatment course of Vowst AND the start of that treatment course was at least 12 days and not more than 8 weeks prior

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Vowst.

REFERENCES
Vowst [Prescribing Information]. Cambridge, MA: Seres Therapeutics, Inc.; April 2023.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FECAL MICROBIOTA CAPSULE (PART D)

For Part D use only:

FECAL MICROBIOTA CAPSULE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	30 DAYS
Other Criteria	CLOSTRIDIOIDES DIFFICILE INFECTION (CDI): 1) HAS NOT PREVIOUSLY RECEIVED VOWST: COMPLETION OF ANTIBIOTIC TREATMENT FOR RECURRENT CDI (AT LEAST 3 CDI EPISODES), OR 2) PREVIOUSLY RECEIVED VOWST: (A) TREATMENT FAILURE (DEFINED AS THE PRESENCE OF CDI DIARRHEA WITHIN 8 WEEKS OF FIRST DOSE OF VOWST AND A POSITIVE STOOL TEST FOR C. DIFFICILE), AND (B) HAS NOT RECEIVED MORE THAN ONE TREATMENT COURSE OF VOWST WHICH WAS AT LEAST 12 DAYS AND NOT MORE THAN 8 WEEKS PRIOR.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FECAL MICROBIOTA SUSPENSION (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FECAL MICROBIOTA, LIVE-JSLM	REBYOTA	48488		GPI-10 (5252201030)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the request for the prevention of recurrent *Clostridioides difficile* infection (CDI) (ICD-10 A04.71) **AND** the patient meets the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient previously received Rebyota?

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet **ALL** of the following criteria?
   - The patient had treatment failure, defined as the presence of CDI diarrhea within 8 weeks of first dose of Rebyota AND a positive stool test for *C. difficile*
   - The patient has not previously received more than one dose of Rebyota AND that dose was at least 7 days and not more than 8 weeks prior

   If yes, **approve for 30 days by HICL or GPI-10 for 1 fill.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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FECAL MICROBIOTA SUSPENSION (PART D)

GUIDELINES FOR USE (CONTINUED)

4. Has the patient completed antibiotic treatment for recurrent CDI (at least 3 CDI episodes) at least 24 hours prior?

   If yes, **approve for 30 days by HICL or GPI-10 for 1 fill.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FECAL MICROBIOTA SUSPENSION (Rebyota)** requires the following rule(s) be met for approval:
   A. You will use Rebyota for the prevention of recurrent *Clostridioides difficile* infection (CDI: a bacterial infection)
   B. You are 18 years of age or older
   C. If you have NOT previously received Rebyota, approval also requires:
      1. You have completed antibiotic treatment for recurrent CDI (at least 3 CDI episodes) at least 24 hours prior
   D. If you have been previously treated with Rebyota, approval also requires:
      1. You had treatment failure, defined as the presence of CDI diarrhea within 8 weeks of first dose of Rebyota AND a positive stool test for *C. difficile*
      2. You have not previously received more than one dose of Rebyota AND that dose was at least 7 days and not more than 8 weeks prior

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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FECAL MICROBIOTA SUSPENSION (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rebyota.

REFERENCES

Rebyota [Prescribing Information]. Parsippany, NJ: Ferring Pharmaceuticals, Inc., November 2022.

For Part D use only:

FECAL MICROBIOTA SUSPENSION (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	30 DAYS
Other Criteria	CLOSTRIDIOIDES DIFFICILE INFECTION (CDI): 1) PATIENT HAS NOT PREVIOUSLY RECEIVED REBYOTA: COMPLETION OF ANTIBIOTIC TREATMENT FOR RECURRENT CDI (AT LEAST 3 CDI EPISODES) AT LEAST 24 HOURS PRIOR, OR 2) PATIENT PREVIOUSLY RECEIVED REBYOTA: (A) TREATMENT FAILURE (DEFINED AS THE PRESENCE OF CDI DIARRHEA WITHIN 8 WEEKS OF FIRST DOSE OF REBYOTA AND A POSITIVE STOOL TEST FOR C. DIFFICILE), AND (B) HAS NOT RECEIVED MORE THAN ONE DOSE OF REBYOTA WHICH WAS AT LEAST 7 DAYS AND NOT MORE THAN 8 WEEKS PRIOR.

Core	Advantage	Plus
No	No	Yes

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FEDRATINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FEDRATINIB DIHYDROCHLORIDE	INREBIC	45953		GPI-10 (2153752020)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF) (ICD-10 D75.81, D47.1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to Jakafi (ruxolitinib)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FEDRATINIB (Inrebic)** requires the following rule(s) be met for approval:
   A. You have intermediate-2 or high-risk primary or secondary (post-polycythemia vera [type of blood cell disorder] or post-essential thrombocythemia [type of blood cell disorder]) myelofibrosis (type of bone marrow cancer)
   B. You are 18 years of age or older
   C. You have tried or have a contraindication to (harmful for you to use) Jakafi (ruxolitinib)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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FEDRATINIB (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF) (ICD-10 D75.81, D47.1) **AND** meet the following criterion?
   - The patient continues to benefit from the medication

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FEDRATINIB (Inrebic)** requires the following rule(s) be met for renewal:
   A. You have intermediate-2 or high-risk primary or secondary (post-polycythemia vera [type of blood cell disorder] or post-essential thrombocythemia [type of blood cell disorder])myelofibrosis (type of bone marrow cancer)
   B. You continue to benefit from the medication

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Inrebic.

REFERENCES

Inrebic [Prescribing Information]. Summit, NJ: Celgene Corporation; December 2021.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FEDRATINIB (PART D)

For Part D use only:

FEDRATINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS
Other Criteria	MYELOFIBROSIS: INITIAL: TRIAL OF OR CONTRAINDICATION TO JAKAFI (RUXOLITINIB). RENEWAL: CONTINUES TO BENEFIT FROM THE MEDICATION.

Core	Advantage	Plus
Yes	Yes	Yes

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FENFLURAMINE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FENFLURAMINE	FINTEPLA	02116		GPI-10 (7260002810)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of seizures associated with Dravet syndrome (ICD-10 G40.833) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of seizures associated with Lennox-Gastaut syndrome (LGS) (ICD-10 Group G40.81) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient had a trial of or contraindication to TWO of the following antiepileptic medications: rufinamide, felbamate, clobazam, topiramate, lamotrigine, clonazepam

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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FENFLURAMINE (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FENFLURAMINE (Fintepla)** requires the following rule(s) be met for approval:

A. You have seizures associated with ONE of the following:
   1. Dravet syndrome (a rare type of seizure)
   2. Lennox-Gastaut syndrome (LGS: a type of seizure disorder in young children)
B. You are 2 years of age or older
C. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
D. If you have Lenox-Gastaut syndrome, approval also requires:
   1. You have tried or have a contraindication to (harmful for you to use) TWO of the following seizure medications: rufinamide, felbamate, clobazam, topiramate, lamotrigine, clonazepam

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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FENFLURAMINE (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of seizures associated with Dravet syndrome (ICD-10 G40.833) or Lennox-Gastaut syndrome (ICD-10 Group G40.81)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FENFLURAMINE (Fintepla)** requires the following rule(s) be met for renewal:
   A. You have seizures associated with ONE of the following:
      1. Dravet syndrome (a rare type of seizure)
      2. Lennox-Gastaut syndrome (LGS: a type of seizure disorder in young children)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Fintepla.

REFERENCES
Fintepla [Prescribing Information]. Emeryville, CA: Zogenix, Inc., March 2022.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FENFLURAMINE (PART D)

For Part D use only:

FENFLURAMINE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: DRAVET SYNDROME, LENNOX-GASTAUT SYNDROME (LGS): PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: LGS: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING ANTIEPILEPTIC MEDICATIONS: RUFINAMIDE, FELBAMATE, CLOBAZAM, TOPIRAMATE, LAMOTRIGINE, CLONAZEPAM.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FENTANYL CITRATE TIRF (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FENTANYL CITRATE	ACTIQ, FENTORA, FENTANYL CITRATE	01747		GPI-10 (6510002510)	ROUTE = BUCCAL

These are TIRF-Like drugs requiring a payment determination for "Part D" or "Non-Part D".

PAYMENT DETERMINATION CRITERIA

1. Does the patient have a diagnosis of cancer-related pain (ICD-10 G89.3) and meet **ONE** of the following criteria?
   - The request is for Actiq (fentanyl citrate) AND the patient is 16 years of age or older
   - The request is for Fentora (fentanyl citrate) AND the patient is 18 years of age or older

   If yes, **set MCARE_DRUG_DETERM_OVR to 'Y' and approve for 12 months by GPID or GPI-14 for all strengths. Document in the PA comments: Part D Determination Override and diagnosis.**

   If no, **do not enter an MCARE override. Then, process as follows:**
   CSR Note:
   - If the caller is a physician, member, and/or AOR, please initiate a verbal PA intake request in MR3.
   - If the caller is a pharmacy, please advise the pharmacy to contact the provider or member to pursue a payment determination and document the diagnosis provided in MedAccess.

   Please follow the clinical authorization process within the HQ notes.

   RPH Note:
   - Review for both FDA and Part D compendial supported off-label indications.
   - If the provided diagnosis is not FDA approved or compendial supported off-label use, **set MCARE_DRUG_DETERM_OVR to 'N' and enter override within the denied PA for 12 months by GPID or GPI-14.**
   - If the diagnosis is UNKNOWN do not enter an MCARE override; follow the criteria for any additional UM and decision the case accordingly. Provide the following PAC instruction: '**PAC: do not enter an MCARE override**.'

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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FENTANYL CITRATE TIRF (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of cancer-related pain (ICD-10 G89.3) and meet **ALL** of the following criteria?
   - The patient is on a maintenance dose of controlled-release opioid pain medication (e.g., MS Contin [morphine extended release], Oxycontin [oxycodone extended release], Duragesic [fentanyl patch])
   - The patient has difficulty swallowing tablets/capsules OR the patient had a trial of or contraindication to at least one immediate-release oral opioid pain agent (e.g., morphine sulfate immediate-release [MSIR], oxycodone/aspirin, oxycodone/acetaminophen, codeine/acetaminophen, hydromorphone, meperidine)

   If yes, continue to #2.
   If no, do not approve.
   - **If not a Part D indication: Set MCARE_DRUG_DETERM_OVR to 'N' and enter override within the denied PA for 12 months by GPID or GPI-14.**
   - **If indication is Part D, but other criteria not met: Set MCARE_DRUG_DETERM_OVR to 'Y' and enter override within the partially denied PA for 12 months by GPID or GPI-14.**

   DENIAL TEXT: See denial text at the end of the guideline.

2. Is the request for Actiq (fentanyl citrate) **AND** the patient is 16 years of age or older?

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths. (NOTE: If the claim rejects for payment determination after analyzing, then follow the above TIRF-Like determination criteria).**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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FENTANYL CITRATE TIRF (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Is the request for Fentora (fentanyl citrate) **AND** the patient is 18 years of age or older?

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths. (NOTE: If the claim rejects for payment determination after analyzing, then follow the above TIRF-Like determination criteria).**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   - **If not a Part D indication: Set MCARE_DRUG_DETERM_OVR to 'N' and enter override within the denied PA for 12 months by GPID or GPI-14.**
   - **If indication is Part D, but other criteria not met: Set MCARE_DRUG_DETERM_OVR to 'Y' and enter override within the partially denied PA for 12 months by GPID or GPI-14.**

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FENTANYL CITRATE (Actiq, Fentora)** requires the following rule(s) be met for approval:
   A. You have cancer-related pain
   B. You are on a maintenance dose of controlled-release opioid pain medication (such as MS Contin [morphine extended release], Oxycontin [oxycodone extended release], Duragesic [fentanyl patch])
   C. You have difficulty swallowing tablets/capsules OR you have tried or have a contraindication to (harmful for you to use) at least one immediate-release oral opioid pain agent (such as morphine sulfate immediate-release [MSIR], oxycodone/aspirin, oxycodone/acetaminophen, codeine/acetaminophen, hydromorphone, meperidine)
   D. If you are requesting Actiq (fentanyl citrate), approval also requires:
      1. You are 16 years of age or older
   E. If you are requesting Fentora (fentanyl citrate), approval also requires:
      1. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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FENTANYL CITRATE TIRF (PART D)

RATIONALE

Prior authorization on these drugs is required due to a high potential for non-Part D use. These drugs should NOT be used for non-medically accepted indications as defined in section 1860D-2(e)(4) of the Act. For further information, please refer to the Prescribing Information and/or Drug Monograph for fentanyl citrate, Actiq, and Fentora.

REFERENCES

Actiq [Prescribing Information]. Frazer, PA: Cephalon, Inc.; December 2023.
Fentora [Prescribing Information]. North Wales, PA: Cephalon; December 2023.
Announcement of Calendar Year (CY) 2015 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. April 7, 2014. Section III – Part D: Appropriate Utilization of Prior Authorization Requirements to Determine Part D Drug Status. Page 112 – 114.

For Part D use only:

FENTANYL CITRATE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	CANCER RELATED PAIN: 1) CURRENTLY ON A MAINTENANCE DOSE OF CONTROLLED-RELEASE OPIOID PAIN MEDICATION, AND 2) TRIAL OF OR CONTRAINDICATION TO AT LEAST ONE IMMEDIATE-RELEASE ORAL OPIOID PAIN AGENT OR PATIENT HAS DIFFICULTY SWALLOWING TABLETS/CAPSULES.

Core	Advantage	Plus
Yes	Yes	Yes

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FENTANYL NASAL SPRAY TIRF (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FENTANYL CITRATE	LAZANDA		27648 29146	GPI-14 (65100025102050, 65100025102060)	

These are TIRF-Like drugs requiring a payment determination for 'Part D' or 'Non-Part D'.

PAYMENT DETERMINATION CRITERIA

1. Does the patient have a diagnosis of cancer-related pain (ICD-10 G89.3) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **set MCARE_DRUG_DETERM_OVR to 'Y' and approve for 12 months for all strengths by GPID or GPI-14. Document in the PA comments: Part D Determination Override and diagnosis.**

   If no, **do not enter an MCARE override. Then, process as follows:**
   CSR Note:
   - If the caller is a physician, member, and/or AOR, please initiate a verbal PA intake request in MR3.
   - If the caller is a pharmacy, please advise the pharmacy to contact the provider or member to pursue a payment determination and document diagnosis provided in MedAccess**.**

   Please follow the clinical authorization process within the HQ notes.

   RPH Note:
   - Review for both FDA and Part D compendial supported off-label indications.
   - If the provided diagnosis is not FDA approved or compendial supported off-label use, **set MCARE_DRUG_DETERM_OVR to 'N' and enter override within the denied PA for 12 months by GPID or GPI-14.**
   - If the diagnosis is UNKNOWN do not enter an MCARE override; follow the criteria for any additional UM and decision the case accordingly. Provide the following PAC instruction**:** '**PAC: do not enter an MCARE override**.'

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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FENTANYL NASAL SPRAY TIRF (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of cancer-related pain (ICD-10 G89.3) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is on a maintenance dose of controlled-release opioid pain medication (e.g., MS Contin [morphine extended release], Oxycontin [oxycodone extended release], Duragesic [fentanyl patch])
   - The patient has difficulty swallowing tablets/capsules OR the patient had a trial of or contraindication to one immediate-release oral opioid pain agent (e.g., morphine sulfate immediate-release [MSIR], oxycodone/aspirin, oxycodone/acetaminophen, codeine/acetaminophen, hydromorphone, meperidine)
   - The patient had a trial of or contraindication to generic fentanyl citrate lozenge

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths. Note: If the claim rejects for payment determination after analyzing, then follow the above TIRF-Like determination criteria.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   - **If not a Part D indication: Set MCARE_DRUG_DETERM_OVR to 'N' and enter override within the denied PA for 12 months by GPID or GPI-14.**
   - **If indication is Part D, but other criteria not met: Set MCARE_DRUG_DETERM_OVR to 'Y' and enter override within the partially denied PA for 12 months by GPID or GPI-14.**

   DENIAL TEXT: See the denial text at the end of the guideline.

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FENTANYL NASAL SPRAY TIRF (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FENTANYL NASAL SPRAY (Lazanda)** requires the following rule(s) be met for approval:

A. You have cancer-related pain
B. You are 18 years of age or older
C. You are on a maintenance dose of controlled-release opioid pain medication (such as MS Contin [morphine extended release], Oxycontin [oxycodone extended release], Duragesic [fentanyl patch])
D. You have difficulty swallowing tablets/capsules OR have tried or have a contraindication to (harmful for you to use) one immediate-release oral opiod pain agent (such as morphine sulfate immediate-release [MSIR], oxycodone/aspirin, oxycodone/acetaminophen, codeine/acetaminophen, hydromorphone, meperidine)
E. You have tried or have a contraindication to generic fentanyl citrate lozenge

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

Prior authorization on Lazanda is required due to a high potential for non-Part D use. Lazanda should NOT be used for non-medically accepted indications as defined in section 1860D-2(e)(4) of the Act. For further information, please refer to the Prescribing Information and/or Drug Monograph for Lazanda.

REFERENCES

Lazanda [Prescribing Information]. Northbrook, IL: West Therapeutic Development, LLC; March 2021.

Announcement of Calendar Year (CY) 2015 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. April 7, 2014. Section III – Part D: Appropriate Utilization of Prior Authorization Requirements to Determine Part D Drug Status. Page 112 – 114.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FENTANYL NASAL SPRAY TIRF (PART D)

For Part D use only:

FENTANYL NASAL SPRAY (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	CANCER RELATED PAIN: 1) CURRENTLY ON A MAINTENANCE DOSE OF CONTROLLED-RELEASE OPIOID PAIN MEDICATION, 2) TRIAL OF OR CONTRAINDICATION TO ONE IMMEDIATE-RELEASE ORAL OPIOID PAIN AGENT OR PATIENT HAS DIFFICULTY SWALLOWING TABLETS/CAPSULES, AND 3) TRIAL OF OR CONTRAINDICATION TO GENERIC FENTANYL CITRATE LOZENGE.

Core	Advantage	Plus
Yes	Yes	Yes

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FENTANYL SUBLINGUAL SPRAY TIRF (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FENTANYL	SUBSYS	06438		GPI-12 (651000250009)	ROUTE = SUBLINGUAL

These are TIRF-Like drugs requiring a payment determination for "Part D" or "Non-Part D".

PAYMENT DETERMINATION CRITERIA

1. Does the patient have a diagnosis of cancer-related pain (ICD-10 G89.3) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **set MCARE_DRUG_DETERM_OVR to 'Y' and approve for 12 months by GPID or GPI-12 for all strengths. Document in the PA comments: Part D Determination Override and diagnosis.**

   If no, **do not enter an MCARE override. Then, process as follows:**
   CSR Note:
   - If the caller is a physician, member, and/or AOR, please initiate a verbal PA intake request in MR3.
   - If the caller is a pharmacy, please advise the pharmacy to contact the provider or member to pursue a payment determination and document diagnosis provided in MedAccess.

   Please follow the clinical authorization process within the HQ notes.

   RPH Note:
   - Review for both FDA and Part D compendial supported off-label indications.
   - If the provided diagnosis is not FDA approved or compendial supported off-label use, **set MCARE_DRUG_DETERM_OVR to 'N' and enter override within the denied PA for 12 months by GPID or GPI-12.**
   - If the diagnosis is UNKNOWN do not enter an MCARE override; follow the criteria for any additional UM and decision the case accordingly. Provide the following PAC instruction**:** '**PAC: do not enter an MCARE override**.'

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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FENTANYL SUBLINGUAL SPRAY TIRF (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of cancer-related pain (ICD-10 G89.3) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is on a maintenance dose of controlled-release opioid pain medication (e.g., MS Contin [morphine extended release], Oxycontin [oxycodone extended release], Duragesic [fentanyl patch])
   - The patient has difficulty swallowing tablets/capsules OR the patient had a trial of or contraindication to one immediate-release oral opioid pain agent (e.g., morphine sulfate immediate-release [MSIR], oxycodone/aspirin, oxycodone/acetaminophen, codeine/acetaminophen, hydromorphone, meperidine)
   - The patient had a trial of or contraindication to generic fentanyl citrate lozenge

   If yes, **approve for 12 months by GPID or GPI-12 for all strengths. (NOTE: If the claim rejects for payment determination after analyzing, then follow the above TIRF-Like determination criteria.)**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   - **If not a Part D indication: Set MCARE_DRUG_DETERM_OVR to 'N' and enter override within the denied PA for 12 months by GPID or GPI-12.**
   - **If indication is Part D, but other criteria not met: Set MCARE_DRUG_DETERM_OVR to 'Y' and enter override within the partially denied PA for 12 months by GPID or GPI-12.**

   DENIAL TEXT: See the denial text at the end of the guideline.

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FENTANYL SUBLINGUAL SPRAY TIRF (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FENTANYL SUBLINGUAL SPRAY (Subsys)** requires the following rule(s) be met for approval:

A. You have cancer-related pain
B. You are 18 years of age or older
C. You are on a maintenance dose of controlled-release opioid pain medication (such as MS Contin [morphine extended release], Oxycontin [oxycodone extended release], Duragesic [fentanyl patch])
D. You have difficulty swallowing tablets/capsules OR have tried or have a contraindication to (harmful for you to use) one immediate-release oral opiold pain agent (such as morphine sulfate immediate-release [MSIR], oxycodone/aspirin, oxycodone/acetaminophen, codeine/acetaminophen, hydromorphone, meperidine)
E. You have tried or have a contraindication to generic fentanyl citrate lozenge

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

Prior authorization on Subsys is required due to a high potential for non-Part D use. Subsys should NOT be used for non-medically accepted indications as defined in section 1860D-2(e)(4) of the Act. For further information, please refer to the Prescribing Information and/or Drug Monograph for Subsys.

REFERENCES

Subsys [Prescribing Information]. Lakewood, NJ: Insys Therapeutics; March 2021.
Announcement of Calendar Year (CY) 2015 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. April 7, 2014. Section III – Part D: Appropriate Utilization of Prior Authorization Requirements to Determine Part D Drug Status. Page 112 – 114.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FENTANYL SUBLINGUAL SPRAY TIRF (PART D)

For Part D use only:

FENTANYL SUBLINGUAL SPRAY (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	CANCER RELATED PAIN: 1) CURRENTLY ON A MAINTENANCE DOSE OF CONTROLLED-RELEASE OPIOID PAIN MEDICATION, 2) TRIAL OF OR CONTRAINDICATION TO ONE IMMEDIATE-RELEASE ORAL OPIOID PAIN AGENT OR PATIENT HAS DIFFICULTY SWALLOWING TABLETS/CAPSULES, AND 3) TRIAL OF OR CONTRAINDICATION TO GENERIC FENTANYL CITRATE LOZENGE.

Core	Advantage	Plus
Yes	Yes	Yes

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Effective: 05/17/25 Client Approval: 05/25 P&T Approval: 11/16

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FERRIC CITRATE DvE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FERRIC CITRATE	AURYXIA, FERRIC CITRATE	41378		GPI-10 (5280003010)	

This is a DvE drug requiring a payment determination for "Part D" or "Non-Part D."

PAYMENT DETERMINATION CRITERIA

1. Does the patient have a diagnosis of end stage renal disease (ESRD) and is on dialysis (ICD-10 N18.6)?

   If yes, **do NOT approve under Part D. Finalize as follows:**

   PAC NOTE: Please defer to a pharmacist for denial.

   CLINICAL SPECIALIST NOTE: This medication is included in the bundled dialysis facility payment which is paid under Medicare Part B and is not a Part D eligible drug. Please follow your internal procedures for denial.

   If no, continue to #2.

2. Is the requested medication for the treatment of iron deficiency anemia?

   If yes, **set CMS_DVE_OVR to 'E' and approve for 12 months by HICL or GPI-10. Document in the PA comments: Payment Determination Override. This is not a Part D indication.**

   If no, **set CMS_DVE_OVR to 'D' and approve for 12 months by HICL or GPI-10. Document in the PA comments: Part D Determination Override.** (**NOTE:** If the ESRD_Dialysis attribute is present, select the 'ESRD' Override Type within the PA, which is available in the 'Additional Overrides' section.)

   NOTE: If the claim rejects after analyzing, then follow the clinical authorization process within the HQ notes.

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FERRIC CITRATE DvE (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FERRIC CITRATE (Auryxia)** requires the following rule(s) be met for approval:

A. You do not have end stage renal disease (ESRD: a type of kidney disease) and are not on dialysis (process of removing excess water, toxins from the blood)
B. The requested medication is NOT used for the treatment of iron deficiency anemia (a type of blood condition)

RATIONALE

To limit the coverage of Auryxia to the Medicare Part D covered indication. Hyperphosphatemia in patients with chronic kidney disease (CKD) on dialysis and iron deficiency anemia in patients with CKD not on dialysis are excluded from Part D coverage. For further information, please refer to the Prescribing Information and/or Drug Monograph for Auryxia.

REFERENCES

Auryxia [Prescribing Information]. Cambridge, MA: Keryx Biopharmaceuticals, Inc.; January 2024.
Centers for Medicare & Medicaid Services (CMS) Part D Including Oral-Only Drugs in the ESRD PPS Bundled. https://www.cms.gov/files/document/including-oral-only-drugs-esrd-pps-bundled-payment.pdf
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements. Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf. [Accessed March 2026].

For Part D use only:

FERRIC CITRATE (PART D)	
Covered Uses	ALL MEDICALLY-ACCEPTED INDICATIONS.
Exclusion Criteria	PART D DOES NOT COVER THIS DRUG WHEN USED FOR IRON DEFICIENCY ANEMIA OR HYPERPHOSPHATEMIA IN CHRONIC KIDNEY DISEASE ON DIALYSIS.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 12/18
Effective: 03/09/26 Client Approval: 03/26 P&T Approval: 10/18

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FEZOLINETANT (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FEZOLINETANT	VEOZAH	48921		GPI-10 (3060603000)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe menopausal vasomotor symptoms (VMS) (ICD-10 N95.1) and meet **ALL** of the following criteria?
   - The patient had a trial of or contraindication to hormonal therapy (e.g., estradiol transdermal patch [Minivelle, Climara], oral conjugated estrogens [Premarin])
   - The patient has undergone laboratory testing to establish baseline hepatic function, and these values will continue to be monitored in accordance with the FDA's current label recommendation
   - Veozah will NOT be used concurrently with another hormonal (e.g., Prempro [conjugated estrogen/medroxyprogesterone]) or non-hormonal (e.g., Brisdelle [paroxetine]) agent for VMS

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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FEZOLINETANT (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FEZOLINETANT (Veozah)** requires the following rule(s) be met for approval:

A. You have moderate to severe menopausal vasomotor symptoms (VMS: a type of symptom related to menopause)
B. You have tried or have a contraindication to (harmful for you to use) hormonal therapy (such as estradiol transdermal patch [Minivelle, Climara], oral conjugated estrogens [such as Premarin])
C. You have had laboratory testing to establish baseline hepatic (liver) function, and these values will continue to be monitored as recommended in the Food and Drug Administration's (FDA's) current label
D. Veozah will NOT be used concurrently (at the same time) with another hormonal (such as Prempro [conjugated estrogen/medroxyprogesterone]) or non-hormonal (such as Brisdelle [paroxetine]) medication for VMS

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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FEZOLINETANT (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe menopausal vasomotor symptoms (VMS) (ICD-10 N95.1) and meet **ALL** of the following criteria?
   - The patient has a continued need for VMS treatment (persistently symptomatic with hot flashes)
   - The patient has had a reduction in VMS frequency OR severity due to Veozah treatment
   - The patient has not experienced new symptoms of liver injury and/or worsening lab values (e.g., ALT, AST, total bilirubin)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FEZOLINETANT (Veozah)** requires the following rule(s) be met for renewal:
   A. You have moderate to severe menopausal vasomotor symptoms (VMS: a type of symptom related to menopause)
   B. You have a continued need for VMS treatment (still experiencing persistent hot flashes)
   C. You have had a reduction in VMS frequency OR severity due to Veozah treatment
   D. You have not had new symptoms of liver injury and/or worsening lab values (such as alanine transaminase [ALT: a type of liver enzyme test], aspartate transaminase [AST: a type of liver enzyme test], total bilirubin [a type of liver function test])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Veozah.

REFERENCES
Veozah [Prescribing Information]. Northbrook, IL: Astellas Pharma US, Inc.; December 2024.

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FEZOLINETANT (PART D)

For Part D use only:

FEZOLINETANT (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS
Other Criteria	MENOPAUSAL VASOMOTOR SYMPTOMS (VMS): INITIAL: 1) TRIAL OF OR CONTRAINDICATION TO HORMONAL THERAPY (E.G., ESTRADIOL TRANSDERMAL PATCH, ORAL CONJUGATED ESTROGENS), 2) LABORATORY TESTING TO ESTABLISH BASELINE HEPATIC FUNCTION AND CONTINUED MONITORING OF THESE VALUES IN ACCORDANCE WITH THE FDA CURRENT LABEL RECOMMENDATION, AND 3) NO CONCURRENT USE WITH ANOTHER HORMONAL (E.G., PREMPRO) OR NON-HORMONAL (E.G., BRISDELLE) AGENT FOR VMS. RENEWAL: 1) CONTINUED NEED FOR VMS TREATMENT (PERSISTENT HOT FLASHES), 2) REDUCTION IN VMS FREQUENCY OR SEVERITY DUE TO VEOZAH TREATMENT, AND 3) NO NEW SYMPTOMS OF LIVER INJURY AND/OR WORSENING LAB VALUES (E.G., ALT, AST, TOTAL BILIRUBIN).

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Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 04/25

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FILGRASTIM (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FILGRASTIM	NEUPOGEN	06070		GPI-10 (8240152000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the patient receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever and meet **ALL** of the following criteria?
   - The patient has a non-myeloid malignancy
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred agent: Nivestym (filgrastim-aafi)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no continue to #2.

2. Has the patient undergone or is undergoing induction or consolidation chemotherapy treatment for acute myeloid leukemia (AML) (ICD-10 Group C92.0) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred agent: Nivestym (filgrastim-aafi)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no continue to #3.

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FILGRASTIM (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Is the patient undergoing myeloablative chemotherapy followed by bone marrow transplantation and meet **ALL** of the following criteria?
   - The patient has a non-myeloid malignancy
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred agent: Nivestym (filgrastim-aafi)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no continue to #4.

4. Is the patient undergoing autologous peripheral blood progenitor cell collection and therapy and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred agent: Nivestym (filgrastim-aafi)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no continue to #5.

5. Does the patient have a diagnosis of congenital neutropenia (ICD-10 D70.0), cyclic neutropenia (ICD-10 D70.4), or idiopathic neutropenia (ICD-10 D70.9), and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred agent: Nivestym (filgrastim-aafi)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no continue to #6.

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FILGRASTIM (PART D)

GUIDELINES FOR USE (CONTINUED)

6. Is the patient acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [H-ARS]) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FILGRASTIM (Neupogen)** requires the following rule(s) be met for approval:

   A. You meet ONE of the following:
      1. You are receiving myelosuppressive anti-cancer drugs (drugs that decrease bone marrow activity) associated with a significant incidence of severe neutropenia (a type of blood condition) with fever
      2. You have undergone or are undergoing induction or consolidation chemotherapy treatment (you are starting cancer treatment or receiving treatment following initial therapy) for acute myeloid leukemia (AML: type of blood cancer)
      3. You undergoing myeloablative chemotherapy (high-dose drugs used to treat cancer) followed by bone marrow transplantation (procedure to get healthy blood-forming cells)
      4. You are undergoing autologous peripheral blood progenitor cell collection and therapy (a type of blood cell is stimulated to be collected by a process where it is separated from the blood)
      5. You have congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia (low levels of a type of white blood cell at birth, in cycles, or due to unknown causes)
      6. You are acutely exposed to myelosuppressive doses (doses that decrease bone marrow activity) of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [H-ARS]: an illness that happens after whole body radiation)

   B. If you are receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever, approval also requires:
      1. You have a non-myeloid malignancy (cancer not affecting bone marrow)
      2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
      3. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Nivestym (filgrastim-aafi)

   (Denial text continued on next page)

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FILGRASTIM (PART D)

GUIDELINES FOR USE (CONTINUED)

C. If you have undergone or are undergoing induction or consolidation chemotherapy treatment for acute myeloid leukemia, approval also requires:
1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
2. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Nivestym (filgrastim-aafi)

D. If you are undergoing myeloablative chemotherapy followed by bone marrow transplantation, approval also requires:
1. You have a non-myeloid malignancy (cancer not affecting bone marrow)
2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
3. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Nivestym (filgrastim-aafi)

E. If you are undergoing autologous peripheral blood progenitor cell collection and therapy, approval also requires:
1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
2. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Nivestym (filgrastim-aafi)

F. If you have congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia, approval also requires:
1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
2. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Nivestym (filgrastim-aafi)

G. If you are acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome), approval also requires:
1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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FILGRASTIM (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Neupogen.

REFERENCES
Neupogen [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; April 2023.

For Part D use only:

FILGRASTIM (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR ONCOLOGIST
Coverage Duration	12 MONTHS
Other Criteria	TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT NIVESTYM, WHERE INDICATIONS ALIGN.

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25 Created: 10/19
Commercial Effective: N/A Client Approval: 06/24 P&T Approval: 05/20

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FILGRASTIM-AAFI (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FILGRASTIM-AAFI	NIVESTYM	45154		GPI-10 (8240152010)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the patient receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever and meet **ALL** of the following criteria?
   - The patient has a non-myeloid malignancy
   - Therapy is prescribed by or in consultation with a hematologist or oncologist

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Has the patient undergone or is undergoing induction or consolidation chemotherapy treatment for acute myeloid leukemia (AML) (ICD-10 Group C92.0) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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FILGRASTIM-AAFI (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Is the patient undergoing myeloablative chemotherapy followed by bone marrow transplantation and meet **ALL** of the following criteria?
   - The has a non-myeloid malignancy
   - Therapy is prescribed by or in consultation with a hematologist or oncologist

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

4. Is the patient undergoing autologous peripheral blood progenitor cell collection and therapy **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Does the patient have a diagnosis of congenital neutropenia (ICD-10 D70.0), cyclic neutropenia (ICD-10 D70.4), or idiopathic neutropenia (ICD-10 D70.9) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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FILGRASTIM-AAFI (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FILGRASTIM-AAFI (Nivestym)** requires the following rule(s) be met for approval:

A. You meet ONE of the following:
   1. You are receiving myelosuppressive anti-cancer drugs (drugs that decrease bone marrow activity) associated with a significant incidence of severe neutropenia (a type of blood condition) with fever
   2. You have undergone or are undergoing induction or consolidation chemotherapy treatment (you are starting cancer treatment or receiving treatment following initial therapy) for acute myeloid leukemia (AML: type of blood cancer)
   3. You are undergoing myeloablative chemotherapy (high-dose drugs used to treat cancer) followed by bone marrow transplantation (procedure to get healthy blood-forming cells)
   4. You are undergoing autologous peripheral blood progenitor cell and therapy (a type of blood cell is stimulated to be collected by a process where it is separated from the blood)
   5. You have congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia (low levels of a type of white blood cell at birth, in cycles, or due to unknown causes)

B. If you are receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever, approval also requires:
   1. You have a non-myeloid malignancy (cancer not affecting bone marrow)
   2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)

C. If you have undergone or are undergoing induction or consolidation chemotherapy treatment for acute myeloid leukemia, approval also requires:
   1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)

D. If you are undergoing myeloablative chemotherapy followed by bone marrow transplantation, approval also requires:
   1. You have a non-myeloid malignancy (cancer not affecting bone marrow)
   2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)

E. If you are undergoing autologous peripheral blood progenitor cell collection and therapy, approval also requires:
   1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)

(Denial text continued on next page)

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FILGRASTIM-AAFI (PART D)

GUIDELINES FOR USE (CONTINUED)

F. If you have congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia, approval also requires:
1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Nivestym.

REFERENCES
Nivestym [Prescribing Information]. Lake Forest, IL: Pfizer; February 2024.

For Part D use only:

FILGRASTIM-AAFI (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR ONCOLOGIST.
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 06/22
Client Approval: 06/24
P&T Approval: 05/20

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FILGRASTIM-AYOW (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FILGRASTIM-AYOW	RELEUKO	47848		GPI-10 (8240152015)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the patient receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever and meet **ALL** of the following criteria?
   - The patient has a nonmyeloid malignancy
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred agent: Nivestym (filgrastim-aafi)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Has the patient undergone oris undergoing induction or consolidation chemotherapy treatment for acute myeloid leukemia (AML) (ICD-10 Group C92.0) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred agent: Nivestym (filgrastim-aafi)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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FILGRASTIM-AYOW (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Is the patient undergoing myeloablative chemotherapy followed by bone marrow transplantation and meet **ALL** of the following criteria?
   - The patient has a nonmyeloid malignancy
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred agent: Nivestym (filgrastim-aafi)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

4. Does the patient have a diagnosis of congenital neutropenia (ICD-10 D70.0), cyclic neutropenia (ICD-10 D70.4), or idiopathic neutropenia (ICD-10 D70.9), and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred agent: Nivestym (filgrastim-aafi)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FILGRASTIM-AYOW (Releuko)** requires the following rule(s) be met for approval:
   A. You meet ONE of the following:
      1. You are receiving myelosuppressive anti-cancer drugs (drugs that decrease bone marrow activity) associated with a significant incidence of severe neutropenia (a type of blood condition) with fever
      2. You have undergone or are undergoing induction or consolidation chemotherapy treatment (you are starting cancer treatment or receiving treatment following initial therapy) for acute myeloid leukemia (AML: a type of blood cancer)
      3. You are undergoing myeloablative chemotherapy (high-dose drugs used to treat cancer) followed by bone marrow transplantation (procedure to get healthy blood-forming cells)
      4. You have congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia (low levels of a type of white blood cell at birth, in cycles, or due to unknown cause)

   (Denial text continued on next page)

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FILGRASTIM-AYOW (PART D)

GUIDELINES FOR USE (CONTINUED)

B. If you are receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever, approval also requires:
1. You have a nonmyeloid malignancy (cancer not affecting bone marrow)
2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
3. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Nivestym (filgrastim-aafi)

C. If you have undergone or are undergoing induction or consolidation chemotherapy treatment for acute myeloid leukemia, approval also requires:
1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
2. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Nivestym (filgrastim-aafi)

D. If you are undergoing myeloablative chemotherapy followed by bone marrow transplantation, approval also requires:
1. You have a nonmyeloid malignancy (cancer not affecting bone marrow)
2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
3. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Nivestym (filgrastim-aafi)

E. If you are congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia, approval also requires:
1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
2. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Nivestym (filgrastim-aafi)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Releuko.

REFERENCES

Releuko [Prescribing Information]. Piscataway, NJ: Kashiv BioSciences, LLC; September 2023.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FILGRASTIM-AYOW (PART D)

For Part D use only:

FILGRASTIM-AYOW (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR ONCOLOGIST.
Coverage Duration	12 MONTHS
Other Criteria	TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT NIVESTYM, WHERE INDICATIONS ALIGN.

Created: 04/22
Effective: 01/01/26 Client Approval: 01/26 P&T Approval: 04/22

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FILGRASTIM-SNDZ (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FILGRASTIM-SNDZ	ZARXIO	41814		GPI-10 (8240152060)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

************Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the patient receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever and meets **ALL** of the following criteria?
   - The patient has a non-myeloid malignancy
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred agent: Nivestym (filgrastim-aafi)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Has the patient undergone oris undergoing induction or consolidation chemotherapy treatment for acute myeloid leukemia (AML) (ICD-10 Group C92.0) and meets **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred agent: Nivestym (filgrastim-aafi)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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FILGRASTIM-SNDZ (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Is the patient undergoing myeloablative chemotherapy followed by bone marrow transplantation and meets **ALL** of the following criteria?
   - The patient has a non-myeloid malignancy
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred agent: Nivestym (filgrastim-aafi)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

4. Is the patient undergoing autologous peripheral blood progenitor cell collection and therapy and meets **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred agent: Nivestym (filgrastim-aafi)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Does the patient have a diagnosis of congenital neutropenia (ICD-10 D70.0), cyclic neutropenia (ICD-10 D70.4), or idiopathic neutropenia (ICD-10 D70.9), and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred agent: Nivestym

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See denial text at the end of the guideline.

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FILGRASTIM-SNDZ (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FILGRASTIM-SNDZ (Zarxio)** requires the following rule(s) be met for approval:

A. You meet ONE of the following:
   1. You are receiving myelosuppressive anti-cancer drugs (drugs that decrease bone marrow activity) associated with a significant incidence of severe neutropenia (a type of blood condition) with fever
   2. You have undergone or are undergoing induction or consolidation chemotherapy (starting cancer treatment or receiving treatment following initial therapy) for acute myeloid leukemia (AML: a type of blood cancer)
   3. You are undergoing myeloablative chemotherapy (high-dose drugs used to treat cancer) followed by bone marrow transplantation (procedure to get healthy blood-forming cells)
   4. You are undergoing autologous peripheral blood progenitor cell collection and therapy (a type of blood cell is stimulated to be collected by a process where it is separated from the blood)
   5. You have congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia (low levels of a type of white blood cell at birth, in cycles, or due to unknown cause)

B. If you are receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever, approval also requires:
   1. You have a non-myeloid malignancy (cancer not affecting bone marrow)
   2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
   3. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Nivestym (filgrastim-aafi)

C. If you have undergone or are undergoing induction or consolidation chemotherapy treatment for acute myeloid leukemia, approval also requires:
   1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
   2. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Nivestym (filgrastim-aafi)

D. If you are undergoing myeloablative chemotherapy followed by bone marrow transplantation, approval also requires:
   1. You have a non-myeloid malignancy (cancer not affecting bone marrow)
   2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
   3. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Nivestym (filgrastim-aafi)

(Denial text continued on next page)

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FILGRASTIM-SNDZ (PART D)

GUIDELINES FOR USE (CONTINUED)

E. If you are undergoing autologous peripheral blood progenitor cell collection and therapy, approval also requires:
1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
2. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Nivestym (filgrastim-aafi)

F. If you have congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia, approval also requires:
1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
2. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Nivestym (filgrastim-aafi)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Zarxio.

REFERENCES
Zarxio [Prescribing Information]. Princeton, NJ: Sandoz Inc.; January 2024.

For Part D use only:

FILGRASTIM-SNDZ (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR ONCOLOGIST.
Coverage Duration	12 MONTHS
Other Criteria	TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT NIVESTYM, WHERE INDICATIONS ALIGN.

Created: 09/22
Effective: 01/01/26 Client Approval: 01/26 P&T Approval: 05/20

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FILGRASTIM-TXID (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FILGRASTIM-TXID	NYPOZI	49813		GPI-10 (8240152075)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the patient receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever and meet **ALL** of the following criteria?
   - The patient has a non-myeloid malignancy
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred medication: Nivestym (filgrastim-aafi)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Has the patient undergone oris undergoing induction or consolidation chemotherapy treatment for acute myeloid leukemia (AML) (ICD-10 Group C92.0) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred medication: Nivestym (filgrastim-aafi)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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FILGRASTIM-TXID (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Is the patient undergoing myeloablative chemotherapy followed by bone marrow transplantation and meet **ALL** of the following criteria?
   - The patient has a non-myeloid malignancy
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred medication: Nivestym (filgrastim-aafi)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

4. Is the patient undergoing autologous peripheral blood progenitor cell collection and therapy and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred medication: Nivestym (filgrastim-aafi)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Does the patient have a diagnosis of congenital neutropenia (ICD-10 D70.0), cyclic neutropenia (ICD-10 D70.4), or idiopathic neutropenia (ICD-10 D70.9), and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred medication: Nivestym (filgrastim-aafi)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #6.

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FILGRASTIM-TXID (PART D)

GUIDELINES FOR USE (CONTINUED)

6. Has the patient been acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [H-ARS]) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FILGRASTIM-TXID (Nypozi)** requires the following rule(s) be met for approval:

   A. You meet ONE of the following:
      1. You are receiving myelosuppressive anti-cancer medications (medications that decrease bone marrow activity) associated with a significant incidence of severe neutropenia (a type of blood condition) with fever, and you have non-myeloid malignancy (cancer not affecting the bone marrow), and you have tried or have a contraindication to (harmful for you to use) the preferred medication: Nivestym (filgrastim-aafi)
      2. You have undergone or are undergoing induction or consolidation chemotherapy treatment (you are starting cancer treatment or receiving treatment following initial therapy) for acute myeloid leukemia (AML: a type of blood cancer), and you have tried or have a contraindication to (harmful for you to use) the preferred medication: Nivestym (filgrastim-aafi)
      3. You are undergoing myeloablative chemotherapy (high-dose medications used to treat cancer) followed by bone marrow transplantation (procedure to get healthy blood-forming cells), and you have non-myeloid malignancy (cancer not affecting the bone marrow), and you have tried or have a contraindication to (harmful for you to use) the preferred medication: Nivestym (filgrastim-aafi)
      4. You are undergoing autologous peripheral blood progenitor cell collection and therapy (a type of blood cancer treatment), and you have tried or have a contraindication to (harmful for you to use) the preferred medication: Nivestym (filgrastim-aafi)

   (Denial text continued on next page)

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FILGRASTIM-TXID (PART D)

GUIDELINES FOR USE (CONTINUED)

5. You have congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia (low levels of a type of white blood cell at birth, in cycles, or due to unknown causes), and you have tried or have a contraindication to (harmful for you to use) the preferred medication: Nivestym (filgrastim-aafi)
6. You have been acutely exposed to myelosuppressive doses (doses that decrease bone marrow activity) of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome[H-ARS]: an illness that happens after whole body radiation)

B. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nypozi.

REFERENCES

Nypozi [Prescribing Information]. San Diego, CA: Tanvex BioPharma USA, Inc.; December 2024.

For Part D use only:

	FILGRASTIM-TXID (PART D)
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR ONCOLOGIST.
Coverage Duration	12 MONTHS
Other Criteria	TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT NIVESTYM, WHERE INDICATIONS ALIGN.

Created: 12/24
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 01/25

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FINASTERIDE-TADALAFIL (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FINASTERIDE/ TADALAFIL	ENTADFI	47719		GPI-10 (5685990230)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the request for a male patient with a diagnosis of benign prostatic hyperplasia (BPH) (ICD-10 Group N40) who meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to ONE 5-alpha-reductase inhibitor (e.g., finasteride, dutasteride)
   - The patient had a trial of or contraindication to tadalafil 2.5 mg or tadalafil 5 mg

   If yes, **approve for 26 weeks by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FINASTERIDE-TADALAFIL (Entadfi)** requires the following rule(s) be met for approval:
   A. You are male and have benign prostatic hyperplasia (BPH: a type of prostate condition)
   B. You are 18 years of age or older
   C. You have tried or have a contraindication to (harmful for you to use) ONE 5-alpha-reductase inhibitor (such as finasteride, dutasteride)
   D. You have tried or have a contraindication to (harmful for you to use) tadalafil 2.5 mg or tadalafil 5 mg

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FINASTERIDE-TADALAFIL (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Entadfi.

REFERENCES
Entadfi [Prescribing Information]. Miami, FL: Veru, Inc.; December 2021.

For Part D use only:

FINASTERIDE/TADALAFIL (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	BENIGN PROSTATIC HYPERPLASIA (BPH): 18 YEARS OF AGE OR OLDER
Prescriber Restrictions	N/A
Coverage Duration	26 WEEKS
Other Criteria	BPH: 1) TRIAL OF OR CONTRAINDICATION TO ONE 5-ALPHA-REDUCTASE INHIBITOR, AND 2) TRIAL OF OR CONTRAINDICATION TO TADALAFIL 2.5MG OR TADALAFIL 5MG.

Core	Advantage	Plus
No	No	Yes

Created: 08/22
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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FINERENONE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FINERENONE	KERENDIA	47487		GPI-10 (3035403000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of chronic kidney disease (CKD) associated with type 2 diabetes (T2D) (ICD-10 Group E11.2) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a history of and will continue on, a contraindication, or intolerance to an angiotensin converting enzyme inhibitor (ACE-I; e.g., benazepril, lisinopril) or an angiotensin receptor blocker (ARB; e.g., losartan, valsartan)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

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FINERENONE (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of heart failure (ICD-10 Group I50) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a cardiologist
   - The patient has New York Heart Association (NYHA) Class II-IV
   - The patient has a left ventricular ejection fraction (LVEF) of at least 40% that is not due to an underlying cause (e.g., infiltrative cardiomyopathy, hypertrophic cardiomyopathy, valvular disease, pericardial disease, or high-output heart failure)
   - Kerendia will NOT be used concurrently with another mineralocorticoid (aldosterone) receptor antagonist (MRA) (e.g., spironolactone, eplerenone)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FINERENONE (Kerendia)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Chronic kidney disease (CKD: long-term kidney disease) associated with type 2 diabetes (a disorder with high blood sugar)
      2. Heart failure (a type of heart condition)

   B. If you have chronic kidney disease associated with type 2 diabetes, approval also requires:
      1. You are 18 years of age or older
      2. You have a history of and will continue to use, or you have a contraindication (harmful for you to use) or intolerance to (side effect) an angiotensin converting enzyme inhibitor (ACE-I, such as benazepril, lisinopril) or an angiotensin receptor blocker (ARB, such as losartan, valsartan)

   (Initial denial text continued on next page)

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FINERENONE (PART D)

INITIAL CRITERIA (CONTINUED)

C. If you have heart failure, approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor)
3. You have New York Heart Association (NYHA) Class II-IV (a way to classify the severity of heart failure symptoms)
4. You have a left ventricular ejection fraction (LVEF: evaluates heart function) of at least 40% that is not due to an underlying cause (such as infiltrative cardiomyopathy [a type of heart condition], hypertrophic cardiomyopathy [a type of heart condition], valvular disease [a type of heart condition], pericardial disease [a type of heart condition], or high-output heart failure [a type of heart condition])
5. You will NOT use Kerendia concurrently (at the same time) with another mineralocorticoid (aldosterone) receptor antagonist (MRA) (such as spironolactone, eplerenone)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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FINERENONE (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of chronic kidney disease (CKD) associated with type 2 diabetes (T2D) (ICD-10 Group E11.2)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.
   If no, continue to #2.

2. Does the patient have a diagnosis of heart failure (ICD-10 Group I50) and meet **ALL** of the following criteria?
   - The patient has a left ventricular ejection fraction (LVEF) of at least 40%
   - Kerendia will NOT be used concurrently with another mineralocorticoid (aldosterone) receptor antagonist (MRA) (e.g., spironolactone, eplerenone)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FINERENONE (Kerendia)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Chronic kidney disease (CKD: long-term kidney disease) associated with type 2 diabetes (T2D: a disorder with high blood sugar)
      2. Heart failure (a type of heart condition)

   B. If you have heart failure, renewal also requires:
      1. You have a left ventricular ejection fraction (LVEF: evaluates heart function) of at least 40%
      2. You will NOT use Kerendia concurrently (at the same time) with another mineralocorticoid (aldosterone) receptor antagonist (MRA) (such as spironolactone, eplerenone)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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FINERENONE (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kerendia.

REFERENCES

Kerendia [Prescribing Information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals, Inc., July 2025.

For Part D use only:

FINERENONE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	INITIAL: HEART FAILURE (HF): 1) NEW YORK HEART ASSOCIATION (NYHA) CLASS II-IV, AND 2) LEFT VENTRICULAR EJECTION FRACTION OF AT LEAST 40 PERCENT NOT DUE TO AN UNDERLYING CAUSE (E.G., INFILTRATIVE CARDIOMYOPATHY, HYPERTROPHIC CARDIOMYOPATHY, VALVULAR DISEASE, PERICARDIAL DISEASE, HIGH-OUTPUT HEART FAILURE).
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: HF: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	CHRONIC KIDNEY DISEASE (CKD) ASSOCIATED WITH TYPE 2 DIABETES (T2D): INITIAL: HISTORY OF AND WILL CONTINUE ON, HAS A CONTRAINDICATION, OR INTOLERANCE TO AN ANGIOTENSIN CONVERTING ENZYME INHIBITOR (ACE-I) OR AN ANGIOTENSIN RECEPTOR BLOCKER (ARB). HF: INITIAL/RENEWAL: NO CONCURRENT USE WITH ANOTHER MINERALOCORTICOID (ALDOSTERONE) RECEPTOR ANTAGONIST.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FINGOLIMOD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FINGOLIMOD HCL	GILENYA, FINGOLIMOD	37180		GPI-10 (6240702510)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), to include clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease, **AND** meet the following criterion?
   - The patient is 10 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FINGOLIMOD (Gilenya)** requires the following rule(s) be met for approval:
   A. You have a relapsing form of multiple sclerosis (MS: type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease returns and goes away), or active secondary progressive disease (advanced disease)
   B. You are 10 years of age and older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FINGOLIMOD (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Gilenya.

REFERENCES

Gilenya [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceutical Corporation; August 2023.

For Part D use only:

FINGOLIMOD (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25
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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FINGOLIMOD LAURYL SULFATE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FINGOLIMOD LAURYL SULFATE	TASCENSO ODT	48165		GPI-10 (6240702520)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), to include clinically isolated syndrome, relapsing-remitting disease or active secondary progressive disease, and meet **ALL** of the following criteria?
   - The patient is 10 years of age or older
   - The patient has a contraindication to or is unable to swallow fingolimod capsules

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FINGOLIMOD LAURYL SULFATE (Tascenso ODT)** requires the following rule(s) be met for approval:
   A. You have a relapsing form of multiple sclerosis (MS: type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease returns and goes away) or active secondary progressive disease (advanced disease)
   B. You are 10 years of age or older
   C. You have a contraindication to (harmful for you to use) or are unable to swallow fingolimod capsules

   (Denial text continued on next page)

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FINGOLIMOD LAURYL SULFATE (PART D)

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tascenso ODT.

REFERENCES

Tascenso ODT [Prescribing Information]. Swindon, United Kingdom: Cycle Pharmaceuticals Ltd ; January 2025.

For Part D use only:

FINGOLIMOD LAURYL SULFATE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	RELAPSING FORM OF MULTIPLE SCLEROSIS (MS): CONTRAINDICATION TO OR UNABLE TO SWALLOW FINGOLIMOD CAPSULES.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FOSCARBIDOPA-FOSLEVODOPA (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FOSCARBIDOPA/FOSLEVODOPA	VYALEV	49183		GPI-10 (7320990213)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of advanced Parkinson's disease (PD) (ICD-10 Group G20) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Vyalev is being used for the treatment of motor fluctuations associated with Parkinson's disease
   - Therapy is prescribed by or in consultation with a neurologist

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient is unable to swallow extended-release tablets or administer extended-release capsules via a feeding tube
   - The patient has failed to adhere to an oral carbidopa/levodopa regimen or tolerate a carbidopa/levodopa regimen via a feeding tube

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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FOSCARBIDOPA-FOSLEVODOPA (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FOSCARBIDOPA-FOSLEVODOPA (Vyalev)** requires the following rule(s) be met for approval:

A. You have advanced Parkinson's disease (PD: a type of movement disorder)
B. You are 18 years of age or older
C. Vyalev is being used for the treatment of motor fluctuations (changes in the ability to move) associated with Parkinson's disease
D. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
E. You meet ONE of the following:
    1. You are unable to swallow extended-release tablets or administer extended-release capsules through a feeding tube
    2. You have failed to adhere to (keep up with) an oral carbidopa/levodopa regimen or tolerate a carbidopa/levodopa regimen through a feeding tube

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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FOSCARBIDOPA-FOSLEVODOPA (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of advanced Parkinson's disease (PD) (ICD-10 Group G20) **AND** meet the following criterion?

- The patient has experienced improvement in motor symptoms while on Vyalev

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FOSCARBIDOPA-FOSLEVODOPA (Vyalev)** requires the following rule(s) be met for renewal:
A. You have advanced Parkinson's disease (PD: a type of movement disorder)
B. You have experienced improvement in motor symptoms with the use of Vyalev

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vyalev.

REFERENCES

Vyalev [Prescribing Information]. North Chicago, IL: AbbVie Inc.; October 2024.

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FOSCARBIDOPA–FOSLEVODOPA (PART D)

For Part D use only:

FOSCARBIDOPA–FOSLEVODOPA (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	PARKINSONS DISEASE (PD): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST.
Coverage Duration	INITIAL: 12 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	PD: INITIAL: ONE OF THE FOLLOWING: 1) UNABLE TO SWALLOW EXTENDED-RELEASE (ER) TABLETS OR ADMINISTER ER CAPSULES VIA A FEEDING TUBE, OR 2) FAILURE TO ADHERE OR TOLERATE VIA A FEEDING TUBE AN ORAL CARBIDOPA/LEVODOPA REGIMEN. RENEWAL: IMPROVEMENT IN MOTOR SYMPTOMS WHILE ON THERAPY.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FOSTAMATINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FOSTAMATINIB DISODIUM	TAVALISSE	44895		GPI-10 (8575604010)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of chronic immune thrombocytopenia (cITP) (ICD-10 D69.3) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had an insufficient response to a previous treatment (e.g., splenectomy, corticosteroids [e.g., prednisone], immunoglobulins Panzyga [immune globulin])
   - Therapy is prescribed by or in consultation with a hematologist or immunologist

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has a platelet count of less than 30 x10^9/L
   - The patient has a platelet count of less than 50 x 10^9/L AND a prior bleeding event

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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FOSTAMATINIB (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FOSTAMATINIB (Tavalisse)** requires the following rule(s) be met for approval:

A. You have chronic immune thrombocytopenia (cITP: a type of blood disorder)
B. You are 18 years of age or older
C. You had an insufficient response (did not work) to a previous treatment (such as splenectomy [surgical removal of spleen], corticosteroids [such as prednisone], immunoglobulins [such as Panzyga (immune globulin)])
D. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or immunologist (immune system doctor)
E. You meet ONE of the following:
    1. You have a platelet (a type of blood cell) count of less than 30 x10^9/L
    2. You have a platelet (a type of blood cell) count of less than 50 x 10^9/L AND had a prior bleeding event

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FOSTAMATINIB (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of chronic immune thrombocytopenia (cITP) (ICD-10 D69.3) **AND** meet the following criterion?
   - The patient has improvement in platelet counts from baseline or reduction in bleeding events

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FOSTAMATINIB (Tavalisse)** requires the following rule(s) be met for renewal:
   A. You have chronic immune thrombocytopenia (cITP: a type of blood disorder)
   B. You have improvement in platelet (a type of blood cell) counts from baseline or reduction in bleeding events

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the prescribing information and/or drug monograph for Tavalisse.

REFERENCES
Tavalisse [Prescribing Information]. South San Francisco, CA: Rigel Pharmaceuticals, Inc.; November 2020.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FOSTAMATINIB (PART D)

For Part D use only:

FOSTAMATINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	CHRONIC IMMUNE THROMBOCYTOPENIA (CITP): INITIAL: 1) PLATELET COUNT OF LESS THAN 30 X 10^9/L, OR 2) PLATELET COUNT OF LESS THAN 50 X 10^9/L AND A PRIOR BLEEDING EVENT.
Age Restrictions	N/A
Prescriber Restrictions	CITP: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR IMMUNOLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	CITP: RENEWAL: IMPROVEMENT IN PLATELET COUNTS FROM BASELINE OR REDUCTION IN BLEEDING EVENTS.

Created: 05/18
Effective: 09/01/25 Client Approval: 08/25 P&T Approval: 07/25

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FREMANEZUMAB-VFRM (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FREMANEZUMAB-VFRM	AJOVY	45236		GPI-10 (6770203020)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of migraine and meet **ALL** of the following criteria?
   - Ajovy is prescribed for the preventive treatment of migraines
   - Ajovy will NOT be used concurrently with other CGRP (calcitonin gene-related peptide) inhibitors (e.g., Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr]) for migraine prevention

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient is 6 to 17 years of age AND the migraine is episodic
   - The patient is 18 years of age or older AND had a trial of or contraindication to one of the following preferred agents: Aimovig (erenumab-aooe), Emgality (galcanezumab-gnlm)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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FREMANEZUMAB-VFRM (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FREMANEZUMAB-VFRM (Ajovy)** requires the following rule(s) be met for approval:

A. You have migraines (a type of headache)
B. Ajovy is prescribed for the preventive treatment of migraine (a type of headache)
C. You will NOT use Ajovy concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr]) for migraine prevention
D. You meet ONE of the following:
    1. You are 6 to 17 years of age AND your migraine is episodic
    2. You are 18 years of age or older AND you have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Aimovig (erenumab-aooe), Emgality (galcanezumab-gnlm)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FREMANEZUMAB-VFRM (PART D)

RENEWAL CRITERIA

1. Is Ajovy being prescribed for the preventive treatment of migraines **AND** the patient meets the following criterion?
   - Ajovy will NOT be used concurrently with other CGRP inhibitors (e.g., Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr]) for migraine prevention

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has experienced a reduction in migraine or headache frequency with therapy
   - The patient has experienced a reduction in migraine severity with therapy
   - The patient has experienced a reduction in migraine duration with therapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FREMANEZUMAB-VFRM (Ajovy)** requires the following rule(s) be met for renewal:
   A. Ajovy is prescribed for the preventive treatment of migraines (a type of headache)
   B. You will NOT use Ajovy concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr]) for migraine prevention
   C. You meet ONE of the following:
      1. You have experienced a reduction in migraine or headache frequency with Ajovy therapy
      2. You have experienced a reduction in migraine severity with Ajovy therapy
      3. You have experienced a reduction in migraine duration (length of time) with Ajovy therapy

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FREMANEZUMAB-VFRM (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ajovy.

REFERENCES

Ajovy [Prescribing Information]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; September 2021.

For Part D use only:

FREMANEZUMAB-VFRM (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS.
Other Criteria	MIGRAINE PREVENTION: INITIAL: TRIAL OF OR CONTRAINDICATION TO ONE OF THE FOLLOWING PREFERRED AGENTS: AIMOVIG, EMGALITY, WHERE AGES ALIGN. INITIAL/RENEWAL: NO CONCURRENT USE WITH OTHER CGRP INHIBITORS FOR MIGRAINE PREVENTION. RENEWAL: REDUCTION IN MIGRAINE OR HEADACHE FREQUENCY, MIGRAINE SEVERITY, OR MIGRAINE DURATION WITH THERAPY.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
OF PRIOR AUTHORIZATION GUIDELINES

FRUQUINTINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FRUQUINTINIB	FRUZAQLA	47169		GPI-10 (2133503500)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic colorectal cancer (mCRC) (ICD-10 C19) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy (e.g., FOLFOX, FOLFIRI, CapeOx)
   - The patient has received previous treatment with an anti-VEGF therapy (e.g., Zaltrap [ziv-aflibercept], Cyramza [ramucirumab])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
OF PRIOR AUTHORIZATION GUIDELINES

FRUQUINTINIB (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FRUQUINTINIB (Fruzaqla)** requires the following rule(s) be met for approval:

A. You have metastatic colorectal cancer (mCRC: a type of digestive system cancer that has spread to other parts of the body)
B. You are 18 years of age or older
C. You have had previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy (such as FOLFOX, FOLFIRI, CapeOx)
D. You have had previous treatment with an anti-vascular endothelial growth factor (VEGF) therapy (a type of treatment such as Zaltrap [ziv-aflibercept], Cyramza [ramucirumab])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Fruzaqla.

REFERENCES

Fruzaqla [Prescribing Information]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; November 2023.

For Part D use only:

FRUQUINTINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FUTIBATINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FUTIBATINIB	LYTGOBI	48369		GPI-10 (2153222800)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma (iCCA) (ICD-10 C22.1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has been previously treated for unresectable, locally advanced or metastatic iCCA
   - The patient has fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements
   - The patient will complete a comprehensive ophthalmological examination, including optical coherence tomography (OCT), prior to the initiation of Lytgobi and at the recommended scheduled intervals

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FUTIBATINIB (Lytgobi)** requires the following rule(s) be met for approval:
   A. You have unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma (iCCA) (a type of bile duct cancer inside the liver that is unable to be removed by surgery, has spread from where it started to nearby tissue/lymph nodes or to other parts of the body)
   B. You are 18 years of age or older
   C. You have been previously treated for unresectable, locally advanced or metastatic iCCA
   D. You have fibroblast growth factor receptor 2 (FGFR2: a type of protein) gene fusions or other rearrangements
   (Denial text continued on the next page)

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FUTIBATINIB (PART D)

GUIDELINES FOR USE (CONTINUED)

E. You will complete a comprehensive ophthalmological examination (eye exam), including optical coherence tomography (OCT: a type of eye imaging test), before starting Lytgobi and at the recommended scheduled times

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lytgobi.

REFERENCES

Lytgobi [Prescribing Information]. Princeton, NJ: Taiho Pharmaceutical Co., Ltd., September 2022.

For Part D use only:

FUTIBATINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	INTRAHEPATIC CHOLANGIOCARCINOMA (ICCA): COMPLETE A COMPREHENSIVE OPHTHALMOLOGICAL EXAMINATION, INCLUDING OPTICAL COHERENCE TOMOGRAPHY (OCT), PRIOR TO THE INITIATION OF THERAPY AND AT THE RECOMMENDED SCHEDULED INTERVALS.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GABAPENTIN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GABAPENTIN	RELGAABI, GABAPENTIN		58981	GPI-14 (72600030000120)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	Yes	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of postherpetic neuralgia (ICD-10 B02.22, B02.29, B02.23) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of epilepsy with partial onset seizures (ICD-10 Groups G40.1, G40.2) and meet **ALL** of the following criteria?
   - The patient is 3 years of age or older
   - Relgaabi will be used as adjunctive therapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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GABAPENTIN (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **GABAPENTIN (Relgaabi)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Postherpetic neuralgia (nerve pain caused by shingles virus)
   2. Epilepsy (a type of brain disorder) with partial onset seizures (a type of seizure)

B. If you have postherpetic neuralgia, approval also requires:
   1. You are 18 years of age or older

C. If you have epilepsy with partial onset seizures, approval also requires:
   1. You are 3 years of age or older
   2. Relgaabi will be used as adjunctive (add-on) therapy

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Relgaabi.

REFERENCES

Relgaabi [Prescribing Information]. Southlake, TX: Method Pharmaceuticals; March 2026.

For Part D use only:

GABAPENTIN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 06/26
Effective: 07/01/26 Client Approval: 06/26 DMC Approval: 05/27/26

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GALCANEZUMAB-GNLM (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GALCANEZUMAB-GNLM	EMGALITY	45281		GPI-10 (6770203530)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for the preventive treatment of migraines (ICD-10 Group G43) and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Emgality will NOT be used concurrently with other CGRP inhibitors (e.g., Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Vyepti [eptinezumab-jjmr]) for migraine prevention

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of episodic cluster headache (ICD-10 Group G44.01) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 3 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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GALCANEZUMAB-GNLM (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **GALCANEZUMAB-GNLM (Emgality)** requires the following rule(s) be met for approval:

A. The request is for ONE of the following:
   1. Preventive treatment of migraines (a type of headache)
   2. Episodic cluster headache (a type of headache)

B. If the request is for preventive treatment of migraines, approval also requires:
   1. You are 18 years of age or older
   2. You will NOT use Emgality concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Vyepti [eptinezumab-jjmr]) for migraine prevention

C. If you have episodic cluster headache, approval also requires:
   1. You are 18 years of age or older

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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GALCANEZUMAB-GNLM (PART D)

RENEWAL CRITERIA

1. Is the request for the preventive treatment of migraines (ICD-10 Group G43) **AND** the patient meets the following criterion?
   - Emgality will NOT be used concurrently with other CGRP inhibitors (e.g., Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Vyepti [eptinezumab-jjmr]) for migraine prevention

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has experienced a reduction in migraine or headache frequency with therapy
   - The patient has experienced a reduction in migraine severity with therapy
   - The patient has experienced a reduction in migraine duration with therapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

3. Does the patient have a diagnosis of episodic cluster headache (ICD-10 Group G44.01) **AND** meet the following criterion?
   - The patient has had improvement in episodic cluster headache frequency as compared to baseline

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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GALCANEZUMAB-GNLM (PART D)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **GALCANEZUMAB-GNLM (Emgality)** requires the following rule(s) be met for renewal:

A. The request is for ONE of the following:
   1. Preventive treatment of migraines (a type of headache)
   2. Episodic cluster headache (a type of headache)

B. If the request is for preventive treatment of migraines, renewal also requires:
   1. You will NOT use Emgality concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Vyepti [eptinezumab-jjmr]) for migraine prevention
   2. You meet ONE of the following:
      a. You have experienced a reduction in migraine or headache frequency with therapy
      b. You have experienced a reduction in migraine severity with therapy
      c. You have experienced a reduction in migraine duration with therapy

C. If you have episodic cluster headache, renewal also requires:
   1. You have had improvement in episodic cluster headache frequency as compared to baseline

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Emgality.

REFERENCES

Emgality [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company. March 2025.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GALCANEZUMAB-GNLM (PART D)

For Part D use only:

GALCANEZUMAB-GNLM (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	INITIAL: MIGRAINE PREVENTION: 6 MOS. EPISODIC CLUSTER HEADACHE: 3 MOS. RENEWAL (ALL): 12 MOS.
Other Criteria	MIGRAINE PREVENTION: INITIAL/RENEWAL: NO CONCURRENT USE WITH OTHER CGRP INHIBITORS FOR MIGRAINE PREVENTION. RENEWAL: REDUCTION IN MIGRAINE OR HEADACHE FREQUENCY, MIGRAINE SEVERITY, OR MIGRAINE DURATION WITH THERAPY. EPISODIC CLUSTER HEADACHE: RENEWAL: IMPROVEMENT IN EPISODIC CLUSTER HEADACHE FREQUENCY AS COMPARED TO BASELINE.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GANAXOLONE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GANAXOLONE	ZTALMY	47912		GPI-10 (7260003300)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of seizures (ICD-10 Group G40) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - The patient's seizures are associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GANAXOLONE (Ztalmy)** requires the following rule(s) be met for approval:
   A. You have seizures
   B. You are 2 years of age or older
   C. Your seizures are associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD: a type of genetic disorder)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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GANAXOLONE (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Ztalmy.

REFERENCES
Ztalmy [Prescribing Information]. Radnor, PA: Marinus Pharmaceuticals, Inc.; June 2022.

For Part D use only:

GANAXOLONE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GARADACIMAB-GXII (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GARADACIMAB-GXII	ANDEMBRY	50645		GPI-10 (8583203001)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hereditary angioedema (HAE) (ICD-10 D84.1) and meet **ALL** of the following criteria?
- The patient is 12 years of age or older
- Andembry will be used for prophylaxis against HAE attacks
- Therapy is prescribed by or in consultation with an allergist, immunologist, hematologist, or pulmonologist
- Andembry will NOT be used concurrently with an alternative prophylactic agent for HAE attacks (e.g., Cinryze [C1 esterase inhibitor], Haegarda [C1 esterase inhibitor], danazol, Orladeyo [berotralstat], Takhzyro [lanadelumab-flyo])
- The patient had a trial of or contraindication to ONE of the following preferred agents: Cinryze (C1 esterase inhibitor), Haegarda (C1 esterase inhibitor), Takhzyro (lanadelumab-flyo)

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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GARADACIMAB-GXII (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient meet **ONE** of the following criteria?
   - The patient has Type I or II HAE, as confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q
   - The patient has Type III HAE

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GARADACIMAB-GXII (Andembry)** requires the following rule(s) be met for approval:
   A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
   B. You are 12 years of age or older
   C. Andembry will be used for the prevention of hereditary angioedema attacks
   D. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), immunologist (a type of immune system doctor), hematologist (a type of blood doctor), or pulmonologist (lung/breathing doctor)
   E. You will NOT use Andembry concurrently (at the same time) with an alternative preventive medication for hereditary angioedema attacks (such as Cinryze [C1 esterase inhibitor], Haegarda [C1 esterase inhibitor], danazol, Orladeyo [berotralstat], Takhzyro [lanadelumab-flyo])
   F. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Cinryze (C1 esterase inhibitor), Haegarda (C1 esterase inhibitor), Takhzyro (lanadelumab-flyo)
   G. You meet ONE of the following:
      1. You have Type I or II hereditary angioedema (a type of gene condition with severe body swelling), as confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q (types of lab tests)
      2. You have Type III hereditary angioedema (a type of gene condition with severe body swelling)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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GARADACIMAB-GXII (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary angioedema (HAE) (ICD-10 D84.1) **AND** meet the following criterion?
   - Andembry will NOT be used concurrently with an alternative prophylactic agent for HAE attacks (e.g., Cinryze [C1 esterase inhibitor], Haegarda [C1 esterase inhibitor], danazol, Orladeyo [berotralstat], Takhzyro [lanadelumab-flyo])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GARADACIMAB-GXII (Andembry)** requires the following rule(s) be met for renewal:
   A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
   B. You will NOT use Andembry concurrently (at the same time) with an alternative preventive medication for hereditary angioedema attacks (such as Cinryze [C1 esterase inhibitor], Haegarda [C1 esterase inhibitor], danazol, Orladeyo [berotralstat], Takhzyro [lanadelumab-flyo])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Andembry.

REFERENCES
Andembry [Prescribing Information]. King of Prussia, PA: CSL Behring; June 2025.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GARADACIMAB-GXII (PART D)

For Part D use only:

GARADACIMAB-GXII (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	HEREDITARY ANGIOEDEMA (HAE): INITIAL: 1) TYPE III HAE, OR 2) TYPE I OR II HAE CONFIRMED BY ONE OF THE FOLLOWING COMPLEMENT TESTS: C1-INH PROTEIN LEVELS, C4 PROTEIN LEVELS, C1-INH FUNCTIONAL LEVELS, C1Q.
Age Restrictions	N/A
Prescriber Restrictions	HAE: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH AN ALLERGIST, IMMUNOLOGIST, HEMATOLOGIST OR PULMONOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS
Other Criteria	HAE: INITIAL: TRIAL OF OR CONTRAINDICATION TO ONE OF THE FOLLOWING PREFERRED AGENTS: CINRYZE, HAEGARDA, TAKHZYRO. INITIAL/RENEWAL: NOT ON CONCURRENT TREATMENT WITH ALTERNATIVE PROPHYLACTIC AGENT FOR HAE ATTACKS.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GEFITINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GEFITINIB	IRESSA, GEFITINIB	25178		GPI-10 (2136003000)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
Yes	No	No	Yes	No	No	Yes	No	No	Yes	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient's tumor has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test
   - The requested medication will NOT be used concurrently with an EGFR tyrosine kinase inhibitor (e.g., Gilotrif [afatinib], Tarceva [erlotinib], Vizimpro [dacomitinib], Tagrisso [osimertinib])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GEFITINIB (Iressa)** requires the following rule(s) be met for approval:
   A. You have metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body)
   B. Your tumor has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations (abnormal changes in a gene) as detected by a Food and Drug Administration (FDA)-approved test
   (Denial text continued on next page)

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GEFITINIB (PART D)

GUIDELINES FOR USE (CONTINUED)

C. You will NOT use the requested medication concurrently (at the same time) with an epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (such as Gilotrif [afatinib], Tarceva [erlotinib], Vizimpro [dacomitinib], Tagrisso [osimertinib])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Iressa.

REFERENCES

Iressa [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals; February 2023.

For Part D use only

GEFITINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) WITH EGFR MUTATION: NOT ON CONCURRENT THERAPY WITH AN EGFR TYROSINE KINASE INHIBITOR.

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 07/15
Client Approval: 06/24
P&T Approval: 04/22

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GEMTUZUMAB OZOGAMICIN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GEMTUZUMAB OZOGAMICIN	MYLOTARG	21218		GPI-10 (2135363020)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of newly-diagnosed CD33-positive acute myeloid leukemia (AML) (ICD-10 Group C92.0) and meet the following criterion?
   - The patient is 1 month of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of relapsed or refractory CD33-positive acute myeloid leukemia (AML) (ICD-10 C92.02, C92.00) and meet the following criterion?
   - The patient is 2 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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GEMTUZUMAB OZOGAMICIN (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **GEMTUZUMAB OZOGAMICIN (Mylotarg)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Newly-diagnosed CD33 (type of molecule that is used as a marker to diagnose AML) -positive acute myeloid leukemia (AML: a type of blood and bone marrow cancer)
   2. Relapsed (returning) or refractory (resistant) CD33 -positive acute myeloid leukemia (AML)

B. If you have newly-diagnosed CD33–positive acute myeloid leukemia, approval also requires:
   1. You are 1 month of age or older

C. If you have relapsed or refractory CD33-positive acute myeloid leukemia, approval also requires:
   1. You are 2 years of age or older

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Mylotarg.

REFERENCES

Mylotarg [Prescribing Information]. Philadelphia, PA: Wyeth Pharmaceuticals, Inc.; June 2020.

For Part D use only:

GEMTUZUMAB OZOGAMICIN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GEPIRONE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GEPIRONE HCL	EXXUA	49298		GPI-10 (5812003010)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of major depressive disorder (MDD) (ICD-10 Groups F32, F33) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to the preferred agents: Trintellix (vortioxetine) AND one generic antidepressant (e.g., sertraline, duloxetine)
   - Exxua will NOT be used concurrently with another 5-HT1A receptor agonist (e.g., buspirone)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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GEPIRONE (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **GEPIRONE (Exxua)** requires the following rule(s) be met for approval:

A. You have major depressive disorder (MDD: a type of mental illness)
B. You are 18 years of age or older
C. You have tried or have a contraindication to (harmful for you to use) the preferred medications: Trintellix (vortioxetine) AND one generic antidepressant (such as sertraline, duloxetine)
D. You will NOT use Exxua concurrently (at the same time) with another 5-HT1A receptor agonist (such as buspirone)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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GEPIRONE (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of major depressive disorder (MDD) (ICD-10 Groups F32, F33) and meet **ALL** of the following criteria?
   - The patient has had a response to or remission of depressive symptoms with Exxua
   - Exxua will NOT be used concurrently with another 5-HT1A receptor agonist (e.g., buspirone)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GEPIRONE (Exxua)** requires the following rule(s) be met for renewal:
   A. You have major depressive disorder (MDD: a type of mental illness)
   B. You have had a response to or remission (reduction or disappearance of the signs and symptoms of a disease) of depressive symptoms with Exxua
   C. You will NOT use Exxua concurrently (at the same time) with another 5-HT1A receptor agonist (such as buspirone)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Exxua.

REFERENCES

Exxua [Prescribing Information]. San Antonio, TX: Mission Pharmacal Company; July 2025.

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GEPIRONE (PART D)

For Part D use only:

GEPIRONE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	MAJOR DEPRESSIVE DISORDER: INITIAL: TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENTS: TRINTELLIX AND ONE GENERIC ANTIDEPRESSANT. INITIAL/RENEWAL: NO CONCURRENT USE WITH ANOTHER 5-HT1A RECEPTOR AGONIST (E.G., BUSPIRONE). RENEWAL: RESPONSE TO OR REMISSION OF DEPRESSIVE SYMPTOMS WITH THERAPY.

Created: 11/25
Effective: 02/04/26 Client Approval: 02/26 P&T Approval: 04/23

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GEPOTIDACIN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GEPOTIDACIN MESYLATE	BLUJEPA	50388		GPI-10 (1680001620)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of uncomplicated urinary tract infection (uUTI) (ICD-10 N39.0) and meet **ALL** of the following criteria?
   - The patient is a female
   - The patient is 12 years of age or older
   - The patient's infection is caused by susceptible *Escherichia coli, Klebsiella pneumoniae, Citrobacter freundii complex, Staphylococcus saprophyticus, or Enterococcus faecalis*

   If yes, continue to #2.
   If no, continue to #3.

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GEPOTIDACIN (PART D)

GUIDELINES FOR USE (CONTINUED)

2. Does the patient meet **ONE** of the following criteria?
   - Therapy is prescribed by or in consultation with an infectious disease (ID) specialist
   - The patient has a documented culture demonstrating uUTI is caused by a bacteria with sensitivity to gepotidacin AND resistance or contraindication to all alternatives (e.g. Pivya [pivmecillinam], trimethoprim-sulfamethoxazole [TMP-SMX], nitrofurantoin, fosfomycin, penicillins [e.g., amoxicillin-clavulanate], cephalosporins [e.g., cephalexin], fluoroquinolones [e.g., ciprofloxacin])
   - The request is for continuation of Blujepa therapy from an inpatient setting

   If yes, **approve for 5 days by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient have a diagnosis of uncomplicated urogenital gonorrhea (ICD-10 Group A54.0) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient's infection has limited or no alternative treatment options
   - The patient's infection is caused by a susceptible strain of *Neisseria gonorrhoeae*
   - The patient had a trial of or contraindication to the clinical standard of care agent: ceftriaxone

   If yes, **approve for 1 month by HICL or GPI-10 for one fill.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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GEPOTIDACIN (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **GEPOTIDACIN (Blujepa)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Uncomplicated urinary tract infection (uUTI: a type of bacterial infection)
   2. Uncomplicated urogenital gonorrhea (a type of bacterial infection)

B. If you have uncomplicated urinary tract infection, approval also requires:
   1. You are a female
   2. You are 12 years of age or older
   3. Your uncomplicated urinary tract infection (a type of bacterial infection) is caused by susceptible *Escherichia coli, Klebsiella pneumoniae, Citrobacter freundii complex, Staphylococcus saprophyticus, or Enterococcus faecalis* (types of bacteria that can be treated with the medication)
   4. You meet ONE of the following:
      a. Therapy is prescribed by or in consultation with an infectious disease specialist (a doctor who specializes in the treatment of infections)
      b. You have a documented culture demonstrating uncomplicated urinary tract infection (a type of bacterial infection is caused by a bacteria with sensitivity (lab test that shows what medications work on which bacteria) to gepotidacin AND resistance (medication will not work for that bacteria) or contraindication to (harmful for you to use) all alternatives (such as Pivya [pivmecillinam], trimethoprim-sulfamethoxazole [TMP-SMX], nitrofurantoin, fosfomycin, penicillins [such as amoxicillin-clavulanate], cephalosporins [such as cephalexin], fluoroquinolones [such as ciprofloxacin])
      c. Your request is for continuation of Blujepa therapy from an inpatient setting

C. If you have uncomplicated urogenital gonorrhea, approval also requires:
   1. You are 12 years of age or older
   2. Your infection has limited or no alternative treatment options
   3. Your infection is caused by a susceptible strain of *Neisseria gonorrhoeae*
   4. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: ceftriaxone

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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GEPOTIDACIN (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Blujepa.

REFERENCES

Blujepa [Prescribing Information]. Durham, NC: GlaxoSmithKline; December 2025.

For Part D use only:

GEPOTIDACIN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	UNCOMPLICATED URINARY TRACT INFECTION (UUTI): 5 DAYS. UNCOMPLICATED UROGENITAL GONORRHEA: 1 MONTH.
Other Criteria	UUTI: 1) PRESCRIBED BY OR IN CONSULTATION WITH AN INFECTIOUS DISEASE SPECIALIST, 2) DOCUMENTED CULTURE DEMONSTRATES UUTI IS CAUSED BY A BACTERIA WITH SENSITIVITY TO GEPOTIDACIN AND RESISTANCE OR CONTRAINDICATION TO ALL ALTERNATIVES (E.G., PIVMECILLINAM, TRIMETHOPRIM-SULFAMETHOXAZOLE, NITROFURANTOIN, FOSFOMYCIN, PENICILLINS, CEPHALOSPORINS, FLUOROQUINOLONES), OR 3) CONTINUATION OF BLUJEPA FROM AN INPATIENT SETTING. UNCOMPLICATED UROGENITAL GONORRHEA: TRIAL OF OR CONTRAINDICATION TO THE CLINICAL STANDARD OF CARE AGENT: CEFTRIAXONE.

Created: 09/25
Effective: 03/01/26 Client Approval: 01/26 P&T Approval: 10/26

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GILTERITINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GILTERITINIB FUMARATE	XOSPATA	45506		GPI-10 (2153302020)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory acute myeloid leukemia (AML) (ICD-10 C92.02, C92.00) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has FMS-like tyrosine kinase 3 (FLT3) mutation, as detected by an FDA-approved test

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GILTERITINIB (Xospata)** requires the following rule(s) be met for approval:
   A. You have relapsed or refractory acute myeloid leukemia (AML: a type of blood cancer that has returned or did not respond to treatment)
   B. You are 18 years of age or older
   C. You have FMS-like tyrosine kinase 3 (FLT3: type of gene) mutation, as detected by a Food and Drug Administration (FDA)-approved test

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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GILTERITINIB (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Xospata.

REFERENCES
Xospata [Prescribing Information]. Northbrook, IL: Astellas Pharma US, Inc., January 2022.

For Part D use only:

GILTERITINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GIVINOSTAT (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GIVINOSTAT HYDROCHLORIDE	DUVYZAT	49667		GPI-10 (7460302520)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Duchenne muscular dystrophy (DMD) (ICD-10 G71.01) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient's diagnosis of DMD is confirmed by genetic testing
   - The patient has been on a stable dose of corticosteroids for at least 6 months AND will continue steroid therapy with Duvyzat

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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GIVINOSTAT (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **GIVINOSTAT (Duvyzat)** requires the following rule(s) be met for approval:

A. You have Duchenne muscular dystrophy (DMD: a type of muscle disorder)
B. You are 6 years of age or older
C. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
D. Your diagnosis of DMD is confirmed by genetic testing
E. You have been on a stable dose of corticosteroids for at least 6 months AND will continue steroid therapy with Duvyzat

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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GIVINOSTAT (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Duchenne muscular dystrophy (DMD) (ICD-10 G71.01) **AND** meet the following criterion?
   - The patient has been on a stable dose of corticosteroids for at least 6 months AND will continue steroid therapy with Duvyzat

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the patient currently ambulatory **AND** meets the following criterion?
   - The patient has shown improvement since starting Duvyzat, as assessed by a standard set of ambulatory or functional status measures (e.g., 6-minute walking distance [6MWD], ascending or descending 4 stairs, rise from floor time [Gower's maneuver], 10-meter [30 feet] run/walk time, North Star Ambulatory Assessment [NSAA])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Is the patient currently non-ambulatory **AND** meets the following criterion?
   - The patient has maintained or demonstrated a less than expected decline in pulmonary function or upper limb strength since starting Duvyzat, as assessed by standard measures (e.g., pulmonary function [FVC, PFTs], upper limb strength)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   RENEWAL DENIAL TEXT: See the renewal denial text at the end of the guideline.

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GIVINOSTAT (PART D)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **GIVINOSTAT (Duvyzat)** requires the following rule(s) be met for renewal:

A. You have Duchenne muscular dystrophy (DMD: a type of muscle disorder)
B. You have been on a stable dose of corticosteroids for at least 6 months AND will continue steroid therapy with Duvyzat
C. If you are currently ambulatory (can walk), approval also requires:
   1. You have shown improvement since starting Duvyzat, as measured by a standard set of ambulatory or functional status measures (such as 6-minute walking distance [6MWD], going up or down 4 stairs, time to rise from the floor [Gower's maneuver], 10-meter [30 feet] run/walk time, North Star Ambulatory Assessment [NSAA: a tool for evaluating Duchenne muscular dystrophy])
D. If you are currently non-ambulatory (cannot walk), approval also requires:
   1. You have maintained or had a less than expected decrease in pulmonary (lung) function or upper limb strength since starting Duvyzat, as assessed by standard measures (such as pulmonary function [forced vital capacity, pulmonary function tests], upper limb strength)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Duvyzat.

REFERENCES

Duvyzat [Prescribing Information]. Concord, MA: ITF Therapeutics, LLC; March 2024.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GIVINOSTAT (PART D)

For Part D use only:

GIVINOSTAT (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	DUCHENNE MUSCULAR DYSTROPHY (DMD): INITIAL: DIAGNOSIS CONFIRMED BY GENETIC TESTING.
Age Restrictions	N/A
Prescriber Restrictions	DMD: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	DMD: INITIAL: HAS BEEN ON A STABLE DOSE OF CORTICOSTEROIDS FOR AT LEAST 6 MONTHS AND WILL CONTINUE STEROID THERAPY WITH DUVYZAT. RENEWAL: 1) HAS BEEN ON A STABLE DOSE OF CORTICOSTEROIDS FOR AT LEAST 6 MONTHS AND WILL CONTINUE STEROID THERAPY WITH DUVYZAT, AND 2) ONE OF THE FOLLOWING: (A) AMBULATORY AND HAS SHOWN IMPROVEMENT AS MEASURED BY A STANDARD SET OF AMBULATORY OR FUNCTIONAL STATUS MEASURES (E.G., 6-MINUTE WALKING DISTANCE, ASCENDING OR DESCENDING 4 STAIRS, RISE FROM FLOOR TIME, 10 METER RUN/WALK TIME, NORTH STAR AMBULATORY ASSESSMENT), OR (B) NON-AMBULATORY AND HAS MAINTAINED OR HAD A LESS THAN EXPECTED DECREASE IN PULMONARY FUNCTION OR UPPER LIMB STRENGTH AS ASSESSED BY STANDARD MEASURES (E.G., PULMONARY FUNCTION [FVC, PFTS], UPPER LIMB STRENGTH).

Part D Effective: 08/01/24 Created: 07/24
Commercial Effective: N/A Client Approval: 07/24 P&T Approval: 10/23

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GIVOSIRAN BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GIVOSIRAN SODIUM	GIVLAARI	46222		GPI-10 (8508002520)	

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue #5.

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GIVOSIRAN BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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GIVOSIRAN BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of acute hepatic porphyria (AHP) (ICD-10 E80.21) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a geneticist, hepatologist, hematologist, gastroenterologist, neurologist, dermatologist, or a healthcare provider experienced in managing AHP
- The patient has genetic confirmation of mutation OR elevated urinary or plasma PBG (porphobilinogen) or ALA (aminolevulinic acid)
- The patient has experienced two or more AHP attacks in the past 12 months

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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GIVOSIRAN BvD (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **GIVOSIRAN (Givlaari)** requires the following rule(s) be met for approval:

A. You have acute hepatic porphyria (AHP: a type of rare genetic disease)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a geneticist (a doctor who treats gene disorders), hepatologist (a type of liver doctor), hematologist (a type of blood doctor), gastroenterologist (a doctor who treats digestive conditions), neurologist (a type of brain and nervous system doctor), dermatologist (a type of skin doctor), or a healthcare provider experienced in managing acute hepatic porphyria
D. You have genetic confirmation of mutation, OR high urinary or plasma porphobilinogen (PBG) or aminolevulinic acid (ALA) levels (PBG and ALA: a type of urine or blood test)
E. You have experienced two or more acute hepatic porphyria attacks in the past 12 months

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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GIVOSIRAN BvD (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of acute hepatic porphyria (AHP) (ICD-10 E80.21) and meet **ALL** of the following criteria?
- The patient has achieved ormaintained clinical benefit compared to baseline (e.g., less hemin use, less AHP attacks, improvement of AHP symptoms)
- The patient has not received a liver transplant

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **GIVOSIRAN (Givlaari)** requires the following rule(s) be met for renewal:
A. You have acute hepatic porphyria (AHP: a type of rare genetic disease)
B. You have achieved or maintained clinical benefit compared to baseline (before treatment) (such as less hemin use, less AHP attacks, improvement of AHP symptoms)
C. You have not received a liver transplant

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Givlaari. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Givlaari [Prescribing Information]. San Diego, CA: Ajinomoto Althea, Inc.; April 2024.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed March 31, 2025].

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GIVOSIRAN BvD (PART D)

For Part D use only:

GIVOSIRAN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	ACUTE HEPATIC PORPHYRIA (AHP): INITIAL: GENETIC CONFIRMATION OF MUTATION OR ELEVATED URINARY OR PLASMA PBG (PORPHOBILINOGEN) OR ALA (AMINOLEVULINIC ACID).
Age Restrictions	N/A
Prescriber Restrictions	AHP: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A GENETICIST, HEPATOLOGIST, HEMATOLOGIST, GASTROENTEROLOGIST, NEUROLOGIST, DERMATOLOGIST, OR A HEALTHCARE PROVIDER EXPERIENCED IN MANAGING AHP.
Coverage Duration	INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS
Other Criteria	AHP: INITIAL: EXPERIENCED TWO OR MORE AHP ATTACKS IN THE PAST 12 MONTHS. RENEWAL: 1) ACHIEVED OR MAINTAINED CLINICAL BENEFIT COMPARED TO BASELINE, AND 2) HAS NOT RECEIVED A LIVER TRANSPLANT.

Created: 01/20
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 01/20

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GLASDEGIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GLASDEGIB MALEATE	DAURISMO	45502		GPI-10 (2137003030)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of newly-diagnosed acute myeloid leukemia (AML) (ICD-10 Group C92.0) **AND** meet the following criterion?
   - Daurismo will be used in combination with low-dose cytarabine

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient is 75 years of age or older
   - The patient has comorbidities that prevent use of intensive induction chemotherapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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GLASDEGIB (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **GLASDEGIB (Daurismo)** requires the following rule(s) be met for approval:

A. You have newly-diagnosed acute myeloid leukemia (AML: a type of blood and bone marrow cancer)
B. Daurismo will be used in combination with low-dose cytarabine
C. You are 75 years of age or older, OR you have comorbidities (more than one disease) that prevents the use of intensive induction chemotherapy (start of high dose cancer treatment)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Daurismo.

REFERENCES

Daurismo [Prescribing Information]. New York, NY: Pfizer Inc.; March 2020.

For Part D use only:

GLASDEGIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Created: 12/18
Effective: 01/01/25 Client Approval: 08/24 P&T Approval: 01/19

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GLATIRAMER (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GLATIRAMER ACETATE	COPAXONE GLATOPA, GLATIRAMER ACETATE	12810		GPI-10 (6240003010)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), including clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease, **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GLATIRAMER (Copaxone, Glatopa)** requires the following rule(s) be met for approval:
   A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease returns and goes away), or active secondary progressive disease (advanced disease)
   B. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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GLATIRAMER (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Copaxone/Glatopa.

REFERENCES

Copaxone [Prescribing Information]. Overland Park, KS: Teva; November 2023.
Glatopa [Prescribing Information]. Princeton, NJ: Sandoz Inc; December 2023.

For Part D use only:

GLATIRAMER (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 10/16
Client Approval: 06/24
P&T Approval: 11/16

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GLECAPREVIR/PIBRENTASVIR (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GLECAPREVIR/ PIBRENTASVIR	MAVYRET	44453		GPI-10 (1235990235)	

Do not review this guideline with physicians; if the caller wishes to initiate a request, then a MRF must be completed (see the MedImpact Standard MRF for HepC).

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of acute hepatitis C virus (HCV) (ICD-10 B17.1) and meet **ALL** of the following criteria?
   - The patient is 3 years of age or older
   - The patient has a genotype 1, 2, 3, 4, 5, or 6 infection

   If yes, continue to #2.
   If no, continue to #4.

2. Does the patient have an HCV RNA level within the past 6 months?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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GLECAPREVIR/PIBRENTASVIR (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient meet **ANY** of the following criteria?
   - The patient has moderate or severe hepatic impairment (decompensated cirrhosis: Child-Pugh B or C)
   - Mavyret will be used concurrently with any of the following medications: rifampin, atazanavir, carbamazepine, efavirenz, darunavir, lopinavir, ritonavir, atorvastatin, lovastatin, simvastatin, rosuvastatin (at doses greater than 10 mg), cyclosporine (for patients requiring stable cyclosporine doses greater than 100 mg/day), medications containing more than 20 mcg of ethinyl estradiol, Epclusa (velpatasvir/sofosbuvir), Harvoni (ledipasvir/sofosbuvir), Vosevi (velpatasvir/sofosbuvir/voxilaprevir), or Zepatier (elbasvir/grazoprevir)

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, **approve for 12 weeks by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

4. Does the patient have a diagnosis of chronic hepatitis C virus (ICD-10 B18.2) and meet **ALL** of the following criteria?
   - The patient is 3 years of age or older
   - The patient has a genotype 1, 2, 3, 4, 5, or 6 infection

   If yes, continue to #5.
   If no, continue to #20.

5. Does the patient have an HCV RNA level within the past 6 months?

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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GLECAPREVIR/PIBRENTASVIR (PART D)

GUIDELINES FOR USE (CONTINUED)

6. Does the patient meet **ANY** of the following criteria?
   - The patient has moderate or severe hepatic impairment (decompensated cirrhosis: Child-Pugh B or C)
   - Mavyret will be used concurrently with any of the following medications: rifampin, atazanavir, carbamazepine, efavirenz, darunavir, lopinavir, ritonavir, atorvastatin, lovastatin, simvastatin, rosuvastatin (at doses greater than 10 mg), cyclosporine (for patients requiring stable cyclosporine doses greater than 100 mg/day), medications containing more than 20 mcg of ethinyl estradiol, Epclusa (velpatasvir/sofosbuvir), Harvoni (ledipasvir/sofosbuvir), Vosevi (velpatasvir/sofosbuvir/voxilaprevir), or Zepatier (elbasvir/grazoprevir)

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #7.

7. Is the patient treatment-naïve?

   If yes, continue to #8.
   If no, continue to #11.

8. Does the patient meet **ONE** of the following criteria?
   - The patient has a genotype 1, 4, 5, or 6 infection AND an intolerance or contraindication to ONE of the following preferred agents: Harvoni, Epclusa
   - The patient has a genotype 2 or 3 infection AND an intolerance or contraindication to the following preferred agent: Epclusa

   If yes, continue to #9.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

9. Does the patient have compensated cirrhosis (Child-Pugh A) or does not have cirrhosis?

   If yes, **approve for 8 weeks by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #10.

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GLECAPREVIR/PIBRENTASVIR (PART D)

GUIDELINES FOR USE (CONTINUED)

10. Is the patient post-liver or post-kidney transplant?

    If yes, **approve for 12 weeks by HICL or GPI-10.**
    APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

11. Is the patient treatment-experienced and meets **ALL** of the following criteria?
    - The patient is less than 18 years of age
    - The patient is interferon-experienced

    If yes, continue to #12.
    If no, continue to #13.

12. Does the patient meet **ONE** of the following criteria?
    - The patient has a genotype 1, 4, 5, or 6 infection AND an intolerance or contraindication to ONE of the following preferred agents: Harvoni, Epclusa
    - The patient has a genotype 2 or 3 infection AND an intolerance or contraindication to the following preferred agent: Epclusa

    If yes, **approve for 8 weeks by HICL or GPI-10.**
    APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

13. Is the patient treatment-experienced and meets **ALL** of the following criteria?
    - The patient has genotype 1 OR genotype 2, 3, 4, 5, or 6 and is less than 18 years of age
    - The patient has compensated cirrhosis (Child-Pugh A) OR does not have cirrhosis
    - The patient has prior treatment experience with an NS5A inhibitor (e.g., Harvoni [ledipasvir/sofosbuvir], Epclusa [velpatasvir/sofosbuvir])
    - The patient has NO prior treatment experience with an NS3/4A protease inhibitor (e.g., Olysio [simeprevir], Zepatier [elbasvir/grazoprevir])

    If yes, continue to #15.
    If no, continue to #14.

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GLECAPREVIR/PIBRENTASVIR (PART D)

GUIDELINES FOR USE (CONTINUED)

14. Is the patient treatment-experienced and meets **ONE** of the following criteria?
    - The patient has failed prior treatment with a sofosbuvir-based regimen with no NS3/4A protease inhibitor (e.g., Epclusa [velpatasvir/sofosbuvir], Harvoni [ledipasvir/sofosbuvir], Sovaldi [sofosbuvir])
    - The patient has failed Mavyret AND Mavyret will be used with Sovaldi (sofosbuvir) and ribavirin
    - The patient has failed Vosevi (sofosbuvir/velpatasvir/voxilaprevir) AND Mavyret will be used with Sovaldi (sofosbuvir) and ribavirin
    - The patient is less than 18 years of age, has genotype 3, AND is interferon-experienced

    If yes, continue to #15.
    If no, continue to #16.

15. Does the patient meet **ONE** of the following criteria?
    - The patient has a genotype 1, 4, 5, or 6 infection AND an intolerance or contraindication to ONE of the following preferred agents: Harvoni, Epclusa
    - The patient has a genotype 2 or 3 infection AND an intolerance or contraindication to the following preferred agent: Epclusa

    If yes, **approve for 16 weeks by HICL or GPI-10.**
    APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

16. Is the patient treatment-experienced and meet **ALL** of the following criteria?
    - The patient has genotype 1, 2, 4, 5, or 6
    - The patient does not have cirrhosis
    - The patient has prior treatment experience with regimens containing interferon/peginterferon, ribavirin, and/or Sovaldi (sofosbuvir)
    - The patient has NO prior treatment experience with an NS3/4A protease inhibitor (e.g., Olysio [simeprevir], Zepatier [elbasvir/grazoprevir]) or an NS5A inhibitor (e.g., Harvoni [ledipasvir/sofosbuvir], Epclusa [velpatasvir/sofosbuvir])

    If yes, **approve for 8 weeks by HICL or GPI-10.**
    APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

    If no, continue to #17.

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GLECAPREVIR/PIBRENTASVIR (PART D)

GUIDELINES FOR USE (CONTINUED)

17. Is the patient treatment-experienced and meet **ALL** of the following criteria?
    - The patient has genotype 1, 2, 4, 5, or 6
    - The patient has compensated cirrhosis (Child-Pugh A)
    - The patient has prior treatment experience with regimens containing interferon/peginterferon, ribavirin, and/or Sovaldi (sofosbuvir)
    - The patient has NO prior treatment experience with an NS3/4A protease inhibitor (e.g., Olysio [simeprevir], Zepatier [elbasvir/grazoprevir]) or an NS5A inhibitor (e.g., Harvoni [ledipasvir/sofosbuvir], Epclusa [velpatasvir/sofosbuvir])

    If yes, **approve for 12 weeks by HICL or GPI-10.**
    APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

    If no, continue to #18.

18. Is the patient treatment-experienced and meets **ALL** of the following criteria?
    - The patient has genotype 1 OR genotype 2, 3, 4, 5, or 6 and is less than 18 years of age
    - The patient has compensated cirrhosis (Child-Pugh A) OR does not have cirrhosis
    - The patient has prior treatment experience with an NS3/4A protease inhibitor (e.g., Olysio [simeprevir], Zepatier [elbasvir/grazoprevir])
    - The patient has NO prior treatment experience with an NS5A inhibitor (e.g., Harvoni [ledipasvir/sofosbuvir], Epclusa [velpatasvir/sofosbuvir])

    If yes, **approve for 12 weeks by HICL or GPI-10.**
    APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

    If no, continue to #19.

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GLECAPREVIR/PIBRENTASVIR (PART D)

GUIDELINES FOR USE (CONTINUED)

19. Is the patient treatment-experienced and meets **ALL** of the following criteria?
    - The patient has genotype 3
    - The patient has compensated cirrhosis (Child-Pugh A) OR does not have cirrhosis
    - The patient has prior treatment experience with regimens containing interferon/peginterferon, ribavirin, and/or Sovaldi (sofosbuvir)
    - The patient has NO prior treatment experience with an NS3/4A protease inhibitor (e.g., Olysio [simeprevir], Zepatier [elbasvir/grazoprevir]) or an NS5A inhibitor (e.g., Harvoni [ledipasvir/sofosbuvir], Epclusa [velpatasvir/sofosbuvir])

    If yes, **approve for 16 weeks by HICL or GPI-10.**
    APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

    If no, continue to #20.

20. Is the requested regimen recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment?

    If yes, **approve as indicated per guidance in AASLD/IDSA.**
    If no, do not approve.

    DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

    Our guideline named **GLECAPREVIR/PIBRENTASVIR (Mavyret)** requires the following rule(s) be met for approval:
    A. You have acute (short-term) or chronic (long-term) hepatitis C virus (HCV: liver inflammation caused by a type of virus)
    B. You are 3 years of age or older
    C. You have a genotype 1, 2, 3, 4, 5, or 6 infection (types of hepatitis C virus)
    D. You have an HCV RNA level (a measure of the amount of hepatitis C virus in the blood) within the past 6 months
    E. You do NOT have moderate or severe liver impairment (decompensated cirrhosis [a condition where there is liver damage and scarring with major symptoms]; Child-Pugh B or C [a score that evaluates the severity of liver damage])
    (Denial text continued on next page)

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GLECAPREVIR/PIBRENTASVIR (PART D)

GUIDELINES FOR USE (CONTINUED)

F. You will NOT be using Mavyret concurrently (at the same time) with any of the following medications: rifampin, atazanavir, carbamazepine, efavirenz, darunavir, lopinavir, ritonavir, atorvastatin, lovastatin, simvastatin, rosuvastatin (at doses greater than 10mg), cyclosporine (for patients requiring stable cyclosporine doses greater than 100mg/day), medications containing more than 20 mcg of ethinyl estradiol, Epclusa (velpatasvir/sofosbuvir), Harvoni (ledipasvir/sofosbuvir), Vosevi (velpatasvir/sofosbuvir/voxilaprevir), or Zepatier (elbasvir/grazoprevir)

G. If you have chronic hepatitis C virus and are treatment-naive (no prior treatment), approval also requires ALL of the following:

1. You meet ONE of the following:
   a. You do not have cirrhosis (liver damage and scarring)
   b. You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage)
   c. You received a liver transplant (replaced your liver)
   d. You received a kidney transplant (replaced your kidney)
2. If you have a genotype 1, 4, 5, or 6 infection, you have an intolerance (side effect) or contraindication to (harmful for you to use) ONE of the following preferred medications: Harvoni, Epclusa; OR if you have a genotype 2 or 3 infection, you have an intolerance (side effect) or contraindication to (harmful for you to use) the preferred medication: Epclusa

H. If you have chronic hepatitis C virus, are treatment-experienced (failed prior treatment) and prior therapy did not contain an NS5A inhibitor, approval also requires ONE of the following:

1. You have a genotype 1, 2, 4, 5, or 6 infection, and you have compensated cirrhosis (a condition where there is liver damage and scarring without major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage) OR you do not have cirrhosis (liver damage and scarring), and you have prior treatment experience with regimens containing interferon/peginterferon, ribavirin, and/or Sovaldi (sofosbuvir), and you do not have prior treatment experience with an NS3/4A protease inhibitor (such as Olysio [simeprevir], Zepatier [elbasvir/grazoprevir]) or an NS5A inhibitor (such as Epclusa [velpatasvir/sofosbuvir], Harvoni [ledipasvir/sofosbuvir])
2. You have genotype 1 OR genotype 2, 3, 4, 5, or 6 and are less than 18 years of age, and you have compensated cirrhosis (Child-Pugh A) OR you do not have cirrhosis, and you have prior treatment experience with an NS3/4A protease inhibitor (such as Olysio [simeprevir], Zepatier [elbasvir/grazoprevir]), and you do not have prior treatment experience with an NS5A inhibitor (such as Epclusa [velpatasvir/sofosbuvir], Harvoni [ledipasvir/sofosbuvir])

(Denial text continued on next page)

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GLECAPREVIR/PIBRENTASVIR (PART D)

GUIDELINES FOR USE (CONTINUED)

3. You have a genotype 3 infection, and you have compensated cirrhosis (Child-Pugh A) OR you do not have cirrhosis, and you have prior treatment experience with regimens containing interferon/peginterferon, ribavirin, and/or Sovaldi (sofosbuvir), and you do not have prior treatment experience with an NS3/4A protease inhibitor (such as Olysio [simeprevir], Zepatier [elbasvir/grazoprevir]) or an NS5A inhibitor (such as Epclusa [velpatasvir/sofosbuvir], Harvoni [ledipasvir/sofosbuvir])

I. If you have chronic hepatitis C virus and are treatment-experienced (failed prior treatment), approval also requires ALL of the following:

1. You meet ONE of the following:
   a. You are less than 18 years of age AND had prior treatment with an interferon
   b. You have genotype 1 OR genotype 2, 3, 4, 5, or 6 and are less than 18 years of age, and you have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage) OR you do not have cirrhosis (liver damage and scarring), and you have prior treatment experience with an NS5A inhibitor (such as Epclusa [velpatasvir/sofosbuvir], Harvoni [ledipasvir/sofosbuvir]), and you do not have prior treatment experience with an NS3/4A protease inhibitor (such as Olysio [simeprevir], Zepatier [elbasvir/grazoprevir])
   c. You have failed prior treatment with a sofosbuvir-based regimen with no NS3/4A protease inhibitor (such as Epclusa [velpatasvir/sofosbuvir], Harvoni [ledipasvir/sofosbuvir], Sovaldi [sofosbuvir])
   d. You have failed Mavyret AND Mavyret will be used with Sovaldi (sofosbuvir) and ribavirin
   e. You have failed Vosevi (sofosbuvir/velpatasvir/voxilaprevir) AND Mavyret will be used with Sovaldi (sofosbuvir) and ribavirin
   f. You are less than 18 years of age, have genotype 3, AND you had prior treatment with an interferon
2. If you have a genotype 1, 4, 5, or 6 infection, you have an intolerance (side effect) or contraindication to (harmful for you to use) ONE of the following preferred medications: Harvoni, Epclusa; OR if you have a genotype 2 or 3 infection, you have an intolerance (side effect) or contraindication to (harmful for you to use) the preferred medication: Epclusa

J. Mavyret will also be approved for any other regimen/condition not listed above that is recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment

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GLECAPREVIR/PIBRENTASVIR (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Mavyret.

REFERENCES

Guidance from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) Recommendations for Testing, Managing, and Treating hepatitis C. Available online at http://www.hcvguidelines.org/full-report-view. Accessed February 2, 2026.

Mavyret [Prescribing Information]. North Chicago, IL: AbbVie; June 2025.

For Part D use only:

GLECAPREVIR/PIBRENTASVIR (PART D)	
Covered uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	HCV RNA LEVEL WITHIN PAST 6 MONTHS
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	CRITERIA WILL BE APPLIED CONSISTENT WITH CURRENT AASLD/IDSA GUIDANCE.
Other Criteria	1) CRITERIA WILL BE APPLIED CONSISTENT WITH CURRENT AASLD/IDSA GUIDANCE, 2) INTOLERANCE OR CONTRAINDICATION TO ONE OF THE PREFERRED FORMULARY AGENTS: HARVONI OR EPCLUSA, WHEN THESE AGENTS ARE CONSIDERED ACCEPTABLE FOR TREATMENT OF THE SPECIFIC GENOTYPE PER AASLD/IDSA GUIDANCE, 3) NO CONCURRENT USE WITH THE FOLLOWING AGENTS: RIFAMPIN, ATAZANAVIR, CARBAMAZEPINE, EFAVIRENZ, DARUNAVIR, LOPINAVIR, RITONAVIR, ATORVASTATIN, LOVASTATIN, SIMVASTATIN, ROSUVASTATIN AT DOSES GREATER THAN 10MG, CYCLOSPORINE AT DOSES GREATER THAN 100MG PER DAY, MEDICATIONS CONTAINING MORE THAN 20MCG OF ETHINYL ESTRADIOL, EPCLUSA, HARVONI, VOSEVI, OR ZEPATIER, AND 4) DOES NOT HAVE MODERATE OR SEVERE HEPATIC IMPAIRMENT (CHILD PUGH B OR C).

Created: 08/17
Effective: 04/10/26 Client Approval: 04/26 P&T Approval: 07/25

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GLOFITAMAB-GXBM BVD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GLOFITAMAB-GXBM	COLUMVI	49012		GPI-10 (2135203500)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	Yes	No	No	Yes	No	No	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #5.

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GLOFITAMAB-GXBM BVD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override)**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GLOFITAMAB-GXBM BVD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified (DLBCL, NOS) (ICD-10 Group C83.3), OR large B-cell lymphoma (LBCL) arising from follicular lymphoma (ICD-10 Groups C83.3, C85.2), and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient previously received at least two lines of systemic therapy (e.g., R-CHOP [rituximab, cyclophosphamide, doxorubicin, vincristine and prednisone], GemOx [gemcitabine, oxaliplatin])
   - The patient will receive or has received a single dose of Gazyva (obinutuzumab) as a pretreatment prior to initiating Columvi
   - The patient has not previously received more than 12 cycles of Columvi

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GLOFITAMAB-GXBM (Columvi)** requires the following rule(s) be met for approval:
   A. You have relapsed or refractory diffuse large B-cell lymphoma (DLBCL: a type of white blood cell cancer that has returned or is not responding to treatment), not otherwise specified (NOS), OR large B-cell lymphoma (LBCL) arising from follicular lymphoma (a type of blood cancer)
   B. You are 18 years of age or older
   (Denial text continued on next page)

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GLOFITAMAB-GXBM BVD (PART D)

GUIDELINES FOR USE (CONTINUED)

C. You previously received at least two lines of systemic therapy (treatment that travels throughout the body) (such as R-CHOP [rituximab, cyclophosphamide, doxorubicin, vincristine and prednisone], GemOx [gemcitabine, oxaliplatin])
D. You will receive or have received a single dose of Gazyva (obinutuzumab) as a pretreatment prior to initiating Columvi
E. You have not previously received more than 12 cycles of Columvi

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Columvi. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Columvi [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; June 2023.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed July 2, 2024].

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GLOFITAMAB-GXBM BVD (PART D)

For Part D use only:

GLOFITAMAB-GXBM (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	1) WILL RECEIVE OR HAS RECEIVED A SINGLE DOSE OF GAZYVA AS A PRETREATMENT PRIOR TO INITIATING COLUMVI, AND 2) HAS NOT PREVIOUSLY RECEIVED MORE THAN 12 CYCLES OF TREATMENT.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GLP1-DULAGLUTIDE TIRF (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DULAGLUTIDE	TRULICITY	41421		GPI-10 (2717001500)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	Yes	No	Yes	Yes	No	Yes	Yes	No	Yes	Yes

These are TIRF-Like drugs requiring a payment determination for 'Part D' or 'Non-Part D'.

PAYMENT DETERMINATION CRITERIA

1. Does the patient have a diagnosis of type 2 diabetes mellitus (ICD-10 Groups E08, E09, E13, E11 except ICD-10 E11.A) **AND** meet the following criterion?
   - The patient is 10 years of age or older

   If yes, **set MCARE_DRUG_DETERM_OVR to 'Y' and approve for 12 months by HICL or GPI-10. Document in the PA comments: Part D Determination Override and diagnosis.**

   If no, **do not enter an MCARE override. Then, process as follows:**
   CSR Note:
   - If the caller is a physician, member, and/or AOR, please initiate a verbal PA intake request in MR4.
   - If the caller is a pharmacy, please advise the pharmacy to contact the provider or memberto pursue a payment determination and document the diagnosis provided in MedAccess.

   Please follow the clinical authorization process within the HQ notes.

   RPH Note:
   - Review for both FDA and Part D compendial supported off-label indications.
   - If the provided diagnosis is not FDA approved or compendial supported off-label use, **set MCARE_DRUG_DETERM_OVR to 'N' and enter override within the denied PA for 12 months by HICL or GPI-10.**
   - If the diagnosis is UNKNOWN do not enter an MCARE override; follow the criteria for any additional UM and decision the case accordingly. Provide the following PAC instruction: '**PAC: do not enter an MCARE override**.'

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GLP1-DULAGLUTIDE TIRF (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **GLP1- DULAGLUTIDE (Trulicity)** requires the following rule(s) be met for approval:

A. You have type 2 diabetes (a disorder with high blood sugar)
B. You are 10 years of age or older

RATIONALE

Prior authorization on Trulicity is required due to a high potential for non-Part D use (D vs. E payment determination only). Trulicity should NOT be used for non-medically accepted indications as defined in section 1860D-2(e)(4) of the Act. For further information, please refer to the Prescribing Information and/or Drug Monograph for Trulicity.

REFERENCES

Trulicity [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; May 2025.
Announcement of Calendar Year (CY) 2015 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. April 7, 2014. Section III – Part D: Appropriate Utilization of Prior Authorization Requirements to Determine Part D Drug Status. Page 112 – 114.

For Part D use only:

GLP1-DULAGLUTIDE (PART D)	
Covered Uses	ALL MEDICALLY-ACCEPTED INDICATIONS.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GLP1-EXENATIDE MICROSPHERES TIRF (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EXENATIDE MICROSPHERES	BYDUREON BCISE	38451		GPI-14 (2717002000D420)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	Yes	No	No	Yes	No	No	Yes	No	Yes	Yes

These are TIRF-Like drugs requiring a payment determination for 'Part D' or 'Non-Part D'.

PAYMENT DETERMINATION CRITERIA

1. Does the patient have a diagnosis of type 2 diabetes mellitus (ICD-10 Groups E08, E09, E13, E11 except ICD-10 E11.A) **AND** meet the following criterion?
   - The patient is 10 years of age or older

   If yes, **set MCARE_DRUG_DETERM_OVR to 'Y' and approve for 12 months by HICL or GPI-14. Document in the PA comments: Part D Determination Override and diagnosis.**

   If no, **do not enter an MCARE override. Then, process as follows:**
   CSR Note:
   - If the caller is a physician, member, and/or AOR, please initiate a verbal PA intake request in MR4.
   - If the caller is a pharmacy, please advise the pharmacy to contact the provider or memberto pursue a payment determination and document the diagnosis provided in MedAccess.

   Please follow the clinical authorization process within the HQ notes.

   RPH Note:
   - Review for both FDA and Part D compendial supported off-label indications.
   - If the provided diagnosis is not FDA approved or compendial supported off-label use, **set MCARE_DRUG_DETERM_OVR to 'N' and enter override within the denied PA for 12 months by HICL or GPI-14.**
   - If the diagnosis is UNKNOWN do not enter an MCARE override; follow the criteria for any additional UM and decision the case accordingly. Provide the following PAC instruction**:** **'PAC: do not enter an MCARE override**.'

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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GLP1-EXENATIDE MICROSPHERES TIRF (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of type 2 diabetes mellitus (ICD-10 Group E08, E09, E13, E11 except ICD-10 E11.A) and meet **ALL** of the following criteria?
   - The patient is 10 years of age or older
   - The patient had a trial of TWO preferred GLP-1 or GIP/GLP-1 agonists (e.g., Trulicity [dulaglutide], Rybelsus [semaglutide], Ozempic [semaglutide], Mounjaro [tirzepatide])

   If yes, **approve for 12 months by HICL or GPI-14. NOTE: If the claim rejects for payment determination after analyzing, then follow the above TIRF-Like determination criteria.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Is the request for any other medically accepted indication that is supported by CMS approved compendia (e.g., American Hospital Formulary Service Drug Information, Micromedex DrugDex)?

   If yes, **please forward to pharmacist for clinical review. Approve for 12 months under Part D by HICL or GPI-14. NOTE: If the claim rejects for payment determination after analyzing, then follow the above TIRF-Like determination criteria.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   - **If not a Part D indication: Set MCARE_DRUG_DETERM_OVR to 'N' and enter override within the denied PA for 12 months by HICL or GPI-14.**
   - **If indication is Part D, but other criteria not met: Set MCARE_DRUG_DETERM_OVR to 'Y' and enter override within the partially denied PA for 12 months by HICL or GPI-14.**

   DENIAL TEXT: See the denial text at the end of the guideline.

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GLP1-EXENATIDE MICROSPHERES TIRF (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **GLP1-EXENATIDE MICROSPHERES (Bydureon BCise)** requires the following rule(s) be met for approval:

A. The request is for ONE of the following:
   1. Type 2 diabetes mellitus (a disorder with high blood sugar)
   2. Any other medically accepted indication that is supported by the Center forMedicare and Medicaid Services (CMS) approved compendia (such as American Hospital Formulary Service Drug Information, Micromedex DrugDex)

B. If you have type 2 diabetes mellitus, approval also requires:
   1. You are 10 years of age or older
   2. You have tried TWO preferred glucagon-like peptide-1 (GLP-1) or glucose-dependent insulinotropic polypeptide (GIP)/GLP-1 agonists (such as Trulicity [dulaglutide], Rybelsus [semaglutide], Ozempic [semaglutide], Mounjaro [tirzepatide])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

Prior authorization on Bydureon BCise is required due to a high potential for non-Part D use (D vs. E payment determination only). Bydureon BCise should NOT be used for non-medically accepted indications as defined in section 1860D-2(e)(4) of the Act. For further information, please refer to the Prescribing Information and/or Drug Monograph for Bydureon BCise.

REFERENCES

Bydureon BCise [Prescribing Information]. Wilmington, DE: AstraZeneca; May 2025.
Announcement of Calendar Year (CY) 2015 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. April 7, 2014. Section III – Part D: Appropriate Utilization of Prior Authorization Requirements to Determine Part D Drug Status. Page 112 – 114.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GLP1-EXENATIDE MICROSPHERES TIRF (PART D)

For Part D use only:

GLP1-EXENATIDE MICROSPHERES (PART D)	
Covered Uses	ALL MEDICALLY-ACCEPTED INDICATIONS.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	TYPE 2 DIABETES: TRIAL OF TWO PREFERRED GLP-1 OR GIP/GLP-1 AGONISTS.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GLP-1 EXENATIDE TIRF (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EXENATIDE	BYETTA, EXENATIDE	32893		GPI-14 (2717002000D240, 2717002000D220)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	Yes	No	No	Yes	No	No	Yes	Yes	Yes	Yes

These are TIRF-Like drugs requiring a payment determination for 'Part D' or 'Non-Part D'.

PAYMENT DETERMINATION CRITERIA

1. Does the patient have a diagnosis of type 2 diabetes mellitus (ICD-10 Groups E08, E09, E13, E11 except ICD-10 E11.A) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **set MCARE_DRUG_DETERM_OVR to 'Y' and approve for 12 months by HICL or GPI-14 for all strengths. Document in the PA comments: Part D Determination Override and diagnosis.**

   If no, **do not enter an MCARE override. Then, process as follows:**
   CSR Note:
   - If the caller is a physician, member, and/or AOR, please initiate a verbal PA intake request in MR4.
   - If the caller is a pharmacy, please advise the pharmacy to contact the provider or memberto pursue a payment determination and document the diagnosis provided in MedAccess.

   Please follow the clinical authorization process within the HQ notes.

   RPH Note:
   - Review for both FDA and Part D compendial supported off-label indications.
   - If the provided diagnosis is not FDA approved or compendial supported off-label use, **set MCARE_DRUG_DETERM_OVR to 'N' and enter override within the denied PA for 12 months by HICL or GPI-14.**
   - If the diagnosis is UNKNOWN do not enter an MCARE override; follow the criteria for any additional UM and decision the case accordingly. Provide the following PAC instruction**:** '**PAC: do not enter an MCARE override**.'

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GLP-1 EXENATIDE TIRF (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of type 2 diabetes mellitus (ICD-10 Groups E08, E09, E13, E11 except ICD-10 E11.A) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of TWO preferred GLP-1 or GIP/GLP-1 agonists (e.g., Trulicity [dulaglutide], Rybelsus [semaglutide], Ozempic [semaglutide], Mounjaro [tirzepatide])

   If yes, **approve for 12 months by HICL or GPI-14 for all strengths. NOTE: If the claim rejects for payment determination after analyzing, then follow the above TIRF-Like determination criteria.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Is the request for any other medically accepted indication that is supported by CMS approved compendia (e.g., American Hospital Formulary Service Drug Information, Micromedex DrugDex)?

   If yes, **please forward to pharmacist for clinical review. Approve for 12 months under Part D by HICL or GPI-14 for all strengths. NOTE: If the claim rejects for payment determination after analyzing, then follow the above TIRF-Like determination criteria.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   - **If not a Part D indication: Set MCARE_DRUG_DETERM_OVR to 'N' and enter override within the denied PA for 12 months by HICL or GPI-14.**
   - **If indication is Part D, but other criteria not met: Set MCARE_DRUG_DETERM_OVR to 'Y' and enter override within the partially denied PA for 12 months by HICL or GPI-14.**

   DENIAL TEXT: See the denial text at the end of the guideline.

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GLP-1 EXENATIDE TIRF (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **GLP1-EXENATIDE (Byetta)** requires the following rule(s) be met for approval:

A. The request is for ONE of the following:
   1. Type 2 diabetes mellitus (a disorder with high blood sugar)
   2. Any other medically accepted indication that is supported by the Center forMedicare and Medicaid Services (CMS) approved compendia (such as American Hospital Formulary Service Drug Information, Micromedex DrugDex)

B. If you have type 2 diabetes mellitus, approval also requires:
   1. You are 18 years of age or older
   2. You have tried TWO preferred glucagon-like peptide-1 (GLP-1) or glucose-dependent insulinotropic polypeptide (GIP)/GLP-1 agonists (such as Trulicity [dulaglutide], Rybelsus [semaglutide], Ozempic [semaglutide], Mounjaro [tirzepatide])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

Prior authorization on Byetta is required due to a high potential for non-Part D use (D vs. E payment determination only). Byetta should NOT be used for non-medically accepted indications as defined in section 1860D-2(e)(4) of the Act. For further information, please refer to the Prescribing Information and/or Drug Monograph for Byetta.

REFERENCES

Byetta [Prescribing Information]. Wilmington, DE: AstraZeneca; September 2025.
Exenatide [Prescribing Information]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; November 2024.
Announcement of Calendar Year (CY) 2015 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. April 7, 2014. Section III – Part D: Appropriate Utilization of Prior Authorization Requirements to Determine Part D Drug Status. Page 112 – 114.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GLP-1 EXENATIDE TIRF (PART D)

For Part D use only:

GLP1-EXENATIDE (PART D)	
Covered Uses	ALL MEDICALLY-ACCEPTED INDICATIONS.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	TYPE 2 DIABETES: TRIAL OF TWO PREFERRED GLP-1 OR GIP/GLP-1 AGONISTS.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GLP1-LIRAGLUTIDE TIRF (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LIRAGLUTIDE	VICTOZA, LIRAGLUTIDE	36436		GPI-10 (2717005000)	BRAND ≠ SAXENDA

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	Yes	No	No	Yes	No	No	Yes	No	Yes	Yes

These are TIRF-Like drugs requiring a payment determination for 'Part D' or 'Non-Part D'.

PAYMENT DETERMINATION CRITERIA

1. Does the patient have a diagnosis of type 2 diabetes mellitus (ICD-10 Groups E08, E09, E13, E11 except ICD-10 E11.A) **AND** meet the following criterion?
   - The patient is 10 years of age or older

   If yes, **set MCARE_DRUG_DETERM_OVR to 'Y' and approve for 12 months by HICL or GPI-10. Document in the PA comments: Part D Determination Override and diagnosis.**

   If no, **do not enter an MCARE override. Then, process as follows:**
   CSR Note:
   - If the caller is a physician, member, and/or AOR, please initiate a verbal PA intake request in MR4.
   - If the caller is a pharmacy, please advise the pharmacy to contact the provider or memberto pursue a payment determination and document the diagnosis provided in MedAccess.

   Please follow the clinical authorization process within the HQ notes.

   RPH Note:
   - Review for both FDA and Part D compendial supported off-label indications.
   - If the provided diagnosis is not FDA approved or compendial supported off-label use, **set MCARE_DRUG_DETERM_OVR to 'N' and enter override within the denied PA for 12 months by HICL or GPI-10.**
   - If the diagnosis is UNKNOWN do not enter an MCARE override; follow the criteria for any additional UM and decision the case accordingly. Provide the following PAC instruction: **'PAC: do not enter an MCARE override**.'

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GLP1- LIRAGLUTIDE TIRF (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of type 2 diabetes mellitus (ICD-10 Group E08, E09, E13, E11 except ICD-10 E11.A) and meet **ALL** of the following criteria?
   - The patient is 10 years of age or older
   - The patient had a trial of TWO preferred GLP-1 or GIP/GLP-1 agonists (e.g., Trulicity [dulaglutide], Rybelsus [semaglutide], Ozempic [semaglutide], Mounjaro [tirzepatide])

   If yes, **approve for 12 months by HICL or GPI-10. NOTE: If the claim rejects for payment determination after analyzing, then follow the above TIRF-Like determination criteria.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Is the request for any other medically accepted indication that is supported by CMS approved compendia (e.g., American Hospital Formulary Service Drug Information, Micromedex DrugDex)?

   If yes, **please forward to pharmacist for clinical review. Approve for 12 months under Part D by HICL or GPI-10. NOTE: If the claim rejects for payment determination after analyzing, then follow the above TIRF-Like determination criteria.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   - **If not a Part D indication: Set MCARE_DRUG_DETERM_OVR to 'N' and enter override within the denied PA for 12 months by HICL or GPI-10.**
   - **If indication is Part D, but other criteria not met: Set MCARE_DRUG_DETERM_OVR to 'Y' and enter override within the partially denied PA for 12 months by HICL or GPI-10.**

   DENIAL TEXT: See the denial text at the end of the guideline.

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GLP1-LIRAGLUTIDE TIRF (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **GLP1-LIRAGLUTIDE (Victoza)** requires the following rule(s) be met for approval:

A. The request is for ONE of the following:
   1. Type 2 diabetes mellitus (a disorder with high blood sugar)
   2. Any other medically accepted indication that is supported by the Center forMedicare and Medicaid Services (CMS) approved compendia (such as American Hospital Formulary Service Drug Information, Micromedex DrugDex)

B. If you have type 2 diabetes mellitus, approval also requires:
   1. You are 10 years of age or older
   2. You have tried TWO preferred glucagon-like peptide-1 (GLP-1) or glucose-dependent insulinotropic polypeptide (GIP)/GLP-1 agonists (such as Trulicity [dulaglutide], Rybelsus [semaglutide], Ozempic [semaglutide], Mounjaro [tirzepatide])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

Prior authorization on Victoza is required due to a high potential for non-Part D use (D vs. E payment determination only). Victoza should NOT be used for non-medically accepted indications as defined in section 1860D-2(e)(4) of the Act. For further information, please refer to the Prescribing Information and/or Drug Monograph for Victoza.

REFERENCES

Victoza [Prescribing Information]. Plainsboro, NJ: Novo Nordisk, Inc.; October 2025.
Announcement of Calendar Year (CY) 2015 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. April 7, 2014. Section III – Part D: Appropriate Utilization of Prior Authorization Requirements to Determine Part D Drug Status. Page 112 – 114.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GLP1-LIRAGLUTIDE TIRF (PART D)

For Part D use only:

GLP1-LIRAGLUTIDE (PART D)	
Covered Uses	ALL MEDICALLY-ACCEPTED INDICATIONS.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	TYPE 2 DIABETES: TRIAL OF TWO PREFERRED GLP-1 OR GIP/GLP-1 AGONISTS.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GLP1-SEMAGLUTIDE TIRF (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SEMAGLUTIDE	OZEMPIC, RYBELSUS	44675		GPI-10 (2717007000)	BRAND = OZEMPIC, RYBELSUS

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	Yes	No	Yes	Yes	No	Yes	Yes	No	Yes	Yes

These are TIRF-Like drugs requiring a payment determination for 'Part D' or 'Non-Part D'.

PAYMENT DETERMINATION CRITERIA

1. Does the patient have a diagnosis of type 2 diabetes mellitus (ICD-10 Groups E08, E09, E13, E11 except ICD-10 E11.A) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **set MCARE_DRUG_DETERM_OVR to 'Y' and approve for 12 months by GPID for all strengths and formulations or by GPI-10. Document in the PA comments: Part D Determination Override and diagnosis.**

   If no, **do not enter an MCARE override. Then, process as follows:**
   CSR Note:
   - If the caller is a physician, member, and/or AOR, please initiate a verbal PA intake request in MR4.
   - If the caller is a pharmacy, please advise the pharmacy to contact the provider or memberto pursue a payment determination and document the diagnosis provided in MedAccess.

   Please follow the clinical authorization process within the HQ notes.

   RPH Note:
   - Review for both FDA and Part D compendial supported off-label indications.
   - If the provided diagnosis is not FDA approved or compendial supported off-label use, **set MCARE_DRUG_DETERM_OVR to 'N' and enter override within the denied PA for 12 months by GPID or GPI-10.**
   - If the diagnosis is UNKNOWN do not enter an MCARE override; follow the criteria for any additional UM and decision the case accordingly. Provide the following PAC instruction**:** '**PAC: do not enter an MCARE override**.'

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GLP1-SEMAGLUTIDE TIRF (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **GLP1-SEMAGLUTIDE (Ozempic, Rybelsus)** requires the following rule(s) be met for approval:

A. You have type 2 diabetes (a disorder with high blood sugar)
B. You are 18 years of age or older

RATIONALE

Prior authorization on Ozempic or Rybelsus are required due to a high potential for non-Part D use (D vs. E payment determination only). Ozempic or Rybelsus should NOT be used for non-medically accepted indications as defined in section 1860D-2(e)(4) of the Act. For further information, please refer to the Prescribing Information and/or Drug Monograph for Ozempic or Rybelsus.

REFERENCES

Ozempic [Prescribing Information]. Plainsboro, NJ: Novo Nordisk Inc.; October 2025.
Rybelsus [Prescribing Information]. Plainsboro, NJ: Novo Nordisk Inc.; January 2026.
Advantage and Part D Payment Policies and Final Call Letter. April 7, 2014. Section III – Part D: Appropriate Utilization of Prior Authorization Requirements to Determine Part D Drug Status. Page 112 – 114.

For Part D use only:

GLP1-SEMAGLUTIDE (PART D)	
Covered Uses	ALL MEDICALLY-ACCEPTED INDICATIONS.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GLP1-TIRZEPATIDE TIRF (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TIRZEPATIDE	MOUNJARO	48014		GPI-10 (2717308000)	BRAND = MOUNJARO

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	Yes	No	Yes	Yes	No	Yes	Yes	No	Yes	Yes

These are TIRF-Like drugs requiring a payment determination for 'Part D' or 'Non-Part D'.

PAYMENT DETERMINATION CRITERIA

1. Does the patient have a diagnosis of type 2 diabetes mellitus (ICD-10 Groups E08, E09, E13, E11 except ICD-10 E11.A) **AND** meet the following criterion?
   - The patient is 10 years of age or older

   If yes, **set MCARE_DRUG_DETERM_OVR to 'Y' and approve for all strengths for 12 months by GPID or GPI-10. Document in the PA comments: Part D Determination Override and diagnosis.**

   If no, **do not enter an MCARE override. Then, process as follows:**
   CSR Note:
   - If the caller is a physician, member, and/or AOR, please initiate a verbal PA intake request in MR4.
   - If the caller is a pharmacy, please advise the pharmacy to contact the provider or memberto pursue a payment determination and document the diagnosis provided in MedAccess.

   Please follow the clinical authorization process within the HQ notes.

   RPH Note:
   - Review for both FDA and Part D compendial supported off-label indications.
   - If the provided diagnosis is not FDA approved or compendial supported off-label use, **set MCARE_DRUG_DETERM_OVR to 'N' and enter override within the denied PA for 12 months by GPID or GPI-10.**
   - If the diagnosis is UNKNOWN do not enter an MCARE override; follow the criteria for any additional UM and decision the case accordingly. Provide the following PAC instruction: '**PAC: do not enter an MCARE override**.'

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GLP1-TIRZEPATIDE TIRF (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **GLP1-TIRZEPATIDE (Mounjaro)** requires the following rule(s) be met for approval:

A. You have type 2 diabetes mellitus (a disorder with high blood sugar)
B. You are 10 years of age or older

RATIONALE

Prior authorization on Mounjaro is required due to a high potential for non-Part D use (D vs. E payment determination only). Mounjaro should NOT be used for non-medically accepted indications as defined in section 1860D-2(e)(4) of the Act. For further information, please refer to the Prescribing Information and/or Drug Monograph for Mounjaro.

REFERENCES

Mounjaro [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; December 2025.
Advantage and Part D Payment Policies and Final Call Letter. April 7, 2014. Section III – Part D: Appropriate Utilization of Prior Authorization Requirements to Determine Part D Drug Status. Page 112 – 114.

For Part D use only:

GLP1-TIRZEPATIDE (PART D)	
Covered Uses	ALL MEDICALLY-ACCEPTED INDICATIONS.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GLYCEROL PHENYLBUTYRATE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GLYCEROL PHENYLBUTYRATE	RAVICTI, GLYCEROL PHENYLBUTYRATE	39990		GPI-10 (3090803000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of a urea cycle disorder (UCD) (ICD-10 E72.2) and meet **ALL** of the following criteria?
   - The patient's disorder cannot be managed by dietary protein restriction and/or amino acid supplementation alone
   - The patient's UCD is confirmed by enzymatic, biochemical, or genetic testing
   - The patient had a trial of or contraindication to sodium phenylbutyrate (Buphenyl)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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GLYCEROL PHENYLBUTYRATE (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **GLYCEROL PHENYLBUTYRATE (Ravicti)** requires the following rule(s) be met for approval:

A. You have a urea cycle disorder (UCD: a genetic disorder that causes high ammonia levels in the blood)
B. Your disorder cannot be managed by dietary protein restriction and/or amino acid supplementation alone
C. Your disorder is confirmed by enzymatic, biochemical, or genetic testing (types of lab tests)
D. You have tried or have a contraindication to (harmful for you to use) sodium phenylbutyrate (Buphenyl)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GLYCEROL PHENYLBUTYRATE (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of a urea cycle disorder (UCD) (ICD-10 E72.2) **AND** meet the following criterion?
   - The patient had a clinical benefit compared to baseline (e.g., normal fasting glutamine, low-normal fasting ammonia levels, mental status clarity)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GLYCEROL PHENYLBUTYRATE (Ravicti)** requires the following rule(s) be met for renewal:
   A. You have a urea cycle disorder (UCD: a genetic disorder that causes high ammonia levels in the blood)
   B. You had a clinical benefit compared to baseline (such as normal fasting glutamine, low-normal fasting ammonia levels, mental status clarity)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Ravicti.

REFERENCES
Ravicti [Prescribing Information]. Deerfield, IL: Horizon Therapeutics USA, Inc; September 2021.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GLYCEROL PHENYLBUTYRATE (PART D)

For Part D use only:

GLYCEROL PHENYLBUTYRATE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	UREA CYCLE DISORDER (UCD): INITIAL: DIAGNOSIS IS CONFIRMED BY ENZYMATIC, BIOCHEMICAL OR GENETIC TESTING
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS
Other Criteria	UCD: INITIAL: TRIAL OF OR CONTRAINDICATION TO SODIUM PHENYLBUTYRATE. RENEWAL: PATIENT HAS CLINICAL BENEFIT FROM BASELINE.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GOLIMUMAB IV BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GOLIMUMAB	SIMPONI ARIA		34983	GPI-14 (66270040002015)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	Yes	No	No	Yes	No	No	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #5.

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GOLIMUMAB IV BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

If yes, **Refer to plan. (The health plan makes the final payment determination decision)**

- **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
- **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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GOLIMUMAB IV BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient will be concurrently using methotrexate
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Simponi Aria will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Orencia (abatacept)

   If yes, **approve for 6 months by GPID or GPI-14.**
   If no, continue to #2.

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GOLIMUMAB IV BvD (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
- Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
- Simponi Aria will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

If yes, continue to #3.
If no, continue to #4.

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GOLIMUMAB IV BvD (PART D)

INITIAL CRITERIA (CONTINUED)

3. Does the patient meet **ONE** of the following criteria?
   - The patient is 2 to 5 years of age AND had a trial of or contraindication to TWO of the following preferred agents:
     - Cosentyx (secukinumab)
     - Orencia (abatacept)
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Enbrel (etanercept)])
     - Xeljanz (tofacitinib IR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
   - The patient is 6 to 17 years of age AND had a trial of or contraindication to TWO of the following preferred agents:
     - Cosentyx (secukinumab)
     - Selarsdi/Yesintek/ustekinumab-aauz
     - Orencia (abatacept)
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Enbrel (etanercept)])
     - Skyrizi (risankizumab-rzaa)
     - Otezla (apremilast)
     - Tremfya (guselkumab)
     - Xeljanz (tofacitinib IR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
   - The patient is 18 years of age or older AND had a trial of or contraindication to TWO of the following preferred agents:
     - Cosentyx (secukinumab)
     - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
     - Selarsdi/Yesintek/ustekinumab-aauz
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Skyrizi (risankizumab-rzaa)
     - Tremfya (guselkumab)
     - Orencia (abatacept)
     - Otezla (apremilast)

   If yes, **approve for 6 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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GOLIMUMAB IV BvD (PART D)

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Simponi Aria will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Cosentyx (secukinumab)
     - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])

   If yes, **approve for 6 months by GPID or GPI-14.**
   If no, continue to #5.

5. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (pJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Simponi Aria will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of pJIA
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
     - Xeljanz (tofacitinib IR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Orencia (abatacept)

   If yes, **approve for 6 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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GOLIMUMAB IV BvD (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: Our guideline named **GOLIMUMAB IV (Simponi Aria)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Ankylosing spondylitis (AS: a type of joint condition)
   4. Polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition in children)

B. If you have moderate to severe rheumatoid arthritis, approval also requires:
   1. You are 18 years of age or older
   2. You will be concurrently (at the same time) using methotrexate
   3. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   4. You will NOT use Simponi Aria concurrently with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
   5. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      a. Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
      b. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
      c. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
      d. Orencia (abatacept)

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INITIAL CRITERIA (CONTINUED)

C. If you have psoriatic arthritis, approval also requires:

1. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (skin doctor)
2. You will NOT use Simponi Aria concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis
3. You meet ONE of the following:
   a. You are 2 to 5 years of age AND have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Cosentyx (secukinumab)
      ii. Orencia (abatacept)
      iii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Enbrel (etanercept)])
      iv. Xeljanz IR (tofacitinib immediate-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
   b. You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Cosentyx (secukinumab)
      ii. Selarsdi/Yesintek/ustekinumab-aauz
      iii. Orencia (abatacept)
      iv. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Enbrel (etanercept)])
      v. Skyrizi (risankizumab-rzaa)
      vi. Otezla (apremilast)
      vii. Tremfya (guselkumab)
      viii. Xeljanz IR (tofacitinib immediate-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])

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GOLIMUMAB IV BvD (PART D)

INITIAL CRITERIA (CONTINUED)

c. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   i. Cosentyx (secukinumab)
   ii. Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
   iii. Selarsdi/Yesintek/ustekinumab-aauz
   iv. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
   v. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as Humira (adalimumab)/ Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
   vi. Skyrizi (risankizumab-rzaa)
   vii. Tremfya (guselkumab)
   viii. Orencia (abatacept)
   ix. Otezla (apremilast)

D. If you have ankylosing spondylitis, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You will NOT use Simponi Aria concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis
4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Cosentyx (secukinumab)
   b. Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
   c. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/ Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
   d. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as Humira (adalimumab)/ Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])

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GOLIMUMAB IV BvD (PART D)

INITIAL CRITERIA (CONTINUED)

E. If you have polyarticular juvenile idiopathic arthritis, approval also requires:

1. You are 2 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You will NOT use Simponi Aria concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis
4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
   b. Xeljanz IR (tofacitinib immediate-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/ Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
   c. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as Humira (adalimumab)/ Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
   d. Orencia (abatacept)

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GOLIMUMAB IV BvD (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Simponi Aria will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Simponi Aria will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, continue to #3.

3. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Simponi Aria will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, continue to #4.

4. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (pJIA) (ICD-10 Group M08) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Simponi Aria will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of pJIA

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: Our guideline named **GOLIMUMAB IV (Simponi Aria)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Ankylosing spondylitis (AS: a type of joint condition)
   4. Polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition in children)

B. If you have moderate to severe rheumatoid arthritis, renewal also requires:
   1. You continue to benefit from the medication
   2. You will NOT use Simponi Aria concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis

C. If you have psoriatic arthritis, renewal also requires:
   1. You continue to benefit from the medication
   2. You will NOT use Simponi Aria concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

D. If you have ankylosing spondylitis, renewal also requires:
   1. You continue to benefit from the medication
   2. You will NOT use Simponi Aria concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis

E. If you have polyarticular juvenile idiopathic arthritis, renewal also requires:
   1. You continue to benefit from the medication
   2. You will NOT use Simponi Aria concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Simponi Aria. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

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GOLIMUMAB IV BvD (PART D)

REFERENCES

Simponi Aria [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc; April 2025.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed March 18, 2026].

For Part D use only:

GOLIMUMAB IV (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: RHEUMATOID ARTHRITIS (RA), ANKYLOSING SPONDYLITIS (AS), POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST OR DERMATOLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: RA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, XELJANZ, RINVOQ, ORENCIA. PSA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS, WHERE AGES ALIGN: COSENTYX, HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, SELARSDI/YESINTEK/USTEKINUMAB-AAUZ, XELJANZ, RINVOQ, SKYRIZI, TREMFYA, ORENCIA, OTEZLA. AS: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: COSENTYX, HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, XELJANZ, RINVOQ. PJIA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, XELJANZ IR, RINVOQ, ORENCIA. INITIAL/RENEWAL: ALL INDICATIONS: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION. RENEWAL: ALL INDICATIONS: CONTINUES TO BENEFIT FROM THE MEDICATION.

Created: 11/07
Effective: 07/15/26 Client Approval: 07/26 P&T Approval: 10/24

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GOLIMUMAB SQ (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GOLIMUMAB	SIMPONI	36278		GPI-10 (6627004000)	ROUTE = SUBCUTANE.

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient will be concurrently using methotrexate
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Simponi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Orencia (abatacept)

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths of the subcutaneous formulation.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.
   If no, continue to #2.

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GOLIMUMAB SQ (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
- Simponi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA
- The patient had a trial of or contraindication to TWO of the following preferred agents:
  - Cosentyx (secukinumab)
  - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
  - Selarsdi/Yesintek/ustekinumab-aauz
  - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
  - Skyrizi (risankizumab-rzaa)
  - Tremfya (guselkumab)
  - Orencia (abatacept)
  - Otezla (apremilast)

If yes, **approve for 6 months by GPID or GPI-14 for all strengths of the subcutaneous formulation.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #3.

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GOLIMUMAB SQ (PART D)

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 excluding Group M45.A) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Simponi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Cosentyx (secukinumab)
     - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths of the subcutaneous formulation.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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GOLIMUMAB SQ (PART D)

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   - The patient weighs at least 15 kg (33 lbs)
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Simponi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

5. Does the patient meet **ONE** of the following criteria?
   - The patient is less than 5 years of age
   - The patient is 5 to 17 years of age AND had a trial of or contraindication to the following preferred agent: Humira (adalimumab)
   - The patient is 18 years of age or older AND had a trial of or contraindication to TWO of the following preferred agents:
     - Selarsdi/Yesintek/ustekinumab-aauz
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Skyrizi (risankizumab-rzaa)
     - Tremfya (guselkumab)

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths of the subcutaneous formulation.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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GOLIMUMAB SQ (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **GOLIMUMAB SQ (Simponi)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Ankylosing spondylitis (AS: a type of joint condition)
   4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. If you have moderate to severe rheumatoid arthritis, approval also requires:
   1. You are 18 years of age or older
   2. You will be concurrently (at the same time) using methotrexate
   3. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   4. You will NOT use Simponi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
   5. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      a. Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
      b. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
      c. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
      d. Orencia (abatacept)

(Initial denial text continued on next page)

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GOLIMUMAB SQ (PART D)

INITIAL CRITERIA (CONTINUED)

C. If you have psoriatic arthritis, approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (skin doctor)
3. You will NOT use Simponi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis
4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Cosentyx (secukinumab)
   b. Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
   c. Selarsdi/Yesintek/ustekinumab-aauz
   d. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
   e. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
   f. Skyrizi (risankizumab-rzaa)
   g. Tremfya (guselkumab)
   h. Orencia (abatacept)
   i. Otezla (apremilast)

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GOLIMUMAB SQ (PART D)

INITIAL CRITERIA (CONTINUED)

D. If you have ankylosing spondylitis, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You will NOT use Simponi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis
4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Cosentyx (secukinumab)
   b. Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
   c. Xeljanz (tofacitinib immediate-release, or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
   d. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])

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GOLIMUMAB SQ (PART D)

INITIAL CRITERIA (CONTINUED)

E. If you have moderate to severe ulcerative colitis, approval also requires:

1. You weigh at least 15 kilograms (33 pounds)
2. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
3. You will NOT use Simponi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis
4. You meet ONE of the following:
   a. You are less than 5 years of age
   b. You are 5 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) the following preferred medication: Humira (adalimumab)
   c. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Selarsdi/Yesintek/ustekinumab-aauz
      ii. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
      iii. Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
      iv. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
      v. Skyrizi (risankizumab-rzaa)
      vi. Tremfya (guselkumab)

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GOLIMUMAB SQ (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Simponi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths of the subcutaneous formulation.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Simponi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths of the subcutaneous formulation.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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GOLIMUMAB SQ (PART D)

RENEWAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 excluding group M45.A), and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Simponi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths of the subcutaneous formulation.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

4. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) **AND** meet the following criterion?
   - Simponi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths of the subcutaneous formulation.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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GOLIMUMAB SQ (PART D)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: : *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **GOLIMUMAB SQ (Simponi)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Ankylosing spondylitis (AS: a type of joint condition)
   4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. If you have moderate to severe rheumatoid arthritis, renewal also requires:
   1. You continue to benefit from the medication
   2. You will NOT use Simponi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis

C. If you have psoriatic arthritis, renewal also requires:
   1. You continue to benefit from the medication
   2. You will NOT use Simponi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

D. If you have ankylosing spondylitis, renewal also requires:
   1. You continue to benefit from the medication
   2. You will NOT use Simponi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis

E. If you have moderate to severe ulcerative colitis, renewal also requires:
   1. You will NOT use Simponi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

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GOLIMUMAB SQ (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Simponi.

REFERENCES
Simponi [Prescribing Information]. Horsham, PA: Janssen Biotech Inc.; October 2025.

For Part D use only:

GOLIMUMAB SQ (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: RHEUMATOID ARTHRITIS (RA), ANKYLOSING SPONDYLITIS (AS): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST. ULCERATIVE COLITIS (UC): PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: RA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, XELJANZ, RINVOQ, ORENCIA. PSA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: COSENTYX, HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, SELARSDI/YESINTEK/USTEKINUMAB-AAUZ, XELJANZ, RINVOQ, SKYRIZI, TREMFYA, ORENCIA, OTEZLA. AS: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: COSENTYX, HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, XELJANZ, RINVOQ. UC: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS, WHERE AGES ALIGN: SELARSDI/YESINTEK/USTEKINUMAB-AAUZ, XELJANZ, HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, RINVOQ, SKYRIZI, TREMFYA. INITIAL/RENEWAL: ALL INDICATIONS: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION. RENEWAL: RA, PSA, AS: CONTINUES TO BENEFIT FROM THE MEDICATION.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GOLODIRSEN BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GOLODIRSEN	VYONDYS-53	46254		GPI-10 (7460004200)	

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, continue to #6.
   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, continue to #6.
   If no, continue to #5.

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

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GOLODIRSEN BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

6. Is the drug administered via an implantable pump?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, continue to #7.

7. Is the drug administered via an external infusion pump?

   If yes, continue to #8.
   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

8. Is the drug specifically infused through an external infusion pump covered by Medicare?

   If yes, **approve for up to 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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GOLODIRSEN BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Duchenne muscular dystrophy (DMD) (ICD-10 G71.01) and meet **ALL** of the following criteria?
   - The patient has a confirmed mutation of the DMD gene that is amenable to exon 53 skipping therapy
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient is ambulatory
   - The patient is currently receiving treatment with or has a contraindication to corticosteroids (e.g., prednisone, prednisolone)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GOLODIRSEN (Vyondys 53)** requires the following rule(s) be met for approval:
   A. You have Duchenne muscular dystrophy (DMD: a type of inherited muscle disorder)
   B. You have a confirmed mutation of the DMD gene that will respond to exon 53 skipping therapy (a process that allows a protein to still function with sections of faulty genetic code)
   C. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor)
   (Initial denial text continued on next page)

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GOLODIRSEN BvD (PART D)

INITIAL CRITERIA (CONTINUED)

D. You are ambulatory (able to walk)
E. You are currently receiving treatment with or you have a contraindication to (harmful for you to use) corticosteroids (such as prednisone, prednisolone)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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GOLODIRSEN BvD (PART D)

RENEWAL CRITERIA

1. Does the patient meet **ONE** of the following criteria?
   - The patient has maintained or demonstrated a less than expected decline in ambulatory ability based on muscle function assessments (e.g., 6-minute walk test)
   - The patient has maintained or demonstrated a less than expected decline in other muscle function (i.e., pulmonary or cardiac function)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GOLODIRSEN (Vyondys 53)** requires ONE of the following rules be met for renewal:
   A. You have maintained or demonstrated a less than expected decline in ambulatory ability (ability to walk) based on muscle function assessments (such as the 6-minute walk test)
   B. You have maintained or demonstrated a less than expected decline in other muscle function (pulmonary [lung] or cardiac [heart] function)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vyondys 53.

The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B. Drugs administered by an implantable pump are covered under Part B. Drugs administered via an external pump are covered under Part B if they are included under the local coverage policy of the applicable Medicare coverage policies (National and/or Local Coverage Policies). Drugs administered via an external pump that are not included under the applicable Medicare coverage policies are covered under Part D. A CMS website to assist with National and Local Coverage Determination for B versus D review is http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx.

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GOLODIRSEN BvD (PART D)

REFERENCES

Vyondys 53 [Prescribing Information]. Cambridge, MA: Sarepta Therapeutics, Inc.; June 2024.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed July 2, 2024].

For Part D use only:

GOLODIRSEN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	DUCHENNE MUSCULAR DYSTROPHY (DMD): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST.
Coverage Duration	INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS.
Other Criteria	DMD: INITIAL: PATIENT IS AMBULATORY AND CURRENTLY RECEIVING TREATMENT WITH OR HAS A CONTRAINDICATION TO CORTICOSTEROIDS. RENEWAL: MAINTAINED OR DEMONSTRATED A LESS THAN EXPECTED DECLINE IN AMBULATORY ABILITY IN MUSCLE FUNCTION ASSESSMENTS OR OTHER MUSCLE FUNCTION (I.E., PULMONARY OR CARDIAC FUNCTION).

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GOSERELIN BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GOSERELIN ACETATE	ZOLADEX	21114		GPI-10 (2140500510)	

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**
   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**
   If no, continue to #5.

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GOSERELIN BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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GOSERELIN BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally confined Stage T2b-T4 (Stage B2-C) carcinoma of the prostate (ICD-10 C61) **AND** meet the following criterion?
   - Zoladex will be used in combination with Eulexin (flutamide)

   If yes, **approve for 4 months by HICL or GPI-10.**

   If no, continue to #2.

2. Does the patient have a diagnosis of advanced prostate cancer (ICD-10 C61)?

   If yes, **approve for 12 months by HICL or GPI-10.**

   If no, continue to #3.

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GOSERELIN BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of endometriosis (ICD-10 Groups N80 and R52) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with an obstetrician/gynecologist
- The patient had a trial of or contraindication to a nonsteroidal anti-inflammatory drug (NSAID) AND a progestin-containing preparation (e.g., combination hormonal contraceptive preparation, progestin-only therapy)
- Zoladex will NOT be used concurrently with another GnRH-modulating agent (e.g., Orilissa [elagolix], Lupron Depot [leuprolide], Synarel [nafarelin])
- The patient has NOT received a total of 6 months of treatment with Zoladex per lifetime

If yes, **approve for 6 months per lifetime by HICL or GPI-10.**

If no, continue to #4.

4. Does the patient have a diagnosis of dysfunctional uterine bleeding (ICD-10 N93.8) **AND** meet the following criterion?
- Zoladex will be used as an endometrial-thinning agent prior to endometrial ablation

If yes, **approve for 12 months by HICL or GPI-10.**

If no, continue to #5.

5. Does the patient have a diagnosis of advanced breast cancer (ICD-10 Group C50) **AND** meet the following criterion?
- The patient is a premenopausal or perimenopausal female

If yes, **approve for 12 months by HICL or GPI-10.**

If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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GOSERELIN BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT:

Our guideline named **GOSERELIN (Zoladex)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Locally confined Stage T2b-T4 (Stage B2-C) carcinoma of the prostate (prostate cancer that has not spread outside the prostate)
   2. Advanced prostate cancer (prostate cancer that has spread to nearby tissue or organs)
   3. Endometriosis (condition affecting the uterus)
   4. Dysfunctional uterine bleeding (abnormal uterine bleeding)
   5. Advanced breast cancer (breast cancer that has spread to nearby tissue or organs)

B. If you have locally confined Stage T2b-T4 (Stage B2-C) carcinoma of the prostate, approval also requires:
   1. Zoladex will be used in combination with Eulexin (flutamide)

C. If you have endometriosis, approval also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an obstetrician/gynecologist (a type of women's health doctor)
   3. You have tried or have a contraindication to (harmful for you to use) a nonsteroidal anti-inflammatory drug (NSAID: such as ibuprofen, meloxicam, naproxen) AND a progestin-containing preparation (such as combination hormonal contraceptive preparation, progestin-only therapy)
   4. Zoladex will NOT be used at the same time with another gonadotropin-releasing hormone (GnRH)-modulating agent (such as Orilissa [elagolix], Lupron Depot [leuprolide], Synarel [nafarelin])
   5. You have NOT received a total of 6 months of treatment with Zoladex per lifetime

D. If you have dysfunctional uterine bleeding, approval also requires:
   1. Zoladex will be used as an endometrial-thinning agent prior to endometrial ablation (a type of surgical procedure)

E. If you have advanced breast cancer, approval also requires:
   1. You are a premenopausal (before menopause) or perimenopausal (time around menopause) female

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GOSERELIN BvD (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zoladex. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Zoladex [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; March 2026.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed August 4, 2024].

For Part D use only:

GOSERELIN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	ENDOMETRIOSIS: PRESCRIBED BY OR IN CONSULTATION WITH AN OBSTETRICIAN/GYNECOLOGIST.
Coverage Duration	STAGE B2-C PROSTATIC CARCINOMA: 4 MOS. ENDOMETRIOSIS: 6 MOS PER LIFETIME. ALL OTHERS: 12 MONTHS.
Other Criteria	ENDOMETRIOSIS: 1) NO CONCURRENT USE WITH ANOTHER GNRH-MODULATING AGENT, 2) TRIAL OF OR CONTRAINDICATION TO NSAID AND PROGESTIN-CONTAINING PREPARATION, AND 3) HAS NOT RECEIVED A TOTAL OF 6 MONTHS OF TREATMENT PER LIFETIME.

Created: 09/22
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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GUSELKUMAB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GUSELKUMAB	TREMFYA	44418		GPI-10 (5250402500, 9025054200)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist
   - The patient has psoriasis covering 3% or more of body surface area (BSA) OR psoriatic lesions affecting the hands, feet, face, scalp, or genital area
   - Tremfya will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

     If yes, continue to #2.
     If no, continue to #3.

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GUSELKUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient meet **ONE** of the following criteria?
   - The patient has had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy)
   - The patient has a contraindication or intolerance to both immunosuppressant and PUVA (phototherapy)
   - The patient is switching from a different biologic (e.g., Humira [adalimumab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   - Tremfya will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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GUSELKUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Tremfya will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Tremfya will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GUSELKUMAB (Tremfya)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
      2. Psoriatic arthritis (PsA: a type of skin and joint condition)
      3. Moderate to severe ulcerative colitis (UC: a type of digestive condition)
      4. Moderate to severe Crohn's disease (CD: a type of bowel disorder)

   (Initial denial text continued on next page)

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GUSELKUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

B. If you have moderate to severe plaque psoriasis, approval also requires:
1. You are 6 years of age or older
2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
3. You have psoriasis covering 3% or more of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, face, scalp, or genital area
4. You will NOT use Tremfya concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis
5. You meet ONE of the following:
   a. You have had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy)
   b. You have a contraindication (harmful for you to use) or intolerance (side effect) to both immunosuppressant (a type of drug that decreases the body's immune response) and PUVA (phototherapy)
   c. You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication

C. If you have psoriatic arthritis, approval also requires:
1. You are 6 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
3. You will NOT use Tremfya concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

D. If you have moderate to severe ulcerative colitis, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
3. You will NOT use Tremfya concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

(Initial denial text continued on next page)

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GUSELKUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

E. If you have moderate to severe Crohn's disease, approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
3. You will NOT use Tremfya concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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GUSELKUMAB (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Tremfya will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Tremfya will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) **AND** meet the following criterion?
   - Tremfya will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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GUSELKUMAB (PART D)

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) **AND** meet the following criterion?
   - Tremfya will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GUSELKUMAB (Tremfya)** requires the following rule(s) be met for renewal:

   A. You have ONE of the following:
      1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
      2. Psoriatic arthritis (PsA: a type of skin and joint condition)
      3. Moderate to severe ulcerative colitis (UC: a type of digestive condition)
      4. Moderate to severe Crohn's disease (CD: a type of bowel disorder)

   B. If you have moderate to severe plaque psoriasis, renewal also requires:
      1. You continue to benefit from the medication
      2. You will NOT use Tremfya concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis

   C. If you have psoriatic arthritis, renewal also requires:
      1. You continue to benefit from the medication
      2. You will NOT use Tremfya concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

   D. If you have moderate to severe ulcerative colitis, renewal also requires:
      1. You will NOT use Tremfya concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

   (Renewal denial text continued on next page)

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GUSELKUMAB (PART D)

RENEWAL CRITERIA (CONTINUED)

E. If you have moderate to severe Crohn's disease, renewal also requires:

1. You will NOT use Tremfya concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tremfya.

REFERENCES

Tremfya [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; September 2025.

For Part D use only:

GUSELKUMAB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	INITIAL: PLAQUE PSORIASIS (PSO): PSORIASIS COVERING 3 PERCENT OR MORE OF BODY SURFACE AREA OR PSORIATIC LESIONS AFFECTING THE HANDS, FEET, FACE, SCALP, OR GENITAL AREA.
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: PSO: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST. PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST OR DERMATOLOGIST. ULCERATIVE COLITIS (UC), CROHNS DISEASE (CD): PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS
Other Criteria	INITIAL: PSO: 1) AT LEAST A 3 MONTH TRIAL OF ONE ORAL IMMUNOSUPPRESSANT (CYCLOSPORINE, METHOTREXATE, TACROLIMUS) OR PUVA (PHOTOTHERAPY), 2) CONTRAINDICATION OR INTOLERANCE TO BOTH IMMUNOSUPPRESSANT AND PUVA, OR 3) PATIENT IS SWITCHING FROM A DIFFERENT BIOLOGIC, PDE-4 INHIBITOR, OR JAK INHIBITOR FOR THE SAME INDICATION. INITIAL/RENEWAL: ALL INDICATIONS: NO CONCURRENT

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	USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION. RENEWAL: PSO, PSA: CONTINUES TO BENEFIT FROM THE MEDICATION.

Created: 07/17
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 01/25

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HEPATITIS B VACCINE BVD DETERMINATION (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
HEPATITIS B VIRUS VACCINE	RECOMBIVAX HB, ENGERIX-B, PREHEVBRIO	34649		GPI-10 (1710001020, 1710001040)	
HEPATITIS B VACCINE/CPG 1018/PF	HEPLISAV-B	44645		GPI-10 (1710001030)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

NOTE: This PA is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

GUIDELINES FOR USE

1. Is the drug to be administered to a member at high or intermediate risk of being infected with Hepatitis B virus?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B. (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field)**

   If no, **approve for 12 months by HICL or GPI-10 under Part D. (Populate the B vs. D field with a 'D' in the PA override field)**

RATIONALE

Hepatitis B vaccine requires a Part B versus Part D payment determination. This drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. This vaccine is covered under Part B if patients in all age groups are at intermediate to high-risk of being infected with Hepatitis B.

High Risk Groups include:
End-Stage Renal Disease (ESRD) patients
Hemophiliacs who receive Factor VIII or IX concentrates
Clients of institutions for individuals with intellectual disabilities
Persons who live in the same household as a hepatitis B carrier
Homosexual men
Illicit injectable drug abusers
Pacific Islanders (that is, those Medicare beneficiaries who reside on Pacific islands under U.S. jurisdiction, other than residents of Hawaii)
Persons diagnosed with diabetes mellitus

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HEPATITIS B VACCINE BVD DETERMINATION (PART D)

RATIONALE (CONTINUED)

Intermediate Risk Groups include:
Staff in institutions for individuals with intellectual disabilities and classroom employees who work with for individuals with intellectual disabilities
Workers in health care professions who have frequent contact with blood or blood-derived body fluids during routine work (including workers who work outside of a hospital and have frequent contact with blood or other infectious secretions)
Heterosexually active persons with multiple sexual partners (that is, those Medicare beneficiaries who have had at least two documented episodes of sexually transmitted diseases within the preceding 5 years)
Individuals who have not previously received a completed hepatitis B vaccination series or whose previous vaccination history is unknown

Exception:
Individuals are not considered at high or intermediate risk of contracting hepatitis B if they have undergone a prevaccination screening and have been found to be currently positive for antibodies to hepatitis B.

REFERENCES

Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Appendix C- Summary of Coverage Policy Medicare Part B Versus Part D Coverage Issues. Rev 10, 02-19-10. Available at: http://www.cms.gov/PrescriptionDrugCovContra/12_PartDManuals.asp. [Accessed July 16, 2024].
Federal Register/Vol 77, No. 222/Friday, November 16, 2012/Rules and Regulations page 69328 [FR DOC # 2012-26900] http://www.gpo.gov/fdsys/pkg/FR-2012-11-16/pdf/2012-26900.pdf
Hepatitis B vaccine and blood clotting factors: Conditions. https://www.ecfr.gov/current/title-42/section-410.63. [Accessed January 24, 2025].

For Part D use only:

HEPATITIS B VACCINE BVD DETERMINATION (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	PART D DOES NOT COVER THIS DRUG FOR PATIENTS AT HIGH OR INTERMEDIATE RISK OF BEING INFECTED WITH HEPATITIS B VIRUS
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HEPATITIS B VACCINE BVD DETERMINATION (PART D)

Core	Advantage	Plus
Yes	Yes	Yes

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HIGH CONCENTRATION OPIOID ORAL SOLUTIONS (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MORPHINE SULFATE	MORPHINE SULFATE		16063	GPI-14 (65100055102090)	
OXYCODONE HCL	OXYCODONE HCL		16281	GPI-14 (65100075101320)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of pain (R52) severe enough to require an opioid analgesic and for which alternative treatments are inadequate?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient been identified as being enrolled in hospice (i.e., plan notification, member attribute, physician/member notification on the medication request form)?

   If yes, continue to #3.
   If no, continue to #4.

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HIGH CONCENTRATION OPIOID ORAL SOLUTIONS (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does the physician attest that the requested medication will be used for an indication that is unrelated to the terminal illness or conditions?

   If yes, **approve under Part D for lifetime by GPID or GPI-14 and override PA_HOSPICE in the PA override field. Change PA type to HE (Hospice Exception).**

   If no, do not approve.**(Change PA type to HP)**
   NOTE: This medication is included in the hospice benefit (Part A) and is not a Part D eligible drug.

   MEMBER NOTIFICATION LANGUAGE/DENIAL TEXT: If you are enrolled in hospice, your requested medication will be covered under your Part D benefit if your doctor confirms that the medication is being used for the treatment of a condition that is not related to your terminal illness. If you are enrolled in hospice and are taking the medication for a condition related to your terminal illness, coverage may be available through your hospice benefit (Medicare Part A). Your doctor should contact your hospice provider or health plan for coverage information. This decision was based on Title XVIII of the Social Security Act (Section 1861(t)).

4. Is the patient receiving palliative care (ICD-10 Z51.5) or end-of-life care?

   If yes, **approve for lifetime by GPID or GPI-14.**
   If no, continue to #5.

5. Does the patient meet **ALL** of the following criteria?
   - The patient has previously used at least 60 mg oral morphine per day, 25 mcg transdermal fentanyl per hour, 30 mg oral oxycodone per day, 8 mg oral hydromorphone per day, 25 mg oral oxymorphone per day, 60 mg oral hydrocodone per day, or an equianalgesic dose of another opioid
   - The patient has trouble swallowing opioid tablets, capsules, or large volumes of liquid

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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HIGH CONCENTRATION OPIOID ORAL SOLUTIONS (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT:

Our guideline named **HIGH CONCENTRATION OPIOID ORAL SOLUTIONS (morphine sulfate, oxycodone hydrochloride)** requires the following rule(s) be met for approval:

A. You have pain severe enough to require opioid analgesic (a class of drugs used to treat pain) and for which alternative treatments are inadequate
B. You meet ONE of the following:
    1. You are enrolled in hospice OR you are receiving palliative care (relieving pain without treating the cause of the condition) or end-of-life care
    2. You meet ALL of the following:
        a. You have previously used at least 60 mg oral morphine per day, 25 mcg transdermal fentanyl per hour, 30 mg oral oxycodone per day, 8 mg oral hydromorphone per day, 25 mg oral oxymorphone per day, 60 mg oral hydrocodone per day, or an equianalgesic dose of another opioid
        b. You have trouble swallowing opioid tablets, capsules, or large volumes of liquid

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Morphine Sulfate or Oxycodone Hydrochloride oral solution.

REFERENCES

Morphine Sulfate [Prescribing Information]. Baudette, MN: ANI Pharmaceuticals Inc., April 2021
Oxycodone Hydrochloride [Prescribing Information]. East Windsor, NJ: Aurobindo Pharma USA, Inc., February 2020.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HIGH CONCENTRATION OPIOID ORAL SOLUTIONS (PART D)

For Part D use only:

HIGH CONCENTRATION OPIOID ORAL SOLUTIONS (PART D	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	OPIOID TOLERANT: 12 MONTHS. HOSPICE, PALLIATIVE CARE OR END OF LIFE CARE: LIFETIME.
Other Criteria	1) OPIOID TOLERANT (I.E. PREVIOUS USE OF 60 MG ORAL MORPHINE PER DAY, 25 MCG TRANSDERMAL FENTANYL PER HOUR, 30 MG ORAL OXYCODONE PER DAY, 8 MG ORAL HYDROMORPHONE PER DAY, 25 MG ORAL OXYMORPHONE PER DAY, 60 MG ORAL HYDROCODONE PER DAY, OR AN EQUIANALGESIC DOSE OF ANOTHER OPIOID) AND HAS TROUBLE SWALLOWING OPIOID TABLETS, CAPSULES, OR LARGE VOLUMES OF LIQUID, OR 2) ENROLLED IN HOSPICE OR PALLIATIVE CARE OR END OF LIFE CARE.

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Effective: 07/09/26 Client Approval: 07/26 P&T Approval: 04/21

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HISTRELIN-SUPPRELIN LA BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
HISTRELIN ACETATE	SUPPRELIN LA	21104		GPI-10 (3008004510)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	Yes	No	No	Yes	No	No	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**
   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**
   If no, continue to #5.

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HISTRELIN-SUPPRELIN LA BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

If yes, **Refer to plan. (The health plan makes the final payment determination decision)**

- **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
- **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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HISTRELIN-SUPPRELIN LA BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of central precocious puberty (CPP) (ICD-10 E30.1) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with an endocrinologist

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See initial denial text at the end of the guideline.

2. Is the request for a female patient who meets **ALL** of the following criteria?
   - The patient has an elevated level of luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
   - The patient is younger than 8 years of age at the onset of CPP
   - The patient is at Tanner stage 2 or above for breast development and pubic hair growth

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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HISTRELIN-SUPPRELIN LA BvD (PART D)

INITIAL CRITERIA (CONTINUED)

3. Is the request for a male patient who meets **ALL** of the following criteria?
   - The patient has an elevated level of luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
   - The patient is younger than 9 years of age at the onset of CPP
   - The patient is at Tanner stage 2 or above for genital development and pubic hair growth

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.
   Our guideline named **HISTRELIN-SUPPRELIN LA** requires the following rule(s) be met for approval:
   A. You have central precocious puberty (CPP: early sexual development in children)
   B. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
   C. If you are a female, approval also requires:
      1. You have a high level of luteinizing hormone (LH: a type of hormone) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
      2. You are/were younger than 8 years of age when your condition started
      3. You are at Tanner stage 2 or above (scale of physical measurements of development based on external sex characteristics) for breast development and pubic hair growth
   D. If you are a male, approval also requires:
      1. You have a high level of luteinizing hormone (LH: a type of hormone) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
      2. You are/were younger than 9 years of age when your condition started
      3. You are at Tanner stage 2 or above (scale of physical measurements of development based on external sex characteristics) for genital development and pubic hair growth

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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HISTRELIN-SUPPRELIN LA BvD (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of central precocious puberty (CPP) (ICD-10 E30.1) and meet **ALL** of the following criteria?
   - The patient's Tanner staging at initial diagnosis has stabilized or regressed during three separate medical visits in the previous year
   - The patient has not reached the actual age which corresponds to current pubertal age

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **HISTRELIN-SUPPRELIN LA** requires the following rule(s) be met for renewal:
   A. You have central precocious puberty (CPP: early sexual development in children)
   B. Your Tanner staging (scale of physical measurements of development based on external sex characteristics) at initial diagnosis has stabilized or regressed (lowered) during three separate medical visits in the previous year
   C. You have not reached the actual age which corresponds to your current pubertal age

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Supprelin LA. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HISTRELIN-SUPPRELIN LA BvD (PART D)

REFERENCES

Supprelin LA [Prescribing Information]. Malvern, PA: Endo Pharmaceuticals Inc.; September 2025.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed February 3, 2026].

For Part D use only:

HISTRELIN-SUPPRELIN LA (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	CENTRAL PRECOCIOUS PUBERTY (CPP): INITIAL: FEMALES/MALES: ELEVATED LUTEINIZING HORMONE (LH) LEVEL GREATER THAN 0.2 TO 0.3 MIU/ML AT DIAGNOSIS.
Age Restrictions	N/A
Prescriber Restrictions	CPP: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	CPP: INITIAL: FEMALES: 1) YOUNGER THAN 8 YEARS OF AGE AT ONSET OF CPP, AND 2) AT TANNER STAGE 2 OR ABOVE FOR BREAST DEVELOPMENT AND PUBIC HAIR GROWTH. MALES: 1) YOUNGER THAN 9 YEARS OF AGE AT ONSET OF CPP, AND 2) AT TANNER STAGE 2 OR ABOVE FOR GENITAL DEVELOPMENT AND PUBIC HAIR GROWTH. RENEWAL: 1) TANNER STAGING AT INITIAL DIAGNOSIS HAS STABILIZED OR REGRESSED DURING THREE SEPARATE MEDICAL VISITS IN THE PREVIOUS YEAR, AND 2) HAS NOT REACHED ACTUAL AGE WHICH CORRESPONDS TO CURRENT PUBERTAL AGE.

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HOSPICE PRIOR AUTHORIZATION GUIDELINES

HOSPICE AVD DETERMINATION (PART D)

Note: This guideline pertains to Generic Therapeutic Category PAIN MANAGEMENT, ANALGESICS and Generic Therapeutic Category ANTIEMESIS/ANTIVERTIGO and Generic Therapeutic Category BEHAVIORAL HEALTH – OTHER as referenced in the HOSPICE DRUG LIST found in the FORMULARY ANALYZER TOOL:

STC	Generic	HICL	GCN	Exception/Other
Laxatives and Cathartics	N/A	N/A	N/A	N/A
Anti-Anxiety	N/A	N/A	N/A	N/A
Antiemetic/Antivertigo Agents	N/A	N/A	N/A	N/A
Analgesics	N/A	N/A	N/A	N/A

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request then a verbal MRF must be completed. Please check the applicable CS note for processing.

NOTE: This PA is for administrative purposes to determine Medicare Part D versus Hospice funding.

Hospice patients will be identified in the Member Attribute Screen (mbr_attribute table where mbr_attribute_type = 'HOSPICE').

GUIDELINES FOR USE

1. Is the requested medication on the “HOSPICE DRUG LIST”? (**NOTE:** Please reference the Formulary Analyzer Tool for drug status.)

   If yes, **Default to PA type HP** and continue to #2.
   If no, guideline does not apply.
   MEMBER NOTIFICATION LANGUAGE/DENIAL TEXT: See member notification/denial text at the end of guideline.

2. Has the patient been identified as being enrolled in hospice (i.e., plan notification, member attribute, physician/member notification on the medication request form)?

   If yes, continue to #3.
   If no, guideline does not apply.
   MEMBER NOTIFICATION LANGUAGE/DENIAL TEXT: See member notification/denial text at the end of guideline.

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GUIDELINES FOR USE (CONTINUED)

3. Does the physician indicate that the patient is no longer in hospice?

   If yes, **approve for 12 months under Part D and override PA_HOSPICE in the PA override field. Change PA type to HE (Hospice Exception). Document in the PA comments: 'Part D Determination Override.'**

   If no, continue to #4.

4. Does the physician attest that the requested medication is being used for an indication that is unrelated to the terminal illness or conditions?

   If yes, **approve for 12 months under Part D and override PA_HOSPICE in the PA override field. Change PA type to HE (Hospice Exception). Document in the PA comments: 'Part D Determination Override.'**

   If no, do not approve.
   NOTE: This medication is included in the hospice benefit (Part A) and is not a Part D eligible drug.
   MEMBER NOTIFICATION LANGUAGE/DENIAL TEXT: For patients enrolled in hospice, attestation by the prescriber must indicate that the requested medication is being used for the treatment of a diagnosis unrelated to the terminal illness or related condition for coverage under their Part D benefit. For patients enrolled in hospice who are taking medications for a diagnosis related to the terminal illness/condition, coverage may be eligible through their hospice benefit (Medicare Part A). Your physician should contact your hospice provider or health plan for coverage information. This decision was based on Title XVIII of the Social Security Act (Section 1861(t)).

RATIONALE

2014 Hospice Drug Policy
CMS requires that Part D sponsors ensure that Part D does not pay for drugs and biologics that may be covered under the Medicare Part A per-diem payment to a hospice program. (As specified in section 1861(dd) of the Social Security Act and in Federal regulations at Part 418, the hospice is responsible for covering all drugs or biologics for the palliation and management of the terminal and related conditions). CMS revised guidance on July 18, 2014, under the memorandum entitled “Part D Payment for Drugs for Beneficiaries Enrolled in Medicare Hospice” to encourage sponsors to place beneficiary-level PA requirements on only four categories of prescription drugs identified by the DHHS Office of Inspector General (OIG): ***analgesics, antinauseants (antiemetics), laxatives, and antianxiety drugs (anxiolytics***).

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HOSPICE AVD DETERMINATION (PART D)

REFERENCES

Federal Register Vol. 78, No. 152. August 7, 2013. DHHS Center for Medicare and Medicaid Service 42 CFR part 418. Medicare Program; FY 2014 Hospice Wage Index and Payment Rate Update; Hospice Quality Reporting Requirements; and Updates on Payment Reform; Final Rule.
CMS Memo: Part D Payment for Drugs for Beneficiaries Enrolled in Medicare Hospice. July 18, 2014
CMS memo: Announcement of Calendar Year (CY) 2014 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter, April 1, 2013.
CMS memo: Part D Payment for Drugs for Beneficiaries Enrolled in Hospice—Final 2014 Guidance, March 10, 2014.

For Part D use only:

HOSPICE AVD DETERMINATION (PART D)	
Covered uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A
Quantity Limit (from Formulary ASCII file)	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 09/20/24 Created: 11/13
Commercial Effective: N/A Client Approval: 09/24 P&T Approval: 11/14

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HRM-BUTALBITAL-CONTAINING AGENTS (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BUTALB/ ACETAMINOPHEN/ CAFFEINE	ESGIC, ZEBUTAL FIORICET, BUTALBITAL-ACETAMINOPHEN-CAFFE	01854		GPI-10 (6499100310)	
BUTALBITAL/ASPIRIN/ CAFFEINE	BUTALBITAL-ASPIRIN-CAFFEINE	01790		GPI-10 (6499100330)	
BUTALBIT/ACETAMIN/ CAFF/CODEINE	FIORICET WITH CODEINE, BUTALB-ACETAMINOPH-CAFF-CODEIN	01713		GPI-10 (6599100410)	
CODEINE/BUTALBITAL/ ASA/CAFFEIN	ASCOMP WITH CODEINE, ASA-BUTALB-CAFFEINE-CODEINE	01699		GPI-10 (6599100430)	
BUTALBITAL/ ACETAMINOPHEN	TENCON, BUPAP, BUTALBITAL-ACETAMINOPHEN	01858		GPI-10 (6499100212)	STRENGTH ≠ 25[MG]-325MG

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the patient 65 years of age or older?

   If yes, continue to #2.
   If no, guideline does not apply.

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HRM-BUTALBITAL-CONTAINING AGENTS (PART D)

GUIDELINES FOR USE (CONTINUED)

2. Is the patient enrolled in hospice?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Is the request for the relief of tension (or muscle contraction) headaches (ICD-10 Group G44.2)?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the prescriber acknowledge or is aware that the requested medication is considered a high-risk medication for patients 65 years or older?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years or older.
   (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **HRM-BUTALBITAL-CONTAINING AGENTS** requires the following rule(s) be met for approval:
   A. The requested medication is being used for the relief of tension and/or muscle contraction headaches
   B. Your prescriber acknowledges or is aware that the requested medication is considered a high-risk medication for patients 65 years or older
   C. If you are enrolled in hospice (end of life), your request will be approved without requiring additional criteria

   NOTE: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years or older.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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HRM-BUTALBITAL-CONTAINING AGENTS (PART D)

RATIONALE

The drug(s) is/are listed as high risk medications in the elderly. The measure is an adaptation of the HEDIS measure, Drugs to Avoid in the Elderly, and calculates the percentage of patients 65 years or older who have received at least one prescription for a high-risk drug and the percentage of Medicare patients 65 years or older who received two or more different prescriptions for high risk medications.

REFERENCES

Butalbital/Acetaminophen/Caffeine tablet [Prescribing Information]. Chantilly, VA: Granules Pharmaceuticals Inc.; April 2022.
Fioricet [Prescribing Information]. Parsippany, NJ: Teva Pharmaceuticals USA, Inc.; January 2021.
Esgic [Prescribing Information]. Greenville, NC: Mayne Pharma; May 2019.
Butalbital/Aspirin/Caffeine [Prescribing Information]. Philadelphia, PA: Lannett Company, Inc.; May 2021.
Butalbital/Acetaminophen/Caffeine/Codeine [Prescribing Information]. Berkeley Heights, NJ: Breckenridge Pharmaceutical, Inc.; October 2023.
Fioricet with Codeine [Prescribing Information]. Parsippany, NJ: Teva Pharmaceuticals USA, Inc.; March 2021.
ASCOMP with Codeine [Prescribing Information]. Irvine, CA: LGM Pharma Solutions, LLC; April 2021.
Aspirin/Butalbital/Caffeine/Codeine [Prescribing Information]. Bridgewater, NJ: Amneal Pharmaceuticals LLC.; January 2024.
Tencon [Prescribing Information]. Atlanta, GA: Mikart, Inc.; July 2017.
Bupap [Prescribing Information]. Bridgewater, NJ: Bausch Health US, LLC; April 2020.
Butalbital/Acetaminophen [Prescribing Information]. Bridgewater, NJ: Oceanside Pharmaceuticals; April 2020.
American Geriatric Society (AGS) Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults (2019). Available at: https://geriatricscareonline.org/ProductAbstract/american-geriatrics-society-updated-beers-criteria/CL001 [Accessed March 20, 2024].
Centers for Medicare & Medicaid Services. Enhancements to the Star Ratings for 2017 and Beyond. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/2017-Star-Ratings-Request-for-Comments.pdf [March 20, 2024].

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HRM-BUTALBITAL-CONTAINING AGENTS (PART D)

For Part D use only:

HIGH RISK DRUGS IN THE ELDERLY - BUTALBITAL-CONTAINING AGENTS (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS.
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	PRESCRIBER ACKNOWLEDGEMENT/AWARENESS DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS ARE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA.

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 03/12
Client Approval: 06/24
P&T Approval: 05/18

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HRM - CARBINOXAMINE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CARBINOXAMINE MALEATE	RYVENT, CARBINOXAMINE MALEATE	04483		GPI-10 (4120001015)	BRAND ≠ KARBINAL ER

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the patient 65 years of age or older?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Is the patient enrolled in hospice?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Is the request for **ONE** of the following?
   - Seasonal or perennial allergic rhinitis (ICD-10 Group J30 except J30.0)
   - Vasomotor rhinitis (ICD-10 J30.0)
   - Allergic conjunctivitis due to inhalant allergens or foods (ICD-10 H10.45)
   - Mild, uncomplicated allergic skin manifestations of urticaria (ICD-10 L50.0) or angioedema (ICD-10 T78.3)
   - Dermatographism (ICD-10 L50.3)
   - As therapy for anaphylactic reactions adjunctive to epinephrine and other standard measures after the acute manifestations have been controlled
   - Amelioration of the severity of allergic reactions to blood or plasma (ICD-10 Group T80.5)

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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HRM - CARBINOXAMINE (PART D)

GUIDELINES FOR USE (CONTINUED)

4. Does the prescriber acknowledge or is aware that the requested medication is considered a high-risk medication for patients 65 years or older?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years or older.
   (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **HRM - CARBINOXAMINE (Ryvent)** requires the following rule(s) be met for approval:

   A. The request is for ONE of the following:
      1. Seasonal (occurring for a season) or perennial (long-lasting) allergic rhinitis (stuffy, runny nose)
      2. Vasomotor rhinitis (chronic condition with sneezing, congestion, runny nose that is not caused by allergy or infection)
      3. Allergic conjunctivitis (eye inflammation caused by allergies) due to inhalant allergens (substances that cause allergic reaction when breathed in) or foods
      4. Mild, uncomplicated allergic skin manifestations of urticaria (hives) or angioedema (a type of swelling)
      5. Dermatographism (a condition in which lightly scratching the skin causes raised, red lines)
      6. As therapy for anaphylactic reactions (severe, potentially life-threatening allergic reactions) in addition to epinephrine and other standard measures after the immediate symptoms have been controlled
      7. Amelioration (improvement) of the severity of allergic reactions to blood or plasma
   B. Your prescriber acknowledges or is aware that the requested medication is considered a high-risk medication for patients 65 years or older
   C. If you are enrolled in hospice (end of life), your request will be approved without requiring additional criteria

   NOTE: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years or older.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HRM - CARBINOXAMINE (PART D)

RATIONALE

The drug(s) is/are listed as high-risk medications in the elderly. The measure is an adaptation of the HEDIS measure Drugs to Avoid in the Elderly, and calculates the percentage of patients 65 years or older who have received at least one prescription for a high-risk drug and the percentage of Medicare patients 65 years or older who received two or more different prescriptions for high risk medications.

REFERENCES

Ryvent [Prescribing Information]. Hazlet, NJ: Carwin Pharmaceutical Associates, LLC; September 2016.

Carbinoxamine [Prescribing Information]. Berlin, CT: Breckenridge Pharmaceutical, Inc.; May 2019.

American Geriatric Society (AGS) Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults (2019). Available at: https://geriatricscareonline.org/ProductAbstract/american-geriatrics-society-updated-beers-criteria/CL001 [Accessed March 13, 2024].

Centers for Medicare & Medicaid Services. Enhancements to the Star Ratings for 2017 and Beyond. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/2017-Star-Ratings-Request-for-Comments.pdf [Accessed March 13, 2024].

For Part D use only:

HIGH RISK DRUGS IN THE ELDERLY - CARBINOXAMINE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS.
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA.

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25 Created: 07/23
Commercial Effective: N/A Client Approval: 06/24 P&T Approval: 05/18

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HRM - CHLORDIAZEPOXIDE-CLIDINIUM (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CHLORDIAZEPOXIDE/ CLIDINIUM BR	LIBRAX, CHLORDIAZEPOXID E-CLIDINIUM	02037		GPI-10 (4910990245)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the patient 65 years of age or older?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Is the patient enrolled in hospice?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Is the requested medication being used for **ONE** of the following?
   - To control emotional and somatic factors in gastrointestinal disorders
   - As adjunctive therapy in the treatment of peptic ulcer (ICD-10 Groups K27, K22.1, K25, K26, K28)
   - As adjunctive therapy in the treatment of irritable bowel syndrome (irritable colon, spastic colon, mucous colitis) (ICD-10 Group K58)
   - As adjunctive therapy in the treatment of acute enterocolitis (ICD-10 K52.9)

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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HRM - CHLORDIAZEPOXIDE-CLIDINIUM (PART D)

GUIDELINES FOR USE (CONTINUED)

4. Does the prescriber acknowledge or is aware that the requested medication is considered a high-risk medication for patients 65 years or older?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years or older.
   (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **HRM - CHLORDIAZEPOXIDE-CLIDINIUM (Librax)** requires the following rule(s) be met for approval:

   A. The request is for ONE of the following:
      1. To control emotional and somatic (physical) factors in gastrointestinal disorders (digestive disorders such as heartburn, stomach discomfort, diarrhea, constipation)
      2. As adjunctive (add-on) therapy for the treatment of peptic ulcer disease (sores on the lining of the esophagus, stomach, or small intestine)
      3. As adjunctive therapy for the treatment of irritable bowel syndrome (irritable colon, spastic colon, mucous colitis) (types of bowel disorders)
      4. As adjunctive therapy for the treatment of acute enterocolitis (inflammation of small intestine and colon)
   B. Your prescriber acknowledges or is aware that the requested medication is considered a high-risk medication for patients 65 years or older
   C. If you are enrolled in hospice (end of life), your request will be approved without requiring additional criteria

   NOTE: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years or older.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

The drug(s) is/are listed as high-risk medications in the elderly. The measure is an adaptation of the HEDIS measure, Drugs to Avoid in the Elderly, and calculates the percentage of patients 65 years or older who have received at least one prescription for a high-risk drug and the percentage of Medicare patients 65 years or older who received two or more different prescriptions for high-risk medications.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HRM - CHLORDIAZEPOXIDE-CLIDINIUM (PART D)

REFERENCES

Librax [Prescribing Information]. Bridgewater, NJ: Bausch Health Companies Inc.; January 2023.

American Geriatric Society (AGS) Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults (2019). Available at: https://geriatricscareonline.org/ProductAbstract/american-geriatrics-society-updated-beers-criteria/CL001 [Accessed March 13, 2024].

Centers for Medicare & Medicaid Services. Enhancements to the Star Ratings for 2017 and Beyond. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/2017-Star-Ratings-Request-for-Comments.pdf [Accessed March 13, 2024].

For Part D use only:

HIGH RISK DRUGS IN THE ELDERLY - CHLORDIAZEPOXIDE-CLIDINIUM (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS.
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA.

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 04/18
Client Approval: 06/24
P&T Approval: 05/20

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HRM - CLEMASTINE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CLEMASTINE FUMARATE	CLEMASTINE FUMARATE	04512		GPI-10 (4120002040)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the patient 65 years of age or older?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Is the patient enrolled in hospice?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Is the request for **ONE** of the following?
   - Allergic rhinitis (e.g., sneezing, rhinorrhea, pruritus, or lacrimation) (ICD-10 Group J30 except J30.0)
   - Mild, uncomplicated allergic skin manifestations of urticaria (ICD-10 L50.0) and angioedema (ICD-10 T78.3)

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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HRM - CLEMASTINE (PART D)

GUIDELINES FOR USE (CONTINUED)

4. Does the prescriber acknowledge or is aware that the requested medication is considered a high-risk medication for patients 65 years or older?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years or older.
   (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **HRM - CLEMASTINE** requires the following rule(s) be met for approval:
   A. The request is for ONE of the following:
      1. Allergic rhinitis such as sneezing, rhinorrhea (runny nose), pruritus (itching), or lacrimation (watery eyes)
      2. Mild, uncomplicated allergic skin conditions of urticaria (hives) and angioedema (a type of swelling)
   B. Your prescriber acknowledges or is aware that the requested medication is considered a high-risk medication for patients 65 years or older
   C. If you are enrolled in hospice (end of life), your request will be approved without requiring additional criteria

   NOTE: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years old or older.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

The drug(s) is/are listed in the high-risk medications in the elderly. The measure is an adaptation of the HEDIS measure, Drugs to Avoid in the Elderly, and calculates the percentage of patients 65 years or older who have received at least one prescription for a high-risk drug and the percentage of Medicare patients 65 years or older who received two or more different prescriptions for high-risk medications.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HRM - CLEMASTINE (PART D)

REFERENCES

Clemastine tablet [Prescribing Information]. Parsippany, NJ: Teva Pharmaceuticals; April 2022.
Clemastine syrup [Prescribing Information]. Congers, NY: Chartwel RX, LLC; July 2023.
American Geriatric Society (AGS) Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults (2019). Available at: https://geriatricscareonline.org/ProductAbstract/american-geriatrics-society-updated-beers-criteria/CL001 [Accessed March 13, 2024].
Centers for Medicare & Medicaid Services. Enhancements to the Star Ratings for 2017 and Beyond. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/2017-Star-Ratings-Request-for-Comments.pdf [Accessed March 13, 2024].

For Part D use only:

HIGH RISK DRUGS IN THE ELDERLY - CLEMASTINE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS.
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA.

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 10/22
Client Approval: 06/24
P&T Approval: 05/18

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HRM - CYPROHEPTADINE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CYPROHEPTADINE HCL	CYPROHEPTADINE HCL	01672		GPI-10 (4150002010)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the patient 65 years of age or older?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Is the patient enrolled in hospice?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Is the request for **ONE** of the following?
   - Perennial or seasonal allergic rhinitis (ICD-10 Group J30 except J30.0)
   - Vasomotor rhinitis (ICD-10 J30.0)
   - Allergic conjunctivitis due to inhalant allergens or foods (ICD-10 H10.45)
   - Mild, uncomplicated allergic skin manifestations of urticaria (ICD-10 L50.0) or angioedema (ICD-10 T78.3)
   - Amelioration of allergic reactions to blood or plasma (ICD-10 Group T80.5)
   - Cold urticaria (ICD-10 L50.2)
   - Dermatographism (ICD-10 L50.3)
   - As therapy for anaphylactic reactions adjunctive to epinephrine and other standard measures after the acute manifestations have been controlled

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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HRM - CYPROHEPTADINE (PART D)

GUIDELINES FOR USE (CONTINUED)

4. Does the prescriber acknowledge or is aware that the requested medication is considered a high-risk medication for patients 65 years or older?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years or older.
   (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **HRM - CYPROHEPTADINE** requires the following rule(s) be met for approval:

   A. The request is for ONE of the following:
      1. Perennial (long-lasting) or seasonal (occurring for a season) allergic rhinitis (stuffy, runny nose)
      2. Vasomotor rhinitis (chronic condition with sneezing, congestion, runny nose that is not caused by allergy or infection)
      3. Allergic conjunctivitis (eye inflammation caused by allergies) due to inhalant allergens (substances that cause allergic reaction when breathed in) or foods
      4. Mild, uncomplicated allergic skin manifestations of urticaria (hives) or angioedema (a type of swelling)
      5. Amelioration (improvement) of allergic reactions to blood or plasma
      6. Cold urticaria (a condition in which exposure to cold causes hives)
      7. Dermatographism (a condition in which lightly scratching the skin causes raised, red lines)
      8. As therapy for anaphylactic reactions (severe, potentially life-threatening allergic reactions) in addition to epinephrine and other standard measures after the immediate symptoms are controlled
   B. Your prescriber acknowledges or is aware that the requested medication is considered a high-risk medication for patients 65 years or older
   C. If you are enrolled in hospice (end of life), your request will be approved without requiring additional criteria

   (Denial text continued on next page)

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HRM - CYPROHEPTADINE (PART D)

GUIDELINES FOR USE (CONTINUED)

NOTE: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years or older.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

The drug(s) is/are listed as high-risk medications in the elderly. The measure is an adaptation of the HEDIS measure, Drugs to Avoid in the Elderly, and calculates the percentage of patients 65 years or older who have received at least one prescription for a high-risk drug and the percentage of Medicare patients 65 years or older who received two or more different prescriptions for high-risk medications.

REFERENCES

Cyproheptadine Tablet [Prescribing Information]. Pennington, NJ: Zydus Pharmaceuticals (USA) Inc.; August 2022.

Cyproheptadine Syrup [Prescribing Information]. Saddle Brook, NJ: Rising Pharmaceuticals, Inc.; October 2020.

American Geriatric Society (AGS) Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults (2019). Available at: https://geriatricscareonline.org/ProductAbstract/american-geriatrics-society-updated-beers-criteria/CL001 [Accessed March 13, 2024].

Centers for Medicare & Medicaid Services. Enhancements to the Star Ratings for 2017 and Beyond. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/2017-Star-Ratings-Request-for-Comments.pdf [Accessed March 13, 2024].

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HRM - CYPROHEPTADINE (PART D)

For Part D use only:

HIGH RISK DRUGS IN THE ELDERLY - CYPROHEPTADINE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS.
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA.

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 07/23
Client Approval: 06/24
P&T Approval: 05/18

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HRM - DIPHENHYDRAMINE ELIXIR (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DIPHENHYDRAMINE HCL	DIPHENHYDRAMINE HCL		46032	GPI-14 (41200030101010)	CLASS = FEDERAL LEGEND

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the patient 65 years of age or older?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Does the patient meet **ONE** of the following criteria?
   - The patient is enrolled in hospice
   - The request is for the treatment of anaphylactic reaction(s)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Is the request for the treatment of pruritus (ICD-10 L29) or urticaria (ICD-10 Group L50) (due to allergic conjunctivitis due to foods; mild, uncomplicated allergic skin manifestations of urticaria and angioedema; amelioration of allergic reactions to blood or plasma; or dermatographism) **AND** the patient meets the following criterion?
   - The patient had a trial of or contraindication to a non-sedating antihistamine (e.g., levocetirizine)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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Revised: 6/18/2024

HRM - DIPHENHYDRAMINE ELIXIR (PART D)

GUIDELINES FOR USE (CONTINUED)

4. Is the request for the treatment of insomnia (as a nighttime sleep-aid) (ICD-10 Group G47.0) **AND** the patient meets the following criterion?
- The patient had a trial of Silenor (doxepin) AND Belsomra (suvorexant)
-

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #5.

5. Is the request for **ONE** of the following?
- Treatment of parkinsonism (ICD-10 Group G20)
- Treatment of motion sickness (ICD-10 T75.3)

If yes, continued to #6.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

6. Does the prescriber acknowledge or is aware that the requested medication is considered a high-risk medication for patients 65 years or older?

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years or older.
(IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HRM - DIPHENHYDRAMINE ELIXIR (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **HRM - DIPHENHYDRAMINE ELIXIR** requires the following rule(s) be met for approval:

A. Your request is for ONE of the following:
   1. Treatment of anaphylactic reaction(s) (severe, life-threatening allergic reaction)
   2. Treatment of pruritus (itching) or urticaria (hives) (due to allergic conjunctivitis [eye inflammation caused by allergies] due to foods; mild, uncomplicated allergic skin manifestations of urticaria and angioedema [a type of swelling]; improvement of allergic reactions to blood or plasma; or dermatographism [a condition in which lightly scratching the skin causes raised, red lines])
   3. Treatment of insomnia (as a nighttime sleep-aid)
   4. Treatment of parkinsonism (a condition of movement abnormalities such as slow movements)
   5. Motion sickness

B. If your request is for the treatment of pruritus or urticaria, approval also requires:
   1. You have tried or have a contraindication to (harmful for you to use) a non-sedating antihistamine (such as levocetirizine)

C. If your request is for the treatment of insomnia, approval also requires:
   1. You have tried Silenor (doxepin) AND Belsomra (suvorexant)

D. If your request is for the treatment of parkinsonism or motion sickness, approval also requires:
   1. Your prescriber acknowledges or is aware that the requested medication is considered a high-risk medication for patients 65 years of age or older

E. If you are enrolled in hospice (end of life), your request will be approved without requiring additional criteria

NOTE: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years or older.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

The drug(s) is/are listed as high-risk medications in the elderly. The measure is an adaptation of the HEDIS measure Drugs to Avoid in the Elderly and calculates: the percentage of patients 65 years or older who have received at least one prescription for a high-risk drug and the percentage of Medicare patients 65 years or older who received two or more different prescriptions for high-risk medications.

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Revised: 6/18/2024

CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HRM - DIPHENHYDRAMINE ELIXIR (PART D)

REFERENCES

Diphenhydramine [Prescribing Information]. Greenville, SC: Pharmaceutical Associates, Inc.; June 2022.

American Geriatric Society (AGS) Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults (2019). Available at: https://geriatricscareonline.org/ProductAbstract/american-geriatrics-society-updated-beers-criteria/CL001 [Accessed March 11, 2024].

Centers for Medicare & Medicaid Services. Enhancements to the Star Ratings for 2017 and Beyond. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/2017-Star-Ratings-Request-for-Comments.pdf [Accessed July 16, 2024].

For Part D use only:

HIGH RISK DRUGS IN THE ELDERLY - DIPHENHYDRAMINE ELIXIR (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS.
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	PRURITUS OR URTICARIA: TRIAL OF OR CONTRAINDICATION TO A NON-SEDATING ANTIHISTAMINE SUCH AS LEVOCETIRIZINE. INSOMNIA: TRIAL OF SILENOR AND BELSOMRA. MOTION SICKNESS AND ANTIPARKINSONISM: PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS AND ANAPHYLACTIC REACTIONS WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA.

Core	Advantage	Plus
Yes	Yes	Yes

Created: 06/16
Effective: 01/01/25 Client Approval: 08/24 P&T Approval: 05/18

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Revised: 6/18/2024

CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HRM - DIPHENOXYLATE-ATROPINE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DIPHENOXYLATE HCL/ATROPINE	LOMOTIL, DIPHENOXYLATE-ATROPINE	01235		GPI-10 (4710001010)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the patient 65 years of age or older?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Is the patient enrolled in hospice?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Will the requested medication be used as adjunctive therapy in the management of diarrhea (ICD-10 R19.7)?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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HRM - DIPHENOXYLATE-ATROPINE (PART D)

GUIDELINES FOR USE (CONTINUED)

4. Does the prescriber acknowledge or is aware that the requested medication is considered a high-risk medication for patients 65 years or older?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years or older.
   (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **HRM - DIPHENOXYLATE-ATROPINE (Lomotil)** requires the following rule(s) be met for approval:
   A. The requested medication will be used as adjunctive (add-on) therapy in the management of diarrhea
   B. Your prescriber acknowledges or is aware that the requested medication is considered a high-risk medication for patients 65 years or older
   C. If you are enrolled in hospice (end of life), your request will be approved without requiring additional criteria

   NOTE: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years or older.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

The drug(s) is/are listed as high-risk medications in the elderly. The measure is an adaptation of the HEDIS measure, Drugs to Avoid in the Elderly, and calculates the percentage of patients 65 years or older who have received at least one prescription for a high-risk drug and the percentage of Medicare patients 65 years or older who received two or more different prescriptions for high-risk medications.

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HRM - DIPHENOXYLATE-ATROPINE (PART D)

REFERENCES

Lomotil [Prescribing Information]. New York, NY: Pfizer Inc.; March 2022.
American Geriatric Society (AGS) Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults (2019). Available at: https://geriatricscareonline.org/ProductAbstract/american-geriatrics-society-updated-beers-criteria/CL001 [Accessed March 11, 2024].
Centers for Medicare & Medicaid Services. Enhancements to the Star Ratings for 2017 and Beyond. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/2017-Star-Ratings-Request-for-Comments.pdf [Accessed March 11, 2024].

For Part D use only:

HIGH RISK DRUGS IN THE ELDERLY - DIPHENOXYLATE-ATROPINE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS.
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA.

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 11/17
Client Approval: 06/24
P&T Approval: 05/18

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HRM - DIPYRIDAMOLE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DIPYRIDAMOLE	DIPYRIDAMOLE	00168		GPI-10 (8515003000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the patient 65 years of age or older?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Is the patient enrolled in hospice?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Will the requested medication be used as an adjunct to a coumarin anticoagulant (e.g., warfarin) in the prevention of postoperative thromboembolic complications of cardiac valve replacement?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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HRM - DIPYRIDAMOLE (PART D)

GUIDELINES FOR USE (CONTINUED)

4. Does the prescriber acknowledge or is aware that the requested medication is considered a high-risk medication for patients 65 years or older?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years or older.
   (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **HRM - DIPYRIDAMOLE** requires the following rule(s) be met for approval:
   A. The requested medication will be used as an adjunct (add-on therapy) to a coumarin anticoagulant (a type of drug that prevents blood clots such as warfarin) to prevent postoperative (after surgery) thromboembolic (blood clot) complications of cardiac (heart) valve replacement
   B. Your prescriber acknowledges or is aware that the requested medication is considered a high-risk medication for patients 65 years or older
   C. If you are enrolled in hospice (end of life), your request will be approved without requiring additional criteria

   NOTE: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years or older.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

The drug(s) is/are listed as high-risk medications in the elderly. The measure is an adaptation of the HEDIS measure, Drugs to Avoid in the Elderly, and calculates the percentage of patients 65 years or older who have received at least one prescription for a high-risk drug and the percentage of Medicare patients 65 years or older who received two or more different prescriptions for high-risk medications.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HRM - DIPYRIDAMOLE (PART D)

REFERENCES

Dipyridamole [Prescribing Information]. Saddle Brook, NJ: Rising Pharmaceuticals, Inc.; December 2019.

American Geriatric Society (AGS) Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults (2019). Available at: https://geriatricscareonline.org/ProductAbstract/american-geriatrics-society-updated-beers-criteria/CL001 [Accessed March 12, 2024].

Centers for Medicare & Medicaid Services. Enhancements to the Star Ratings for 2017 and Beyond. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/2017-Star-Ratings-Request-for-Comments.pdf [Accessed March 12, 2024].

For Part D use only:

HIGH RISK DRUGS IN THE ELDERLY - DIPYRIDAMOLE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS.
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA.

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 11/18
Client Approval: 06/24
P&T Approval: 05/18

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HRM - DISOPYRAMIDE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DISOPYRAMIDE PHOSPHATE	NORPACE, NORPACE CR, DISOPYRAMIDE PHOSPHATE	00077		GPI-10 (3510001010)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the patient 65 years of age or older?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Is the patient enrolled in hospice?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Is the requested medication for the treatment of documented ventricular arrhythmias (ICD-10 I49.3, I49.01; Group I47 except I47.9), such as sustained ventricular tachycardia that is life-threatening, **AND** the patient meets the following criterion?
   - The patient does NOT have asymptomatic ventricular premature contractions

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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HRM - DISOPYRAMIDE (PART D)

GUIDELINES FOR USE (CONTINUED)

4. Does the prescriber acknowledge or is aware that the requested medication is considered a high-risk medication for patients 65 years or older?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years or older.
   (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **HRM - DISOPYRAMIDE (Norpace, Norpace CR)** requires the following rule(s) be met for approval:
   A. The requested medication is for the treatment of documented ventricular arrhythmias (a type of irregular heartbeat), such as sustained ventricular tachycardia (a type of fast heartbeat) that is life-threatening
   B. You do NOT have asymptomatic ventricular premature contractions (a type of abnormal heartbeat)
   C. Your prescriber acknowledges or is aware that the requested medication is considered a high-risk medication for patients 65 years or older
   D. If you are enrolled in hospice (end of life), your request will be approved without requiring additional criteria

   NOTE: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years or older.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

The drug(s) is/are listed as high-risk medications in the elderly. The measure is an adaptation of the HEDIS measure, Drugs to Avoid in the Elderly, and calculates the percentage of patients 65 years or older who have received at least one prescription for a high-risk drug and the percentage of Medicare patients 65 years or older who received two or more different prescriptions for high-risk medications.

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HRM - DISOPYRAMIDE (PART D)

REFERENCES

Disopyramide [Prescribing Information]. Parsippany, NJ: Teva Pharmaceuticals; April 2022.
American Geriatric Society (AGS) Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults (2019). Available at: https://geriatricscareonline.org/ProductAbstract/american-geriatrics-society-updated-beers-criteria/CL001 [Accessed March 12, 2024].
Centers for Medicare & Medicaid Services. Enhancements to the Star Ratings for 2017 and Beyond. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/2017-Star-Ratings-Request-for-Comments.pdf [Accessed March 12, 2024].

For Part D use only:

HIGH RISK DRUGS IN THE ELDERLY - DISOPYRAMIDE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS.
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA.

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 11/18
Client Approval: 06/24
P&T Approval: 05/18

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HRM - DROSPIRENONE-ESTRADIOL (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DROSPIRENONE/ ESTRADIOL	ANGELIQ	32896		GPI-10 (2499300240)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the patient 65 years of age or older?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Is the patient enrolled in hospice?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Is the request for the treatment of moderate to severe vasomotor symptoms due to menopause (ICD-10 N95.1) **AND** the patient meets the following criterion?
   - The prescriber acknowledges or is aware that the requested medication is considered a high-risk medication for patients 65 years or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years or older.
   (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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HRM - DROSPIRENONE-ESTRADIOL (PART D)

GUIDELINES FOR USE (CONTINUED)

4. Is the request for the treatment of moderate to severe vulvar and vaginal atrophy due to menopause (ICD-10 N95.2, N90.5) and the patient meets **ALL** of the following criteria?
   - The request is for Angeliq (drospirenone/estradiol) 0.5mg/1mg
   - The prescriber acknowledges or is aware that the requested medication is considered a high-risk medication for patients 65 years or older

   If yes, **approve Angeliq 0.5mg/1mg for 12 months by GPID or GPI-14.**
   APPROVAL TEXT: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years or older.
   (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **HRM - DROSPIRENONE-ESTRADIOL (Angeliq)** requires the following rule(s) be met for approval:

   A. The request is for ONE of the following:
      1. Treatment of moderate to severe vasomotor symptoms (such as night sweats, hot flashes) due to menopause
      2. Treatment of moderate to severe vulvar and vaginal atrophy (dryness, discomfort, and pain in the vaginal area) due to menopause

   B. If your request is for treatment of moderate to severe vasomotor symptoms due to menopause, approval also requires:
      1. Your prescriber acknowledges or is aware that the requested medication is considered a high-risk medication for patients 65 years or older

   C. If your request is for treatment of moderate to severe vulvar and vaginal atrophy due to menopause, approval also requires:
      1. Your request is for Angeliq (drospirenone/estradiol) 0.5mg/1mg
      2. Your prescriber acknowledges or is aware that the requested medication is considered a high-risk medication for patients 65 years or older

   D. If you are enrolled in hospice (end of life), your request will be approved without requiring additional criteria

   NOTE: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years or older.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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HRM - DROSPIRENONE-ESTRADIOL (PART D)

RATIONALE

The drug(s) is/are listed as high-risk medications in the elderly. The measure is an adaptation of the HEDIS measure, Drugs to Avoid in the Elderly, and calculates the percentage of patients 65 years or older who have received at least one prescription for a high-risk drug and the percentage of Medicare patients 65 years or older who received two or more different prescriptions for high-risk medications.

REFERENCES

Angeliq [Prescribing Information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; October 2023.

Use in Older Adults (2019). Available at: https://geriatricscareonline.org/ProductAbstract/american-geriatrics-society-updated-beers-criteria/CL001 [Accessed March 12, 2024].

Centers for Medicare & Medicaid Services. Enhancements to the Star Ratings for 2017 and Beyond. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/2017-Star-Ratings-Request-for-Comments.pdf [Accessed March 12, 2024].

For Part D use only:

HIGH RISK DRUGS IN THE ELDERLY - DROSPIRENONE-ESTRADIOL (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS.
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA.

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 07/23
Client Approval: 06/24
P&T Approval: 04/19

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HRM - ESTRADIOL-LEVONORGESTREL (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ESTRADIOL/ LEVONORGESTREL	CLIMARA PRO	12871		GPI-10 (2499300258)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the patient 65 years of age or older?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Is the patient enrolled in hospice?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Is the request for **ONE** of the following?
   - Treatment of moderate to severe vasomotor symptoms due to menopause (ICD-10 N95.1)
   - Prevention of postmenopausal osteoporosis

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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HRM - ESTRADIOL-LEVONORGESTREL (PART D)

GUIDELINES FOR USE (CONTINUED)

4. Does the prescriber acknowledge or is aware that the requested medication is considered a high-risk medication for patients 65 years or older?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years or older.
   (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **HRM - ESTRADIOL-LEVONORGESTREL (Climara Pro)** requires the following rule(s) be met for approval:
   A. The request is for ONE of the following:
      1. Treatment of moderate to severe vasomotor symptoms (such as night sweats, hot flashes) due to menopause
      2. Prevention of postmenopausal osteoporosis (a type of bone condition in women after menopause)
   B. Your prescriber acknowledges or is aware that the requested medication is considered a high-risk medication for patients 65 years or older
   C. If you are enrolled in hospice (end of life), your request will be approved without requiring additional criteria

   NOTE: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years or older.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

The drug(s) is/are listed as high-risk medications in the elderly. The measure is an adaptation of the HEDIS measure, Drugs to Avoid in the Elderly, and calculates the percentage of patients 65 years or older who have received at least one prescription for a high-risk drug and the percentage of Medicare patients 65 years or older who received two or more different prescriptions for high-risk medications.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HRM - ESTRADIOL-LEVONORGESTREL (PART D)

REFERENCES

Climara Pro [Prescribing Information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; February 2024.

American Geriatric Society (AGS) Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults (2019). Available at: https://geriatricscareonline.org/ProductAbstract/american-geriatrics-society-updated-beers-criteria/CL001 [Accessed March 15, 2024].

Centers for Medicare & Medicaid Services. Enhancements to the Star Ratings for 2017 and Beyond. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/2017-Star-Ratings-Request-for-Comments.pdf [Accessed March 15, 2024].

For Part D use only:

HIGH RISK DRUGS IN THE ELDERLY - ESTRADIOL-LEVONORGESTREL (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS.
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA.

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
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Client Approval: 06/24
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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HRM - ESTRADIOL-NORETHINDRONE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ESTRADIOL/ NORETHINDRONE ACET	ACTIVELLA, AMABELZ, COMBIPATCH, MIMVEY, ESTRADIOL-NORETHINDRONE ACETAT	07310		GPI-10 (2499300212)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the patient 65 years of age or older?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Is the patient enrolled in hospice?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Is the request for the treatment of moderate to severe vasomotor symptoms due to menopause (ICD-10 N95.1) **AND** the patient meets the following criterion?
   - The prescriber acknowledges or is aware that the requested medication is considered a high-risk medication for patients 65 years or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years or older.
   (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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HRM - ESTRADIOL-NORETHINDRONE (PART D)

GUIDELINES FOR USE (CONTINUED)

4. Is the request for the treatment of moderate to severe vulvar and vaginal atrophy due to menopause (ICD-10 N95.2, N90.5) **AND** the patient meets the following criterion?
   - The prescriber acknowledges or is aware that the requested medication is considered a high-risk medication for patients 65 years or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years or older.
   (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Is the request for the treatment of hypoestrogenism due to hypogonadism, castration, or primary ovarian failure (ICD-10 Group E28.3) **AND** the patient meets the following criterion?
   - The request is for CombiPatch

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #6.

6. Is the request for the prevention of postmenopausal osteoporosis and the patient meets **ALL** of the following criteria?
   - The prescriber acknowledges or is aware that the requested medication is considered a high-risk medication for patients 65 years or older
   - The request is for ANY of the following:
     - Mimvey
     - Activella
     - Amabelz
     - Estradiol/norethindrone acetate

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths of the requested drug.**
   APPROVAL TEXT: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years or older.
   (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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HRM - ESTRADIOL-NORETHINDRONE (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **HRM - ESTRADIOL-NORETHINDRONE (CombiPatch, Mimvey, Activella, Amabelz)** requires the following rule(s) be met for approval:

A. The request is for ONE of the following:
   1. Treatment of moderate to severe vasomotor symptoms (such as night sweats, hot flashes) due to menopause
   2. Treatment of moderate to severe vulvar and vaginal atrophy (dryness, discomfort, and pain in the vaginal areas) due to menopause
   3. Treatment of hypoestrogenism (lower than normal estrogen levels) due to hypogonadism (a condition where your body does not produce enough sex hormones), castration (removal of ovaries), or primary ovarian failure (ovaries stop working)
   4. Prevention of postmenopausal osteoporosis (a type of bone condition in women after menopause)

B. If your request is for treatment of moderate to severe vasomotor symptoms due to menopause, approval also requires:
   1. Your prescriber acknowledges or is aware that the requested medication is considered a high-risk medication for patients 65 years or older

C. If your request is for treatment of moderate to severe vulvar and vaginal atrophy due to menopause, approval also requires:
   1. Your prescriber acknowledges or is aware that the requested medication is considered a high-risk medication for patients 65 years or older

D. If your request is for treatment of hypoestrogenism due to hypogonadism, castration, or primary ovarian failure, approval also requires:
   1. Your request is for CombiPatch

E. If your request is for prevention of postmenopausal osteoporosis, approval also requires:
   1. Your prescriber acknowledges or is aware that the requested medication is considered a high-risk medication for patients 65 years or older
   2. Your request is for any of the following:
      a. Mimvey
      b. Activella
      c. Amabelz
      d. Estradiol/norethindrone acetate

F. If you are enrolled in hospice (end of life care), your request will be approved without requiring additional criteria

(Denial text continued on the next page)

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HRM - ESTRADIOL-NORETHINDRONE (PART D)

GUIDELINES FOR USE (CONTINUED)

NOTE: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years or older.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

The drug(s) is/are listed as high-risk medications in the elderly. The measure is an adaptation of the HEDIS measure, Drugs to Avoid in the Elderly, and calculates the percentage of patients 65 years or older who have received at least one prescription for a high-risk drug and the percentage of Medicare patients 65 years or older who received two or more different prescriptions for high-risk medications.

REFERENCES

CombiPatch [Prescribing Information]. Miami, FL: Noven Pharmaceuticals Inc.; February 2024.
Mimvey [Prescribing Information]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; January 2022.
Activella [Prescribing Information]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; November 2023.
Amabelz [Prescribing Information]. Baltimore, MD: Lupin Pharmaceuticals, Inc.; March 2024.
American Geriatric Society (AGS) Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults (2019). Available at: https://geriatricscareonline.org/ProductAbstract/american-geriatrics-society-updated-beers-criteria/CL001 [Accessed March 15, 2024].
Centers for Medicare & Medicaid Services. Enhancements to the Star Ratings for 2017 and Beyond. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/2017-Star-Ratings-Request-for-Comments.pdf [Accessed March 15, 2024].

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HRM - ESTRADIOL-NORETHINDRONE (PART D)

For Part D use only:

HIGH RISK DRUGS IN THE ELDERLY - ESTRADIOL-NORETHINDRONE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS.
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	VULVAR/VAGINAL ATROPHY, OSTEOPOROSIS, AND VASOMOTOR SYMPTOMS OF MENOPAUSE: PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HYPOESTROGENISM TREATMENT AND HOSPICE PATIENTS WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA.

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25 Created: 07/23
Commercial Effective: N/A Client Approval: 06/24 P&T Approval: 04/19

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HRM - ESTRADIOL-PROGESTERONE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ESTRADIOL/ PROGESTERONE	BIJUVA	01417		GPI-10 (2499300214)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the patient 65 years of age or older?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Is the patient enrolled in hospice?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Is the request for the treatment of moderate to severe vasomotor symptoms due to menopause (ICD-10 N95.1) **AND** the patient meets the following criterion?
   - The prescriber acknowledges or is aware that the requested medication is considered a high-risk medication for patients 65 years or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years or older.
   (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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HRM - ESTRADIOL-PROGESTERONE (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **HRM - ESTRADIOL-PROGESTERONE (Bijuva)** requires the following rule(s) be met for approval:

A. Your request is for the treatment of moderate to severe vasomotor symptoms (such as night sweats, hot flashes) due to menopause
B. Your prescriber acknowledges or is aware that the requested medication is considered a high-risk medication for patients 65 years or older
C. If you are enrolled in hospice (end of life), your request will be approved without requiring additional criteria

NOTE: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years or older.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

The drug(s) is/are listed as high-risk medications in the elderly. The measure is an adaptation of the HEDIS measure, Drugs to Avoid in the Elderly, and calculates the percentage of patients 65 years or older who have received at least one prescription for a high-risk drug and the percentage of Medicare patients 65 years or older who received two or more different prescriptions for high-risk medications.

REFERENCES

Bijuva [Prescribing Information]. Boca Raton, FL: TherapeuticsMD, Inc., February 2024.
American Geriatric Society (AGS) Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults (2019). Available at: https://geriatricscareonline.org/ProductAbstract/american-geriatrics-society-updated-beers-criteria/CL001 [Accessed March 15, 2024].
Centers for Medicare & Medicaid Services. Enhancements to the Star Ratings for 2017 and Beyond. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/2017-Star-Ratings-Request-for-Comments.pdf [Accessed March 15, 2024].

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HRM - ESTRADIOL-PROGESTERONE (PART D)

For Part D use only:

HIGH RISK DRUGS IN THE ELDERLY - ESTRADIOL-PROGESTERONE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS.
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA.

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 07/23
Client Approval: 06/24
P&T Approval: 04/19

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ADVANTAGE AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HRM - ESTROGEN-BAZEDOXIFENE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ESTROGENS,CONJ/ BAZEDOXIFENE	DUAVEE	40855		GPI-10 (2499500210)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the patient 65 years of age or older?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Is the patient enrolled in hospice?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Is the request for **ONE** of the following?
   - Treatment of moderate to severe vasomotor symptoms due to menopause (ICD-10 N95.1)
   - Prevention of postmenopausal osteoporosis

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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HRM - ESTROGEN-BAZEDOXIFENE (PART D)

GUIDELINES FOR USE (CONTINUED)

4. Does the prescriber acknowledge or is aware that the requested medication is considered a high-risk medication for patients 65 years or older?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years or older.
   (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **HRM - ESTROGEN-BAZEDOXIFENE (Duavee)** requires the following rule(s) be met for approval:
   A. The request is for ONE of the following:
      1. Treatment of moderate to severe vasomotor symptoms (such as night sweats, hot flashes) due to menopause
      2. Prevention of postmenopausal osteoporosis (a type of bone condition in women after menopause)
   B. Your prescriber acknowledges or is aware that the requested medication is considered a high-risk medication for patients 65 years or older
   C. If you are enrolled in hospice (end of life), your request will be approved without requiring additional criteria

   NOTE: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years or older.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

The drug(s) is/are listed as high-risk medications in the elderly. The measure is an adaptation of the HEDIS measure, Drugs to Avoid in the Elderly, and calculates the percentage of patients 65 years or older who have received at least one prescription for a high-risk drug and the percentage of Medicare patients 65 years or older who received two or more different prescriptions for high-risk medications.

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HRM - ESTROGEN-BAZEDOXIFENE (PART D)

REFERENCES

Duavee [Prescribing Information]. Philadelphia, PA: Wyeth Pharmaceuticals LLC; March 2024.
American Geriatric Society (AGS) Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults (2019). Available at: https://geriatricscareonline.org/ProductAbstract/american-geriatrics-society-updated-beers-criteria/CL001 [Accessed March 15, 2024].
Centers for Medicare & Medicaid Services. Enhancements to the Star Ratings for 2017 and Beyond. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/2017-Star-Ratings-Request-for-Comments.pdf [Accessed March 15, 2024].

For Part D use only:

HIGH RISK DRUGS IN THE ELDERLY - ESTROGEN-BAZEDOXIFENE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS.
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA.

Core	Advantage	Plus
No	Yes	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 07/23
Client Approval: 06/24
P&T Approval: 04/19

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ADVANTAGE AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HRM - ESTROGEN-MEDROXYPROGESTERONE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ESTROGEN,CON/ M-PROGEST ACET	PREMPRO, PREMPHASE	09649		GPI-10 (249930020)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the patient 65 years of age or older?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Is the patient enrolled in hospice?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Is the request for **ONE** of the following?
   - Treatment of moderate to severe vasomotor symptoms due to menopause (ICD-10 N95.1)
   - Treatment of moderate to severe vulvar and vaginal atrophy due to menopause (ICD-10 N95.2, N90.5)
   - Prevention of postmenopausal osteoporosis

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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HRM - ESTROGEN-MEDROXYPROGESTERONE (PART D)

GUIDELINES FOR USE (CONTINUED)

4. Does the prescriber acknowledge or is aware that the requested medication is considered a high-risk medication for patients 65 years or older?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years or older.
   (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **HRM - ESTROGEN-MEDROXYPROGESTERONE (Prempro, Premphase)** requires the following rule(s) be met for approval:
   A. The request is for ONE of the following:
      1. Treatment of moderate to severe vasomotor symptoms (such as night sweats, hot flashes) due to menopause
      2. Treatment of moderate to severe vulvar and vaginal atrophy (dryness, discomfort, and pain in the vaginal areas) due to menopause
      3. Prevention of postmenopausal osteoporosis (a type of bone condition in women after menopause)
   B. Your prescriber acknowledges or is aware that the requested medication is considered a high-risk medication for patients 65 years or older
   C. If you are enrolled in hospice (end of life), your request will be approved without requiring additional criteria

   NOTE: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years or older.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

The drug(s) is/are listed as high-risk medications in the elderly. The measure is an adaptation of the HEDIS measure, Drugs to Avoid in the Elderly, and calculates the percentage of patients 65 years or older who have received at least one prescription for a high-risk drug and the percentage of Medicare patients 65 years or older who received two or more different prescriptions for high-risk medications.

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ADVANTAGE AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HRM - ESTROGEN-MEDROXYPROGESTERONE (PART D)

REFERENCES

Prempro and Premphase [Prescribing Information]. Philadelphia, PA: Wyeth Pharmaceuticals LLC; February 2024.

American Geriatric Society (AGS) Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults (2019). Available at: https://geriatricscareonline.org/ProductAbstract/american-geriatrics-society-updated-beers-criteria/CL001 [Accessed March 14, 2024].

Centers for Medicare & Medicaid Services. Enhancements to the Star Ratings for 2017 and Beyond. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/2017-Star-Ratings-Request-for-Comments.pdf [Accessed March 14, 2024].

For Part D use only:

HIGH RISK DRUGS IN THE ELDERLY - ESTROGEN-MEDROXYPROGESTERONE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS.
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA.

Core	Advantage	Plus
No	Yes	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
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Client Approval: 06/24
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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HRM - GLYBURIDE FORMULATIONS (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GLYBURIDE	GLYBURIDE	00802		GPI-10 (2720004000)	
GLYBURIDE, MICRONIZED	GLYNASE, GLYBURIDE MICRONIZED	12257		GPI-10 (2720004010)	
GLYBURIDE/ METFORMIN HCL	GLYBURIDE-METFORMIN HCL	09690		GPI-10 (2799700240)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the patient 65 years of age or older?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Is the patient enrolled in hospice?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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HRM - GLYBURIDE FORMULATIONS (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of type 2 diabetes mellitus (ICD-10 Groups E08, E09, E11, E13) and meet **ONE** of the following criteria?
   - The patient had a trial of or contraindication to glimepiride or glipizide
   - The prescriber acknowledges or is aware that the requested medication is considered a high-risk medication for patients 65 years or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years or older.
   (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **HRM - GLYBURIDE FORMULATIONS (glyburide, Glynase, glyburide/metformin)** requires the following rule(s) be met for approval:
   A. You have type 2 diabetes mellitus (a disorder with high blood sugar)
   B. You meet ONE of the following:
      1. You have tried or have a contraindication to (harmful for you to use) glimepiride or glipizide
      2. Your prescriber acknowledges or is aware that the requested medication is considered a high-risk medication for patients 65 years or older
   C. If you are enrolled in hospice (end of life), your request will be approved without requiring additional criteria

   NOTE: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years or older.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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HRM - GLYBURIDE FORMULATIONS (PART D)

RATIONALE

The drug(s) is/are listed as high-risk medications in the elderly. The measure is an adaptation of the HEDIS measure, Drugs to Avoid in the Elderly, and calculates the percentage of patients 65 years or older who have received at least one prescription for a high-risk drug and the percentage of Medicare patients 65 years or older who received two or more different prescriptions for high-risk medications.

REFERENCES

Glyburide [Prescribing Information]. Whippany, NJ: Halo Pharmaceutical; July 2017.
Glynase [Prescribing Information]. New York, NY: Pfizer; August 2023.
Glyburide/Metformin [Prescribing Information]. East Windsor, NJ: Aurobindo Pharma USA, Inc.; December 2021.
American Geriatric Society (AGS) Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults (2019). Available at: https://geriatricscareonline.org/ProductAbstract/american-geriatrics-society-updated-beers-criteria/CL001 [Accessed March 20, 2024].
Centers for Medicare & Medicaid Services. Enhancements to the Star Ratings for 2017 and Beyond. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/2017-Star-Ratings-Request-for-Comments.pdf [Accessed March 20, 2024].

For Part D use only:

HIGH RISK DRUGS IN THE ELDERLY - GLYBURIDE FORMULATIONS (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	TYPE 2 DIABETES MELLITUS (DM): 1) TRIAL OF OR CONTRAINDICATION TO GLIMEPIRIDE OR GLIPIZIDE, OR 2) PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS ARE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA.

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 07/23
Client Approval: 06/24
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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HRM - INDOMETHACIN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INDOMETHACIN	INDOCIN, INDOMETHACIN	03719		GPI-10 (6610003000)	GPID ≠ 35690

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

************Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the patient 65 years of age or older?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Is the patient enrolled in hospice?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Does the patient have **ONE** of the following FDA-approved diagnoses?
   - Moderate to severe rheumatoid arthritis including acute flares of chronic disease (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8)
   - Moderate to severe ankylosing spondylitis (ICD-10 Group M45. Exclude M45.A)
   - Moderate to severe osteoarthritis (ICD-10 M19.9)
   - Acute painful shoulder (bursitis and/or tendinitis) (ICD-10 Group M75)
   - Acute gouty arthritis (ICD-10 Group M10)

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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HRM - INDOMETHACIN (PART D)

GUIDELINES FOR USE (CONTINUED)

4. Does the prescriber acknowledge or is aware that the requested medication is considered a high-risk medication for patients 65 years or older?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years or older.
   (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **HRM - INDOMETHACIN (Indocin)** requires the following rule(s) be met for approval:
   A. You have ONE of the following FDA (Food and Drug Administration) approved indications:
      1. Moderate to severe rheumatoid arthritis (a type of joint condition) including acute (short-term) flares of chronic disease
      2. Moderate to severe ankylosing spondylitis (a type of joint condition)
      3. Moderate to severe osteoarthritis (a type of joint condition)
      4. Acute painful shoulder (bursitis and/or tendinitis)
      5. Acute gouty arthritis (a type of joint condition)
   B. Your prescriber acknowledges or is aware that the requested medication is considered a high-risk medication for patients 65 years or older
   C. If you are enrolled in hospice (end of life), your request will be approved without requiring additional criteria

   NOTE: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years or older.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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HRM - INDOMETHACIN (PART D)

RATIONALE

The drug(s) is/are listed as high-risk medications in the elderly. The measure is an adaptation of the HEDIS measure Drugs to Avoid in the Elderly and calculates: the percentage of patients 65 years or older who have received at least one prescription for a high-risk drug and the percentage of Medicare patients 65 years or older who received two or more different prescriptions for high-risk medications.

REFERENCES

Indomethacin [Prescribing Information]. Wayne, PA: Zyla Life Sciences US, Inc; April 2021.
Indocin oral suspension [Prescribing Information]. Ontario, Canada: Patheon Inc.; April 2021.
Indocin suppository [Prescribing Information]. Lincolnton, NC: Cosette Pharmaceuticals, INC; April 2021.
American Geriatric Society (AGS) Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults (2019). Available at: https://geriatricscareonline.org/ProductAbstract/american-geriatrics-society-updated-beers-criteria/CL001 [Accessed March 20, 2024].
Centers for Medicare & Medicaid Services. Enhancements to the Star Ratings for 2017 and Beyond. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/2017-Star-Ratings-Request-for-Comments.pdf [Accessed March 20, 2024].

For Part D use only:

HIGH RISK DRUGS IN THE ELDERLY - INDOMETHACIN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS.
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	PRESCRIBER ACKNOWLEDGEMENT/AWARENESS DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA.

Created: 11/13
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 05/18

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HRM - KETOROLAC (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
KETOROLAC TROMETHAMINE	KETOROLAC TROMETHAMINE	05175		GPI-10 (6610003710)	ROUTE ≠ OPHTHALMIC, NASAL

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the patient 65 years of age or older?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Is the patient enrolled in hospice?

   If yes, **approve for 30 days by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Does the patient have a diagnosis of moderately severe acute pain (ICD-10 R52) and meet **ALL** of the following criteria?
   - The request is for short-term use (i.e., 5 days or less of total combined duration of use of ketorolac tromethamine tablets and injection)
   - The patient's pain requires analgesia at the opioid level (usually in a postoperative setting)

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Is the request for ketorolac IV or IM?

   If yes, continue to #6.
   If no, continue to #5.

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HRM - KETOROLAC (PART D)

GUIDELINES FOR USE (CONTINUED)

5. Is the request for ketorolac tablet **AND** the patient meets the following criterion?
   - The medication will be used only as continuation treatment that was initiated with ketorolac tromethamine IV or IM

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

6. Does the prescriber acknowledge or is aware that the requested medication is considered a high-risk medication for patients 65 years or older?

   If yes, **approve for 30 days by HICL or GPI-10.**
   APPROVAL TEXT: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years or older.
   (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **HRM - KETOROLAC** requires the following rule(s) be met for approval:
   A. Your request is for short-term (5 days or less) management of moderately severe acute pain that requires analgesia (pain control) at the opioid level, usually in a postoperative (after surgery) setting
   B. Request for ketorolac tablets must be used only as continuation treatment that was initiated with ketorolac IV (intravenous) or IM (intramuscular)
   C. The total combined duration of use of ketorolac tromethamine tablets and injection is 5 days or less
   D. Your prescriber acknowledges or is aware that the requested medication is considered a high-risk medication for patients 65 years or older
   E. If you are enrolled in hospice (end of life), your request will be approved without requiring additional criteria

   NOTE: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years or older.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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HRM - KETOROLAC (PART D)

RATIONALE

The drug(s) is/are listed as high-risk medications in the elderly. The measure is an adaptation of the HEDIS measure Drugs to Avoid in the Elderly and calculates: the percentage of patients 65 years or older who have received at least one prescription for a high-risk drug and the percentage of Medicare patients 65 years or older who received two or more different prescriptions for high-risk medications.

REFERENCES

Ketorolac Injection [Prescribing Information]. Berkeley Heights, NJ: Hikma Pharmaceuticals USA Inc.; October 2021.

Ketorolac Tablet [Prescribing Information]. Mason, OH: Burel Pharmaceuticals, LLC; September 2022.

American Geriatric Society (AGS) Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults (2019). Available at: https://geriatricscareonline.org/ProductAbstract/american-geriatrics-society-updated-beers-criteria/CL001 [Accessed March 14, 2024].

Centers for Medicare & Medicaid Services. Enhancements to the Star Ratings for 2017 and Beyond. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/2017-Star-Ratings-Request-for-Comments.pdf [March 14, 2024].

For Part D use only:

HIGH RISK DRUGS IN THE ELDERLY - KETOROLAC (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS.
Prescriber Restrictions	N/A
Coverage Duration	30 DAYS
Other Criteria	PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA.

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 11/18
Client Approval: 06/24
P&T Approval: 05/18

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HRM - MEGESTROL (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MEGESTROL ACETATE	MEGESTROL ACETATE	03923		GPI-10 (2140402010, 2600002320)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the patient 65 years of age or older?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Is the patient enrolled in hospice?

   If yes, **approve for 12 months by HICL or GPI-10 for all strengths.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Is the request for megestrol acetate oral suspension and the patient meets **ALL** of the following criteria?
   - The patient has acquired immunodeficiency syndrome (AIDS)
   - The request is for the treatment of anorexia, cachexia, or an unexplained significant weight loss

   If yes, continue to #5.
   If no, continue to #4.

4. Is the request for megestrol acetate **oral tablet AND** the patient meets the following criterion?
   - The request is for palliative treatment of advanced carcinoma of the breast or endometrium (i.e., recurrent, inoperable, or metastatic disease)

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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HRM - MEGESTROL (PART D)

GUIDELINES FOR USE (CONTINUED)

5. Does the prescriber acknowledge or is aware that the requested medication is considered a high-risk medication for patients 65 years or older?

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths of the requested dosage form.**
   APPROVAL TEXT: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years or older.
   (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **HRM - MEGESTROL** requires the following rule(s) be met for approval:
   A. You meet ONE of the following:
      1. Your request is for megestrol oral suspension, you have acquired immunodeficiency syndrome (AIDS: a type of immune system disorder caused by virus infection), and you are being treated for anorexia (a type of eating disorder), cachexia (severe weight and muscle loss), or an unexplained significant weight loss
      2. Your request is for megestrol oral tablet which is being used for palliative treatment (treatment for pain or discomfort) of advanced breast cancer or endometrial (uterus) cancer that keeps returning, cannot be operated on, or is spreading to other parts of the body

   B. Your prescriber acknowledges or is aware that the requested medication is considered a high-risk medication for patients 65 years or older
   C. If you are enrolled in hospice (end of life), your request will be approved without requiring additional criteria

   NOTE: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years or older.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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HRM - MEGESTROL (PART D)

RATIONALE

The drug(s) is/are listed as high-risk medications in the elderly. The measure is an adaptation of the HEDIS measure Drugs to Avoid in the Elderly and calculates: the percentage of patients 65 years or older who have received at least one prescription for a high-risk drug and the percentage of Medicare patients 65 years or older who received two or more different prescriptions for high-risk medications.

REFERENCES

Megestrol Oral Suspension [Prescribing Information]. Gurnee, IL: Akorn Operating Company LLC.; June 2022.

Megestrol Oral tablet [Prescribing Information]. Chestnut Ridge, NY: Par Pharmaceutical; May 2022.

American Geriatric Society (AGS) Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults (2019). Available at: https://geriatricscareonline.org/ProductAbstract/american-geriatrics-society-updated-beers-criteria/CL001 [Accessed March 14, 2024].

Centers for Medicare & Medicaid Services. Enhancements to the Star Ratings for 2017 and Beyond. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/2017-Star-Ratings-Request-for-Comments.pdf [Accessed March 14, 2024].

For Part D use only:

HIGH RISK DRUGS IN THE ELDERLY - MEGESTROL (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS.
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA.

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 05/17
Client Approval: 06/24
P&T Approval: 05/18

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HRM - MEPROBAMATE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MEPROBAMATE	MEPROBAMATE	01605		GPI-10 (5720005000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug, is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the patient 65 years of age or older?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Is the patient enrolled in hospice?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Does the patient have a diagnosis of anxiety?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the prescriber acknowledge or is aware that the requested medication is considered a high-risk medication for patients 65 years or older?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years or older.
   (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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HRM - MEPROBAMATE (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **HRM - MEPROBAMATE** requires the following rule(s) be met for approval:

A. Your requested medication is being used for the treatment of anxiety
B. Your prescriber acknowledges or is aware that the requested medication is considered a high-risk medication for patients 65 years or older
C. If you are enrolled in hospice (end of life), your request will be approved without requiring additional criteria

NOTE: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years or older.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

The drug(s) is/are listed as high-risk medications in the elderly. The measure is an adaptation of the HEDIS measure, Drugs to Avoid in the Elderly, and calculates the percentage of patients 65 years or older who have received at least one prescription for a high-risk drug and the percentage of Medicare patients 65 years or older who received two or more different prescriptions for high-risk medications.

REFERENCES

Meprobamate [Prescribing Information]. Bedminster, NJ: Alembic Pharmaceuticals, Inc.; September 2021.

American Geriatric Society (AGS) Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults (2019). Available at: https://geriatricscareonline.org/ProductAbstract/american-geriatrics-society-updated-beers-criteria/CL001 [Accessed March 14, 2024].

Centers for Medicare & Medicaid Services. Enhancements to the Star Ratings for 2017 and Beyond. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/2017-Star-Ratings-Request-for-Comments.pdf [Accessed March 14, 2024].

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HRM - MEPROBAMATE (PART D)

For Part D use only:

HIGH RISK DRUGS IN THE ELDERLY - MEPROBAMATE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS.
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	ANXIETY: PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA.

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25 Created: 10/12
Commercial Effective: N/A Client Approval: 06/24 P&T Approval: 05/18

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HRM - NORETHINDRONE-ESTRADIOL (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NORETHINDRONE AC-ETH ESTRADIOL	FYAVOLV, JINTELI, NORETHINDRON-ETHINYL ESTRADIOL		15567 92296	GPI-10 (2499300225)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the patient 65 years of age or older?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Is the patient enrolled in hospice?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Is the request for **ONE** of the following?
   - Treatment of moderate to severe vasomotor symptoms due to menopause (ICD-10 N95.1)
   - Prevention of postmenopausal osteoporosis

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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HRM - NORETHINDRONE-ESTRADIOL (PART D)

GUIDELINES FOR USE (CONTINUED)

4. Does the prescriber acknowledge or is aware that the requested medication is considered a high-risk medication for patients 65 years or older?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years or older.
   (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **HRM - NORETHINDRONE-ESTRADIOL (Fyavolv, Jinteli)** requires the following rule(s) be met for approval:
   A. The request is for ONE of the following:
      1. Treatment of moderate to severe vasomotor symptoms (such as night sweats, hot flashes) due to menopause
      2. Prevention of postmenopausal osteoporosis (a type of bone condition in women after menopause)
   B. Your prescriber acknowledges or is aware that the requested medication is considered a high-risk medication for patients 65 years of age or older
   C. If you are enrolled in hospice (end of life), your request will be approved without requiring additional criteria

   NOTE: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years or older.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

The drug(s) is/are listed as high-risk medications in the elderly. The measure is an adaptation of the HEDIS measure, Drugs to Avoid in the Elderly, and calculates the percentage of patients 65 years or older who have received at least one prescription for a high-risk drug and the percentage of Medicare patients 65 years or older who received two or more different prescriptions for high-risk medications.

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HRM - NORETHINDRONE-ESTRADIOL (PART D)

REFERENCES

Fyavolv [Prescribing Information]. Baltimore, MD: Lupin Pharmaceuticals, Inc.; December 2023.
Jinteli [Prescribing Information]. Parsippany, NJ: Teva Pharmaceuticals; February 2024.
American Geriatric Society (AGS) Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults (2019). Available at: https://geriatricscareonline.org/ProductAbstract/american-geriatrics-society-updated-beers-criteria/CL001 [Accessed March 14, 2024].
Centers for Medicare & Medicaid Services. Enhancements to the Star Ratings for 2017 and Beyond. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/2017-Star-Ratings-Request-for-Comments.pdf [Accessed March 14, 2024].

For Part D use only:

HIGH RISK DRUGS IN THE ELDERLY - NORETHINDRONE-ESTRADIOL (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS.
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA.

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 07/23
Client Approval: 06/24
P&T Approval: 04/19

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HRM - PAROXETINE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PAROXETINE HCL	PAXIL, PAROXETINE HCL, PAXIL CR, PAROXETINE CR, PAROXTINE ER	07344		GPI-10 (5816006000)	
PAROXETINE MESYLATE	PEXEVA		20854 20855 20856	GPI-14 (58160060300310, 58160060300320, 58160060300330)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the patient 65 years of age or older?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Is the patient enrolled in hospice?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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HRM - PAROXETINE (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Is the request for Paxil (paroxetine tablet or suspension) for the treatment of **ONE** of the following?
   - Major depressive disorder (MDD) (ICD-10 Groups F32, F33)
   - Obsessive compulsive disorder (OCD) (ICD-10 F60.5, R46.81; Group F42)
   - Panic disorder (PD) (ICD-10 F41.0, F40.01)
   - Social anxiety disorder (SAD) (ICD-10 Group F40.1)
   - Generalized anxiety disorder (GAD) (ICD-10 F41.1)
   - Posttraumatic stress disorder (PTSD) (ICD-10 Group F43.1)

   If yes, continue to #6.
   If no, continue to #4.

4. Is the request for Paxil CR (paroxetine CR/ER) for the treatment of **ONE** of the following?
   - Major depressive disorder (MDD) (ICD-10 Groups F32, F33)
   - Panic disorder (PD) (ICD-10 F41.0, F40.01)
   - Social anxiety disorder (SAD) (ICD-10 Group F40.1)
   - Premenstrual dysphoric disorder (PMDD) (ICD-10 F32.81)

   If yes, continue to #6.
   If no, continue to #5.

5. Is the request for Pexeva (paroxetine mesylate) for the treatment of **ONE** of the following?
   - Major depressive disorder (MDD) (ICD-10 Groups F32, F33)
   - Obsessive compulsive disorder (OCD) (ICD-10 F60.5, R46.81; Group F42)
   - Panic disorder (PD) (ICD-10 F41.0, F40.01)
   - Generalized anxiety disorder (GAD) (ICD-10 F41.1)

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

6. Does the prescriber acknowledge or is aware that the requested medication is considered a high-risk medication for patients 65 years or older?

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   APPROVAL TEXT: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years or older.
   (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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HRM - PAROXETINE (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **HRM - PAROXETINE (Paxil, Paxil CR, Pexeva)** requires the following rule(s) be met for approval:

A. If your request is for Paxil (paroxetine tablets or suspension), approval requires you are being treated for ONE of the following:
1. Major depressive disorder (MDD: a type of mental health condition)
2. Obsessive compulsive disorder (OCD: a type of mental health condition)
3. Panic disorder (PD: a type of mental health condition)
4. Social anxiety disorder (SAD: a type of mental health condition)
5. Generalized anxiety disorder (GAD: a type of mental health condition)
6. Posttraumatic stress disorder (PTSD: a type of mental health condition)

B. If your request is for Paxil CR (paroxetine controlled-release/extended-release), approval requires you are being treated for ONE of the following:
1. Major depressive disorder (MDD: a type of mental health condition)
2. Panic disorder (PD: a type of mental health condition)
3. Social anxiety disorder (SAD: a type of mental health condition)
4. Premenstrual dysphoric disorder (PMDD: a type of mental health condition)

C. If your request is for Pexeva (paroxetine mesylate), approval requires you are being treated for ONE of the following:
1. Major depressive disorder (MDD: a type of mental health condition)
2. Obsessive compulsive disorder (OCD: a type of mental health condition)
3. Panic disorder (PD: a type of mental health condition)
4. Generalized anxiety disorder (GAD: a type of mental health condition)

D. Your prescriber acknowledges or is aware that the requested medication is considered a high-risk medication for patients 65 years or older

E. If you are enrolled in hospice (end of life), your request will be approved without requiring additional criteria

NOTE: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years or older.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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HRM - PAROXETINE (PART D)

RATIONALE

The drug(s) is/are listed as high-risk medications in the elderly. The measure is an adaptation of the HEDIS measure Drugs to Avoid in the Elderly and calculates: the percentage of patients 65 years or older who have received at least one prescription for a high-risk drug and the percentage of Medicare patients 65 years or older who received two or more different prescriptions for high-risk medications.

REFERENCES

Paxil [Prescribing Information]. Weston, FL: Apotex Corp.; August 2023.
Paxil CR [Prescribing Information]. Weston, FL: Apotex Corp.; February 2024.
Pexeva [Prescribing Information]. Roswell, GA: Sebela Pharmaceuticals Inc.; August 2023.
American Geriatric Society (AGS) Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults (2019). Available at: https://geriatricscareonline.org/ProductAbstract/american-geriatrics-society-updated-beers-criteria/CL001 [Accessed March 20, 2024].
Centers for Medicare & Medicaid Services. Enhancements to the Star Ratings for 2017 and Beyond. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/2017-Star-Ratings-Request-for-Comments.pdf [Accessed March 20, 2024].

For Part D use only:

HIGH RISK DRUGS IN THE ELDERLY - PAROXETINE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS.
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA.

Created: 05/17
Effective: 03/09/26 Client Approval: 03/26 P&T Approval: 05/18

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HRM - PAROXETINE - BRISDELLE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PAROXETINE MESYLATE	PAROXETINE MESYLATE		34876	GPI-10 (6222606030)	BRAND ≠ BRISDELLE

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the patient 65 years of age or older?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Is the patient enrolled in hospice?

   If yes, **approve for 12 months by GPID or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Is the request for the treatment of moderate to severe vasomotor symptoms associated with menopause (ICD-10 N95.1)?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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HRM - PAROXETINE - BRISDELLE (PART D)

GUIDELINES FOR USE (CONTINUED)

4. Does the prescriber acknowledge or is aware that the requested medication is considered a high-risk medication for patients 65 years or older?

   If yes, **approve for 12 months by GPID or GPI-10.**
   APPROVAL TEXT: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years or older.
   (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **HRM - PAROXETINE-BRISDELLE** requires the following rule(s) be met for approval:
   A. You are being treated for moderate to severe vasomotor symptoms (such as night sweats, hot flashes) due to menopause
   B. Your prescriber acknowledges or is aware that the requested medication is considered a high-risk medication for patients 65 years or older
   C. If you are enrolled in hospice (end of life), your request will be approved without requiring additional criteria

   NOTE: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years or older.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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HRM - PAROXETINE - BRISDELLE (PART D)

RATIONALE

The drug(s) is/are listed as high-risk medications in the elderly. The measure is an adaptation of the HEDIS measure Drugs to Avoid in the Elderly and calculates: the percentage of patients 65 years or older who have received at least one prescription for a high-risk drug and the percentage of Medicare patients 65 years or older who received two or more different prescriptions for high-risk medications.

REFERENCES

Brisdelle [Prescribing Information]. Roswell, GA: Sebela Pharmaceuticals Inc.; August 2023.
American Geriatric Society (AGS) Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults (2019). Available at: https://geriatricscareonline.org/ProductAbstract/american-geriatrics-society-updated-beers-criteria/CL001 [Accessed March 14, 2024].
Centers for Medicare & Medicaid Services. Enhancements to the Star Ratings for 2017 and Beyond. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/2017-Star-Ratings-Request-for-Comments.pdf [Accessed March 14, 2024].

For Part D use only:

HIGH RISK DRUGS IN THE ELDERLY - PAROXETINE - BRISDELLE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS.
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA.

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 10/22
Client Approval: 06/24
P&T Approval: 05/18

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HRM - PHENOBARBITAL (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PHENOBARBITAL	PHENOBARBITAL	01561		GPI-10 (6010006000)	ROUTE = ORAL

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the patient 65 years of age or older?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Is the patient enrolled in hospice?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.
   If no, continue to #3.

3. Will phenobarbital be used for the treatment of epilepsy or seizures (ICD-10 Group G40)?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Has the patient NOT responded to at least one other anticonvulsant (e.g., Depakote [divalproex sodium], Topamax [topiramate])?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

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HRM - PHENOBARBITAL (PART D)

GUIDELINES FOR USE (CONTINUED)

5. Does the prescriber acknowledge or is aware that the requested medication is considered a high-risk medication for patients 65 years or older?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years or older.
   (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **HRM - PHENOBARBITAL** requires the following rule(s) be met for approval:
   A. You have epilepsy (a type of seizure disorder) or seizures
   B. You meet ONE of the following:
      1. You have not responded to at least one other anticonvulsant (medications used to treat seizures such as Depakote [divalproex sodium], Topamax [topiramate])
      2. Your prescriber acknowledges or is aware that the requested medication is considered a high-risk medication for patients 65 years of age or older
   C. If you are enrolled in hospice (end of life), your request will be approved without requiring additional criteria

   NOTE: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years or older.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

The drug(s) is/are listed as high-risk medications. The measure is an adaptation of the HEDIS measure Drugs to Avoid in the Elderly and calculates: the percentage of patients 65 years or older who have received at least one prescription for a high-risk drug and the percentage of Medicare patients 65 years or older who received two or more different prescriptions for high-risk medications.

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HRM - PHENOBARBITAL (PART D)

REFERENCES

Phenobarbital elixir [Prescribing Information]. Fort Lauderdale, FL: BioRamo, LLC; March 2022.
Phenobarbital tablet [Prescribing Information]. Fort Lauderdale, FL: ECI Pharmaceuticals, LLC. January 2023.
American Geriatric Society (AGS) Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults (2019). Available at: https://geriatricscareonline.org/ProductAbstract/american-geriatrics-society-updated-beers-criteria/CL001 [Accessed March 14, 2024].
CMS Memo: Transition to Part D Coverage of Benzodiazepines and Barbiturates Beginning in 2013. October 2, 2012. From Cynthia G. Tutor, Ph.D., Director, Medicare Drug Benefit and C & D Data Group.
Centers for Medicare & Medicaid Services. Enhancements to the Star Ratings for 2017 and Beyond. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/2017-Star-Ratings-Request-for-Comments.pdf [Accessed March 14, 2024].

For Part D use only:

HIGH RISK DRUGS IN THE ELDERLY - PHENOBARBITAL (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS.
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	EPILEPSY/SEIZURES: PATIENTS WHO ARE NEWLY PRESCRIBED PHENOBARBITAL: 1) HAS NOT RESPONDED TO AT LEAST ONE ANTICONVULSANT, OR 2) PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA.

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 04/17
Client Approval: 06/24
P&T Approval: 05/19

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HRM - PROMETHAZINE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PROMETHAZINE HCL	PROMETHEGAN, PROMETHAZINE HCL	12014		GPI-10 (4140002010)	BRAND ≠ PHENERGAN

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the patient 65 years of age or older?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Has the patient been identified as being enrolled in hospice (i.e., plan notification, member attribute, physician/member notification on the medication request form)?

   If yes, continue #3.
   If no, continue to #4.

3. Has the prescriber indicated that the requested medication is being used for an indication that is unrelated to the terminal illness or conditions related to the terminal illness?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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Revised: 6/18/2024

HRM - PROMETHAZINE (PART D)

GUIDELINES FOR USE (CONTINUED)

4. Is the request for the treatment of pruritus (ICD-10 Group L29) or urticaria (ICD-10 L50.0, L50.8, L50.9) (due to vasomotor rhinitis [ICD-10 J30.0]; allergic conjunctivitis due to inhalant allergens or foods [ICD-10 H10.45]; mild, uncomplicated allergic skin manifestations of urticaria [ICD-10 L50.0] or angioedema [T78.3]; amelioration of allergic reactions to blood or plasma [ICD-10 Group T80.5]; or dermatographism [ICD-10 L50.3]) and the patient meets **ONE** of the following criteria?
   - The patient had a trial of or contraindication to a non-sedating antihistamine (e.g., levocetirizine)
   - The prescriber acknowledges or is aware that the requested medication is considered a high-risk medication for patients 65 years or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years or older.
   (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Is the request for the treatment of seasonal allergic rhinitis (ICD-10 J30.1, J30.2) or perennial allergic rhinitis (ICD-10 J30.9, J30.5; Group J30.8) and the patient meets **ONE** of the following criteria?
   - The patient had a trial of or contraindication to a non-sedating antihistamine (e.g., levocetirizine)
   - The prescriber acknowledges or is aware that the requested medication is considered a high-risk medication for patients 65 years or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years or older.
   (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #6.

6. Is the request for the treatment of nausea and vomiting (ICD-10 Group R11) **AND** the patient meets the following criterion?
   - The prescriber acknowledges or is aware that the requested medication is considered a high-risk medication for patients 65 years or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years or older.
   (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #7.

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Revised: 6/18/2024

HRM - PROMETHAZINE (PART D)

GUIDELINES FOR USE (CONTINUED)

7. Is the request for **ANY** of the following FDA approved indications?
   - Treatment of anaphylactic reactions
   - For use in preoperative, postoperative, or obstetric sedation
   - For control of post-operative pain (ICD-10 Groups G89.1, 89.2 except G89.29)
   - For sedation in adults
   - Treatment of motion sickness (ICD-10 T75. 3)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **HRM - PROMETHAZINE (Promethegan)** requires the following rule(s) be met for approval:

   A. You are using the requested medication for ONE of the following:
      1. Pruritus (itching) or urticaria (hives) (due to vasomotor rhinitis [chronic condition with sneezing, congestion, runny nose that is not caused by allergy or infection]; allergic conjunctivitis [eye inflammation caused by allergies] due to inhalant allergens [substances that cause allergic reaction when breathed in] or foods; mild, uncomplicated allergic skin manifestations of urticaria or angioedema [a type of swelling]; improvement of allergic reactions to blood or plasma; or dermatographism [a condition in which lightly scratching the skin causes raised, red lines])
      2. Seasonal (occurring for a season) or perennial (long-lasting) allergic rhinitis (stuffy, runny nose)
      3. Nausea and vomiting
      4. Anaphylactic reactions (severe, potentially life-threatening allergic reactions)
      5. Use in preoperative (before surgery), postoperative (after surgery), or obstetric (during childbirth) sedation (to help you relax and fall asleep)
      6. Control of post-operative (after surgery) pain
      7. Sedation (to help you relax and fall asleep) in an adult
      8. Motion sickness

   (Denial text continued on next page)

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Revised: 6/18/2024

HRM - PROMETHAZINE (PART D)

GUIDELINES FOR USE (CONTINUED)

B. If you have seasonal or perennial allergies, pruritus, or urticaria, approval also requires ONE of the following:
1. You have tried or have a contraindication to (harmful for you to use) a non-sedating antihistamine (such as levocetirizine)
2. Your prescriber acknowledges or is aware that the requested medication is considered a high-risk medication for patients 65 years or older

C. If you have nausea and vomiting, approval also requires:
1. Your prescriber acknowledges or is aware that the requested medication is considered a high-risk medication for patients 65 years or older

D. If you are enrolled in hospice (end of life) and your doctor confirms that the requested medication is being used for the treatment of a diagnosis that is unrelated to your terminal illness, your request will be approved without requiring additional criteria

NOTE: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years or older.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

The drug(s) is/are listed as high-risk medications in the elderly. The measure is an adaptation of the HEDIS measure Drugs to Avoid in the Elderly and calculates: the percentage of patients 65 years or older who have received at least one prescription for a high-risk drug and the percentage of Medicare patients 65 years or older who received two or more different prescriptions for high-risk medications. Treatment of cough is not covered under Part D.

REFERENCES

Promethazine tablets [Prescribing information]. Parsippany, NJ: Actavis Pharma, Inc.; December 2016.

American Geriatric Society (AGS) Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults (2019). Available at: https://geriatricscareonline.org/ProductAbstract/american-geriatrics-society-updated-beers-criteria/CL001 [Accessed March 14, 2024].

Centers for Medicare & Medicaid Services. Enhancements to the Star Ratings for 2017 and Beyond. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/2017-Star-Ratings-Request-for-Comments.pdf [Accessed March 14, 2024].

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Revised: 6/18/2024

CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HRM - PROMETHAZINE (PART D)

For Part D use only:

HIGH RISK DRUGS IN THE ELDERLY - PROMETHAZINE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS.
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	PRURITUS/URTICARIA/SEASONAL/PERENNIAL ALLERGY: 1) TRIAL OF OR CONTRAINDICATION TO A NON-SEDATING ANTIHISTAMINE SUCH AS LEVOCETIRIZINE, OR 2) PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. NAUSEA AND VOMITING: PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH-RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS REQUIRE PHYSICIAN ATTESTATION THAT REQUESTED MEDICATION IS USED TO TREAT A DIAGNOSIS UNRELATED TO THE TERMINAL ILLNESS OR RELATED CONDITION, AND ARE APPROVED WITHOUT TRIAL OF FORMULARY ALTERNATIVES NOR REQUIRING PRESCRIBER ACKNOWLEDGEMENT.

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 11/07
Client Approval: 06/24
P&T Approval: 05/19

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Revised: 6/18/2024

CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HRM - SCOPOLAMINE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SCOPOLAMINE	SCOPOLAMINE, TRANSDERM-SCOP	12306		GPI-10 (5020006000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the patient 65 years of age or older?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Has the patient been identified as being enrolled in hospice (i.e., plan notification, member attribute, physician/member notification on the medication request form)?

   If yes, continue #3.
   If no, continue to #4.

3. Has the prescriber indicated that scopolamine patch is being used for an indication that is unrelated to the terminal illness or conditions related to the terminal illness?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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HRM - SCOPOLAMINE (PART D)

GUIDELINES FOR USE (CONTINUED)

4. Is the request for the prevention of nausea and vomiting associated with motion sickness **OR** for post-operative nausea and vomiting (PONV)?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Does the prescriber acknowledge or is aware that the requested medication is considered a high-risk medication for patients 65 years or older?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years or older.
   (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: **Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **HRM - SCOPOLAMINE (Transderm-Scop)** requires the following rule(s) be met for approval:
   A. Your requested medication is being used for the prevention of nausea and vomiting associated with motion sickness or post-operative (after surgery) nausea and vomiting
   B. Your prescriber acknowledges or is aware that the requested medication is considered a high-risk medication for patients 65 years or older
   C. If you are enrolled in hospice (end of life care) and your doctor confirms that scopolamine patch is being used for the treatment of a condition that is not related to your terminal illness, your request will be approved without requiring additional criteria

   NOTE: The American Geriatrics Society (AGS) considers the requested medication a high-risk medication (HRM) if you are 65 years or older.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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HRM - SCOPOLAMINE (PART D)

RATIONALE

The drug(s) is/are listed as high-risk medications in the elderly. The measure is an adaptation of the HEDIS measure Drugs to Avoid in the Elderly and calculates: the percentage of patients 65 years or older who have received at least one prescription for a high-risk drug and the percentage of Medicare patients 65 years or older who received two or more different prescriptions for high-risk medications.

REFERENCES

Scopolamine Patch [Prescribing Information]. Allegan, MI: Perrigo; July 2023.
Transderm Scop [Prescribing Information]. Deerfield, IL: Baxter Healthcare Corporation; December 2023.
American Geriatric Society (AGS) Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults (2019). Available at: https://geriatricscareonline.org/ProductAbstract/american-geriatrics-society-updated-beers-criteria/CL001 [Accessed March 14, 2024].
Centers for Medicare & Medicaid Services. Enhancements to the Star Ratings for 2017 and Beyond. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/2017-Star-Ratings-Request-for-Comments.pdf [Accessed March 14, 2024].

For Part D use only:

HIGH RISK DRUGS IN THE ELDERLY - SCOPOLAMINE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS.
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS REQUIRE PHYSICIAN ATTESTATION THAT REQUESTED MEDICATION IS USED TO TREAT A DIAGNOSIS UNRELATED TO THE TERMINAL ILLNESS OR RELATED CONDITION, AND ARE APPROVED WITHOUT REQUIRING PRESCRIBER ACKNOWLEDGEMENT.

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 10/22
Client Approval: 06/24
P&T Approval: 05/18

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HYDROCHLOROTHIAZIDE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
HYDROCHLOROTHIAZIDE	INZIRQO	03649		GPI-10 (3760004000)	BRAND = INZIRQO

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of hypertension (ICD-10 I10) **AND** meet the following criterion?
   - The patient has a contraindication to or is unable to swallow hydrochlorothiazide tablets

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of edema (ICD-10 Group R60) associated with congestive heart failure, hepatic cirrhosis, or renal disease (including nephrotic syndrome) **AND** meet the following criterion?
   - The patient has a contraindication to or is unable to swallow hydrochlorothiazide tablets

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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HYDROCHLOROTHIAZIDE (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **HYDROCHLOROTHIAZIDE (Inzirqo)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Hypertension (high blood pressure)
   2. Edema (swelling caused by fluid build-up in the body) associated with congestive heart failure (a type of heart condition), hepatic cirrhosis (liver damage and scarring), or renal (kidney) disease (including nephrotic syndrome [a type of kidney disorder])

B. If you have hypertension, approval also requires:
   1. You have a contraindication to (harmful for you to use) or are unable to swallow hydrochlorothiazide tablets

C. If you have edema associated with congestive heart failure, hepatic cirrhosis, or renal disease (including nephrotic syndrome), approval also requires:
   1. You have a contraindication to (harmful for you to use) or are unable to swallow hydrochlorothiazide tablets

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Inzirqo.

REFERENCES

Inzirqo [Prescribing Information]. Baudette, MN: ANI Pharmaceuticals, Inc.; January 2025.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HYDROCHLOROTHIAZIDE (PART D)

For Part D use only:

HYDROCHLOROTHIAZIDE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	HYPERTENSION, EDEMA ASSOCIATED WITH CONGESTIVE HEART FAILURE, HEPATIC CIRRHOSIS, OR RENAL DISEASE (INCLUDING NEPHROTIC SYNDROME): CONTRAINDICATION TO OR UNABLE TO SWALLOW HYDROCHLOROTHIAZIDE TABLETS.

Created: 03/25
Effective: 04/07/25 Client Approval: 03/25 P&T Approval: 04/25

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HYDROCODONE BITARTRATE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
HYDROCODONE BITARTRATE	HYSINGLA ER, HYDROCODONE BITARTRATE ER	01731		GPI-10 (6510003010)	BRAND = HYSINGLA ER, HYDROCODONE BITARTRATE ER

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the request being used as an 'as-needed' (prn) pain analgesic?

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #2.

2. Is the medication being used for the management of pain (ICD-10 R52) that is severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Is the request for either hydrocodone ER capsule 10mg every 12 hours OR Hysingla ER (hydrocodone ER tablet) 20mg every 24 hours?

   If yes, **approve for 12 months by GPID or GPI-14 for the requested agent.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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HYDROCODONE BITARTRATE (PART D)

GUIDELINES FOR USE (CONTINUED)

4. Is the patient opioid tolerant (receiving, for one week or longer, at least 60mg oral morphine per day, 25mcg transdermal fentanyl per hour, 30mg oral oxycodone per day, 8mg oral hydromorphone per day, 25mg oral oxymorphone per day, or an equianalgesic dose of another opioid)?

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths of the requested drug.** **APPROVAL TEXT (IF APPLICABLE):** The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **HYDROCODONE BITARTRATE (Hysingla ER, Hydrocodone Bitartrate ER)** requires the following rule(s) be met for approval:
   A. You are using the requested drug for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment
   B. Alternative treatment options are inadequate
   C. You are not using this drug on an 'as-needed' basis
   D. If you are requesting a dose that is more than 20 mg in one day, you must be opioid tolerant (you have been receiving, for one week or longer, at least 60mg oral morphine per day, 25mcg transdermal fentanyl per hour, 30mg oral oxycodone per day, 8mg oral hydromorphone per day, 25mg oral oxymorphone per day, or an equianalgesic dose [the equivalent dose that produces the same degree of pain relief] of another opioid)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the prescribing information and/or drug monograph for Hysingla ER and Hydrocodone Bitartrate ER.

REFERENCES

Hysingla ER [Prescribing Information]. Stamford, CT: Purdue Pharma; March 2021.
Hydrocodone Bitartrate ER [Prescribing Information]. Morristown, NJ: Alvogen, Inc; March 2021.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HYDROCODONE BITARTRATE (PART D)

For Part D use only:

HYDROCODONE BITARTRATE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	NA
Coverage Duration	12 MONTHS
Other Criteria	SEVERE PAIN: 1) NOT FOR USE ON AN AS-NEEDED PAIN ANALGESIC. 2) FOR STARTING DOSES OF HYDROCODONE ER CAPSULES GREATER THAN 10MG EVERY 12 HOURS OR HYSINGLA ER (HYDROCODONE ER TABLETS) GREATER THAN 20MG EVERY 24 HOURS: PATIENT IS OPIOID TOLERANT (RECEIVING, FOR ONE WEEK OR LONGER, AT LEAST 60 MG ORAL MORPHINE PER DAY, 25 MCG TRANSDERMAL FENTANYL PER HOUR, 30 MG ORAL OXYCODONE PER DAY, 8 MG ORAL HYDROMORPHONE PER DAY, 25 MG ORAL OXYMORPHONE PER DAY, OR AN EQUIANALGESIC DOSE OF ANOTHER OPIOID)

Core	Advantage	Plus
No	No	Yes

Created: 10/20
Effective: 01/01/25 Client Approval: 08/24 P&T Approval: 05/20

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HYDROCORTISONE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
HYDROCORTISONE	ALKINDI SPRINKLE		46547 46548 46549 46551	GPI-14 (22100025006810, 22100025006815, 22100025006820, 22100025006830)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of adrenocortical insufficiency (ICD-10 E27.40) and meet **ALL** of the following criteria?
   - The patient is less than 18 years of age
   - The patient is unable to take the tablet formulation of hydrocortisone (e.g., need for lower strength, difficulty in swallowing)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **HYDROCORTISONE (Alkindi Sprinkle)** requires the following rule(s) be met for approval:
   A. You have adrenocortical insufficiency (your body does not produce enough of certain hormones)
   B. You are less than 18 years of age
   C. You are unable to take the tablet form of hydrocortisone (for example you need a lower strength, or you have difficulty swallowing)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HYDROCORTISONE (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Alkindi Sprinkle.

REFERENCES

Alkindi Sprinkle [Prescribing Information]. Baden-Wuerttemberg, Germany: Eton Pharmaceuticals, Inc.; October 2020.

For Part D use only:

HYDROCORTISONE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 MONTHS
Other Criteria	ADRENOCORTICAL INSUFFICIENCY: PATIENT IS UNABLE TO TAKE TABLET FORMULATION OF HYDROCORTISONE.

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25 Created: 10/20
Commercial Effective: N/A Client Approval: 08/24 P&T Approval: 01/21

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HYDROMORPHONE ER (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
HYDROMORPHONE HCL	HYDROMORPHONE ER		22056 28427 22098 33088	GPI-14 (65100035107531, 65100035107541, 65100035107556, 65100035107521)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS notes for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the request form indicate that this medication will be used on an 'as needed' or 'PRN' basis?

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.
   If no, continue to #2.

2. Is the medication being used for the management of pain (ICD-10 R52) that is severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet the definition of opioid tolerant (defined as those who are taking, for one week or longer, at least 60mg oral morphine per day, 25mcg transdermal fentanyl per hour, 30mg oral oxycodone per day, 8mg oral hydromorphone per day, 25mg oral oxymorphone per day, 60mg oral hydrocodone per day, or an equianalgesic dose of another opioid)?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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HYDROMORPHONE ER (PART D)

GUIDELINES FOR USE (CONTINUED)

4. Does the patient require a dosage of 16mg or less?

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following strengths:**
   - **Hydromorphone ER 8mg**
   - **Hydromorphone ER 12mg**
   - **Hydromorphone ER 16mg**

   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Does the patient require a dosage of more than 16mg **AND** the requested dose is recommended by a pain specialist?

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following strengths:**
   - **Hydromorphone ER 8mg**
   - **Hydromorphone ER 12mg**
   - **Hydromorphone ER 16mg**
   - **Hydromorphone ER 32mg**

   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **HYDROMORPHONE ER** requires the following rule(s) be met for approval:
   A. You are using the requested medication for the management of pain that is severe enough to require daily, around-the-clock, long-term opioid treatment and for which other treatment options are inadequate
   B. You meet the definition of opioid tolerant (defined as taking, for one week or longer, at least 60mg oral morphine per day, 25mcg transdermal fentanyl per hour, 30mg oral oxycodone per day, 8mg oral hydromorphone per day, 25mg oral oxymorphone per day, 60 mg oral hydrocodone per day, or an equianalgesic dose of another opioid)
   C. You will not be using the requested medication on an 'as needed' basis
   D. For dosages above 16mg, a recommendation from a pain specialist must be obtained

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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HYDROMORPHONE ER (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Hydromorphone ER.

REFERENCES

Hydromorphone HCl tablet, extended release [Prescribing Information]. Alpharetta, GA: Trigen Laboratories, LLC; November 2021.

For Part D use only:

HYDROMORPHONE ER (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	SEVERE PAIN: 1) MEETS THE DEFINITION OF OPIOID TOLERANT (DEFINED AS TAKING, FOR ONE WEEK OR LONGER, AT LEAST 60 MG ORAL MORPHINE PER DAY, 25 MCG TRANSDERMAL FENTANYL/HOUR, 30 MG ORAL OXYCODONE/DAY, 8 MG ORAL HYDROMORPHONE/DAY, 25 MG ORAL OXYMORPHONE/DAY, 60 MG ORAL HYDROCODONE PER DAY, OR AN EQUIANALGESIC DOSE OF ANOTHER OPIOID), 2) REQUESTS ABOVE 16MG STRENGTH REQUIRE PAIN SPECIALIST RECOMMENDATION, AND 3) NOT FOR USE ON AN AS NEEDED BASIS.

Core	Advantage	Plus
No	No	Yes

Created: 04/10
Effective: 01/01/25 Client Approval: 08/24 P&T Approval: 04/15

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HYDROXYUREA (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
HYDROXYUREA	XROMI	03897		GPI-10 (8280303000)	BRAND = XROMI

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of sickle cell anemia (ICD-10 Group D57.0) and meet **ALL** of the following criteria?
   - The patient is 6 months to 17 years of age
   - The patient has recurrent moderate to severe painful crises

   If yes, **approve for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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HYDROXYUREA (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **HYDROXYUREA (Xromi)** requires the following rule(s) be met for approval:

A. You have sickle cell anemia (a type of blood disorder)
B. You are 6 months to 17 years of age
C. You have recurrent moderate to severe painful crises (repeated episodes of extreme pain)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xromi.

REFERENCES

Xromi [Prescribing Information]. Franklin, TN: Rare Disease Therapeutics, Inc.; December 2024.

For Part D use only:

HYDROXYUREA (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 03/25
Effective: 01/01/26 Client Approval: 01/26 P&T Approval: 04/25

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IBRUTINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IBRUTINIB	IMBRUVICA	40745		GPI-10 (2153213300)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic lymphocytic leukemia (CLL) (ICD-10 Group C91.1) or small lymphocytic lymphoma (SLL) (ICD-10 Group C83.0) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of Waldenstrom's macroglobulinemia (WM) (ICD-10 C88.0) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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IBRUTINIB (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of chronic graft versus host disease (cGVHD) (ICD-10 D89.811, D89.812) and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - The patient has failed at least ONE line of systemic therapy (e.g., prednisone, methotrexate, mycophenolate mofetil)
   - Imbruvica will NOT be used concurrently with Jakafi (ruxolitinib), Niktimvo (axatilimab-csfr), or Rezurock (belumosudil)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **IBRUTINIB (Imbruvica)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Chronic lymphocytic leukemia (CLL: type of blood cancer)
      2. Small lymphocytic lymphoma (SLL: type of blood cancer)
      3. Waldenstrom's macroglobulinemia (WM: type of blood cancer)
      4. Chronic graft versus host disease (cGVHD: a type of long-term immune disorder)

   B. If you have chronic lymphocytic leukemia, small lymphocytic lymphoma, or Waldenstrom's macroglobulinemia, approval also requires:
      1. You are 18 years of age or older

   C. If you have chronic graft versus host disease, approval also requires:
      1. You are 1 year of age or older
      2. You have failed at least ONE line of systemic therapy (treatment that targets the entire body such as prednisone, methotrexate, mycophenolate mofetil)
      3. You will NOT use Imbruvica concurrently (at the same time) with Jakafi (ruxolitinib), Niktimvo (axatilimab-csfr), or Rezurock (belumosudil)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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IBRUTINIB (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Imbruvica.

REFERENCES

Imbruvica [Prescribing Information]. South San Francisco, CA: Pharmacyclics LLC; December 2024.

For Part D use only:

IBRUTINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	CHRONIC GRAFT VS HOST DISEASE (CGVHD): NO CONCURRENT USE WITH JAKAFI, NIKTIMVO, OR REZUROCK.

Created: 01/14
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 07/24

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IBUPROFEN-FAMOTIDINE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IBUPROFEN/ FAMOTIDINE	DUEXIS, IBUPROFEN-FAMOTIDINE	37986		GPI-10 (6610990232)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of rheumatoid arthritis (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) or osteoarthritis (ICD-10 Groups M15, M16, M17, M18, M19, M47) and meet **ALL** of the following criteria?
   - The requested medication will be used to decrease the risk of developing upper gastrointestinal ulcers (defined as a gastric and/or duodenal ulcer)
   - The patient had a trial of ONE of the following generic, prescription-only histamine H2-receptor antagonists: famotidine, cimetidine, or nizatidine
   - The patient had a trial of generic, prescription-only ibuprofen

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **IBUPROFEN-FAMOTIDINE (Duexis)** requires the following rule(s) be met for approval:
   A. You have rheumatoid arthritis (a type of joint condition) or osteoarthritis (a type of joint condition)
   B. You need this medication to decrease the risk of developing upper gastrointestinal ulcers (defined as a gastric and/or duodenal ulcer: a type of digestive condition)
   C. You have tried one of the following generic, prescription-only histamine H2-receptor antagonists: famotidine, cimetidine, or nizatidine
   D. You have tried generic, prescription-only ibuprofen
   (Denial text continued on next page)

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IBUPROFEN-FAMOTIDINE (PART D)

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Duexis.

REFERENCES

Duexis [Prescribing Information]. Lake Forest, IL: Horizon Pharma USA, Inc.; April 2021.

For Part D use only:

IBUPROFEN-FAMOTIDINE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Medical Required Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	TRIAL OF ONE OF THE FOLLOWING GENERIC, FEDERAL LEGEND HISTAMINE H2-RECEPTOR ANTAGONISTS: FAMOTIDINE, CIMETIDINE, OR NIZATIDINE, AND TRIAL OF GENERIC, FEDERAL LEGEND IBUPROFEN.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ICATIBANT (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ICATIBANT ACETATE	FIRAZYR, SAJAZIR, ICATIBANT	35962		GPI-10 (8582004010)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
Yes	No	No	Yes	No	No	Yes	No	No	Yes	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hereditary angioedema (HAE) (ICD-10 D84.1) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- The requested medication will be used for the treatment of acute HAE attacks
- Therapy is prescribed by or in consultation with an allergist, immunologist, hematologist or pulmonologist
- The requested medication will NOT be used concurrently with other agents used for the treatment of acute HAE attacks (e.g., Ruconest [C1 esterase inhibitor], Berinert [C1 esterase inhibitor], Kalbitor [ecallantide])

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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ICATIBANT (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient meet **ONE** of the following criteria?
   - The patient has Type I or II HAE, as confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q
   - The patient has Type III HAE

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ICATIBANT (Firazyr, Sajazir)** requires the following rule(s) be met for approval:
   A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
   B. You are 18 years of age or older
   C. The requested medication will be used for the treatment of acute (sudden and severe) hereditary angioedema attacks
   D. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), immunologist (a type of immune system doctor), hematologist (a type of blood doctor) or pulmonologist (lung/breathing doctor)
   E. You will NOT use the requested medication concurrently (at the same time) with other medications used for the treatment of acute (sudden and severe) HAE attacks (such as Ruconest [C1 esterase inhibitor], Berinert [C1 esterase inhibitor], Kalbitor [ecallantide])
   F. You meet ONE of the following:
      1. You have Type I or II hereditary angioedema (a type of gene condition with severe body swelling), as confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q (types of lab tests)
      2. You have Type III hereditary angioedema (a type of gene condition with severe body swelling)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ICATIBANT (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary angioedema (HAE) (ICD-10 D84.1) **AND** meet the following criterion?
   - The requested medication will NOT be used concurrently with other agents used for the treatment of acute HAE attacks (e.g., Ruconest [C1 esterase inhibitor], Berinert [C1 esterase inhibitor], Kalbitor [ecallantide])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ICATIBANT (Firazyr, Sajazir)** requires the following rule(s) be met for renewal:
   A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
   B. You will NOT use the requested medication concurrently (at the same time) with other medications used for the treatment of acute (sudden and severe) HAE attacks (such as Ruconest [C1 esterase inhibitor], Berinert [C1 esterase inhibitor], Kalbitor[ecallantide])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Firazyr and Sajazir.

REFERENCES

Firazyr [Prescribing Information]. Lexington, MA: Shire Orphan Therapies; June 2025.
Sajazir [Prescribing Information]. Cambridge, United Kingdom: Cycle Pharmaceuticals Ltd; February 2024.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ICATIBANT (PART D)

For Part D use only:

ICATIBANT (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	HEREDITARY ANGIOEDEMA (HAE): INITIAL: 1) TYPE III HAE, OR 2) TYPE I OR II HAE CONFIRMED BY ONE OF THE FOLLOWING COMPLEMENT TESTS: C1-INH PROTEIN LEVELS, C4 PROTEIN LEVELS, C1-INH FUNCTIONAL LEVELS, C1Q.
Age Restrictions	N/A
Prescriber Restrictions	HAE: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH AN ALLERGIST, IMMUNOLOGIST, HEMATOLOGIST OR PULMONOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS
Other Criteria	HAE: INITIAL/RENEWAL: NO CONCURRENT USE WITH OTHER MEDICATIONS FOR THE TREATMENT OF ACUTE HAE ATTACKS.

Created: 10/19
Effective: 03/01/26 Client Approval: 02/26 P&T Approval: 04/25

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IDELALISIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IDELALISIB	ZYDELIG	41297		GPI-10 (2153804000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed chronic lymphocytic leukemia (CLL) (ICD-10 Group C91.1) **AND** meet the following criterion?
   - Zydelig will be used in combination with rituximab

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **IDELALISIB (Zydelig)** requires the following rule(s) be met for approval:
   A. You have relapsed chronic lymphocytic leukemia (CLL: a type of blood cancer)
   B. Zydelig will be used in combination with rituximab

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the prescribing information and/or drug monograph for Zydelig.

REFERENCES
Zydelig [Prescribing Information]. Foster City, CA: Gilead Sciences, Inc.; February 2022.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IDELALISIB (PART D)

For Part D use only:

IDELALISIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Created: 08/14
Effective: 01/01/25 Client Approval: 08/24 P&T Approval: 11/14

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ILOPROST INHALED (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ILOPROST TROMETHAMINE	VENTAVIS	26287		GPI-10 (4017006000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

This is an inhalation drug that normally requires a nebulizer. If Payment Determination has not been assessed and/or is being contested, please reanalyze or refer to the NEBULIZER BVD DETERMINATION guideline in the library.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist

   If yes, continue to #2.
   If no, do no approve.
   DENIAL TEXT: See initial denial text at the end of the guideline.

2. Is the PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of 15 mmHg or less
   - Pulmonary vascular resistance (PVR) greater than 2 Wood units

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See initial denial text at the end of the guideline.

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ILOPROST INHALED (PART D)

INITIAL CRITERIA (CONTINUED)

3. Has the patient had a trial of or contraindication to **TWO** of the following agents from different drug classes?
   - Oral endothelin receptor antagonist (e.g., Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
   - Oral phosphodiesterase-5 inhibitor indicated for PAH (e.g., Revatio [sildenafil], Adcirca [tadalafil], Alyq [tadalafil], Tadliq [tadalafil])
   - Oral cGMP stimulator (e.g., Adempas [riociguat])
   - IV/SQ prostacyclin (e.g., Flolan [epoprostenol], Veletri [epoprostenol], Remodulin [treprostinil])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ILOPROST INHALED (Ventavis)** requires the following rule(s) be met for approval:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1: a way to classify the severity of disease)
   B. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   C. Your pulmonary arterial hypertension diagnosis is confirmed by right heart catheterization (a test used to measure how well the heart is pumping) with ALL of the following lab values:
      1. Mean pulmonary artery pressure (PAP: a type of measurement for pulmonary arterial hypertension) greater than 20 mmHg
      2. Pulmonary capillary wedge pressure (PCWP: a type of measurement for pulmonary arterial hypertension) of 15 mmHg or less
      3. Pulmonary vascular resistance (PVR: a type of measurement for pulmonary arterial hypertension) greater than 2 Wood units

   (Initial denial text continued on next page)

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ILOPROST INHALED (PART D)

INITIAL CRITERIA (CONTINUED)

D. You have tried or have a contraindication to (harmful for you to use) TWO of the following medications from different drug classes:
   1. Oral endothelin receptor antagonist (such as Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
   2. Oral phosphodiesterase-5 inhibitor indicated for PAH (such as Adcirca [tadalafil], Alyq [tadalafil], Tadliq [tadalafil], Revatio [sildenafil])
   3. Oral cGMP stimulator (such as Adempas [riociguat])
   4. Intravenous or subcutaneous prostacyclin (such as Flolan [epoprostenol], Veletri [epoprostenol], Remodulin [treprostinil])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ILOPROST INHALED (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ILOPROST INHALED (Ventavis)** requires the following rule(s) be met for renewal:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1: a way to classify the severity of disease)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

This drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination.
50.16.2 – Inhalation Durable Medical Equipment (DME) Supply Drugs (Rev. 18, 09-17-18)
Medicare Part B covers certain inhalation drugs, such as Albuterol and Levalbuterol nebulizer solutions, as supplies under the DME benefit. The DME benefit, however, is not available to beneficiaries residing in long-term care facilities (i.e. Nursing Facilities and Intermediate Care Facilities for Individuals with Intellectual Disabilities). Consequently, if the beneficiary is not on a Part A stay in one of these facilities, these inhalation drugs can be covered under Medicare Part D. CMS permits Part D sponsors to rely on a patient residence code of “3” or “9” on a pharmacy claim for determining when such inhalation drugs may be covered under Part D. Moreover, we expect that sponsors will only pay claims for these products when the pharmacy claim includes these specified patient residence codes regardless of any prior coverage determination based upon a prescriber statement indicating that the beneficiary resides in a long-term care facility (i.e. the prescriber statement and patient residence code must be aligned).
For further information, please refer to the Prescribing Information and/or Drug Monograph for Ventavis.

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ILOPROST INHALED (PART D)

REFERENCES

Ventavis [Prescribing Information]. South San Francisco, CA: Actelion Pharmaceuticals US, Inc.; March 2022.

Medicare Prescription Drug Benefit Manual Chapter 6 – Part D Drugs and Formulary Requirements, Appendix C- Summary of Coverage Policy Medicare Part B Versus Part D Coverage Issues. Rev 10, 02-19-10. Available at: http://www.cms.gov/PrescriptionDrugCovContra/12_PartDManuals.asp. [Accessed March 5, 2023].

For Part D use only:

ILOPROST INHALED (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	PULMONARY ARTERIAL HYPERTENSION (PAH): INITIAL: DIAGNOSIS CONFIRMED BY RIGHT HEART CATHETERIZATION WITH THE FOLLOWING PARAMETERS: 1) MEAN PULMONARY ARTERY PRESSURE (PAP) GREATER THAN 20 MMHG, 2) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF 15 MMHG OR LESS, AND 3) PULMONARY VASCULAR RESISTANCE (PVR) GREATER THAN 2 WOOD UNITS.
Age Restrictions	N/A
Prescriber Restrictions	PAH: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS
Other Criteria	PAH: INITIAL: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING AGENTS FROM DIFFERENT DRUG CLASSES: 1) ORAL ENDOTHELIN RECEPTOR ANTAGONIST, 2) ORAL PHOSPHODIESTERASE TYPE-5 INHIBITOR FOR PAH, 3) ORAL CGMP STIMULATOR, 4) IV/SQ PROSTACYCLIN. THIS DRUG MAY BE COVERED UNDER MEDICARE PART B OR D DEPENDING UPON THE CIRCUMSTANCES.

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25 Created: 10/16
Commercial Effective: N/A Client Approval: 06/24 P&T Approval: 01/24

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IMATINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IMATINIB MESYLATE	GLEEVEC, IMATINIB MESYLATE	22096		GPI-10 (2153183510)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have **ONE** of the following diagnoses?
   - Newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase (ICD-10 Group C92.1)
   - Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in blast crisis (BC), accelerated phase (AP), or in chronic phase (CP) (ICD-10 Group C92.1) after failure of interferon-alpha therapy

   If yes, continue to #2.
   If no, continue to #3.

2. Has the patient received previous treatment with another tyrosine kinase inhibitor [e.g., Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Iclusig (ponatinib)]?

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

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IMATINIB (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) (ICD-10 Group C91.0) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

4. Does the patient have a newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) (ICD-10 Group C91.0) **AND** meet the following criterion?
   - The requested medication will be used in combination with chemotherapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Does the patient have a diagnosis of a myelodysplastic/myeloproliferative disease (MDS/MPD) (ICD-10 C94.6) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The disease is associated with platelet-derived growth factor receptor (PDGFR) gene re-arrangements

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #6.

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IMATINIB (PART D)

GUIDELINES FOR USE (CONTINUED)

6. Does the patient have a diagnosis of aggressive systemic mastocytosis (ASM) (ICD-10 C96.21) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The disease is without the D816V c-Kit mutation OR c-Kit mutational status is unknown

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #7.

7. Does the patient have a diagnosis of hypereosinophilic syndrome (HES) (ICD-10 Group D72.11) and/or chronic eosinophilic leukemia (CEL) (ICD-10 C94.8) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #8.

8. Does the patient have a diagnosis of unresectable, recurrent, and/or metastatic dermatofibrosarcoma protuberans (DFSP) (ICD-10 C44.99) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #9.

9. Does the patient have a diagnosis of unresectable and/or metastatic malignant gastrointestinal stromal tumor (GIST) (ICD-10 Group C49.A) **AND** meet the following criterion?
   - The patient's tumor is Kit (CD117) positive

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #10.

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IMATINIB (PART D)

GUIDELINES FOR USE (CONTINUED)

10. Does the patient have a diagnosis of gastrointestinal stromal tumor (GIST) (ICD-10 Group C49.A) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - The request is for adjuvant treatment following complete gross resection of Kit (CD117) positive GIST

    If yes, **approve for 36 months by HICL or GPI-10.**
    APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

    If no, do not approve.

    DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

    Our guideline named **IMATINIB (Gleevec)** requires the following rule(s) be met for approval:
    A. You have ONE of the following:
        1. Newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+CML: type of blood cancer) in chronic phase
        2. Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in blast crisis, accelerated phase, or chronic phase after failure of interferon-alpha therapy
        3. Relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL: type of blood cancer that has returned or did not respond to treatment)
        4. Newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL)
        5. Myelodysplastic/myeloproliferative disease (MDS/MPD: type of blood cancer)
        6. Aggressive systemic mastocytosis (ASM: a type of blood disorder)
        7. Hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (type of inflammatory cancer)
        8. Unresectable, recurrent, and/or metastatic dermatofibrosarcoma protuberans (DFSP: type of rare skin tumor that cannot be completely removed by surgery or returns/spreads)
        9. Unresectable and/or metastatic malignant gastrointestinal stromal tumor (GIST: type of digestive tumor that spreads or cannot be removed by surgery)
        10. Adjuvant (add-on) treatment after complete gross resection (surgical removal) of Kit (CD117) positive gastrointestinal stromal tumor (GIST: a type of digestive tumor)

    (Denial text continued on next page)

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IMATINIB (PART D)

GUIDELINES FOR USE (CONTINUED)

B. If you have newly diagnosed Philadelphia positive chronic myeloid leukemia in chronic phase OR Philadelphia chromosome positive chronic myeloid leukemia in blast crisis, accelerated phase, or chronic phase, approval also requires:
1. You have NOT received previous treatment with another tyrosine kinase inhibitor such as Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Iclusig (ponatinib)

C. If you have relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukemia, approval also requires:
1. You are 18 years of age or older

D. If you have newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia, approval also requires:
1. The requested medication will be used in combination with a chemotherapy (drugs used to treat cancer)

E. If you have myelodysplastic/myeloproliferative diseases, approval also requires:
1. You are 18 years of age or older
2. Your disease is associated with platelet-derived growth factor receptor (PDGFR) gene re-arrangements (a type of gene mutation)

F. If you have aggressive systemic mastocytosis, approval also requires:
1. You are 18 years of age or older
2. Your disease is without the D816V c-Kit mutation (abnormal change in a type of gene) OR c-Kit mutational status is unknown

G. If you have hypereosinophilic syndrome and/or chronic eosinophilic leukemia, approval also requires:
1. You are 18 years of age or older

H. If you have unresectable, recurrent, and/or metastatic dermatofibrosarcoma protuberans, approval also requires:
1. You are 18 years of age or older

I. If you have unresectable and/or metastatic malignant gastrointestinal stromal tumor, approval also requires:
1. Your tumor is Kit (CD117: a type of protein) positive

J. If you have gastrointestinal stromal tumor, approval also requires:
1. You are 18 years of age or older
2. The request is for adjuvant (add-on) treatment following complete gross resection (complete removal) of Kit (CD117: a type of protein) positive GIST

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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IMATINIB (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Gleevec.

REFERENCES

Gleevec [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; August 2020.

For Part D use only:

IMATINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	ADJUVANT GASTROINTESTINAL STROMAL TUMOR TREATMENT: 36 MONTHS. ALL OTHER DIAGNOSES: 12 MONTHS.
Other Criteria	PHILADELPHIA CHROMOSOME POSITIVE CHRONIC MYELOID LEUKEMIA: PATIENT HAS NOT RECEIVED A PREVIOUS TREATMENT WITH ANOTHER TYROSINE KINASE INHIBITOR.

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25 Created: 11/11
Commercial Effective: N/A Client Approval: 08/24 P&T Approval: 10/20

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IMATINIB SOLUTION (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IMATINIB MESYLATE	IMKELDI	22096		GPI-10 (2153183510)	BRAND = IMKELDI

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) (ICD-10 Group C92.1) and meet **ONE** of the following criteria?
   - The patient has newly diagnosed Ph+ CML in chronic phase
   - The patient has Ph+ CML in blast crisis (BC), accelerated phase (AP), or chronic phase (CP) after failure of interferon-alpha therapy

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ALL** of the following criteria?
   - The patient has not received previous treatment with another tyrosine kinase inhibitor [e.g., Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Iclusig (ponatinib)]
   - The patient is unable to swallow generic imatinib tablets

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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IMATINIB SOLUTION (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) (ICD-10 Group C91.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is unable to swallow generic imatinib tablets

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

4. Does the patient have a newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) (ICD-10 Group C91.0) and meet **ALL** of the following criteria?
   - Imkeldi will be used in combination with chemotherapy
   - The patient is unable to swallow generic imatinib tablets

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Does the patient have a diagnosis of a myelodysplastic/myeloproliferative disease (MDS/MPD) (ICD-10 C94.6) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's disease is associated with platelet-derived growth factor receptor (PDGFR) gene rearrangements
   - The patient is unable to swallow generic imatinib tablets

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #6.

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IMATINIB SOLUTION (PART D)

GUIDELINES FOR USE (CONTINUED)

6. Does the patient have a diagnosis of aggressive systemic mastocytosis (ASM) (ICD-10 C96.21) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's disease is without the D816V c-Kit mutation OR c-Kit mutational status is unknown
   - The patient is unable to swallow generic imatinib tablets

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #7.

7. Does the patient have a diagnosis of hypereosinophilic syndrome (HES) (ICD-10 Group D72.11) and/or chronic eosinophilic leukemia (CEL) (ICD-10 C94.8) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is unable to swallow generic imatinib tablets

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #8.

8. Does the patient have a diagnosis of unresectable, recurrent, and/or metastatic dermatofibrosarcoma protuberans (DFSP) (ICD-10 C44.99) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is unable to swallow generic imatinib tablets

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #9.

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IMATINIB SOLUTION (PART D)

GUIDELINES FOR USE (CONTINUED)

9. Does the patient have a diagnosis of unresectable and/or metastatic malignant gastrointestinal stromal tumor (GIST) (ICD-10 Group C49.A) and meet **ALL** of the following criteria?
   - The patient's tumor is Kit (CD117) positive
   - The patient is unable to swallow generic imatinib tablets

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #10.

10. Does the patient have a diagnosis gastrointestinal stromal tumor (GIST) (ICD-10 Group C49.A) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - The request is for adjuvant treatment following complete gross resection of Kit (CD117) positive GIST
    - The patient is unable to swallow generic imatinib tablets

    If yes, **approve for 36 months by HICL or GPI-10.**
    APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

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IMATINIB SOLUTION (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **IMATINIB SOLUTION (Imkeldi)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML: a type of blood cancer)
   2. Relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL: type of blood cancer that has returned or did not respond to treatment)
   3. Newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) (type of blood cancer)
   4. Myelodysplastic/myeloproliferative disease (MDS/MPD: type of blood cancer)
   5. Aggressive systemic mastocytosis (ASM: a type of blood disorder)
   6. Hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL) (types of inflammatory cancer)
   7. Unresectable, recurrent, and/or metastatic dermatofibrosarcoma protuberans (DFSP: type of rare skin tumor that cannot be completely removed by surgery, has returned, and/or has spread to other parts of the body)
   8. Unresectable and/or metastatic malignant gastrointestinal stromal tumor (GIST: type of digestive tumor that cannot be removed by surgery and/or has spread to other parts of the body)
   9. Gastrointestinal stromal tumor (GIST: type of digestive tumor)

B. If you have Philadelphia chromosome positive chronic myeloid leukemia, approval also requires:
   1. You meet ONE of the following:
      a. You have newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML: type of blood cancer) in chronic phase
      b. You have Ph+ CML in blast crisis (BC), accelerated phase (AP), or chronic phase (CP) after failure of interferon-alpha therapy
   2. You have NOT received previous treatment with another tyrosine kinase inhibitor, such as Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Iclusig (ponatinib)
   3. You are unable to swallow generic imatinib tablets

C. If you have relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukemia, approval also requires:
   1. You are 18 years of age or older
   2. You are unable to swallow generic imatinib tablets

(Denial text continued on next page)

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IMATINIB SOLUTION (PART D)

GUIDELINES FOR USE (CONTINUED)

D. If you have newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia, approval also requires:
1. Imkeldi will be used in combination with chemotherapy (a type of cancer treatment)
2. You are unable to swallow generic imatinib tablets

E. If you have myelodysplastic/myeloproliferative disease, approval also requires:
1. You are 18 years of age or older
2. Your disease is associated with platelet-derived growth factor receptor (PDGFR) gene rearrangements (a type of gene mutation)
3. You are unable to swallow generic imatinib tablets

F. If you have aggressive systemic mastocytosis, approval also requires:
1. You are 18 years of age or older
2. Your disease is without the D816V c-Kit mutation (abnormal change in a type of gene) OR c-Kit mutational status is unknown
3. You are unable to swallow generic imatinib tablets

G. If you have hypereosinophilic syndrome and/or chronic eosinophilic leukemia, approval also requires:
1. You are 18 years of age or older
2. You are unable to swallow generic imatinib tablets

H. If you have unresectable, recurrent, and/or metastatic dermatofibrosarcoma protuberans, approval also requires:
1. You are 18 years of age or older
2. You are unable to swallow generic imatinib tablets

I. If you have unresectable and/or metastatic malignant gastrointestinal stromal tumor, approval also requires:
1. Your tumor is Kit (CD117: a type of protein) positive
2. You are unable to swallow generic imatinib tablets

J. If you have gastrointestinal stromal tumor, approval also requires:
1. You are 18 years of age or older
2. The request is for adjuvant (add-on) treatment following complete gross resection of Kit (CD117: a type of protein) positive gastrointestinal stromal tumor (GIST)
3. You are unable to swallow generic imatinib tablets

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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IMATINIB SOLUTION (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Imkeldi.

REFERENCES
Imkeldi [Prescribing Information]. Cambridge, MA: Shorla Oncology Inc.; November 2024.

For Part D use only:

IMATINIB SOLUTION (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	ADJUVANT GASTROINTESTINAL STROMAL TUMOR TREATMENT: 36 MONTHS. ALL OTHER DIAGNOSES: 12 MONTHS.
Other Criteria	PHILADELPHIA CHROMOSOME POSITIVE CHRONIC MYELOID LEUKEMIA: PATIENT HAS NOT RECEIVED A PREVIOUS TREATMENT WITH ANOTHER TYROSINE KINASE INHIBITOR. ALL INDICATIONS: UNABLE TO SWALLOW GENERIC IMATINIB TABLETS.

Created: 12/24
Effective: 01/01/25 Client Approval: 12/24 P&T Approval: 01/25

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IMETELSTAT (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IMETELSTAT SODIUM	RYTELO	49663		GPI-10 (2153532560)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of myelodysplastic syndrome (MDS) (ICD-10 Group D46) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer is low- to intermediate-1 risk
   - The patient has transfusion-dependent anemia requiring at least 4 red blood cell (RBC) units over 8 weeks
   - The patient's cancer is unresponsive to erythropoiesis-stimulating agents (ESA) (e.g., Retacrit [epoetin alfa-epbx]) OR the patient is ESA ineligible

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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IMETELSTAT (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **IMETELSTAT (Rytelo)** requires the following rule(s) be met for approval:

A. You have myelodysplastic syndrome (MDS: a type of blood cancer)
B. You are 18 years of age or older
C. Your cancer is low- to intermediate-1 risk
D. You have transfusion-dependent anemia (a type of blood condition) requiring at least 4 red blood cell (RBC) units over 8 weeks
E. Your cancer did not respond to treatment with erythropoiesis-stimulating agents (ESA: a type of medication that increases the production of red blood cells, such as Retacrit [epoetin alfa-epbx]) OR you are NOT able to be treated with ESA

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rytelo.

REFERENCES

Rytelo [Prescribing Information]. Foster City, CA: Geron Corporation; June 2024.

For Part D use only:

IMETELSTAT (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Part D Effective: 09/01/24
Commercial Effective: N/A
Created: 08/24
Client Approval: 08/24
P&T Approval: 07/24

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IMIQUIMOD - ZYCLARA (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IMIQUIMOD	ZYCLARA		31436 32958 28216	GPI-14 (90773040003715) (90773040003710)	BRAND = ZYCLARA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of actinic keratosis (ICD-10 L57.0) of the full face or balding scalp and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is immunocompetent
   - The patient had a trial of or contraindication to generic imiquimod 5 percent cream

   If yes, **approve for 4 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of external genital or perianal warts (ICD-10 A63.0) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient had a trial of or contraindication to generic imiquimod 5 percent cream

   If yes, **approve for 4 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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IMIQUIMOD - ZYCLARA (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **IMIQUIMOD - ZYCLARA** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Actinic keratosis (AK: a type of skin condition) of the full face or balding scalp
   2. External genital or perianal (around the anus) warts

B. If you have actinic keratosis of the full face or balding scalp, approval also requires:
   1. You are 18 years of age or older
   2. You are immunocompetent (healthy immune system)
   3. You have tried or have a contraindication to (harmful for you to use) generic imiquimod 5 percent cream

C. If you have external genital or perianal warts, approval also requires:
   1. You are 12 years of age or older
   2. You have tried or have a contraindication to (harmful for you to use) generic imiquimod 5 percent cream

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zyclara.

REFERENCES

Zyclara [Prescribing Information]. Bridgewater, NJ: Bausch Health US, LLC; June 2020.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IMIQUIMOD - ZYCLARA (PART D)

For Part D use only:

IMIQUIMOD - ZYCLARA (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	4 MONTHS
Other Criteria	ACTINIC KERATOSIS, EXTERNAL GENITAL OR PERIANAL WARTS: TRIAL OF OR CONTRAINDICATION TO GENERIC IMIQUIMOD 5% CREAM.

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 11/16
Client Approval: 06/24
P&T Approval: 04/21

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IMLUNESTRANT (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IMLUNESTRANT TOSYLATE	INLURIYO	50911		GPI-10 (2140353670)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced or metastatic breast cancer (ICD-10 Group C50) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The disease is estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative with estrogen receptor-1 (ESR1) gene mutation(s)
   - The patient has had disease progression following at least ONE line of endocrine therapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **IMLUNESTRANT (Inluriyo)** requires the following rule(s) be met for approval:
   A. You have advanced or metastatic breast cancer (a type of cancer that has spread from where it started to nearby tissue or lymph nodes or to other parts of the body)
   B. You are 18 years of age or older
   (Denial text continued on the next page)

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IMLUNESTRANT (PART D)

GUIDELINES FOR USE (CONTINUED)

C. Your disease is estrogen receptor (ER: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative with estrogen receptor-1 (ESR1) gene mutation(s) (abnormal changes in a type of gene)
D. You have had disease progression (worsening) following at least ONE line of endocrine therapy (a type of hormone therapy)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Inluriyo.

REFERENCES

Inluriyo [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; September 2025.

For Part D use only:

IMLUNESTRANT (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 10/25
Effective: 10/20/25 Client Approval: 10/25 P&T Approval: 10/25

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IMMUNE GLOBULIN BVD DETERMINATION (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IMMUNE GLOBULIN	GAMIMUNE, OTHERS	25631 04202 41391 33220 41995 41796 45354 45734 45891 46208 41798 49343 49682 50913		GPI-10 (1910002030, 1910002010, 1910002020, 1910002000, 1999000235, 1910002060, 1910002057, 1910002064, 1910002080, 1910002083, 1910002051, 1910002084)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

NOTE: This PA is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

GUIDELINES FOR USE

1. Does the patient meet **ONE** of the following criteria?
   - The patient is receiving IVIG or SCIG at home for a diagnosis of primary immune deficiency disease (ICD-10 D80.0, D80.2, D80.3, D80.4, D80.5, D80.6, D80.7, D81.0, D81.1, D81.2, D81.5, D81.6, D81.7, D81.82, D81.89, D81.9, D82.0, D82.1, D82.4, D83.0, D83.1, D83.2, D83.8, D83.9)
   - The patient is receiving IVIG or SCIG at home for the treatment of an ICD-10-CM diagnosis code: G11.3

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, continue to #2.

2. Is the drug specifically infused through an external infusion pump covered by Medicare?

   If yes, **approve the requested drug for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, **approve as requested for 12 months by HICL or GPI-10 under Part D (Populate B vs. D field with a 'D' in the PA override field).**

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IMMUNE GLOBULIN BVD DETERMINATION (PART D)

RATIONALE

The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. IVIG/SCIG for use at home for patients with a diagnosis of primary immune deficiency disease or ICD-10 G11.3 is covered under Part B. Drugs administered via an external pump are covered under Part B if they are specifically infused through an external infusion pump covered by Medicare.

REFERENCES

Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Appendix C - Summary of Coverage Policy Medicare Part B Versus Part D Coverage Issues. Rev 10, 02-19-10. Available at: http://www.cms.gov/PrescriptionDrugCovContra/12_PartDManuals.asp. [Accessed December 1, 2025].

Medicare Benefit Policy Manual Chapter 15 – Covered Medical and Other Health Services, Section 50.6. Rev 241, 02-02-18). http://www.cms.gov/

2015 ICD-1-CM and GEMs. [Accessed December 1, 2025]. https://www.cms.gov/Medicare/Coding/ICD10/2015-ICD-10-CM-and-GEMs.html

2019 CMS Manual System – Pub 100-02 Medicare Benefit Policy (Transmittal 259) – Section 50.6. https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2019Downloads/R259BP.pdf [Accessed December 1, 2025].

For Part D use only:

IMMUNE GLOBULIN BVD DETERMINATION (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	PART D DOES NOT COVER THIS DRUG FOR PATIENTS RECEIVING IVIG/SCIG AT HOME FOR A DIAGNOSIS OF PRIMARY IMMUNE DEFICIENCY DISEASE
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 11/07
Effective: 03/27/26 Client Approval: 03/26 P&T Approval: 01/20

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IMMUNOSUPPRESSANT BVD DETERMINATION (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LYMPHOCYTE IG,ANTITHYMOCYT, EQU	ATGAM				TCC = Z2E HICL ≠ 47077 GPID ≠ 55684 GPI-10 ≠ 9940208000 GPI-14 ≠ 99403030101830
AZATHIOPRINE	AZASAN, IMURAN, AZATHIOPRINE				
AZATHIOPRINE SODIUM	AZATHIOPRINE SODIUM				
BELATACEPT	NULOJIX				
CYCLOSPORINE	SANDIMMUNE, CYCLOSPORINE				
CYCLOSPORINE, MODIFIED	GENGRAF, NEORAL, CYCLOSPORINE, CYCLOSPORINE MODIFIED				
EVEROLIMUS	ZORTRESS, EVEROLIMUS				
MYCOPHENOLATE MOFETIL, MYCOPHENOLATE MOFETIL HCL	CELLCEPT, MYCOPHENOLATE MOFETIL				
MYCOPHENOLATE SODIUM	MYFORTIC, MYCOPHENOLIC ACID				
SIROLIMUS	RAPAMUNE, SIROLIMUS				
TACROLIMUS	PROGRAF, ASTAGRAF XL, ENVARSUS XR, TACROLIMUS, TACROLIMUS ER				
ANTI-THYMOCYTE GLOBULIN,RABBIT	THYMOGLOBULIN				
BASILIXIMAB	SIMULECT	18390			
PREDNISOLONE	MILLIPRED, PREDNISOLONE	02874		GPI-10 (2210004000)	
PREDNISOLONE SODIUM PHOSPHATE	ORAPRED ODT, VERIPRED 20, PREDNISOLONE SODIUM PHOSPHATE, PREDNISOLONE SODIUM PHOS ODT,	02871		GPI-10 (2210004020)	ROUTE = ORAL

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	PEDIAPRED				
PREDNISONE	RAYOS, PREDNISONE, PREDNISONE INTENSOL	02879		GPI-10 (2210004500)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

NOTE: This PA is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

GUIDELINES FOR USE

1. Is the medication being used for the prevention of an organ transplant rejection?

   If yes, do not approve.
   MEMBER NOTIFICATION LANGUAGE/DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #2.

2. Is the medication being used for a Part D approved indication other than transplant?

   If yes, **approve for 12 months under Part D by GPID or GPI-14 for all strengths of the requested drug with no quantity limit (Populate the PA_OVR_TYPE with TRANSPLANT and PA_OVR_VALUE with 'Y').**

   If no, do not approve.
   MEMBER NOTIFICATION LANGUAGE/DENIAL TEXT: The guideline named **IMMUNOSUPPRESSANT BVD DETERMINATION** applies to drugs that are used to prevent organ transplant rejection. These drugs are covered under Medicare Part B (Medical Insurance) if they are being used for transplant related purposes and your transplant was covered by Medicare. However, if you are using the drug for a Part D approved indication that is not related to transplant, it is covered under Medicare Part D. Centers for Medicare and Medicaid Services (CMS) has clarified that the Medicare Part B or D coverage for these medicines should be determined by the data indicating a Medicare Covered transplant which is provided by CMS.

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IMMUNOSUPPRESSANT BVD DETERMINATION (PART D)

RATIONALE

Immunosuppressant therapy is covered under Part B for patients who received a Medicare covered organ transplant. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination.

The 2019 Call Letter provided new guidance on how Part D sponsors are expected to determine whether immunosuppressants are coverable under Part D. Beginning in 2019, when the Part D plan receives new information from CMS (in MARx, ABII, or through a CMS program audit) indicating a Medicare covered transplant, it should rely on the new CMS information from that point forward, even if it is in conflict with the plan's prior research. ABII will not include renal transplants at this time, plans will continue to rely on MARx for renal transplant information).

REFERENCES

Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. Available at: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf [Accessed 06/23/25]

Medicare Prescription Drug Benefit Manual – Chapter 14: Coordination of Benefits (Rev 18, 09-17-18). Available at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter-14-Coordination-of-Benefits-v09-14-2018.pdf [Accessed 06/23/25].

For Part D use only:

IMMUNOSUPPRESSANT BVD DETERMINATION (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	PART D DOES NOT COVER THIS DRUG WHEN USED FOR A MEDICARE APPROVED ORGAN TRANSPLANT INDICATION.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

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IMMUNOSUPPRESSANT BVD DETERMINATION (PART D)

CORTICOSTEROID BVD DETERMINATION (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	PART D DOES NOT COVER THIS DRUG WHEN USED FOR A MEDICARE APPROVED ORGAN TRANSPLANT INDICATION.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 09/05
Effective: 05/16/26 Client Approval: 05/26 P&T Approval: 05/19

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INAVOLISIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INAVOLISIB	ITOVEBI	49923		GPI-10 (2153804500)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced or metastatic breast cancer (ICD-10 Group C50) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative
   - The patient's tumor has a PIK3CA mutation as detected by an FDA-approved test
   - Itovebi will be used in combination with palbociclib (Ibrance) and fulvestrant (Faslodex)
   - The patient has experienced disease recurrence on or after completing adjuvant endocrine therapy (e.g., letrozole, anastrozole, tamoxifen)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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INAVOLISIB (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **INAVOLISIB (Itovebi)** requires the following rule(s) be met for approval:

A. You have locally advanced or metastatic breast cancer (breast cancer that has spread to other parts of the body)
B. You are 18 years of age or older
C. Your cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative
D. Your tumor has a PIK3CA mutation (abnormal change in a type of gene) as detected by a Food and Drug Administration (FDA)-approved test
E. Itovebi will be used in combination with palbociclib (Ibrance) and fulvestrant (Faslodex)
F. You have experienced disease recurrence (disease has returned) on or after completing adjuvant (add-on) endocrine (hormone) therapy (such as letrozole, anastrozole, tamoxifen)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Itovebi.

REFERENCES

Itovebi [Prescribing Information]. South San Francisco, CA: Genentech USA, Inc.; January 2025.

For Part D use only:

INAVOLISIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 11/24
Effective: 07/01/25 Client Approval: 05/25 P&T Approval: 01/25

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INCOBOTULINUM TOXIN A BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INCOBOTULINUMTOXINA	XEOMIN	36687		GPI-10 (7440002020)	

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #5.

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INCOBOTULINUM TOXIN A BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

If yes, **Refer to plan. (The health plan makes the final payment determination decision)**

- **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
- **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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INCOBOTULINUM TOXIN A BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the request for the treatment of a cosmetic indication (e.g., wrinkles - glabellar lines, lateral canthal lines, forehead lines) (ICD-10 L98.8)?

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of chronic sialorrhea (drooling or excessive salivation) (ICD-10 K11.7) **AND** meet the following criterion?
   - The patient is 2 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

3. Does the patient have a diagnosis of cervical dystonia (spasmodic torticollis or involuntary contracting of the neck muscles) (ICD-10 G24.3) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #4.

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INCOBOTULINUM TOXIN A BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

4. Does the patient have a diagnosis of blepharospasm (involuntary forcible closure of the eyelid) (ICD-10 G24.5) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #5.

5. Does the patient have a diagnosis of upper limb spasticity (ICD-10 G04.1, G11.4, G80.0, G80.1, G80.2; Group G81.1) **AND** meet the following criterion?
   - The patient is 2 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   DENIAL TEXT: Our guideline named **INCOBOTULINUM TOXIN A (Xeomin)** requires the following rule(s) be met for approval:
   A. The request is for ONE of the following:
      1. Chronic sialorrhea (drooling)
      2. Cervical dystonia (a type of muscle condition)
      3. Blepharospasm (a type of eye disease)
      4. Upper limb spasticity (stiffness or tightness of the muscles)
   B. If you have chronic sialorrhea or upper limb spasticity, approval also requires:
      1. You are 2 years of age or older
   C. If you have cervical dystonia or blepharospasm, approval also requires:
      1. You are 18 years of age or older

   NOTE: This medication will not be approved for the treatment of a cosmetic indication (such as wrinkles - glabellar lines [wrinkle between the eyebrows], lateral canthal lines [wrinkles in outer corner of eye], forehead lines).

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INCOBOTULINUM TOXIN A BvD (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xeomin. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Xeomin [Prescribing Information]. Raleigh, NC: Merz Pharmaceuticals, LLC; June 2026.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed July 1, 2024].

For Part D use only:

INCOBOTULINUM TOXIN A (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	COSMETIC DIAGNOSIS SUCH AS WRINKLES.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 10/22
Effective: 07/15/26 Client Approval: 07/26 DMC Approval: 07/26

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INEBILIZUMAB-CDON BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INEBILIZUMAB-CDON	UPLIZNA	46617		GPI-10 (9940504020)	

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #5.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INEBILIZUMAB-CDON BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

If yes, **Refer to plan. (The health plan makes the final payment determination decision)**

- **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
- **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INEBILIZUMAB-CDON BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of neuromyelitis optica spectrum disorder (NMOSD) (ICD-10 G36.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist or ophthalmologist
   - The patient has a positive serologic test for anti-aquaporin-4 (AQP4) antibodies
   - Uplizna will NOT be used concurrently with another NMOSD agent (e.g., Rituxan [rituximab], Enspryng [satralizumab-mwge], Ultomiris [ravulizumab-cwvz], Soliris [eculizumab])

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient have at least **ONE** of the following core clinical characteristics?
   - Optic neuritis
   - Acute myelitis
   - Area postrema syndrome
   - Acute brainstem syndrome
   - Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions
   - Symptomatic cerebral syndrome with NMOSD-typical brain lesions

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INEBILIZUMAB-CDON BvD (PART D)

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of immunoglobulin G4-related disease (IgG4-RD) (ICD-10 D89.84) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

4. Does the patient have a diagnosis of generalized myasthenia gravis (gMG) (ICD-10 Group G70.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is anti-acetylcholine receptor (AChR) antibody positive OR anti-muscle-specific tyrosine kinase (MuSK) antibody positive
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient is Myasthenia Gravis Foundation of America class II, III, or IV
   - Uplizna will NOT be used concurrently with another neonatal Fc receptor blocker (e.g., Vyvgart [efgartigimod alfa-fcab], Rystiggo [rozanolixizumab-noli]) or complement inhibitor (e.g., Soliris [eculizumab], Zilbrysq [zilucoplan]) for the treatment of gMG
   - The patient had a trial of or contraindication to ONE standard of care corticosteroid (e.g., prednisone)
   - The patient had a trial of or contraindication to ONE standard of care non-steroidal immunosuppressive therapy (e.g., azathioprine, cyclophosphamide, methotrexate)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INEBILIZUMAB-CDON BvD (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **INEBILIZUMAB-CDON (Uplizna)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Neuromyelitis optica spectrum disorder (NMOSD: a type of brain disorder)
   2. Immunoglobulin G4-related disease (IgG4-RD: a type of inflammatory disorder)
   3. Generalized myasthenia gravis (gMG: a chronic autoimmune disorder)

B. If you have neuromyelitis optica spectrum disorder, approval also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor) or ophthalmologist (a type of eye doctor)
   3. You have a positive serologic (blood) test for anti-aquaporin-4 (AQP4: type of protein) antibodies
   4. You will NOT use Uplizna concurrently (at the same time) with another NMOSD medication (such as Rituxan [rituximab], Enspryng [satralizumab-mwge], Ultomiris [ravulizumab-cwvz], Soliris [eculizumab])
   5. You have at least ONE of the following core clinical characteristics:
      a. Optic neuritis (type of brain disorder)
      b. Acute myelitis (type of brain disorder)
      c. Area postrema syndrome (type of brain disorder)
      d. Acute brainstem syndrome (type of brain disorder)
      e. Symptomatic narcolepsy (type of sleep condition) or acute diencephalic clinical syndrome (type of brain disorder) with NMOSD-typical diencephalic magnetic resonance imaging (MRI: a type of imaging lab) lesions (affected areas)
      f. Symptomatic cerebral syndrome with NMOSD-typical brain lesions

C. If you have immunoglobulin G4-related disease, approval also requires:
   1. You are 18 years of age or older

(Initial denial text continued on next page)

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INEBILIZUMAB-CDON BvD (PART D)

INITIAL CRITERIA (CONTINUED)

D. If you have generalized myasthenia gravis, approval also requires:

1. You are 18 years of age or older
2. You are anti-acetylcholine receptor (AChR) antibody positive (an indicator of myasthenia gravis) OR anti-muscle-specific tyrosine kinase (MuSK) antibody positive (an indicator of myasthenia gravis)
3. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
4. You have Myasthenia Gravis Foundation of America class II, III, or IV (types of severity of disease)
5. You will NOT use Uplizna concurrently (at the same time) with another neonatal Fc receptor blocker (such as Vyvgart [efgartigimod alfa-fcab], Rystiggo [rozanolixizumab-noli]) or complement inhibitor (such as Soliris [eculizumab], Zilbrysq [zilucoplan]) for the treatment of generalized myasthenia gravis (a chronic autoimmune disorder)
6. You have tried or have a contraindication to (harmful for you to use) ONE standard of care corticosteroid (such as prednisone)
7. You have tried or have a contraindication to (harmful for you to use) ONE standard of care non-steroidal immunosuppressive therapy (such as azathioprine, cyclophosphamide, methotrexate)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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INEBILIZUMAB-CDON BvD (PART D)

RENEWAL CRITERIA

NOTE: For the diagnosis of immunoglobulin G4-related disease, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of neuromyelitis optica spectrum disorder (NMOSD) (ICD-10 G36.0) and meet **ALL** of the following criteria?
   - The patient has shown clinical benefit (e.g., reduction in relapse frequency from baseline or a decrease in NMOSD-related hospitalizations) while on therapy with Uplizna
   - Uplizna will NOT be used concurrently with another NMOSD agent (e.g., Rituxan [rituximab], Enspryng [satralizumab-mwge], Ultomiris [ravulizumab-cwvz], Soliris [eculizumab])

   If yes, **approve 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of generalized myasthenia gravis (gMG) (ICD-10 Group G70.0) and meet **ALL** of the following criteria?
   - The patient has shown a clinical benefit compared to baseline (e.g., Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool)
   - Uplizna will NOT be used concurrently with another neonatal Fc receptor blocker (e.g., Vyvgart [efgartigimod alfa-fcab], Rystiggo [rozanolixizumab-noli]) or complement inhibitor (e.g., Soliris [eculizumab], Zilbrysq [zilucoplan]) for the treatment of gMG

   If yes, **approve 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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INEBILIZUMAB-CDON BvD (PART D)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **INEBILIZUMAB-CDON (Uplizna)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Neuromyelitis optica spectrum disorder (NMOSD: a type of brain disorder)
   2. Generalized myasthenia gravis (gMG: a chronic autoimmune disorder)

B. If you have neuromyelitis optica spectrum disorder, renewal also requires:
   1. You have shown clinical benefit (such as reduction in relapse frequency from baseline [before treatment] or a decrease in NMOSD-related hospitalizations) while on therapy with Uplizna
   2. You will NOT use Uplizna concurrently (at the same time) with another NMOSD medication (such as Rituxan [rituximab], Enspryng [satralizumab-mwge], Ultomiris [ravulizumab-cwvz], Soliris [eculizumab])

C. If you have generalized myasthenia gravis, renewal also requires:
   1. You have shown a clinical benefit compared to baseline (such as Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool)
   2. You will NOT use Uplizna concurrently (at the same time) with another neonatal Fc receptor blocker (such as Vyvgart [efgartigimod alfa-fcab], Rystiggo [rozanolixizumab-noli]) or complement inhibitor (such as Soliris [eculizumab], Zilbrysq [zilucoplan]) for the treatment of generalized myasthenia gravis (a chronic autoimmune disorder)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Uplizna. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Uplizna [Prescribing Information]. Dublin, Ireland: Amgen, Inc., December 2025.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed July 17, 2025].

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INEBILIZUMAB-CDON BvD (PART D)

For Part D use only:

INEBILIZUMAB-CDON (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: NEUROMYELITIS OPTICA SPECTRUM DISORDER (NMOSD): PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST OR OPHTHALMOLOGIST. GENERALIZED MYASTHENIA GRAVIS (GMG): PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST.
Coverage Duration	INITIAL: NMOSD, IMMUNOGLOBULIN G4-RELATED DISEASE: 12 MO. GMG: 6 MO. RENEWAL: NMOSD, GMG: 12 MO.
Other Criteria	INITIAL: NMOSD: 1) ONE OF THE FOLLOWING CORE CLINICAL CHARACTERISTICS: (A) OPTIC NEURITIS, (B) ACUTE MYELITIS, (C) AREA POSTREMA SYNDROME, (D) ACUTE BRAINSTEM SYNDROME, (E) SYMPTOMATIC NARCOLEPSY OR ACUTE DIENCEPHALIC CLINICAL SYNDROME WITH NMOSD-TYPICAL DIENCEPHALIC MRI LESIONS, OR (F) SYMPTOMATIC CEREBRAL SYNDROME WITH NMOSD-TYPICAL BRAIN LESIONS, AND 2) NO CONCURRENT USE WITH ANOTHER NMOSD AGENT. GMG: 1) MYASTHENIA GRAVIS FOUNDATION OF AMERICA CLASS II, III, OR IV, 2) NO CONCURRENT USE WITH ANOTHER NEONATAL FC RECEPTOR BLOCKER OR COMPLEMENT INHIBITOR FOR GMG, 3) TRIAL OF OR CONTRAINDICATION TO ONE STANDARD OF CARE CORTICOSTEROID, AND 4) TRIAL OF OR CONTRAINDICATION TO ONE STANDARD OF CARE NON-STEROIDAL IMMUNOSUPPRESSIVE THERAPY. RENEWAL: NMOSD: 1) PATIENT HAS SHOWN CLINICAL BENEFIT, AND 2) NO CONCURRENT USE WITH ANOTHER NMOSD AGENT. GMG: 1) CLINICAL BENEFIT COMPARED TO BASELINE, 2) NO CONCURRENT USE WITH ANOTHER NEONATAL FC RECEPTOR BLOCKER OR COMPLEMENT INHIBITOR FOR GMG.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INFLIXIMAB BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INFLIXIMAB	REMICADE, INFLIXIMAB	18747		GPI-10 (5250504000)	

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, continue to #6.
   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, continue to #6.
   If no, continue to #5.

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

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INFLIXIMAB BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

6. Is the drug administered via an implantable pump?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, continue to #7.

7. Is the drug administered via an external pump?

   If yes, continue to #8.
   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

8. Is the drug specifically infused through an external infusion pump covered by Medicare?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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INFLIXIMAB BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is concurrently using methotrexate
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Orencia (abatacept)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

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INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
- The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA
- The patient had a trial of or contraindication to TWO of the following preferred agents:
  - Cosentyx (secukinumab)
  - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
  - Selarsdi /Yesintek /ustekinumab-aauz
  - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
  - Skyrizi (risankizumab-rzaa)
  - Tremfya (guselkumab)
  - Orencia (abatacept)
  - Otezla (apremilast)

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #3.

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INFLIXIMAB BvD (PART D)

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Cosentyx (secukinumab)
     - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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INFLIXIMAB BvD (PART D)

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of severe chronic plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is a candidate for systemic therapy
   - Therapy is prescribed by or in consultation with a dermatologist
   - The patient has psoriasis covering 3% or more of body surface area (BSA) OR psoriatic lesions affecting the hands, feet, genital area, scalp, or face
   - The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Cosentyx (secukinumab), Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima, Selarsdi/Yesintek/ustekinumab-aauz, Skyrizi (risankizumab-rzaa), Tremfya (guselkumab), Otezla (apremilast)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, continue to #6.
   If no, continue to #7.

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INFLIXIMAB BvD (PART D)

INITIAL CRITERIA (CONTINUED)

6. Does the patient meet **ONE** of the following criteria?
   - The patient is 6 to 17 years of age AND had a trial of or contraindication to the preferred agent: Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
   - The patient is 18 years of age or older AND had a trial of or contraindication to TWO of the following preferred agents:
     - Selarsdi/Yesintek/ustekinumab-aauz
     - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Skyrizi (risankizumab-rzaa)
     - Tremfya (guselkumab)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

7. Does the patient have a diagnosis of fistulizing Crohn's disease (CD) (ICD-10 K50.913, K50.013, K50.113, K50.813) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #8.

8. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, continue to #9.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INFLIXIMAB BvD (PART D)

INITIAL CRITERIA (CONTINUED)

9. Does the patient meet **ONE** of the following criteria?
   - The patient is 6 to 17 years of age AND had a trial of or contraindication to the preferred agent: Humira (adalimumab)
   - The patient is 18 years of age or older and had a trial of or contraindication to TWO of the following preferred agents:
     - Selarsdi/Yesintek/ustekinumab-aauz
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Skyrizi (risankizumab-rzaa)
     - Tremfya (guselkumab)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INFLIXIMAB (Remicade)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
      2. Psoriatic arthritis (PsA: a type of skin and joint condition)
      3. Ankylosing spondylitis (AS: a type of joint condition)
      4. Severe chronic plaque psoriasis (PsO: a type of skin condition)
      5. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
      6. Fistulizing (abnormal connection between two body parts) Crohn's disease
      7. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

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INFLIXIMAB BvD (PART D)

INITIAL CRITERIA (CONTINUED)

B. If you have moderate to severe rheumatoid arthritis, approval also requires:
1. You are 18 years of age or older
2. You are concurrently (at the same time) using methotrexate
3. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
4. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
5. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
   b. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
   c. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
   d. Orencia (abatacept)

C. If you have psoriatic arthritis, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (skin doctor)
3. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

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INFLIXIMAB BvD (PART D)

INITIAL CRITERIA (CONTINUED)

4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Cosentyx (secukinumab)
   b. Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
   c. Selarsdi /Yesintek /ustekinumab-aauz
   d. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
   e. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
   f. Skyrizi (risankizumab-rzaa)
   g. Tremfya (guselkumab)
   h. Orencia (abatacept)
   i. Otezla (apremilast)

D. If you have ankylosing spondylitis, approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis
4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Cosentyx (secukinumab)
   b. Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
   c. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
   d. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])

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INITIAL CRITERIA (CONTINUED)

E. If you have severe chronic plaque psoriasis, approval also requires:
1. You are 18 years of age or older
2. You are a candidate for systemic therapy (treatment that travels through the entire body)
3. Therapy is prescribed by or in consultation with a dermatologist (skin doctor)
4. You have psoriasis covering 3% or more of body surface area (BSA) OR psoriatic lesions (patches) affecting the hands, feet, face, scalp, or genital area
5. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis
6. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Cosentyx (secukinumab), Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima, Selarsdi /Yesintek /ustekinumab-aauz, Skyrizi (risankizumab-rzaa), Tremfya (guselkumab), Otezla (apremilast)

F. If you have moderate to severe Crohn's disease, approval also requires:
1. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
2. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease
3. You meet ONE of the following:
   a. You are 6 to 17 years old AND have tried or have a contraindication to (harmful for you to use) the preferred medication: Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
   b. You are 18 years of age or older AND have tried or have a contraindication to TWO of the following preferred medications:
      i. Selarsdi /Yesintek /ustekinumab-aauz
      ii. Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
      iii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
      iv. Skyrizi (risankizumab-rzaa)
      v. Tremfya (guselkumab)

G. If you have fistulizing Crohn's disease, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)

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INITIAL CRITERIA (CONTINUED)

H. If you have moderate to severe ulcerative colitis, approval also requires:

1. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
2. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis
3. You meet ONE of the following:
   a. You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) the preferred medication: Humira (adalimumab)
   b. You are 18 years of age or older AND have tried or have a contraindication to TWO of the following preferred medications:
      i. Selarsdi /Yesintek /ustekinumab-aauz
      ii. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
      iii. Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
      iv. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a TNF blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
      v. Skyrizi (risankizumab-rzaa)
      vi. Tremfya (guselkumab)

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INFLIXIMAB BvD (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - The requested medication will NOT be used concurrently with anothersystemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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INFLIXIMAB BvD (PART D)

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of severe chronic plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Does the patient have a diagnosis of fistulizing Crohn's disease (CD) (ICD-10 K50.913, K50.013, K50.113, K50.813)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #6.

6. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) **AND** meet the following criterion?
   - The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #7.

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INFLIXIMAB BvD (PART D)

RENEWAL CRITERIA (CONTINUED)

7. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) **AND** meet the following criterion?
   - The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INFLIXIMAB (Remicade)** requires the following rule(s) be met for renewal:

   A. You have ONE of the following:
      1. Moderate to severe rheumatoid arthritis (RA: a type of joint disorder)
      2. Psoriatic arthritis (PsA: a type of skin and joint disorder)
      3. Ankylosing spondylitis (AS: a type of joint disorder)
      4. Severe chronic plaque psoriasis (PsO: a type of skin disorder)
      5. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
      6. Fistulizing (abnormal connection between two body parts) Crohn's disease
      7. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

   B. If you have moderate to severe rheumatoid arthritis, renewal also requires:
      1. You continue to benefit from the medication
      2. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis

   C. If you have psoriatic arthritis, renewal also requires:
      1. You continue to benefit from the medication
      2. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

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INFLIXIMAB BvD (PART D)

RENEWAL CRITERIA (CONTINUED)

D. If you have ankylosing spondylitis, renewal also requires:
1. You continue to benefit from the medication
2. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis

E. If you have severe chronic plaque psoriasis, renewal also requires:
1. You continue to benefit from the medication
2. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis

F. If you have moderate to severe Crohn's disease, renewal also requires:
1. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease

G. If you have moderate to severe ulcerative colitis, renewal also requires:
1. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

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INFLIXIMAB BvD (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Remicade.

The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B. Drugs administered by an implantable pump are covered under Part B. Drugs administered via an external pump are covered under Part B if they are included under the local coverage policy of the applicable Medicare coverage policies (National and/or Local Coverage Policies). Drugs administered via an external pump that are not included under the applicable Medicare coverage policies are covered under Part D. A CMS website to assist with National and Local Coverage Determination for B versus D review is http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx.

REFERENCES

Remicade [Prescribing Information] Horsham, PA: Janssen Biotech, Inc.; February 2025.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed March 18, 2026].

For Part D use only:

INFLIXIMAB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	INITIAL: PLAQUE PSORIASIS (PSO): PSORIASIS COVERING 3 PERCENT OR MORE OF BODY SURFACE AREA OR PSORIATIC LESIONS AFFECTING THE HANDS, FEET, GENITAL AREA, SCALP, OR FACE.
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: RHEUMATOID ARTHRITIS (RA), ANKYLOSING SPONDYLITIS (AS): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST. PSO: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST. CROHNS DISEASE (CD), ULCERATIVE COLITIS (UC): PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: RA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, XELJANZ, RINVOQ, ORENCIA. PSA: TRIAL OF OR CONTRAINDICATION TO TWO

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	OF THE FOLLOWING PREFERRED AGENTS: COSENTYX, HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, SELARSDI/YESINTEK/USTEKINUMAB-AAUZ, XELJANZ, RINVOQ, SKYRIZI, TREMFYA, ORENCIA, OTEZLA. PSO: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: COSENTYX, HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, SELARSDI/YESINTEK/USTEKINUMAB-AAUZ, SKYRIZI, TREMFYA, OTEZLA. AS: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: COSENTYX, HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, XELJANZ, RINVOQ. MODERATE TO SEVERE CD: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS, WHERE AGES ALIGN: SELARSDI/YESINTEK/USTEKINUMAB-AAUZ, HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, RINVOQ, SKYRIZI, TREMFYA. UC: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS, WHERE AGES ALIGN: SELARSDI/YESINTEK/USTEKINUMAB-AAUZ, XELJANZ, HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, RINVOQ, SKYRIZI, TREMFYA. INITIAL/RENEWAL: RA, PSA, AS, PSO, MODERATE TO SEVERE CD, UC: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION. RENEWAL: RA, PSA, AS, PSO: CONTINUES TO BENEFIT FROM THE MEDICATION.

Created: 11/07
Effective: 05/01/26 Client Approval: 04/26 P&T Approval: 04/25

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INFLIXIMAB-ABDA BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INFLIXIMAB-ABDA	RENFLEXIS	44432		GPI-10 (5250504010)	

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, continue to #6.
   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, continue to #6.
   If no, continue to #5.

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

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INFLIXIMAB-ABDA BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

6. Is the drug administered via an implantable pump?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, continue to #7.

7. Is the drug administered via an external pump?

   If yes, continue to #8.
   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

8. Is the drug specifically infused through an external infusion pump covered by Medicare?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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INFLIXIMAB-ABDA BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is concurrently using methotrexate
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Renflexis will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Orencia (abatacept)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

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INFLIXIMAB-ABDA BvD (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
- Renflexis will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA
- The patient had a trial of or contraindication to TWO of the following preferred agents:
  - Cosentyx (secukinumab)
  - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
  - Selarsdi /Yesintek /ustekinumab-aauz
  - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
  - Skyrizi (risankizumab-rzaa)
  - Tremfya (guselkumab)
  - Orencia (abatacept)
  - Otezla (apremilast)

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #3.

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INFLIXIMAB-ABDA BvD (PART D)

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Renflexis will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Cosentyx (secukinumab)
     - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.
   If no, continue to #4.

4. Does the patient have a diagnosis of severe chronic plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is a candidate for systemic therapy
   - Therapy is prescribed by or in consultation with a dermatologist
   - The patient has psoriasis covering 3% or more of body surface area (BSA) OR psoriatic lesions affecting the hands, feet, genital area, scalp, or face
   - Renflexis will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Cosentyx (secukinumab), Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima, Selarsdi /Yesintek /ustekinumab-aauz, Skyrizi (risankizumab-rzaa), Tremfya (guselkumab), Otezla (apremilast)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.
   If no, continue to #5.

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INFLIXIMAB-ABDA BvD (PART D)

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Renflexis will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, continue to #6.
   If no, continue to #7.

6. Does the patient meet **ONE** of the following criteria?
   - The patient is 6 to 17 years of age AND had a trial of or contraindication to the preferred agent: Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
   - The patient is 18 years of age or older AND had a trial of or contraindication to TWO of the following preferred agents:
     - Selarsdi /Yesintek /ustekinumab-aauz
     - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Skyrizi (risankizumab-rzaa)
     - Tremfya (guselkumab)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

7. Does the patient have a diagnosis of fistulizing Crohn's disease (CD) (ICD-10 K50.913, K50.013, K50.113, K50.813) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #8.

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INFLIXIMAB-ABDA BvD (PART D)

INITIAL CRITERIA (CONTINUED)

8. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Renflexis will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, continue to #9.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

9. Does the patient meet **ONE** of the following criteria?
   - The patient is 6 to 17 years of age AND had a trial of or contraindication to the preferred agent: Humira (adalimumab)
   - The patient is 18 years of age or older AND had a trial of or contraindication to TWO of the following preferred agents:
     - Selarsdi /Yesintek /ustekinumab-aauz
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Skyrizi (risankizumab-rzaa)
     - Tremfya (guselkumab)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INFLIXIMAB-ABDA BvD (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **INFLIXIMAB-ABDA (Renflexis)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Ankylosing spondylitis (AS: a type of joint condition)
   4. Severe chronic plaque psoriasis (PsO: a type of skin condition)
   5. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   6. Fistulizing (abnormal connection between two body parts) Crohn's disease
   7. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. If you have moderate to severe rheumatoid arthritis, approval also requires:
   1. You are 18 years of age or older
   2. You are concurrently (at the same time) using methotrexate
   3. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   4. You will NOT use Renflexis concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
   5. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      a. Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
      b. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
      c. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
      d. Orencia (abatacept)

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INFLIXIMAB-ABDA BvD (PART D)

INITIAL CRITERIA (CONTINUED)

C. If you have psoriatic arthritis, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (skin doctor)
3. You will NOT use Renflexis concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis
4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Cosentyx (secukinumab)
   b. Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
   c. Selarsdi /Yesintek /ustekinumab-aauz
   d. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
   e. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
   f. Skyrizi (risankizumab-rzaa)
   g. Tremfya (guselkumab)
   h. Orencia (abatacept)
   i. Otezla (apremilast)

D. If you have ankylosing spondylitis, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You will NOT use Renflexis concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis

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INITIAL CRITERIA (CONTINUED)

4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Cosentyx (secukinumab)
   b. Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
   c. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
   d. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])

E. If you have severe chronic plaque psoriasis, approval also requires:

1. You are 18 years of age or older
2. You are a candidate for systemic therapy (treatment that travels through the entire body)
3. Therapy is prescribed by or in consultation with a dermatologist (skin doctor)
4. You have psoriasis covering 3% or more of body surface area (BSA) OR psoriatic lesions (patches) affecting the hands, feet, face, scalp, or genital area
5. You will NOT use Renflexis concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis
6. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Cosentyx (secukinumab), Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima, Selarsdi /Yesintek /ustekinumab-aauz, Skyrizi (risankizumab-rzaa), Tremfya (guselkumab), Otezla (apremilast)

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INFLIXIMAB-ABDA BvD (PART D)

INITIAL CRITERIA (CONTINUED)

F. If you have moderate to severe Crohn's disease, approval also requires:
1. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
2. You will NOT use Renflexis concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease
3. You meet ONE of the following:
   a. You are 6 to 17 years old AND have tried or have a contraindication to (harmful for you to use) the preferred medication: Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
   b. You are 18 years of age or older AND have tried or have a contraindication to TWO of the following preferred medications:
      i. Selarsdi /Yesintek /ustekinumab-aauz
      ii. Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
      iii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
      iv. Skyrizi (risankizumab-rzaa)
      v. Tremfya (guselkumab)

G. If you have fistulizing Crohn's disease, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)

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INFLIXIMAB-ABDA BvD (PART D)

INITIAL CRITERIA (CONTINUED)

H. If you have moderate to severe ulcerative colitis, approval also requires:

1. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
2. You will NOT use Renflexis concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis
3. You meet ONE of the following:
   a. You are 6 to 17 years old AND have tried or have a contraindication to (harmful for you to use) the preferred medication: Humira (adalimumab)
   b. You are 18 years of age or older AND have tried or have a contraindication to TWO of the following preferred medications:
      i. Selarsdi /Yesintek /ustekinumab-aauz
      ii. Xeljanz (tofacitinib immediate-release or extended-release) (NOTE: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
      iii. Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
      iv. Rinvoq (upadacitinib) (NOTE: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
      v. Skyrizi (risankizumab-rzaa)
      vi. Tremfya (guselkumab)

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INFLIXIMAB-ABDA BvD (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Renflexis will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Renflexis will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Renflexis will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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INFLIXIMAB-ABDA BvD (PART D)

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of severe chronic plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Renflexis will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Does the patient have a diagnosis of fistulizing Crohn's disease (CD) (ICD-10 K50.913, K50.013, K50.113, K50.813)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #6.

6. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) **AND** meet the following criterion?
   - Renflexis will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #7.

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RENEWAL CRITERIA (CONTINUED)

7. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) **AND** meet the following criterion?
   - Renflexis will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INFLIXIMAB-ABDA (Renflexis)** requires the following rule(s) be met for renewal:

   A. You have ONE of the following:
      1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
      2. Psoriatic arthritis (PsA: a type of skin and joint condition)
      3. Ankylosing spondylitis (AS: a type of joint condition)
      4. Severe chronic plaque psoriasis (PsO: a type of skin condition)
      5. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
      6. Fistulizing (abnormal connection between two body parts) Crohn's disease
      7. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

   B. If you have moderate to severe rheumatoid arthritis, renewal also requires:
      1. You continue to benefit from the medication
      2. You will NOT use Renflexis concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis

   C. If you have psoriatic arthritis, renewal also requires:
      1. You continue to benefit from the medication
      2. You will NOT use Renflexis concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

   (Renewal denial text continued on next page)

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INFLIXIMAB-ABDA BvD (PART D)

RENEWAL CRITERIA (CONTINUED)

D. If you have ankylosing spondylitis, renewal also requires:
1. You continue to benefit from the medication
2. You will NOT use Renflexis concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis

E. If you have severe chronic plaque psoriasis, renewal also requires:
1. You continue to benefit from the medication
2. You will NOT use Renflexis concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis

F. If you have moderate to severe Crohn's disease, renewal also requires:
1. You will NOT use Renflexis concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease

G. If you have moderate to severe ulcerative colitis, renewal also requires:
1. You will NOT use Renflexis concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

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INFLIXIMAB-ABDA BvD (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Renflexis.

The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B. Drugs administered by an implantable pump are covered under Part B. Drugs administered via an external pump are covered under Part B if they are included under the local coverage policy of the applicable Medicare coverage policies (National and/or Local Coverage Policies). Drugs administered via an external pump that are not included under the applicable Medicare coverage policies are covered under Part D. A CMS website to assist with National and Local Coverage Determination for B versus D review is http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx.

REFERENCES

Renflexis [Prescribing Information]. Kenilworth, NJ: Merck & Co., Inc.; October 2025.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. Accessed March 18, 2026].

For Part D use only:

INFLIXIMAB-ABDA (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	INITIAL: PLAQUE PSORIASIS (PSO): PSORIASIS COVERING 3 PERCENT OR MORE OF BODY SURFACE AREA OR PSORIATIC LESIONS AFFECTING THE HANDS, FEET, GENITAL AREA, SCALP, OR FACE.
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: RHEUMATOID ARTHRITIS (RA), ANKYLOSING SPONDYLITIS (AS): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST. PSO: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST. CROHNS DISEASE (CD), ULCERATIVE COLITIS (UC): PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: RA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, XELJANZ, RINVOQ, ORENCIA. PSA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: COSENTYX,

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	HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, SELARSDI/YESINTEK/USTEKINUMAB-AAUZ, XELJANZ, RINVOQ, SKYRIZI, TREMFYA, ORENCIA, OTEZLA. PSO: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: COSENTYX, HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, SELARSDI/YESINTEK/USTEKINUMAB-AAUZ, SKYRIZI, TREMFYA, OTEZLA. AS: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: COSENTYX, HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, XELJANZ, RINVOQ. MODERATE TO SEVERE CD: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS, WHERE AGES ALIGN: SELARSDI/YESINTEK/USTEKINUMAB-AAUZ, HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, RINVOQ, SKYRIZI, TREMFYA. UC: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS, WHERE AGES ALIGN: SELARSDI/YESINTEK/USTEKINUMAB-AAUZ, XELJANZ, HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, RINVOQ, SKYRIZI, TREMFYA. INITIAL/RENEWAL: RA, PSA, AS, PSO, MODERATE TO SEVERE CD, UC: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION. RENEWAL: RA, PSA, AS, PSO: CONTINUES TO BENEFIT FROM THE MEDICATION.

Created: 08/17
Effective: 05/01/26 Client Approval: 04/26 P&T Approval: 04/25

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INFLIXIMAB-AXXQ BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INFLIXIMAB-AXXQ	AVSOLA	46242		GPI-10 (5250504013)	

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, continue to #6.
   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, continue to #6.
   If no, continue to #5.

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

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INFLIXIMAB-AXXQ BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

6. Is the drug administered via an implantable pump?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, continue to #7.

7. Is the drug administered using an external infusion pump?

   If yes, continue to #8.
   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

8. Is the drug specifically infused through an external infusion pump covered by Medicare?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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INFLIXIMAB-AXXQ BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is concurrently using methotrexate
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Avsola will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Orencia (abatacept)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

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INFLIXIMAB-AXXQ BvD (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
- Avsola will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA
- The patient had a trial of or contraindication to TWO of the following preferred agents:
  - Cosentyx (secukinumab)
  - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
  - Selarsdi /Yesintek /ustekinumab-aauz
  - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
  - Skyrizi (risankizumab-rzaa)
  - Tremfya (guselkumab)
  - Orencia (abatacept)
  - Otezla (apremilast)

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #3.

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INFLIXIMAB-AXXQ BvD (PART D)

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Avsola will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Cosentyx (secukinumab)
     - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of severe chronic plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is a candidate for systemic therapy
   - Therapy is prescribed by or in consultation with a dermatologist
   - The patient has psoriasis covering 3% or more of body surface area (BSA) OR psoriatic lesions affecting the hands, feet, genital area, scalp, or face
   - Avsola will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Cosentyx (secukinumab), Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima, Selarsdi /Yesintek /ustekinumab-aauz, Skyrizi (risankizumab-rzaa), Tremfya (guselkumab), Otezla (apremilast)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Avsola will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, continue to #6.
   If no, continue to #7.

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INFLIXIMAB-AXXQ BvD (PART D)

INITIAL CRITERIA (CONTINUED)

6. Does the patient meet **ONE** of the following criteria?
   - The patient is 6 to 17 years of age AND had a trial of or contraindication to the preferred agent: Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
   - The patient is 18 years of age or older AND had a trial of or contraindication to TWO of the following preferred agents:
     - Selarsdi /Yesintek /ustekinumab-aauz
     - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Skyrizi (risankizumab-rzaa)
     - Tremfya (guselkumab)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

7. Does the patient have a diagnosis of fistulizing Crohn's disease (CD) (ICD-10 K50.913, K50.013, K50.113, K50.813) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #8.

8. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Avsola will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, continue to #9.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INFLIXIMAB-AXXQ BvD (PART D)

INITIAL CRITERIA (CONTINUED)

9. Does the patient meet **ONE** of the following criteria?
   - The patient is 6 to 17 years of age AND had a trial of or contraindication to the preferred agent: Humira (adalimumab)
   - The patient is 18 years of age or older and had a trial of or contraindication to TWO of the following preferred agents:
     - Selarsdi /Yesintek /ustekinumab-aauz
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Skyrizi (risankizumab-rzaa)
     - Tremfya (guselkumab)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INFLIXIMAB-AXXQ (Avsola)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
      2. Psoriatic arthritis (PsA: a type of skin and joint condition)
      3. Ankylosing spondylitis (AS: a type of joint condition)
      4. Severe chronic plaque psoriasis (PsO: a type of skin condition)
      5. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
      6. Fistulizing (abnormal connection between two body parts) Crohn's disease
      7. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

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INFLIXIMAB-AXXQ BvD (PART D)

INITIAL CRITERIA (CONTINUED)

B. If you have moderate to severe rheumatoid arthritis, approval also requires:

1. You are 18 years of age or older
2. You are concurrently (at the same time) using methotrexate
3. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
4. You will NOT use Avsola concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
5. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
   b. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
   c. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
   d. Orencia (abatacept)

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INFLIXIMAB-AXXQ BvD (PART D)

INITIAL CRITERIA (CONTINUED)

C. If you have psoriatic arthritis, approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (skin doctor)
3. You will NOT use Avsola concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis
4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Cosentyx (secukinumab)
   b. Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
   c. Selarsdi /Yesintek /ustekinumab-aauz
   d. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
   e. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
   f. Skyrizi (risankizumab-rzaa)
   g. Tremfya (guselkumab)
   h. Orencia (abatacept)
   i. Otezla (apremilast)

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INFLIXIMAB-AXXQ BvD (PART D)

INITIAL CRITERIA (CONTINUED)

D. If you have ankylosing spondylitis, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You will NOT use Avsola concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis
4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Cosentyx (secukinumab)
   b. Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
   c. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
   d. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])

E. If you have severe chronic plaque psoriasis, approval also requires:
1. You are 18 years of age or older
2. You are a candidate for systemic therapy (treatment that travels through the entire body)
3. Therapy is prescribed by or in consultation with a dermatologist (skin doctor)
4. You have psoriasis covering 3% or more of body surface area (BSA) OR psoriatic lesions (patches) affecting the hands, feet, face, scalp, or genital area
5. You will NOT use Avsola concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis
6. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Cosentyx (secukinumab), Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima, Selarsdi /Yesintek /ustekinumab-aauz, Skyrizi (risankizumab-rzaa), Tremfya (guselkumab), Otezla (apremilast)

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INITIAL CRITERIA (CONTINUED)

F. If you have moderate to severe Crohn's disease, approval also requires:
1. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
2. You will NOT use Avsola concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease
3. You meet ONE of the following:
   a. You are 6 to 17 years old AND have tried or have a contraindication to (harmful for you to use) the preferred medication: Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
   b. You are 18 years of age or older AND have tried or have a contraindication to TWO of the following preferred medications:
      i. Selarsdi /Yesintek /ustekinumab-aauz
      ii. Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
      iii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
      iv. Skyrizi (risankizumab-rzaa)
      v. Tremfya (guselkumab)

G. If you have fistulizing Crohn's disease, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)

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INITIAL CRITERIA (CONTINUED)

H. If you have moderate to severe ulcerative colitis, approval also requires:

1. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
2. You will NOT use Avsola concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis
3. You meet ONE of the following:
   a. You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) the preferred medication: Humira (adalimumab)
   b. You are 18 years of age or older AND have tried or have a contraindication to TWO of the following preferred medications:
      i. Selarsdi /Yesintek /ustekinumab-aauz
      ii. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
      iii. Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
      iv. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
      v. Skyrizi (risankizumab-rzaa)
      vi. Tremfya (guselkumab)

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INFLIXIMAB-AXXQ BvD (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Avsola will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Avsola will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Avsola will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of severe chronic plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Avsola will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Does the patient have a diagnosis of fistulizing Crohn's disease (CD) (ICD-10 K50.913, K50.013, K50.113, K50.813)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #6.

6. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) **AND** meet the following criterion?
   - Avsola will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #7.

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RENEWAL CRITERIA (CONTINUED)

7. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) **AND** meet the following criterion?
   - Avsola will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INFLIXIMAB-AXXQ (Avsola)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
      2. Psoriatic arthritis (PsA: a type of skin and joint condition)
      3. Ankylosing spondylitis (AS: a type of joint condition)
      4. Severe chronic plaque psoriasis (PsO: a type of skin condition)
      5. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
      6. Fistulizing (abnormal connection between two body parts) Crohn's disease
      7. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

   B. If you have moderate to severe rheumatoid arthritis, renewal also requires:
      1. You continue to benefit from the medication
      2. You will NOT use Avsola concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis

   C. If you have psoriatic arthritis, renewal also requires:
      1. You continue to benefit from the medication
      2. You will NOT use Avsola concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

   (Renewal denial text continued on next page)

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RENEWAL CRITERIA (CONTINUED)

D. If you have ankylosing spondylitis, renewal also requires:
1. You continue to benefit from the medication
2. You will NOT use Avsola concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis

E. If you have severe chronic plaque psoriasis, renewal also requires:
1. You continue to benefit from the medication
2. You will NOT use Avsola concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis

F. If you have moderate to severe Crohn's disease, renewal also requires:
1. You will NOT use Avsola concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease

G. If you have moderate to severe ulcerative colitis, renewal also requires:
1. You will NOT use Avsola concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

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INFLIXIMAB-AXXQ BvD (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Avsola.

The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B. Drugs administered by an implantable pump are covered under Part B. Drugs administered via an external pump are covered under Part B if they are included under the local coverage policy of the applicable Medicare coverage policies (National and/or Local Coverage Policies). Drugs administered via an external pump that are not included under the applicable Medicare coverage policies are covered under Part D. A CMS website to assist with National and Local Coverage Determination for B versus D review is http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx.

REFERENCES

Avsola [Prescribing Information]. Thousand Oaks, CA: Amgen, Inc.; September 2021.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals.[Accessed July 5, 2024].

For Part D use only:

INFLIXIMAB-AXXQ (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	INITIAL: PLAQUE PSORIASIS (PSO): PSORIASIS COVERING 3 PERCENT OR MORE OF BODY SURFACE AREA OR PSORIATIC LESIONS AFFECTING THE HANDS, FEET, GENITAL AREA, SCALP, OR FACE.
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: RHEUMATOID ARTHRITIS (RA), ANKYLOSING SPONDYLITIS (AS): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST. PSO: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST. CROHNS DISEASE (CD), ULCERATIVE COLITIS (UC): PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: RA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, XELJANZ, RINVOQ, ORENCIA. PSA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: COSENTYX,

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	HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, SELARSDI/YESINTEK/USTEKINUMAB-AAUZ, XELJANZ, RINVOQ, SKYRIZI, TREMFYA, ORENCIA, OTEZLA. PSO: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: COSENTYX, HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, SELARSDI/YESINTEK/USTEKINUMAB-AAUZ, SKYRIZI, TREMFYA, OTEZLA. AS: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: COSENTYX, HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, XELJANZ, RINVOQ. MODERATE TO SEVERE CD: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS, WHERE AGES ALIGN: SELARSDI/YESINTEK/USTEKINUMAB-AAUZ, HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, RINVOQ, SKYRIZI, TREMFYA. UC: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS, WHERE AGES ALIGN: SELARSDI/YESINTEK/USTEKINUMAB-AAUZ, XELJANZ, HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, RINVOQ, SKYRIZI, TREMFYA. INITIAL/RENEWAL: RA, PSA, AS, PSO, MODERATE TO SEVERE CD, UC: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION. RENEWAL: RA, PSA, AS, PSO: CONTINUES TO BENEFIT FROM THE MEDICATION.

Created: 06/20
Effective: 05/01/26 Client Approval: 04/26 P&T Approval: 04/25

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INFLIXIMAB-DYYB IV BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INFLIXIMAB-DYYB	INFLECTRA		40977	GPI-14 (52505040202120)	

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, continue to #6.
   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, continue to #6.
   If no, continue to #5.

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

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INFLIXIMAB-DYYB IV BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

6. Is the drug administered via an implantable pump?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, continue to #7.

7. Is the drug administered via an external pump?

   If yes, continue to #8.
   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

8. Is the drug specifically infused through an external infusion pump covered by Medicare?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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INFLIXIMAB-DYYB IV BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is concurrently using methotrexate
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Inflectra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Orencia (abatacept)

   If yes, **approve for 6 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

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INFLIXIMAB-DYYB IV BvD (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
- Inflectra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA
- The patient had a trial of or contraindication to TWO of the following preferred agents:
  - Cosentyx (secukinumab)
  - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
  - Selarsdi /Yesintek /ustekinumab-aauz
  - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
  - Skyrizi (risankizumab-rzaa)
  - Tremfya (guselkumab)
  - Orencia (abatacept)
  - Otezla (apremilast)

If yes, **approve for 6 months by GPID or GPI-14.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #3.

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INFLIXIMAB-DYYB IV BvD (PART D)

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Inflectra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Cosentyx (secukinumab)
     - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])

   If yes, **approve for 6 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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INFLIXIMAB-DYYB IV BvD (PART D)

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of severe chronic plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is a candidate for systemic therapy
   - Therapy is prescribed by or in consultation with a dermatologist
   - The patient has psoriasis covering 3% or more of body surface area (BSA) OR psoriatic lesions affecting the hands, feet, genital area, scalp, or face
   - Inflectra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Cosentyx (secukinumab), Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima, Selarsdi /Yesintek /ustekinumab-aauz, Skyrizi (risankizumab-rzaa), Tremfya (guselkumab), Otezla (apremilast)

   If yes, **approve for 6 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Inflectra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, continue to #6.
   If no, continue to #7.

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INFLIXIMAB-DYYB IV BvD (PART D)

INITIAL CRITERIA (CONTINUED)

6. Does the patient meet **ONE** of the following criteria?
   - The patient is 6 to 17 years of age AND had a trial of or contraindication to the preferred agent: Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
   - The patient is 18 years of age or older AND had a trial of or contraindication to TWO of the following preferred agents:
     - Selarsdi /Yesintek /ustekinumab-aauz
     - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Skyrizi (risankizumab-rzaa)
     - Tremfya (guselkumab)

   If yes, **approve for 6 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

7. Does the patient have a diagnosis of fistulizing Crohn's disease (CD) (ICD-10 K50.913, K50.013, K50.113, K50.813) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist

   If yes, **approve for 6 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #8.

8. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Inflectra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, continue to #9.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INFLIXIMAB-DYYB IV BvD (PART D)

INITIAL CRITERIA (CONTINUED)

9. Does the patient meet **ONE** of the following criteria?
   - The patient is 6 to 17 years of age AND had a trial of or contraindication to the preferred agent: Humira (adalimumab)
   - The patient is 18 years of age or older AND had a trial of or contraindication to TWO of the following preferred agents:
     - Selarsdi /Yesintek /ustekinumab-aauz
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Skyrizi (risankizumab-rzaa)
     - Tremfya (guselkumab)

   If yes, **approve for 6 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INFLIXIMAB-DYYB IV (Inflectra)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
      2. Psoriatic arthritis (PsA: a type of skin and joint condition)
      3. Ankylosing spondylitis (AS: a type of joint condition)
      4. Severe chronic plaque psoriasis (PsO: a type of skin condition)
      5. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
      6. Fistulizing (abnormal connection between two body parts) Crohn's disease
      7. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

   (Initial denial text continued on next page)

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INFLIXIMAB-DYYB IV BvD (PART D)

INITIAL CRITERIA (CONTINUED)

B. If you have moderate to severe rheumatoid arthritis, approval also requires:

1. You are 18 years of age or older
2. You are concurrently (at the same time) using methotrexate
3. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
4. You will NOT use Inflectra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
5. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
   b. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
   c. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
   d. Orencia (abatacept)

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INFLIXIMAB-DYYB IV BvD (PART D)

INITIAL CRITERIA (CONTINUED)

C. If you have psoriatic arthritis, approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (skin doctor)
3. You will NOT use Inflectra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis
4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Cosentyx (secukinumab)
   b. Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
   c. Selarsdi /Yesintek /ustekinumab-aauz
   d. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
   e. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
   f. Skyrizi (risankizumab-rzaa)
   g. Tremfya (guselkumab)
   h. Orencia (abatacept)
   i. Otezla (apremilast)

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INFLIXIMAB-DYYB IV BvD (PART D)

INITIAL CRITERIA (CONTINUED)

D. If you have ankylosing spondylitis, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You will NOT use Inflectra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis
4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Cosentyx (secukinumab)
   b. Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
   c. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
   d. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])

E. If you have severe chronic plaque psoriasis, approval also requires:
1. You are 18 years of age or older
2. You are a candidate for systemic therapy (treatment that travels through the entire body)
3. Therapy is prescribed by or in consultation with a dermatologist (skin doctor)
4. You have psoriasis covering 3% or more of body surface area (BSA) OR psoriatic lesions (patches) affecting the hands, feet, face, scalp, or genital area
5. You will NOT use Inflectra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis
6. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Cosentyx (secukinumab), Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima, Selarsdi /Yesintek /ustekinumab-aauz, Skyrizi (risankizumab-rzaa), Tremfya (guselkumab), Otezla (apremilast)

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INFLIXIMAB-DYYB IV BvD (PART D)

INITIAL CRITERIA (CONTINUED)

F. If you have moderate to severe Crohn's disease, approval also requires:
1. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
2. You will NOT use Inflectra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease
3. You meet ONE of the following:
   a. You are 6 to 17 years old AND have tried or have a contraindication to (harmful for you to use) the preferred medication: Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
   b. You are 18 years of age or older AND have tried or have a contraindication to TWO of the following preferred medications:
      i. Selarsdi /Yesintek /ustekinumab-aauz
      ii. Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
      iii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
      iv. Skyrizi (risankizumab-rzaa)
      v. Tremfya (guselkumab)

G. If you have fistulizing Crohn's disease, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)

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INFLIXIMAB-DYYB IV BvD (PART D)

INITIAL CRITERIA (CONTINUED)

H. If you have moderate to severe ulcerative colitis, approval also requires:

1. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
2. You will NOT use Inflectra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis
3. You meet ONE of the following:
   a. You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) the preferred medication: Humira (adalimumab)
   b. You are 18 years of age or older AND have tried or have a contraindication to TWO of the following preferred medications:
      i. Selarsdi /Yesintek /ustekinumab-aauz
      ii. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
      iii. Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
      iv. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
      v. Skyrizi (risankizumab-rzaa)
      vi. Tremfya (guselkumab)

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INFLIXIMAB-DYYB IV BvD (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Inflectra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, **approve for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Inflectra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, **approve for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Inflectra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS

   If yes, **approve for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of severe chronic plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Inflectra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, **approve for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Does the patient have a diagnosis of fistulizing Crohn's disease (CD) (ICD-10 K50.913, K50.013, K50.113, K50.813)?

   If yes, **approve for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #6.

6. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) **AND** meet the following criterion?
   - Inflectra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, **approve for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #7.

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INFLIXIMAB-DYYB IV BvD (PART D)

RENEWAL CRITERIA (CONTINUED)

7. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) **AND** meet the following criterion?
   - Inflectra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, **approve for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INFLIXIMAB-DYYB IV (Inflectra)** requires the following rule(s) be met for renewal:

   A. You have ONE of the following:
      1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
      2. Psoriatic arthritis (PsA: a type of skin and joint condition)
      3. Ankylosing spondylitis (AS: a type of joint condition)
      4. Severe chronic plaque psoriasis (PsO: a type of skin condition)
      5. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
      6. Fistulizing (abnormal connection between two body parts) Crohn's disease
      7. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

   B. If you have moderate to severe rheumatoid arthritis, renewal also requires:
      1. You continue to benefit from the medication
      2. You will NOT use Inflectra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis

   C. If you have psoriatic arthritis, renewal also requires:
      1. You continue to benefit from the medication
      2. You will NOT use Inflectra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

   (Renewal denial text continued on next page)

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INFLIXIMAB-DYYB IV BvD (PART D)

RENEWAL CRITERIA (CONTINUED)

D. If you have ankylosing spondylitis, renewal also requires:
1. You continue to benefit from the medication
2. You will NOT use Inflectra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis

E. If you have severe chronic plaque psoriasis, renewal also requires:
1. You continue to benefit from the medication
2. You will NOT use Inflectra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis

F. If you have moderate to severe Crohn's disease, renewal also requires:
1. You will NOT use Inflectra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease

G. If you have moderate to severe ulcerative colitis, renewal also requires:
1. You will NOT use Inflectra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

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RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Inflectra.

The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B. Drugs administered by an implantable pump are covered under Part B. Drugs administered via an external pump are covered under Part B if they are included under the local coverage policy of the applicable Medicare coverage policies (National and/or Local Coverage Policies). Drugs administered via an external pump that are not included under the applicable Medicare coverage policies are covered under Part D. A CMS website to assist with National and Local Coverage Determination for B versus D review is http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx.

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INFLIXIMAB-DYYB IV BvD (PART D)

REFERENCES

Inflectra [Prescribing Information]. New York, NY: Pfizer Laboratories Div. Pfizer Inc.; September 2025.

Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals.[Accessed March 18, 2026].

For Part D use only:

INFLIXIMAB-DYYB IV (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	INITIAL: PLAQUE PSORIASIS (PSO): PSORIASIS COVERING 3 PERCENT OR MORE OF BODY SURFACE AREA OR PSORIATIC LESIONS AFFECTING THE HANDS, FEET, GENITAL AREA, SCALP, OR FACE.
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: RHEUMATOID ARTHRITIS (RA), ANKYLOSING SPONDYLITIS (AS): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST. PSO: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST. CROHNS DISEASE (CD), ULCERATIVE COLITIS (UC): PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: RA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, XELJANZ, RINVOQ, ORENCIA. PSA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: COSENTYX, HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, SELARSDI/YESINTEK/USTEKINUMAB-AAUZ, XELJANZ, RINVOQ, SKYRIZI, TREMFYA, ORENCIA, OTEZLA. PSO: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: COSENTYX, HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, SELARSDI/YESINTEK/USTEKINUMAB-AAUZ, SKYRIZI, TREMFYA, OTEZLA. AS: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: COSENTYX, HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, XELJANZ, RINVOQ. MODERATE TO SEVERE CD: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS, WHERE AGES ALIGN: SELARSDI/YESINTEK/USTEKINUMAB-AAUZ,

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	HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, RINVOQ, SKYRIZI, TREMFYA. UC: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS, WHERE AGES ALIGN: SELARSDI/YESINTEK/USTEKINUMAB-AAUZ, XELJANZ, HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, RINVOQ, SKYRIZI, TREMFYA. INITIAL/RENEWAL: RA, PSA, AS, PSO, MODERATE TO SEVERE CD, UC: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION. RENEWAL: RA, PSA, AS, PSO: CONTINUES TO BENEFIT FROM THE MEDICATION.

Created: 05/16
Effective: 05/01/26 Client Approval: 04/26 P&T Approval: 04/25

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INFLIXIMAB-DYYB SQ (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INFLIXIMAB-DYYB	ZYMFENTRA		55099 55098	GPI-14 (5250504020F530, 5250504020F830)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Zymfentra will be used following treatment with an intravenous infliximab agent (e.g., Remicade, Renflexis, Avsola)
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Zymfentra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Selarsdi /Yesintek /ustekinumab-aauz
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Skyrizi (risankizumab-rzaa)
     - Tremfya (guselkumab)

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INFLIXIMAB-DYYB SQ (PART D)

INITIAL CRITERIA (CONTINUED)

If yes, **approve all formulations of the 120mg/mL strength for 6 months by GPID or GPI-14.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Zymfentra will be used following treatment with an intravenous infliximab agent (e.g., Remicade, Renflexis, Avsola)
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Zymfentra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Selarsdi /Yesintek /ustekinumab-aauz
     - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Skyrizi (risankizumab-rzaa)
     - Tremfya (guselkumab)

   If yes, **approve all formulations of the 120mg/mL strength for 6 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INFLIXIMAB-DYYB SQ (Zymfentra)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
      2. Moderate to severe Crohn's disease (CD: a type of bowel disorder)

(Initial denial text continued on the next page)
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INFLIXIMAB-DYYB SQ (PART D)

INITIAL CRITERIA (CONTINUED)

B. If you have moderate to severe ulcerative colitis, approval also requires:

1. You are 18 years of age or older
2. Zymfentra will be used after treatment with an intravenous (injection into the vein) infliximab medication (such as Remicade, Renflexis, Avsola)
3. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
4. You will NOT use Zymfentra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis
5. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Selarsdi /Yesintek /ustekinumab-aauz
   b. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
   c. Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
   d. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
   e. Skyrizi (risankizumab-rzaa)
   f. Tremfya (guselkumab)

(Initial denial text continued on the next page)

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INFLIXIMAB-DYYB SQ (PART D)

INITIAL CRITERIA (CONTINUED)

C. If you have moderate to severe Crohn's disease, approval also requires:

1. You are 18 years of age or older
2. Zymfentra will be used after treatment with an intravenous (injection into the vein) infliximab medication (such as Remicade, Renflexis, Avsola)
3. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
4. You will NOT use Zymfentra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease
5. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Selarsdi /Yesintek /ustekinumab-aauz
   b. Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
   c. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
   d. Skyrizi (risankizumab-rzaa)
   e. Tremfya (guselkumab)

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INFLIXIMAB-DYYB SQ (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) **AND** meet the following criterion?
   - Zymfentra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, **approve all formulations of the 120mg/mL strength for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) **AND** meet the following criterion?
   - Zymfentra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, **approve all formulations of the 120mg/mL strength for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See renewal denial text at the end of the guideline.

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INFLIXIMAB-DYYB SQ (PART D)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **INFLIXIMAB-DYYB SQ (Zymfentra)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   2. Moderate to severe Crohn's disease (CD: a type of bowel disorder)

B. If you have moderate to severe ulcerative colitis, renewal also requires:
   1. You will NOT use Zymfentra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

C. If you have moderate to severe Crohn's disease, renewal also requires:
   1. You will NOT use Zymfentra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease

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RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zymfentra.

REFERENCES

Zymfentra [Prescribing Information]. Jersey City, New Jersey: Celltrion USA, Inc.; May 2025.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INFLIXIMAB-DYYB - SQ (PART D)

For Part D use only:

INFLIXIMAB-DYYB SQ (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: ULCERATIVE COLITIS (UC), CROHNS DISEASE (CD): PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: UC: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: SELARSDI/YESINTEK/USTEKINUMAB-AAUZ, XELJANZ, HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, RINVOQ, SKYRIZI, TREMFYA. CD: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: SELARSDI/YESINTEK/USTEKINUMAB-AAUZ, HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, RINVOQ, SKYRIZI, TREMFYA. INITIAL/RENEWAL: ALL INDICATIONS: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION.

Created: 03/24
Effective: 05/01/26 Client Approval: 04/26 P&T Approval: 04/25

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INFUSIBLE DRUG BVD DETERMINATION (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/ Other
ACYCLOVIR SODIUM	ACYCLOVIR SODIUM		43396 43390 43391	GPI-10 (1240501010)	
AMPHOTERICIN B	AMPHOTERICIN B		42420	GPI-10 (1100001000)	
AMPHOTERICIN B LIPID COMPLEX	ABELCET	10219		GPI-10 (1100001030)	
AMPHOTERICIN B LIPOSOME	AMBISOME, AMPHOTERICIN B LIPOSOME	12800		GPI-10 (1100001040)	
CAFFEINE CITRATE	CAFCIT, CAFFEINE CITRATE		50748	GPI-14 (61300010102020)	
CEFIDEROCOL SULFATE TOSYLATE	FETROJA	46229		GPI-10 (0280002070)	
CISPLATIN	CISPLATIN	03902		GPI-10 (2110002000)	ROUTE = INTRAVEN.
CLADRIBINE	CLADRIBINE		880	GPI-10 (2130000700)	
CYCLOPHOSPHAMIDE	CYCLOPHOSPHAMIDE		38352 38357 38353 48433 54284 54762	GPI-14 (21101020002125, 21101020002030, 21101020002130, 21101020002120, 21101020002020, 21101020002005, 21101020002070)	
CYTARABINE CYTARABINE/PF	CYTARABINE	03910		GPI-10 (2130001000)	
DAUNORUBICIN/ CYTARABINE LIPOSOMAL	VYXEOS	44461		GPI-10 (2199000220)	
DOBUTAMINE HCL	DOBUTAMINE HCL	00040		GPI-10 (3135001510)	
DOBUTAMINE HCL IN DEXTROSE 5 %	DOBUTAMINE HCL IN DEXTROSE	08777		GPI-10 (3135001511)	
DOXORUBICIN HCL	ADRIAMYCIN, DOXORUBICIN HCL	03916		GPI-10 (2120004010)	
DOXORUBICIN HCL PEG-LIPOSOMAL	DOXIL, CAELYX,	10222		GPI-10 (2120004040)	

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	DOXORUBICIN HCL LIPOSOME				
FLOXURIDINE	FLOXURIDINE	03909		GPI-10 (2130002000)	
FLUOROURACIL	ADRUCIL, FLUOROURACIL		97457 97458 97456 97455	GPI-10 (2130003000)	
FOSCARNET SODIUM	FOSCARNET SODIUM	13221		GPI-10 (1220002010)	
FOSDENOPTERIN HYDROBROMIDE	NULIBRY	47158		GPI-10 (3090643020)	
GARETOSMAB-GRTS	PASATRU	51491		GPI-10 (7588102000)	
MILRINONE LACTATE	MILRINONE LACTATE	06549		GPI-10 (3135005010)	
MILRINONE LACTATE/D5W	MILRINONE IN 5% DEXTROSE		5320	GPI-10 (3135005011)	
OLICERIDINE FUMARATE	OLINVYK		48499	GPI-14 (65100070202040)	
PEGLOTICASE	KRYSTEXXA	37154		GPI-10 (6800005000)	
POTASSIUM CHLORIDE IN WATER, POTASSIUM CHLORIDE	POTASSIUM CHLORIDE	44754 00549		GPI-10 (7970003000)	ROUTE = INTRAVENOUS
POTASSIUM CHLORIDE IN 0.9% NACL	POTASSIUM CHL-NORMAL SALINE		56590 56591	GPI-14 (79992002102020, 79992002102030)	
POTASSIUM CHLORIDE IN D5W	DEXTROSE 5%-POTASSIUM CHLORIDE	14775		GPI-10 (7999300210)	
POTASSIUM CHLORIDE/D5-0.45NACL	DEXTROSE 5%-0.45% NACL-KCL, DEXTROSE 5%-1/2NS-KCL	14778		GPI-14 (79993003102015, 79993003102025, 79993003102038, 79993003102050)	
POTASSIUM PHOS, M-BASIC-D-BASIC	POTASSIUM PHOSPHATE	00551		GPI-10 (7960001005)	
POTASSIUM PHOS IN 0.9 % NACL	POTASSIUM PHOSPHATE-0.9% NACL	37356		GPI-10 (7960001010)	
REMDESIVIR	VEKLURY	46410		GPI-10 (1270008000)	

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TEMSIROLIMUS	TORISEL, TEMSIROLIMUS	34870		GPI-10 (2153257000)	
TREOSULFAN	GRAFAPEX			GPI-10 (2110006000)	
VINBLASTINE SULFATE	VINBLASTINE SULFATE	03912		GPI-10 (2150003010)	
VINCRISTINE SULFATE	VINCASAR PFS, VINCRISTINE SULFATE	03913		GPI-10 (2150002010)	
VERTEPORFIN	VISUDYNE	21150		GPI-10 (8670006500)	

NOTE: This PA is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

GUIDELINES FOR USE

1. Is the drug administered via an implantable pump?

   If yes, **approve for 12 months under Part B for the requested drug. Please note: Multiple approvals by GPID or GPI-14 and/or HICL or GPI-10 may be necessary depending on the drug requested. Please refer to the drug list at the end of the guideline for approval instructions. (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in PA override field)**

   If no, continue to #2.

2. Is the drug administered using an external pump?

   If yes, continue to #3.
   If no, **approve for 12 months under Part D for the requested drug. Please note: Multiple approvals by GPID or GPI-14 and/or HICL or GPI-10 may be necessary depending on the drug requested. Please refer to the drug list at the end of the guideline for approval instructions. (Populate the B vs. D field with a 'D' in the PA override field)**

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INFUSIBLE DRUG BVD DETERMINATION (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Is the drug specifically infused through an external infusion pump covered by Medicare?

   If yes, **approve for 12 months under Part B for the requested drug. Please note: Multiple approvals by GPID or GPI-14 and/or HICL or GPI-10 may be necessary depending on the drug requested. Please refer to the drug list at the end of the guideline for approval instructions. (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in PA override field)**

   If no, **approve for 12 months under Part D for the requested drug. Please note: Multiple approvals by GPID or GPI-14 and/or HICL or GPI-10 may be necessary depending on the drug requested. Please refer to the drug list at the end of the guideline for approval instructions. (Populate the B vs. D field with a 'D' in the PA override field)**

Drug List:

Infusible Drug Requested	Approval Instructions	HICL	GPID	Medi-Span
ACYCLOVIR SODIUM	Enter multiple approvals by GPID or GPI-10 as listed.		43396 43390 43391	GPI-10 (1240501010)
AMPHOTERICIN B	Enter approval by GPID or GPI-10 as listed.		42420	GPI-10 (1100001000)
AMPHOTERICIN B LIPID COMPLEX (ABELCET)	Enter approval by HICL or GPI-10 as listed.	10219		GPI-10 (1100001030)
AMPHOTERICIN B LIPOSOME (AMBISOME)	Enter approval by HICL or GPI-10 as listed.	12800		GPI-10 (1100001040)
CAFFEINE CITRATE (CAFCIT)	Enter approval by GPID or GPI-14 as listed.		50748	GPI-14 (61300010102020)
CEFIDEROCOL (FETROJA)	Enter approval by HICL or GPI-10 as listed.	46229		GPI-10 (0280002070)
CISPLATIN	Enter approval by HICL or GPI-14 as listed.	03902		GPI-14 (21100020002020)
CLADRIBINE	Enter approval by GPID or GPI-10 as listed.		880	GPI-10 (2130000700)
CYCLOPHOSPHAMIDE	Enter multiple approvals by GPID or GPI-14 as listed.		38352 38357 38353 48433 54284 54762	GPI-14 (21101020002125, 21101020002030, 21101020002130, 21101020002120, 21101020002020, 21101020002005, 21101020002070)
CYTARABINE, CYTARABINE/PF	Enter approval by HICL or GPI-10 as listed.	03910		GPI-10 (2130001000)

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DAUNORUBICIN/ CYTARABINE LIPOSOMAL (VYXEOS)	Enter approval by HICL or GPI-10 as listed.	44461		GPI-10 (2199000220)
DOBUTAMINE HCL, DOBUTAMINE HCL/D5W	Enter multiple approvals by HICL or GPI-10 as listed.	00040 08777		GPI-10 (3135001510, 3135001511)
DOXORUBICIN HCL (ADRIAMYCIN)	Enter approval by HICL or GPI-10 as listed.	03916		GPI-10 (2120004010)
DOXORUBICIN HCL PEG-LIPOSOMAL (DOXIL, CAELYX)	Enter approval by HICL or GPI-10 as listed.	10222		GPI-10 (2120004040)
FLOXURIDINE	Enter approval by GPID or GPI-10 as listed.		38531	GPI-10 (2130002000)
FLUOROURACIL (ADRUCIL)	Enter multiple approvals by GPID or GPI-14 as listed.		97457 97458 97456 97455	GPI-14 (21300030002020, 21300030002025, 21300030002035)
FOSCARNET SODIUM	Enter approval by HICL or GPI-10 as listed.	13221		GPI-10 (1220002010)
FOSDENOPTERIN HYDROBROMIDE	Enter approval by HICL or GPI-10 as listed	47158		GPI-10 (3090643020)
GARETOSMAB-GRTS (PASATRU)	Enter approval by HICL or GPI-10 as listed	51491		GPI-10 (7588102000)
MILRINONE LACTATE (HICL 06549), MILRINONE LACTATE/D5W (HICL 09744)	Enter multiple approvals by HICL and GPID or GPI-10 as listed.	06549	5320	GPI-10 (3135005010, 3135005011)
OLICERIDINE FUMARATE (OLINVYK)	Enter approval by GPID or GPI-14 as listed.		48499	GPI-14 (65100070202040)
PEGLOTICASE (KRYSTEXXA)	Enter approval by HICL or GPI-10 as listed.	37154		GPI-10 (6800005000)
POTASSIUM CHLORIDE	Enter multiple approvals by GPID or GPI-14 as listed.		3281 3282 3283 3284 3342 3350 41321 41331	GPI-14 (79700030002050, 79700030002060, 79700030002005, 79700030002075, 79700030002055, 79700030002070)
POTASSIUM CHLORIDE IN 0.9%NACL	Enter multiple approvals by GPID or GPI-14 as listed.		56590 56591	GPI-14 (79992002102020, 79992002102030)
POTASSIUM CHLORIDE/D5W	Enter approval by HICL or GPI-10 as listed.	14775		GPI-10 (7999300210)
POTASSIUM CHLORIDE/D5W-0.45NACL	Enter multiple approvals by HICL or GPI-14 as listed.	14778		GPI-14 (79993003102015, 79993003102025,

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				79993003102038, 79993003102050)
POTASSIUM PHOSPHATE	Enter approval by HICL or GPI-10 as listed.	00551		GPI-10 (7960001005)
POTASSIUM PHOSPHATE-0.9% NACL	Enter approval by HICL or GPI-10 as listed.	37356		GPI-10 (7960001010)
REMDESIVIR (VEKLURY)	Enter approval by HICL or GPI-10 as listed.	46410		GPI-10 (1270008000)
TEMSIROLIMUS (TORISEL)	Enter approval by HICL or GPI-10 as listed.	34870		GPI-10 (2153257000)
TREOSULFAN (GRAFAPEX)	Enter approval by GPI-10 as listed.			GPI-10 (2110006000)
VINBLASTINE SULFATE	Enter approval by HICL or GPI-10 as listed.	03912		GPI-10 (2150003010)
VINCRISTINE SULFATE (VINCASAR PFS)	Enter approval by GPID or GPI-10 as listed.		97630	GPI-10 (2150002010)
VERTEPORFIN (VISUDYNE)	Enter approval by HICL or GPI-10 as listed.	21150		GPI-10 (8670006500)

RATIONALE

The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs administered by an implantable pump are covered under Part B. Drugs administered via an external pump are covered under Part B if they are included under the local coverage policy of the applicable Medicare coverage policies (National and/or Local Coverage Policies). Drugs administered via an external pump that are not included under the applicable Medicare coverage policies are covered under Part D. A CMS website to assist with National and Local Coverage Determination for B versus D review is http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx

REFERENCES

Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed June 17, 2025].

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INFUSIBLE DRUG BVD DETERMINATION (PART D)

For Part D use only:

INFUSIBLE DRUG BVD DETERMINATION (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	PART D DOES NOT COVER INFUSIBLE DRUGS USED VIA 1) AN IMPLANTABLE PUMP OR 2) EXTERNAL PUMP AND THE PUMP IS COVERED BY MEDICARE
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 08/05
Effective: 09/05/26 Client Approval: 09/26 DMC Approval: 09/01/26

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INHALED INSULIN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INSULIN REGULAR, HUMAN	AFREZZA	00768		GPI-10 (2710401000)	ROUTE = INHALATION

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient meet **ONE** of the following criteria?
   - The patient has chronic lung disease (such as asthma or chronic obstructive pulmonary disease)
   - The patient has lung cancer
   - The patient has diabetic ketoacidosis
   - The patient smokes or has quit smoking within the past 6 months

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of type 1 diabetes mellitus (ICD-10 Group E10) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - A baseline spirometry has been performed to measure FEV1
   - The patient is concurrently using a long-acting insulin (e.g., Lantus, Tresiba, Toujeo, Basaglar)
   - The patient had a trial of or contraindication to ONE of the following preferred rapid-acting insulins: Novolog, Fiasp

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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INHALED INSULIN (PART D)

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of type 2 diabetes mellitus (ICD-10 Groups E08, E09, E11, E13) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - A baseline spirometry has been performed to measure FEV1

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient meet **ONE** of the following criteria?
   - The patient had a trial of or contraindication to ONE of the following preferred rapid-acting insulins: Novolog, Fiasp
   - The prescriber has indicated that the patient is physically unable to or unwilling to administer injectable insulin

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INHALED INSULIN (Afrezza)** requires the following rule(s) be met for approval:
   A. You have type 1 or type 2 diabetes mellitus (disorders with high blood sugar)
   B. You are 6 years of age or older
   C. You have a baseline spirometry (test to measure how well your lungs work) to measure FEV1 (forced expiratory volume: amount of air exhaled in one second)
   D. You do not have chronic lung disease (a type of long-term lung disease), lung cancer, or diabetic ketoacidosis (condition where body breaks down fat too fast)
   E. You do not currently smoke or did not quit smoking within the past 6 months
   F. If you have type 1 diabetes mellitus, approval also requires:
      1. You are using a long-acting insulin (such as Lantus, Tresiba, Toujeo, Basaglar) with Afrezza
      2. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred rapid-acting insulins: Novolog, Fiasp

   (Initial denial text continued on next page)

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INHALED INSULIN (PART D)

INITIAL CRITERIA (CONTINUED)

G. If you have type 2 diabetes mellitus, approval also requires ONE of the following:
1. You have tried or have a contraindication to (harmful for you to use) one of the following preferred rapid-acting insulins: Novolog, Fiasp
2. Your prescriber indicated that you are physically unable to or unwilling to administer injectable insulin

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INHALED INSULIN (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of type 1 diabetes mellitus (ICD-10 Group E10) **AND** meet the following criterion?
   - The patient is currently on a long-acting insulin (e.g., Lantus, Tresiba, Toujeo, Basaglar)

   If yes, continue to #3.
   If no, continue to #2.

2. Does the patient have a diagnosis of type 2 diabetes mellitus (ICD-10 Groups E08, E09, E11, E13)?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

3. Did the patient have a follow-up spirometry to measure FEV1 after 6 months of treatment and annually thereafter?

   If yes, continue to #4.
   If no, **approve for 1 month by HICL or GPI-10 (to allow for follow-up spirometry evaluation).**
   APPROVAL TEXT: Renewal requires a follow-up spirometry after 6 months of treatment and annually thereafter.
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

4. Has the patient's FEV1 declined 20 percent or more from baseline?

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

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INHALED INSULIN (PART D)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **INHALED INSULIN (Afrezza)** requires the following rule(s) be met for renewal:

A. You have type 1 or type 2 diabetes mellitus (disorders with high blood sugar)
B. You had a follow-up spirometry (test to measure how well your lungs work) to measure FEV1 (forced expiratory volume in 1 second) after 6 months of treatment and annually thereafter
C. Your FEV1 has not declined 20 percent or more from baseline
D. If you have type 1 diabetes mellitus, approval also requires:
   1. You are currently using a long-acting insulin (such as Lantus, Tresiba, Toujeo, Basaglar)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Afrezza.

REFERENCES

Afrezza [Prescribing Information]. Danbury, CT: Mannkind Corporation; May 2026.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INHALED INSULIN (PART D)

For Part D use only:

INHALED INSULIN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	TYPE 1 AND TYPE 2 DIABETES MELLITUS (DM): INITIAL: BASELINE SPIROMETRY TO MEASURE FEV1.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: TYPE 1 DM, TYPE 2 DM: 1) DOES NOT HAVE CHRONIC LUNG DISEASE (E,G., ASTHMA, CHRONIC OBSTRUCTIVE PULMONARY DISEASE), 2) DOES NOT HAVE LUNG CANCER, 3) DOES NOT HAVE DIABETIC KETOACIDOSIS, OR 4) DOES NOT SMOKE OR DID NOT QUIT SMOKING WITHIN THE PAST 6 MONTHS. TYPE 1 DM: 1) CONCURRENT USE OF LONG ACTING INSULIN, AND 2) TRIAL OF OR CONTRAINDICATION TO ONE PREFERRED RAPID ACTING INSULIN: NOVOLOG OR FIASP. TYPE 2 DM: 1) TRIAL OF OR CONTRAINDICATION TO ONE PREFERRED RAPID ACTING INSULIN: NOVOLOG OR FIASP, OR 2) PRESCRIBER INDICATED PATIENT IS PHYSICALLY UNABLE TO OR UNWILLING TO ADMINISTER INJECTABLE INSULIN. RENEWAL: TYPE 1 DM: CURRENTLY USING A LONG-ACTING INSULIN. TYPE 1 DM, TYPE 2 DM: 1) FOLLOW UP SPIROMETRY TO MEASURE FEV1 AFTER 6 MONTHS OF TREATMENT AND ANNUALLY THEREAFTER, AND 2) FEV1 HAS NOT DECLINED 20% OR MORE FROM BASELINE. IF FOLLOW UP SPIROMETRY TO MEASURE FEV1 WAS NOT PERFORMED, ONLY APPROVE FOR 1 MONTH TO ALLOW TIME FOR FOLLOW UP.

Created: 02/15
Effective: 06/24/26 Client Approval: 06/26 DMC Approval: 06/16/26

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INOTERSEN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INOTERSEN SODIUM	TEGSEDI	45353		GPI-10 (6270104010)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR) with polyneuropathy (ICD-10 E85.1) and meet **ALL** the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist, cardiologist, physician at an amyloidosis treatment center, or medical geneticist
   - The patient is ambulatory (i.e., familial amyloid polyneuropathy [FAP] stage 1 - 2, OR polyneuropathy disability [PND] stage I - IIIb polyneuropathy)
   - Tegsedi will NOT be used concurrently with other hATTR-PN agents (e.g., Wainua [eplontersen], Amvuttra [vutrisiran], Onpattro [patisiran])

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the hATTR diagnosis confirmed by **ONE** of the following?
   - Biopsy of tissue/organ to confirm amyloid presence AND chemical typing to confirm presence of TTR (transthyretin) protein
   - DNA genetic sequencing to confirm hATTR mutation

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INOTERSEN (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **INOTERSEN (Tegsedi)** requires the following rule(s) be met for approval:

A. You have hereditary transthyretin-mediated amyloidosis (hATTR: a rare genetic disorder) with polyneuropathy (widespread nerve pain/damage)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a neurologist (nerve doctor), cardiologist (heart doctor), physician at an amyloidosis treatment center, or medical geneticist (doctor who treats gene disorders)
D. You are ambulatory (able to walk) (you have familial amyloid polyneuropathy [FAP: a tool used to evaluate disease severity] stage 1 to 2, OR polyneuropathy disability [PND: a tool used to evaluate disease severity] stage I to IIIb polyneuropathy)
E. You will NOT use Tegsedi concurrently (at the same time) with other Hattr-PN medications (such as Wainua [eplontersen], Amvuttra [vutrisiran], Onpattro [patisiran])
F. Your diagnosis is confirmed by ONE of the following:
    1. Biopsy (removal of cells from the body for examination) of tissue/organ to confirm amyloid (type of abnormal protein) presence AND chemical typing to confirm presence of TTR (transthyretin) protein
    2. DNA (deoxyribonucleic acid) genetic sequencing (type of lab test) to confirm hATTR mutation (type of abnormal gene)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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INOTERSEN (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR) with polyneuropathy (ICD-10 E85.1) and meet **ALL** of the following criteria?
   - The patient has not progressed to familial amyloid polyneuropathy (FAP) stage 3 or polyneuropathy disability (PND) stage 4 polyneuropathy, as evidenced by functional decline (e.g., wheelchair-bound, bedridden)
   - Tegsedi will NOT be used concurrently with other hATTR-PN agents (e.g., Wainua [eplontersen], Amvuttra [vutrisiran], Onpattro [patisiran])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INOTERSEN (Tegsedi)** requires the following rule(s) be met for renewal:
   A. You have hereditary transthyretin-mediated amyloidosis (hATTR: a rare genetic disorder) with polyneuropathy (widespread nerve pain/damage)
   B. You have not progressed to familial amyloid polyneuropathy (FAP: a tool used to evaluate disease severity) stage 3 or polyneuropathy disability (PND: a tool used to evaluate disease severity) stage 4 polyneuropathy, as shown by functional decline (such as being wheelchair-bound, being bedridden)
   C. You will NOT use Tegsedi concurrently (at the same time) with other hATTR-PN medications (such as Wainua [eplontersen], Amvuttra [vutrisiran], Onpattro [patisiran])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tegsedi.

REFERENCES

Tegsedi [Prescribing Information]. Waltham, MA: Sobi, Inc.; January 2024.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INOTERSEN (PART D)

For Part D use only:

INOTERSEN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	HEREDITARY TRANSTHYRETIN-MEDIATED AMYLOIDOSIS WITH POLYNEUROPATHY (HATTR-PN): INITIAL: DIAGNOSIS CONFIRMED BY: 1) BIOPSY OF TISSUE/ORGAN TO CONFIRM AMYLOID PRESENCE AND CHEMICAL TYPING TO CONFIRM PRESENCE OF TTR PROTEIN, OR 2) DNA GENETIC SEQUENCING TO CONFIRM HATTR MUTATION.
Age Restrictions	N/A
Prescriber Restrictions	HATTR-PN: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST, CARDIOLOGIST, PHYSICIAN AT AN AMYLOIDOSIS TREATMENT CENTER, OR MEDICAL GENETICIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	HATTR-PN: INITIAL: 1) FAMILIAL AMYLOID POLYNEUROPATHY (FAP) STAGE 1 OR 2, OR UP TO POLYNEUROPATHY DISABILITY (PND) STAGE IIIB POLYNEUROPATHY, AND 2) NO CONCURRENT USE WITH OTHER HATTR-PN AGENTS. RENEWAL: 1) NOT PROGRESSED TO FAP STAGE 3 OR PND STAGE 4 POLYNEUROPATHY AS EVIDENCED BY FUNCTIONAL DECLINE, AND 2) NO CONCURRENT USE WITH OTHER HATTR-PN AGENTS.

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25 Created: 10/18
Commercial Effective: N/A Client Approval: 06/24 P&T Approval: 04/24

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INOTUZUMAB OZOGAMICIN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INOTUZUMAB OZOGAMICIN	BESPONSA	44438		GPI-10 (2135264020)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory CD22-positive B-cell precursor acute lymphoblastic leukemia (ALL) (ICD-10 Group C91.0) and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - The patient has NOT previously received 6 cycles of Besponsa treatment

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INOTUZUMAB OZOGAMICIN (Besponsa)** requires the following rule(s) be met for approval:
   A. You have relapsed or refractory CD22-positive B-cell precursor acute lymphoblastic leukemia (ALL: a type of blood cancer that has returned or did not respond to treatment)
   B. You are 1 year of age or older
   C. You have not previously received 6 cycles of Besponsa treatment

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INOTUZUMAB OZOGAMICIN (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Besponsa.

REFERENCES
Besponsa [Prescribing Information]. Philadelphia, PA: Wyeth Pharmaceuticals, Inc.; March 2024.

For Part D use only:

INOTUZUMAB OZOGAMICIN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	RELAPSED OR REFRACTORY B-CELL PRECURSOR ACUTE LYMPHOBLASTIC LEUKEMIA: HAS NOT PREVIOUSLY RECEIVED 6 CYCLES OF BESPONSA TREATMENT.

Created: 08/17
Effective: 01/01/26 Client Approval: 01/26 P&T Approval: 04/24

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INSULIN SUPPLIES PAYMENT DETERMINATION (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ALCOHOL PADS, VARIOUS	ALCOHOL PADS, VARIOUS	04266		GPI-10 (9770304000, 9097150140)	
GAUZE BANDAGE, VARIOUS	GAUZE BANDAGE, VARIOUS	04348		GPI-10 (9730300000)	
PEN NEEDLE, VARIOUS	PEN NEEDLE, VARIOUS	08966 34833 39104 42217 38116		GPI-10 (9705105014)	
SYRINGE-NEEDLE, VARIOUS	INSULIN SYRINGE, VARIOUS			GPI-10 (9705103090)	STC = 0541

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
N/A	N/A	Yes	N/A	N/A	Yes	N/A	N/A	Yes	N/A	N/A	Yes

NOTE: This is an administrative Step Override to determine "Part D" or "Non-Part D" coverage.

PAYMENT DETERMINATION CRITERIA

1. Is the patient concurrently on insulin?

   If yes, **approve by HICL for lifetime. Enter an override for Insulin Supply and Step Therapy restriction.**

   If no, do not approve.

   CSR Note:
   Please advise pharmacy that they can enter a DUR override code if the patient is concurrently on insulin.

   RPH NOTE:
   MEMBER NOTIFICATION LANGUAGE/DENIAL TEXT: The guideline named **INSULIN SUPPLIES PAYMENT DETERMINATION** requires that you are concurrently (at the same time) on insulin.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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INSULIN SUPPLIES PAYMENT DETERMINATION (PART D)

RATIONALE

To ensure appropriate use of insulin medical supplies. These insulin supplies would be covered under Medicare Part D only if associated with the injection of insulin. They do not meet the definition of a Medicare Part D drug and are not payable under the Part D benefit if they are used for purposes other than the delivery of insulin to the body.

REFERENCES

Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/medicare/coverage/prescription-drug-coverage-contracting/prescription-drug-benefit-manual. [Accessed August 2, 2024].

For Part D use only:

INSULIN SUPPLIES PAYMENT DETERMINATION (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	ONLY COVERED UNDER PART D WHEN USED CONCURRENTLY WITH INSULIN.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	LIFETIME
Other Criteria	N/A

Created: 11/24
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 06/24

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INTERFERON FOR MS-AVONEX (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INTERFERON BETA-1A	AVONEX, AVONEX PEN	11253		GPI-14 (6240306045F530, 6240306045F830)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), to include clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease, **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-14 for all formulations.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INTERFERONS FOR MS - Avonex** requires the following rule(s) be met for approval:
   A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease returns and goes away), or active secondary progressive disease (advanced disease)
   B. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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INTERFERON FOR MS-AVONEX (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Avonex.

REFERENCES
Avonex [Prescribing Information]. Cambridge, MA: Biogen Inc.; July 2023.

For Part D use only:

INTERFERON FOR MS-AVONEX (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25 Created: 10/22
Commercial Effective: N/A Client Approval: 06/24 P&T Approval: 05/21

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INTERFERON FOR MS-BETASERON (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INTERFERON BETA-1B	BETASERON	08537		GPI-10 (6240306050)	BRAND = BETASERON

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), to include clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease, **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve all NDCs or GPI-14 of Betaseron for 12 months.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INTERFERON FOR MS - BETASERON** requires the following rule(s) be met for approval:
   A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease returns and goes away), or active secondary progressive disease (advanced disease)
   B. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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INTERFERON FOR MS-BETASERON (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Betaseron.

REFERENCES

Betaseron [Prescribing Information]. Whippany, NJ: Bayer Healthcare Pharmaceuticals Inc.; July 2023.

For Part D use only:

INTERFERON FOR MS-BETASERON (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 10/22
Client Approval: 06/24
P&T Approval: 05/21

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INTERFERON FOR MS-EXTAVIA (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INTERFERON BETA-1B	EXTAVIA	08537		GPI-10 (6240306050)	BRAND = EXTAVIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), to include clinically isolated syndrome, relapsing remitting disease, or active secondary progressive disese, and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Aubagio (teriflunomide), Avonex (interferon beta-1a), Plegridy (peginterferon beta-1a), Tecfidera (dimethyl fumarate), Copaxone/Glatopa (glatiramer), Betaseron (interferon beta-1b), Vumerity (diroximel fumarate), Kesimpta (ofatumumab)

   If yes, **approve all NDCs of Extavia for 12 months.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INTERFERON FOR MS - EXTAVIA** requires the following rule(s) be met for approval:
   A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease returns and goes away), or active secondary progressive disease (advanced disease)
   B. You are 18 years of age or older
   (Denial text continued on next page)

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INTERFERON FOR MS-EXTAVIA (PART D)

GUIDELINES FOR USE (CONTINUED)

C. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Aubagio (teriflunomide), Avonex (interferon beta-1a), Plegridy (peginterferon beta-1a), Tecfidera (dimethyl fumarate), Copaxone/Glatopa (glatiramer), Betaseron (interferon beta-1b), Vumerity (diroximel fumarate), Kesimpta (ofatumumab)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Extavia.

REFERENCES

Extavia [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2023.

INTERFERON FOR MS-EXTAVIA (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	RELAPSING FORM OF MULTIPLE SCLEROSIS (MS): TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: AUBAGIO, AVONEX, PLEGRIDY, TECFIDERA, COPAXONE/GLATOPA, BETASERON, VUMERITY, KESIMPTA.

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 10/22
Client Approval: 06/24
P&T Approval: 05/21

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ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INTERFERON FOR MS-PLEGRIDY (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGINTERFERON BETA-1A	PLEGRIDY, PLEGRIDY PEN	41331		GPI-10 (6240307530)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), to include clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INTERFERON FOR MS - PLEGRIDY** requires the following rule(s) be met for approval:
   A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease returns and goes away), or active secondary progressive disease (advanced disease)
   B. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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INTERFERON FOR MS-PLEGRIDY (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Plegridy.

REFERENCES

Plegridy [Prescribing Information]. Cambridge, MA: Biogen Inc.; July 2023.

For Part D use only:

INTERFERON FOR MS-PLEGRIDY (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
No	Yes	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 10/22
Client Approval: 06/24
P&T Approval: 05/21

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INTERFERON FOR MS-REBIF (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INTERFERON BETA-1A/ALBUMIN	REBIF, REBIF REBIDOSE	23353		GPI-10 (6240306045)	MEDI-SPAN: BRAND = REBIF, REBIF REBIDOSE, REBIF TITRATION PACK, REBIF REBIDOSE TITRATIONPACK

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), to include clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease, and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Aubagio (teriflunomide), Avonex (interferon beta-1a), Plegridy (peginterferon beta-1a), Tecfidera (dimethyl fumarate), Copaxone/Glatopa (glatiramer), Betaseron (interferon beta-1b), Vumerity (diroximel fumarate), Kesimpta (ofatumumab)

   If yes, **approve for 12 months by HICL or GPI-14 for all strengths.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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INTERFERON FOR MS-REBIF (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **INTERFERON FOR MS - REBIF** requires the following rule(s) be met for approval:

A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease returns and goes away), or active secondary progressive disease (advanced disease)
B. You are 18 years of age or older
C. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Aubagio (teriflunomide), Avonex (interferon beta-1a), Plegridy (peginterferon beta-1a), Tecfidera (dimethyl fumarate), Copaxone/Glatopa (glatiramer), Betaseron (interferon beta-1b), Vumerity (diroximel fumarate), Kesimpta (ofatumumab)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rebif.

REFERENCES

Rebif [Prescribing Information]. Rockland, MA: EMD Serono, Inc.; July 2023.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INTERFERON FOR MS-REBIF (PART D)

For Part D use only:

INTERFERON FOR MS-REBIF (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	RELAPSING FORM OF MULTIPLE SCLEROSIS (MS): TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: AUBAGIO, AVONEX, PLEGRIDY, TECFIDERA, COPAXONE/GLATOPA, BETASERON, VUMERITY, KESIMPTA.

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25 Created: 10/22
Commercial Effective: N/A Client Approval: 06/24 P&T Approval: 05/21

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INTERFERON GAMMA-1B (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INTERFERON GAMMA-1B, RECOMB.	ACTIMMUNE	06068		GPI-10 (2170006070)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of chronic granulomatous disease (CGD) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with a hematologist, infectious disease specialist, or immunologist

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of severe malignant osteopetrosis (SMO) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with an endocrinologist or hematologist

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INTERFERON GAMMA-1B (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **INTERFERON GAMMA-1B, RECOMB (Actimmune)** requires the following rules be met for approval:

A. You have ONE of the following:
   1. Chronic granulomatous disease (CGD: a type of immune disorder)
   2. Severe malignant osteopetrosis (SMO: a type of bone condition)

B. If you have chronic granulomatous disease, approval also requires:
   1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor), infectious disease specialist (a doctor that specializes in treating infections), or immunologist (a type of immune system doctor)

C. If you have severe malignant osteopetrosis, approval also requires:
   1. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor) or hematologist (a type of blood doctor)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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INTERFERON GAMMA-1B (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of chronic granulomatous disease (CGD) or severe malignant osteopetrosis (SMO) and meet **ALL** of the following criteria?
   - The patient has demonstrated clinical benefit compared to baseline (e.g., reduction in frequency and severity of serious infections)
   - The patient has not received hematopoietic cell transplantation

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INTERFERON GAMMA-1B (Actimmune)** requires the following rules be met for renewal:
   A. You have ONE of the following:
      1. Chronic granulomatous disease (CGD: a type of immune disorder)
      2. Severe malignant osteopetrosis (SMO: a type of bone condition)
   B. You have shown clinical benefit compared to baseline (such as reduction in frequency and severity of serious infections)
   C. You have not received hematopoietic cell transplantation (bone marrow transplant)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Actimmune.

REFERENCES

Actimmune [Prescribing Information] Lake Forest, IL: Horizon Therapeutics USA, Inc., January 2020.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INTERFERON GAMMA-1B (PART D)

For Part D use only:

INTERFERON GAMMA-1B (PART D)	
Covered uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: CHRONIC GRANULOMATOUS DISEASE (CGD): PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST, INFECTIOUS DISEASE SPECIALIST, OR IMMUNOLOGIST. SEVERE MALIGNANT OSTEOPETROSIS (SMO): PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST OR HEMATOLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS
Other Criteria	RENEWAL: CGD, SMO: 1) DEMONSTRATED CLINICAL BENEFIT COMPARED TO BASELINE, AND 2) HAS NOT RECEIVED HEMATOPOIETIC CELL TRANSPLANTATION.

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25 Created: 10/20
Commercial Effective: N/A Client Approval: 11/24 P&T Approval: 01/20

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IPILIMUMAB BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IPILIMUMAB	YERVOY	37503		GPI-10 (2135523200)	

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit).**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #5.

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IPILIMUMAB BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

If yes, **Refer to plan. (The health plan makes the final payment determination decision).**

- **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enterany override).**
- **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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IPILIMUMAB BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of unresectable or metastatic melanoma (ICD-10 Group C43) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Yervoy will be used as a single agent OR in combination with Opdivo (nivolumab)

   If yes, **approve for 4 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of cutaneous melanoma (ICD-10 Group C43) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Yervoy will be used for adjuvant treatment
   - There is pathologic involvement of regional lymph nodes of more than 1mm
   - The patient has undergone complete resection, including total lymphadenectomy

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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IPILIMUMAB BvD (PART D)

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC) (ICD-10 Groups C64, C65) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Yervoy will be used in combination with Opdivo (nivolumab)
   - The patient has intermediate or poor risk disease

   If yes, **approve for 3 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

4. Does the patient have a diagnosis of unresectable or metastatic colorectal cancer (ICD-10 C19) and meet **ALL** the following criteria?
   - The patient is 12 years of age or older
   - Yervoy will be used in combination with Opdivo (nivolumab)
   - The patient's cancer is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)

   If yes, **approve for 3 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Does the patient have a diagnosis of unresectable or metastatic hepatocellular carcinoma (ICD-10 C22.0) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #6.
   If no, continue to #7.

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IPILIMUMAB BvD (PART D)

INITIAL CRITERIA (CONTINUED)

6. Does the patient meet **ONE** of the following criteria?
   - Yervoy will be used in combination with Opdivo (nivolumab) as first-line treatment
   - Yervoy will be used in combination with Opdivo (nivolumab), AND the patient has previously been treated with Nexavar (sorafenib)

   If yes, **approve for 3 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

7. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's tumors express PD-L1 (at least 1%), as determined by an FDA-approved test
   - The tumor does NOT have EGFR or ALK genomic tumor aberrations
   - Yervoy will be used in combination with Opdivo (nivolumab)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #8.

8. Does the patient have a diagnosis of metastatic or recurrent non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The tumor does NOT have EGFR or ALK genomic tumor aberrations
   - Yervoy will be used in combination with Opdivo (nivolumab) and 2 cycles of platinum-doublet chemotherapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #9.

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IPILIMUMAB BvD (PART D)

INITIAL CRITERIA (CONTINUED)

9. Does the patient have a diagnosis of unresectable malignant pleural mesothelioma (ICD-10 C45.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Yervoy will be used in combination with Opdivo (nivolumab)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #10.

10. Does the patient have a diagnosis of unresectable advanced or metastatic esophageal squamous cell carcinoma (ESCC) (ICD-10 Group C15) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Yervoy will be used in combination with Opdivo (nivolumab)

    If yes, **approve for 12 months by HICL or GPI-10.**
    APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

    If no, do not approve.
    DENIAL TEXT: See the initial denial text at the end of the guideline.

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IPILIMUMAB BvD (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **IPILIMUMAB (Yervoy)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Unresectable or metastatic melanoma (a type of skin cancer that cannot be completely removed by surgery or has spread to other parts of the body)
   2. Cutaneous melanoma (a type of skin cancer)
   3. Advanced renal cell carcinoma (a type of kidney cancer)
   4. Unresectable or metastatic colorectal cancer (type of digestive tract cancer that cannot be completely removed by surgery or has spread to other parts of the body)
   5. Unresectable or metastatic hepatocellular carcinoma (a type of liver cancer that cannot be completely removed by surgery or has spread to other parts of the body)
   6. Metastatic or recurrent non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of the body or has returned)
   7. Unresectable (cannot be removed by surgery) malignant pleural mesothelioma (a tumor of the tissue that has spread and lines the lungs, stomach, heart, and other organs)
   8. Unresectable advanced or metastatic esophageal squamous cell carcinoma (ESCC: a type of digestive cancer that cannot be removed by surgery or has spread to other parts of the body)

B. If you have unresectable or metastatic melanoma, approval also requires:
   1. You are 12 years of age or older
   2. Yervoy will be used as a single medication OR in combination with Opdivo (nivolumab)

C. If you have cutaneous melanoma, approval also requires:
   1. You are 18 years of age or older
   2. Yervoy will be used for adjuvant (add-on) treatment
   3. There is pathologic (disease) involvement of regional lymph nodes of more than 1mm
   4. You have undergone complete resection (surgery to completely remove cancer), including total lymphadenectomy (lymph glands are surgically removed)

D. If you have advanced renal cell carcinoma, approval also requires:
   1. You are 18 years of age or older
   2. Yervoy will be used in combination with Opdivo (nivolumab)
   3. You have intermediate or poor risk disease

E. If you have unresectable or metastatic colorectal cancer, approval also requires:
   1. You are 12 years of age or older
   2. Yervoy will be used in combination with Opdivo (nivolumab)
   3. Your cancer is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) (types of genetic abnormalities)

(Initial denial text continued on next page)

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IPILIMUMAB BvD (PART D)

INITIAL CRITERIA (CONTINUED)

F. If you have unresectable or metastatic hepatocellular carcinoma, approval also requires:
1. You are 18 years of age or older
2. You meet ONE of the following:
   a. Yervoy will be used in combination with Opdivo (nivolumab) as first-line treatment
   b. Yervoy will be used in combination with Opdivo (nivolumab), AND you have previously been treated with Nexavar (sorafenib)

G. If you have metastatic or recurrent non-small cell lung cancer, approval also requires:
1. You are 18 years of age or older
2. Your tumor does NOT have epidermal growth factor receptor (EGFR: type of protein) or anaplastic lymphoma kinase (ALK: type of protein) genomic tumor aberrations (types of gene mutations)
3. You meet ONE of the following:
   a. **For metastatic NSCLC,** Yervoy will be used in combination with Opdivo (nivolumab) AND your tumor expresses programmed death-ligand 1 (PD-L1: type of protein) (at least 1%), as determined by an FDA (Food and Drug Administration)-approved test
   b. **For metastatic or recurrent NSCLC,** Yervoy will be used in combination with Opdivo (nivolumab) and 2 cycles of platinum-doublet chemotherapy (type of cancer medication)

H. If you have unresectable malignant pleural mesothelioma, approval also requires:
1. You are 18 years of age or older
2. Yervoy will be used in combination with Opdivo (nivolumab)

I. If you have unresectable advanced or metastatic esophageal squamous cell carcinoma, approval also requires:
1. You are 18 years of age or older
2. Yervoy will be used in combination with Opdivo (nivolumab)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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IPILIMUMAB BvD (PART D)

RENEWAL CRITERIA

NOTE: For the diagnoses of unresectable or metastatic melanoma, advanced renal cell carcinoma, unresectable or metastatic colorectal cancer, unresectable or metastatic hepatocellular carcinoma, metastatic/recurrent non-small cell lung cancer (NSCLC), unresectable malignant pleural mesothelioma, or unresectable advanced or metastatic esophageal squamous cell carcinoma (ESCC), please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of cutaneous melanoma (ICD-10 Group C43) and meet **ALL** of the following criteria?
   - Yervoy will be used for adjuvant treatment
   - There is NO evidence of disease recurrence (defined as the appearance of one or more new melanoma lesions: local, regional or distant metastasis)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **IPILIMUMAB (Yervoy)** requires the following rule(s) be met for renewal:
   A. You have cutaneous melanoma (a type of skin cancer)
   B. Yervoy will be used for adjuvant (add-on) treatment
   C. You do NOT have evidence of disease recurrence (defined as the appearance of one or more new melanoma lesions: local, regional or distant metastasis [cancer has spread from original site])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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IPILIMUMAB BvD (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Yervoy. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Yervoy [Prescribing Information]. Princeton, NJ: Bristol-Myers Squibb Company; April 2025.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed April 21, 2025].

For Part D use only:

IPILIMUMAB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	INITIAL: UNRESECT/MET MEL: 4MO, RCC/CRC/HCC: 3MO, ALL OTHERS: 12MO. INITIAL/RENEWAL: CUTAN MEL: 6MO
Other Criteria	RENEWAL: ADJUVANT CUTANEOUS MELANOMA: NO EVIDENCE OF DISEASE RECURRENCE (DEFINED AS THE APPEARANCE OF ONE OR MORE NEW MELANOMA LESIONS: LOCAL, REGIONAL OR DISTANT METASTASIS).

Created: 11/07
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 04/23

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IPTACOPAN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IPTACOPAN HCL	FABHALTA	49336		GPI-10 (8580753520)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) (ICD-10 D59.5) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a hematologist
   - The patient's diagnosis is confirmed by flow cytometry that shows PNH granulocyte clone size of at least 10% AND at least 2 different GPI-protein deficiencies (e.g., CD55, CD59) on at least 2 cell lineages (e.g., erythrocytes, granulocytes)
   - Fabhalta will NOT be used concurrently with a C5 complement inhibitor (e.g., Soliris [eculizumab], Ultomiris [ravulizumab-cwvz], Piasky [crovalimab-akkz]), C3 complement inhibitor (e.g., Empaveli [pegcetacoplan]), or factor D inhibitor (e.g., Voydeya [danicopan])

   If yes, **approve for 4 months by HICL or GPI-10.**
   If no, continue to #2.

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IPTACOPAN (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of primary immunoglobulin A nephropathy (IgAN) (ICD-10 Group N02.B) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is at risk of rapid disease progression (e.g., urine protein-to-creatinine ratio [UPCR] of at least 1.5 g/g)
   - Therapy is prescribed by or in consultation with a nephrologist
   - The patient's diagnosis is confirmed by renal biopsy
   - The patient has an eGFR of at least 20 mL/min/1.73 m(2)
   - The patient has tried an ACE inhibitor (e.g., benazepril, lisinopril) or an ARB (e.g., losartan, valsartan) for at least three months at a maximum tolerated dose and will continue use, OR has a contraindication to both drug classes

   If yes, **approve for 9 months by HICL or GPI-10.**
   If no, continue to #3.

3. Does the patient have a diagnosis of complement 3 glomerulopathy (C3G) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a nephrologist
   - The patient's diagnosis is confirmed by renal biopsy
   - The patient has an eGFR of at least 30 mL/min/1.73 m(2)
   - The patient has a urine-protein creatine ratio (UPCR) of at least 1 g/g
   - The patient has tried an ACE inhibitor (e.g., benazepril, lisinopril) or an ARB (e.g., losartan, valsartan) for at least three months at a maximum tolerated dose and will continue use, OR has a contraindication to both drug classes
   - Fabhalta will NOT be used concurrently with another complement inhibitor (e.g., Empaveli [pegcetacoplan]) for the treatment of C3G

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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IPTACOPAN (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **IPTACOPAN (Fabhalta)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
   2. Primary immunoglobulin A nephropathy (IgAN: a type of kidney disease)
   3. Complement 3 glomerulopathy (C3G: a type of kidney disease)

B. If you have paroxysmal nocturnal hemoglobinuria, approval also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
   3. Your PNH diagnosis is confirmed by flow cytometry (a type of lab test) that shows ALL of the following:
      a. You have at least 2 different GPI-protein deficiencies (missing a certain type of protein, such as CD55, CD59) on at least 2 cell lineages (types of cells, such as erythrocytes [red blood cells], granulocytes [a type of white blood cell])
      b. PNH granulocyte clone size of at least 10%
   4. You will NOT use Fabhalta concurrently (at the same time) with a C5 complement inhibitor (such as Soliris [eculizumab], Ultomiris [ravulizumab-cwvz], Piasky [crovalimab-akkz]), C3 complement inhibitor (such as Empaveli [pegcetacoplan]), or factor D inhibitor (such as Voydeya [danicopan])

C. If you have primary immunoglobulin A nephropathy, approval also requires:
   1. You are 18 years of age or older
   2. You are at risk of rapid disease progression (such as a urine protein-to-creatinine ratio [UPCR: test that measures the amount of protein in urine] of at least 1.5 g/g)
   3. Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor)
   4. Your diagnosis is confirmed by a renal biopsy (removal of cells or tissue from the kidney for examination)
   5. You have an estimated glomerular filtration rate (eGFR: a tool for evaluating kidney function) of at least 20 mL/min/1.73 m(2)
   6. You have tried an angiotensin converting enzyme inhibitor (ACE-I: a type of medication used to protect kidneys such as benazepril, lisinopril) or an angiotensin receptor blocker (ARB: a type of medication used to protect kidneys such as losartan, valsartan) for at least three months at a maximum tolerated dose and will continue use, OR you have a contraindication to (harmful for you to use) both of these medication classes

(Initial denial text continued on next page)

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IPTACOPAN (PART D)

INITIAL CRITERIA (CONTINUED)

D. If you have complement 3 glomerulopathy, approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor)
3. Your diagnosis is confirmed by a renal biopsy (removal of cells or tissue from the kidney for examination)
4. You have an estimated glomerular filtration rate (eGFR: a tool for evaluating kidney function) of at least 30 mL/min/1.73 m(2)
5. You have a urine protein-to-creatinine ratio (UPCR: test that measures the amount of protein in urine) of at least 1 g/g
6. You have tried an angiotensin converting enzyme inhibitor (ACE-I: a type of medication used to protect kidneys such as benazepril, lisinopril) or an angiotensin receptor blocker (ARB: a type of medication used to protect kidneys such as losartan, valsartan) for at least three months at a maximum tolerated dose and will continue use, OR you have a contraindication to (harmful for you to use) both of these medication classes
7. You will NOT use Fabhalta concurrently (at the same time) with another complement inhibitor (such as Empaveli [pegcetacoplan]) for the treatment of complement 3 glomerulopathy (a type of kidney disease)

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IPTACOPAN (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) (ICD-10 D59.5) **AND** meet **ALL** of the following criteria?
   - The patient experienced clinical benefit while on Fabhalta (e.g., reduction in number of blood transfusions, improvement/stabilization of lactate dehydrogenase [LDH] and hemoglobin levels) compared to baseline
   - Fabhalta will NOT be used concurrently with a C5 complement inhibitor (e.g., Soliris [eculizumab], Ultomiris [ravulizumab-cwvz], Piasky [crovalimab-akkz]), C3 complement inhibitor (e.g., Empaveli [pegcetacoplan]), or factor D inhibitor (e.g., Voydeya [danicopan])

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of primary immunoglobulin A nephropathy (IgAN) (ICD-10 Group N02.B) **AND** meet the following criterion?
   - The patient has improved or stable kidney function compared to baseline OR has a reduction in proteinuria

   If yes, **approve for 9 months by HICL or GPI-10.**
   If no, continue to #3.

3. Does the patient have a diagnosis of complement 3 glomerulopathy (C3G) and meet **ALL** of the following criteria?
   - The patient has improved or stable kidney function compared to baseline OR has a reduction in proteinuria
   - Fabhalta will NOT be used concurrently with another complement inhibitor (e.g., Empaveli [pegcetacoplan]) for the treatment of C3G

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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IPTACOPAN (PART D)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **IPTACOPAN (Fabhalta)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
   2. Primary immunoglobulin A nephropathy (IgAN: a type of kidney disease)
   3. Complement 3 glomerulopathy (C3G: a type of kidney disease)

B. If you have paroxysmal nocturnal hemoglobinuria, renewal also requires:
   1. You have had clinical benefit while on Fabhalta (such as a reduction in the number of blood transfusions [adding blood to the body], improvement/stabilization of lactate dehydrogenase [LDH: a type of enzyme] and hemoglobin [type of protein in red blood cells] levels) compared to baseline (before treatment)
   2. You will NOT use Fabhalta concurrently (at the same time) with a C5 complement inhibitor (such as Soliris [eculizumab], Ultomiris [ravulizumab-cwvz], Piasky [crovalimab-akkz]), C3 complement inhibitor (such as Empaveli [pegcetacoplan]), or factor D inhibitor (such as Voydeya [danicopan])

C. If you have primary immunoglobulin A nephropathy, renewal also requires:
   1. You have improved or stable kidney function compared to baseline OR you have a reduction (decrease) in proteinuria (increased levels of protein in urine)

D. If you have complement 3 glomerulopathy, renewal also requires:
   1. You have improved or stable kidney function compared to baseline OR you have a reduction (decrease) in proteinuria (increased levels of protein in urine)
   2. You will NOT use Fabhalta concurrently (at the same time) with another complement inhibitor (such as Empaveli [pegcetacoplan]) for the treatment of complement 3 glomerulopathy (a type of kidney disease)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Fabhalta.

REFERENCES

Fabhalta [Prescribing Information]. East Hanover, NJ: Novartis Pharma Corp; March 2025.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IPTACOPAN (PART D)

For Part D use only:

IPTACOPAN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	INITIAL: PAROXYSMAL NOCTURNAL HEMOGLOBINURIA (PNH): DIAGNOSIS CONFIRMED VIA FLOW CYTOMETRY BY DEMONSTRATING: 1) AT LEAST TWO DIFFERENT GPI PROTEIN DEFICIENCIES ON AT LEAST TWO CELL LINEAGES, AND 2) PNH GRANULOCYTE CLONE SIZE OF AT LEAST 10 PERCENT. PRIMARY IMMUNOGLOBULIN A NEPHROPATHY (IGAN): 1) DIAGNOSIS CONFIRMED BY A RENAL BIOPSY, AND 2) EGFR OF AT LEAST 20 ML/MIN/1.73 M2. COMPLEMENT 3 GLOMERULOPATHY (C3G): 1) DIAGNOSIS CONFIRMED BY RENAL BIOPSY, 2) URINE-PROTEIN CREATINE RATIO (UPCR) OF AT LEAST 1 G/G, AND 3) EGFR OF AT LEAST 30 ML/MIN/1.73 M2.
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: PNH: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST. PRIMARY IGAN, C3G: PRESCRIBED BY OR IN CONSULTATION WITH A NEPHROLOGIST.
Coverage Duration	INITIAL/RENEWAL: PNH: 4 MOS/12 MOS. PRIMARY IGAN: 9 MOS/9 MOS. C3G: 6 MOS/12 MOS.
Other Criteria	INITIAL: PNH: NO CONCURRENT USE WITH C5 COMPLEMENT INHIBITOR, C3 COMPLEMENT INHIBITOR, OR FACTOR D INHIBITOR. PRIMARY IGAN: TRIAL AND CONTINUATION OF AN ACE INHIBITOR OR ARB AT MAXIMUM TOLERATED DOSE FOR AT LEAST 3 MONTHS OR CONTRAINDICATION TO BOTH CLASSES. C3G: 1) TRIAL AND CONTINUATION OF AN ACE INHIBITOR OR ARB AT MAXIMUM TOLERATED DOSE FOR AT LEAST 3 MONTHS OR CONTRAINDICATION TO BOTH CLASSES, AND 2) NO CONCURRENT USE WITH ANOTHER COMPLEMENT INHIBITOR FOR C3G. RENEWAL: PNH: 1) CLINICAL BENEFIT WHILE ON FABHALTA COMPARED TO BASELINE, AND 2) NO CONCURRENT USE WITH C5 COMPLEMENT INHIBITOR, C3 COMPLEMENT INHIBITOR, OR FACTOR D INHIBITOR. PRIMARY IGAN: IMPROVED OR STABLE KIDNEY FUNCTION COMPARED TO BASELINE OR REDUCTION IN PROTEINURIA. C3G: 1) IMPROVED OR STABLE KIDNEY FUNCTION COMPARED TO BASELINE OR REDUCTION IN PROTEINURIA, AND 2) NO CONCURRENT USE WITH ANOTHER COMPLEMENT INHIBITOR FOR C3G.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ISATUXIMAB-IRFC BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ISATUXIMAB-IRFC	SARCLISA	46389		GPI-10 (2135403320)	BRAND = SARCLISA

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #5.

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ISATUXIMAB-IRFC BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ISATUXIMAB-IRFC BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of multiple myeloma (ICD-10 Group C90.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Sarclisa will be used in combination with Pomalyst (pomalidomide) and dexamethasone
   - The patient has received at least two prior therapies including Revlimid (lenalidomide) and a proteasome inhibitor (e.g., Ninlaro [ixazomib], Kyprolis [carfilzomib])

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of relapsed or refractory multiple myeloma (ICD-10 Group C90.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Sarclisa will be used in combination with Kyprolis (carfilzomib) and dexamethasone
   - The patient has received one to three prior lines of therapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

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ISATUXIMAB-IRFC BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have newly diagnosed multiple myeloma (ICD-10 Group C90.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Sarclisa will be used in combination with Velcade (bortezomib), Revlimid (lenalidomide) and dexamethasone
   - The patient is not eligible for autologous stem cell transplant (ASCT)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ISATUXIMAB-IRFC (Sarclisa)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Multiple myeloma (type of blood cancer)
      2. Relapsed or refractory multiple myeloma (type of blood cancer that has returned or no longer responds to treatment)

   B. If you have multiple myeloma, approval also requires:
      1. You are 18 years of age or older
      2. Sarclisa will be used in combination with Pomalyst (pomalidomide) and dexamethasone
      3. You have received at least two prior therapies including Revlimid (lenalidomide) and a proteasome inhibitor (such as Ninlaro [ixazomib], Kyprolis [carfilzomib])

   C. If you have relapsed or refractory multiple myeloma, approval also requires:
      1. You are 18 years of age or older
      2. Sarclisa will be used in combination with Kyprolis (carfilzomib) and dexamethasone
      3. You have received one to three prior lines of therapy

   D. If you have newly diagnosed multiple myeloma, approval also requires:
      1. You are 18 years of age or older
      2. Sarclisa will be used in combination with Velcade (bortezomib), Revlimid (lenalidomide) and dexamethasone
      3. You are not eligible for autologous stem cell transplant (ASCT: a type of treatment that uses your own healthy blood cells)

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ISATUXIMAB-IRFC BvD (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sarclisa. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Sarclisa [Prescribing Information]. Bridgewater, NJ: Sanofi-aventis U.S. LLC, June 2026.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed July 1, 2024].

For Part D use only:

ISATUXIMAB-IRFC (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ISAVUCONAZONIUM (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ISAVUCONAZONIUM SULFATE	CRESEMBA	41817		GPI-10 (1140703010)	ROUTE = ORAL

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the request for **ONE** of the following diagnoses?
   - Invasive aspergillosis (ICD-10 B44.0)
   - Invasive mucormycosis (ICD-10 B46.5)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the request for continuation of therapy after the patient was started on Cresemba in the hospital?

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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ISAVUCONAZONIUM (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of invasive aspergillosis (ICD-10 B44.0) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older and weighs at least 16 kg (35.2 lbs)
   - Therapy is prescribed by or in consultation with an infectious disease specialist
   - The patient had a trial of or contraindication to Vfend (voriconazole)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

4. Does the patient have a diagnosis of invasive mucormycosis (ICD-10 B46.5) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older and weighs at least 16 kg (35.2 lbs)
   - Therapy is prescribed by or in consultation with an infectious disease specialist

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ISAVUCONAZONIUM (Cresemba)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Invasive aspergillosis (a type of fungal infection)
      2. Invasive mucormycosis (a type of fungal infection)

   B. If you have invasive aspergillosis, approval also requires:
      1. You are 6 years of age or older and weigh at least 16 kg (35.2 pounds)
      2. Therapy is prescribed by or in consultation with an infectious disease specialist (a doctor who specializes in the treatment of infections)
      3. You have tried or have a contraindication to (harmful for you to use) Vfend (voriconazole)

   (Denial text continues on the next page)

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ISAVUCONAZONIUM (PART D)

GUIDELINES FOR USE (CONTINUED)

C. If you have invasive mucormycosis, approval also requires:
1. You are 6 years of age or older and weigh at least 16 kg (35.2 pounds)
2. Therapy is prescribed by or in consultation with an infectious disease specialist (a doctor who specializes in the treatment of infections)

D. Request for continuation of therapy after hospital discharge does not require extra criteria

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Cresemba.

REFERENCES
Cresemba [Prescribing Information]. Northbrook, IL: Astellas Pharma US, Inc.; December 2023.

For Part D use only:

ISAVUCONAZONIUM (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	INVASIVE ASPERGILLOSIS, INVASIVE MUCORMYCOSIS: PRESCRIBED BY OR IN CONSULTATION WITH AN INFECTIOUS DISEASE SPECIALIST.
Coverage Duration	6 MONTHS
Other Criteria	INVASIVE ASPERGILLOSIS: TRIAL OF OR CONTRAINDICATION TO VORICONAZOLE. CONTINUATION OF THERAPY AFTER HOSPITAL DISCHARGE REQUIRES NO EXTRA CRITERIA.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ISTRADEFYLLINE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ISTRADEFYLLINE	NOURIANZ	45994		GPI-10 (7340102500)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Parkinson's disease (PD) (ICD-10 Group G20) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- The patient is experiencing 'off' episodes
- Nourianz will be used as adjunctive treatment to levodopa/carbidopa (e.g., Sinemet, Sinemet CR, Parcopa)

If yes, **approve for lifetime by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ISTRADEFYLLINE (Nourianz)** requires the following rule(s) be met for approval:
A. You have Parkinson's disease (a type of movement disorder)
B. You are 18 years of age or older
C. You are experiencing 'off' episodes (times when medication wears off and you have movement problems)
D. Nourianz will be used as adjunctive (add-on) treatment to levodopa/carbidopa (such as Sinemet, Sinemet Controlled Release [CR], Parcopa)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ISTRADEFYLLINE (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Nourianz.

REFERENCES
Nourianz [Prescribing Information]. Bedminster, NJ: Kyowa Kirin, Inc.; September 2019.

For Part D use only:

ISTRADEFYLLINE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	LIFETIME
Other Criteria	N/A

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 10/19
Client Approval: 08/24
P&T Approval: 10/19

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ITRACONAZOLE SOLUTION (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ITRACONAZOLE	SPORANOX, ITRACONAZOLE		49100	GPI-14 (11407035002020)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of oropharyngeal candidiasis (ICD-10 B37.0) or esophageal candidiasis (ICD-10 B37.81) **AND** meet the following criterion?
   - The patient had a trial of or contraindication to fluconazole

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ITRACONAZOLE SOLUTION (Sporanox)** requires the following rule(s) be met for approval:
   A. You have oropharyngeal candidiasis (fungal infection of the throat) or esophageal candidiasis (fungal infection of the throat to the stomach)
   B. You have tried or have a contraindication to (harmful for you to use) fluconazole

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ITRACONAZOLE SOLUTION (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sporanox.

REFERENCES

Sporanox solution [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; March 2024.

For Part D use only:

ITRACONAZOLE SOLUTION (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 MONTHS
Other Criteria	ESOPHAGEAL CANDIDIASIS AND OROPHARYNGEAL CANDIDIASIS: TRIAL OF OR CONTRAINDICATION TO FLUCONAZOLE.

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 11/21
Client Approval: 06/24
P&T Approval: 04/21

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IVACAFTOR (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IVACAFTOR	KALYDECO	38461		GPI-10 (4530203000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of cystic fibrosis (CF) (ICD-10 Group E84) and meet **ALL** of the following criteria?
   - The patient is 1 month of age or older
   - Therapy is prescribed by or in consultation with a pulmonologist or cystic fibrosis expert
   - Kalydeco will NOT be used concurrently with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (e.g., medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)
   - The patient is NOT homozygous for the *F508del* mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene
   - The patient has a responsive mutation in the CFTR gene

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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IVACAFTOR (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **IVACAFTOR (Kalydeco)** requires the following rule(s) be met for approval:

A. You have cystic fibrosis (CF: a type of lung disorder)
B. You are 1 month of age or older
C. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or cystic fibrosis (CF) expert
D. You will NOT use Kalydeco concurrently (at the same time) with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (such as medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)
E. You are NOT homozygous (have two copies of the same gene) for the F508del mutation (abnormal change) in the cystic fibrosis transmembrane conductance regulator (CFTR) gene
F. You have responsive mutation in the CFTR gene

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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IVACAFTOR (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of cystic fibrosis (CF) (ICD-10 Group E84) and meet **ALL** of the following criteria?
   - The patient has experienced an improvement in clinical status
   - Kalydeco will NOT be used concurrently with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (e.g., medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)

   If yes, **approve for lifetime by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **IVACAFTOR (Kalydeco)** requires the following rule(s) be met for renewal:
   A. You have cystic fibrosis (CF: a type of lung disorder)
   B. You have experienced an improvement in your clinical status
   C. You will NOT use Kalydeco concurrently (at the same time) with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (such as medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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IVACAFTOR (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kalydeco.

REFERENCES

Kalydeco [Prescribing Information]. Boston, MA: Vertex Pharmaceuticals Incorporated; May 2023.

For Part D use only:

IVACAFTOR (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	CYSTIC FIBROSIS (CF): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A PULMONOLOGIST OR CYSTIC FIBROSIS EXPERT
Coverage Duration	INITIAL: 12 MONTHS. RENEWAL: LIFETIME
Other Criteria	CF: INITIAL: 1) NOT HOMOZYGOUS FOR F508DEL MUTATION IN THE CYSTIC FIBROSIS TRANSMEMBRANE CONDUCTANCE REGULATOR (CFTR) GENE, AND 2) NO CONCURRENT USE WITH ANOTHER CFTR MODULATOR. RENEWAL: 1) IMPROVEMENT IN CLINICAL STATUS, AND 2) NO CONCURRENT USE WITH ANOTHER CFTR MODULATOR.

Created: 11/07
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 01/25

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IVOSIDENIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IVOSIDENIB	TIBSOVO	45096		GPI-10 (2153494000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of acute myeloid leukemia (AML) (ICD-10 Group C92.0) and meet **ALL** of the following criteria?
   - The patient has newly diagnosed AML
   - Tibsovo will be used in combination with azacitidine (Onureg) or as monotherapy
   - The patient's cancer has a susceptible isocitrate dehydrogenase-1 (IDH1) mutation, as detected by an FDA-approved test

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient is 75 years of age or older
   - The patient is 18 years of age or older AND has comorbidities that prevent the use of intensive induction chemotherapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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IVOSIDENIB (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of relapsed or refractory acute myeloid leukemia (AML) (ICD-10 C92.02, C92.00) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer has a susceptible isocitrate dehydrogenase-1 (IDH1) mutation, as detected by an FDA-approved test

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

4. Does the patient have a diagnosis of myelodysplastic syndromes (MDS) (ICD-10 Group D46) and meet **ALL** of the following criteria?
   - The patient has relapsed or refractory MDS
   - The patient is 18 years of age or older
   - The patient's cancer has a susceptible isocitrate dehydrogenase-1 (IDH1) mutation, as detected by an FDA-approved test

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Does the patient have a diagnosis of cholangiocarcinoma (ICD-10 C22.1) and meet **ALL** of the following criteria?
   - The patient has locally advanced or metastatic cholangiocarcinoma
   - The patient is 18 years of age or older
   - The patient's cancer has an isocitrate dehydrogenase-1 (IDH1) mutation, as detected by an FDA-approved test
   - The patient's cancer has been previously treated

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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IVOSIDENIB (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **IVOSIDENIB (Tibsovo)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Acute myeloid leukemia (AML: a type of blood cancer)
   2. Relapsed or refractory acute myeloid leukemia (AML: a type of blood cancer that has returned or has not responded to treatment)
   3. Myelodysplastic syndromes (MDS: a type of blood cancer)
   4. Cholangiocarcinoma (bile duct cancer)

B. If you have acute myeloid leukemia, approval also requires:
   1. You have newly-diagnosed acute myeloid leukemia
   2. Tibsovo will be used in combination with azacitidine (Onureg) OR as monotherapy (one drug treatment)
   3. Your cancer has a susceptible isocitrate dehydrogenase-1 (IDH1) mutation (a type of enzyme mutation that can be treated with Tibsovo), as detected by a Food and Drug Administration (FDA)-approved test
   4. You meet ONE of the following:
      a. You are 75 years of age or older
      b. You are 18 years of age or older AND have comorbidities (additional diseases) that prevent the use of intensive induction chemotherapy (start of a type of cancer treatment)

C. If you have relapsed or refractory acute myeloid leukemia, approval also requires:
   1. You are 18 years of age or older
   2. Your cancer has a susceptible isocitrate dehydrogenase-1 (IDH1) mutation (a type of enzyme mutation that can be treated with Tibsovo), as detected by a Food and Drug Administration (FDA)-approved test

D. If you have myelodysplastic syndromes, approval also requires:
   1. You have relapsed or refractory (cancer that has returned or has not responded to treatment) myelodysplastic syndrome
   2. You are 18 years of age or older
   3. Your cancer has a susceptible isocitrate dehydrogenase-1 (IDH1) mutation (a type of enzyme mutation that can be treated with Tibsovo), as detected by a Food and Drug Administration (FDA)-approved test

(Denial text continued on next page)

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IVOSIDENIB (PART D)

GUIDELINES FOR USE (CONTINUED)

E. If you have cholangiocarcinoma, approval also requires:

1. You have locally advanced or metastatic (cancer that has spread from where it started to nearby tissue/lymph nodes or to other parts of the body) cholangiocarcinoma
2. You are 18 years of age or older
3. Your cancer has an isocitrate dehydrogenase-1 (IDH1) mutation (type of enzyme mutation), as detected by a Food and Drug Administration (FDA)-approved test
4. Your cancer has been previously treated

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tibsovo.

REFERENCES

Tibsovo [Prescribing Information]. Boston, MA: Servier Pharmaceuticals; October 2023.

For Part D use only:

IVOSIDENIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 07/18
Client Approval: 06/24
P&T Approval: 01/24

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IXAZOMIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IXAZOMIB CITRATE	NINLARO	42826		GPI-10 (2153604510)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of multiple myeloma (ICD-10 Group C90.0) and have **ALL** of the following criteria been met?
   - Ninlaro will be used in combination with Revlimid (lenalidomide) and dexamethasone
   - The patient has received at least one prior therapy for the treatment of multiple myeloma (e.g., Velcade [bortezomib], Kyprolis [carfilzomib], Thalomid [thalidomide], Revlimid [lenalidomide], Alkeran [melphalan], stem cell transplantation)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **IXAZOMIB (Ninlaro)** requires the following rule(s) be met for approval:
   A. You have multiple myeloma (a type of blood cancer)
   B. Ninlaro will be used in combination with Revlimid (lenalidomide) and dexamethasone
   C. You have received at least one prior therapy (such as Velcade [bortezomib], Kyprolis [carfilzomib], Thalomid [thalidomide], Revlimid [lenalidomide], Alkeran [melphalan], stem cell transplantation [a type of procedure to replace damaged bone marrow])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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IXAZOMIB (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ninlaro.

REFERENCES

Ninlaro [Prescribing Information]. Cambridge, MA; Takeda Pharmaceutical Company Limited. March 2021.

For Part D use only:

IXAZOMIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 12/15
Client Approval: 08/24
P&T Approval: 11/16

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IXEKIZUMAB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IXEKIZUMAB	TALTZ SYRINGE, TALTZ AUTOINJECTOR	43193		GPI-10 (9025055400)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient is a candidate for phototherapy or systemic therapy
   - Therapy is prescribed by or in consultation with a dermatologist
   - The patient has psoriasis covering 3% or more of body surface area (BSA) OR psoriatic lesions affecting the hands, feet, face, scalp, or genital area
   - Taltz will NOT be used concurrently with another systemic biologic (e.g., Humira[adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, continue to #2.
   If no, continue to #3.

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IXEKIZUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient meet **ONE** of the following criteria?
   - The patient is 6 to 17 years of age AND had a trial of or contraindication to TWO of the following preferred agents: Cosentyx (secukinumab), Selarsdi /Yesintek /ustekinumab-aauz, Otezla (apremilast), Skyrizi (risankizumab-rzaa), Tremfya (guselkumab)
   - The patient is 18 years of age or older AND had a trial of or contraindication to TWO of the following preferred agents: Cosentyx (secukinumab), Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima, Selarsdi/Yesintek/ustekinumab-aauz, Skyrizi (risankizumab-rzaa), Tremfya (guselkumab), Otezla (apremilast)

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   - Taltz will NOT be used concurrently with another systemic biologic (e.g., Humira[adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Cosentyx (secukinumab)
     - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
     - Selarsdi /Yesintek /ustekinumab-aauz
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Skyrizi (risankizumab-rzaa)
     - Tremfya (guselkumab)
     - Orencia (abatacept)
     - Otezla (apremilast)

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, continue to #4.

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IXEKIZUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 excluding Group M45.A) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Taltz will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Cosentyx (secukinumab)
     - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, continue to #5.

5. Does the patient have a diagnosis of non-radiographic axial spondyloarthritis (nr-axSpA) (ICD-10 Group M45.A) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Taltz will NOT be used concurrently with another systemic biologic (e.g., Cimzia [certolizumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of nr-axSpA
   - The patient has C-reactive protein (CRP) levels above the upper limit of normal OR has sacroiliitis on magnetic resonance imaging (MRI)
   - The patient had a trial of or contraindication to TWO of the preferred agents:
     - Cosentyx (secukinumab)
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Cimzia (certolizumab pegol)

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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IXEKIZUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: Our guideline named **IXEKIZUMAB (Taltz)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Ankylosing spondylitis (AS: a type of joint condition)
   4. Non-radiographic axial spondyloarthritis (nr-axSpA: type of spine pain that does not show any visible damage on X-ray)

B. If you have moderate to severe plaque psoriasis, approval also requires:
   1. You are a candidate for phototherapy (light therapy) or systemic therapy (therapy that travels through the entire body)
   2. Therapy is prescribed by or in consultation with a dermatologist (skin doctor)
   3. You have psoriasis covering 3% or more of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, face, scalp, or genital area
   4. You will NOT use Taltz concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis
   5. You meet ONE of the following:
      a. You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Cosentyx (secukinumab), Selarsdi /Yesintek /ustekinumab-aauz, Otezla (apremilast), Skyrizi (risankizumab-rzaa), Tremfya (guselkumab)
      b. You are 18 years of age or older AND have tried or have a contraindication to TWO of the following preferred medications: Cosentyx (secukinumab), Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima, Selarsdi/Yesintek /ustekinumab-aauz, Skyrizi (risankizumab-rzaa), Tremfya (guselkumab), Otezla (apremilast)

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IXEKIZUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

C. If you have psoriatic arthritis, approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (skin doctor)
3. You will NOT use Taltz concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis
4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Cosentyx (secukinumab)
   b. Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
   c. Selarsdi /Yesintek /ustekinumab-aauz
   d. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
   e. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
   f. Skyrizi (risankizumab-rzaa)
   g. Tremfya (guselkumab)
   h. Orencia (abatacept)
   i. Otezla (apremilast)

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IXEKIZUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

D. If you have ankylosing spondylitis, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You will NOT use Taltz concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis
4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Cosentyx (secukinumab)
   b. Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
   c. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
   d. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])

E. If you have non-radiographic axial spondyloarthritis, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. Your C-reactive protein (CRP: a measure of inflammation) levels are above the upper limit of normal, OR you have sacroiliitis (inflammation where lower spine and pelvis connect) on magnetic resonance imaging (MRI)
4. You will NOT use Taltz concurrently (at the same time) with another systemic biologic (such as Cimzia [certolizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-radiographic axial spondyloarthritis
5. You have tried or have a contraindication to (harmful for you to use) TWO of the preferred medications:
   a. Cosentyx (secukinumab)
   b. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
   c. Cimzia (certolizumab pegol)

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IXEKIZUMAB (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Taltz will NOT be used concurrently with another systemic biologic (e.g., Humira[adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Taltz will NOT be used concurrently with another systemic biologic (e.g., Humira[adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

3. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 excluding Group M45.A) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Taltz will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #4.

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IXEKIZUMAB (PART D)

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of non-radiographic axial spondyloarthritis (nr-axSpA) (ICD-10 Group M45.A) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Taltz will NOT be used concurrently with another systemic biologic (e.g., Cimzia [certolizumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of nr-axSpA

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: Our guideline named **IXEKIZUMAB (Taltz)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
      2. Psoriatic arthritis (PsA: a type of skin and joint condition)
      3. Ankylosing spondylitis (AS: a type of joint condition)
      4. Non-radiographic axial spondyloarthritis (nr-axSpA: type of spine pain that does not show any visible damage on X-rays)

   B. If you have moderate to severe plaque psoriasis, renewal also requires:
      1. You continue to benefit from the medication
      2. You will NOT use Taltz concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis

   C. If you have psoriatic arthritis, renewal also requires:
      1. You continue to benefit from the medication
      2. You will NOT use Taltz concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

   (Renewal denial text continued on next page)

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IXEKIZUMAB (PART D)

RENEWAL CRITERIA (CONTINUED)

D. If you have ankylosing spondylitis, renewal also requires:
1. You continue to benefit from the medication
2. You will NOT use Taltz concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis

E. If you have non-radiographic axial spondyloarthritis, renewal also requires:
1. You continue to benefit from the medication
2. You will NOT use Taltz concurrently (at the same time) with another systemic biologic (such as Cimzia [certolizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-radiographic axial spondyloarthritis

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Taltz.

REFERENCES
Taltz [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; August 2024.

For Part D use only:

IXEKIZUMAB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	INITIAL: PLAQUE PSORIASIS (PSO): PSORIASIS COVERING 3 PERCENT OR MORE OF BODY SURFACE AREA OR PSORIATIC LESIONS AFFECTING THE HANDS, FEET, FACE, SCALP, OR GENITAL AREA. NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS (NR-AXSPA): 1) C-REACTIVE PROTEIN (CRP) LEVELS ABOVE THE UPPER LIMIT OF NORMAL, OR 2) SACROILIITIS ON MAGNETIC RESONANCE IMAGING (MRI).
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: PSO: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST. PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST OR DERMATOLOGIST. ANKYLOSING SPONDYLITIS (AS), NR-AXSPA: PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: PSO: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS, WHERE AGES ALIGN: COSENTYX, HUMIRA/CYLTEZO/YUFLYMA/HADLIMA,

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	SELARSDI/YESINTEK/USTEKINUMAB-AAUZ, SKYRIZI, TREMFYA, OTEZLA. PSA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: COSENTYX, HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, SELARSDI/YESINTEK/USTEKINUMAB-AAUZ, XELJANZ, RINVOQ, SKYRIZI, TREMFYA, ORENCIA, OTEZLA. AS: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: COSENTYX, HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, XELJANZ, RINVOQ. NR-AXSPA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE PREFERRED AGENTS: COSENTYX, RINVOQ, CIMZIA. INITIAL/RENEWAL: ALL INDICATIONS: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION. RENEWAL: ALL INDICATIONS: CONTINUES TO BENEFIT FROM THE MEDICATION.

Created: 04/16
Effective: 07/15/26 Client Approval: 07/26 P&T Approval: 10/24

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LACOSAMIDE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LACOSAMIDE	MOTPOLY XR		54119 54121 54122	GPI-14 (72600036007020, 72600036007025, 72600036007030)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

************Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of partial-onset seizures (ICD-10 Groups G40.1, G40.2) and meet **ALL** of the following criteria?
   - The patient weighs at least 50 kgs (110 lbs.)
   - The patient had a trial of or contraindication to TWO generic antiepileptic agents (e.g., lacosamide IR, carbamazepine, divalproex sodium, gabapentin, lamotrigine, levetiracetam IR or ER, oxcarbazepine, tiagabine, topiramate, valproic acid, zonisamide)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

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LACOSAMIDE (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of primary generalized tonic-clonic seizures (ICD-10 Group G40.3) and meet **ALL** of the following criteria?
   - The patient weighs at least 50 kg (110 lbs.)
   - Motpoly XR will be used as adjunctive treatment
   - The patient had a trial of or contraindication to TWO generic antiepileptic agents (e.g., lacosamide IR, carbamazepine, divalproex sodium, lamotrigine, levetiracetam IR, topiramate, valproic acid)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LACOSAMIDE (Motpoly XR)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Partial-onset seizures (a type of seizure)
      2. Primary generalized tonic-clonic seizures (a type of seizure)
   B. If you have partial-onset seizures, approval also requires:
      1. You weigh at least 50 kilograms (110 pounds)
      2. You have tried or have a contraindication to (harmful for you to use) TWO generic anti-seizure medications (such as lacosamide immediate-release, carbamazepine, divalproex sodium, gabapentin, lamotrigine, levetiracetam immediate-release or extended-release, oxcarbazepine, tiagabine, topiramate, valproic acid, zonisamide)
   C. If you have primary generalized tonic-clonic seizures, approval also requires:
      1. You weigh at least 50 kilograms (110 pounds)
      2. Motpoly XR will be used as adjunctive (add-on) treatment
      3. You have tried or have a contraindication to (harmful for you to use) TWO generic anti-seizure medications (such as lacosamide immediate-release, carbamazepine, divalproex sodium, lamotrigine, levetiracetam immediate-release, topiramate, valproic acid)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LACOSAMIDE (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of partial-onset seizures (ICD-10 Groups G40.1, G40.2)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of primary generalized tonic-clonic seizures (ICD-10 Group G40.3)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LACOSAMIDE (Motpoly XR)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Partial-onset seizures (a type of seizure)
      2. Primary generalized tonic-clonic seizures (a type of seizure)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LACOSAMIDE (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Motpoly XR.

REFERENCES

Motpoly XR [Prescribing Information]. Piscataway, NJ: Aucta Pharmaceuticals, Inc.; January 2025.

For Part D use only:

LACOSAMIDE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS
Other Criteria	PARTIAL-ONSET SEIZURES, TONIC-CLONIC SEIZURES: INITIAL: TRIAL OF OR CONTRAINDICATION TO TWO GENERIC ANTIEPILEPTIC AGENTS.

Created: 02/24
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 07/25

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LACTIC ACID/CITRIC/POTASSIUM (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LACTIC ACID/ CITRIC/POTASSIUM	PHEXXI	46568		GPI-10 (5532990340)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the request for prevention of pregnancy in a female patient with reproductive potential and the patient meets **ALL** of the following criteria?
   - Phexxi will NOT be used concurrently with vaginal ring products (e.g., Annovera [segesterone/ethinyl estradiol], Nuvaring [etonogestrel/ethinyl estradiol])
   - The patient had a trial of or contraindication to TWO contraceptive agents (e.g., Ortho Tri-Cyclen [norgestimate-ethinyl estradiol], Loestrin [norethindrone ac-eth estradiol], Yaz [ethinyl estradiol/drospirenone])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LACTIC ACID/CITRIC/POTASSIUM (Phexxi)** requires the following rule(s) be met for approval:
   A. You are a female with reproductive potential using Phexxi for prevention of pregnancy
   B. You will NOT use Phexxi concurrently (at the same time) with vaginal ring products (such as Annovera [segesterone/ethinyl estradiol], Nuvaring [etonogestrel/ethinyl estradiol])
   C. You have tried or have a contraindication to (harmful for you to use) TWO contraceptive agents (birth control such as Ortho Tri-Cyclen [norgestimate-ethinyl estradiol], Loestrin [norethindrone ac-eth estradiol], Yaz [ethinyl estradiol/drospirenone])
   (Denial text continued on next page)

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LACTIC ACID/CITRIC/POTASSIUM (PART D)

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Phexxi.

REFERENCES

Phexxi [Prescribing Information]. San Diego, CA: Evofem, Inc., February 2022.

For Part D use only:

LACTIC ACID/CITRIC/POTASSIUM (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	PREGNANCY PREVENTION: 1) NOT CONCURRENTLY USING VAGINAL PRODUCTS (E.G., ANNOVERA, NUVARING), AND 2) TRIAL OF OR CONTRAINDICATION TO TWO CONTRACEPTIVE AGENTS (E.G., NORGESTIMATE-ETHINYL ESTRADIOL, NORETHINDRONE AC-ETH ESTRADIOL, ETHINYL ESTRADIOL/DROSPIRENONE)

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 02/22
Client Approval: 06/24
P&T Approval: 07/20

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LAMOTRIGINE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LAMOTRIGINE	SUBVENITE		58364	GPI-14 (72600040001820)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of partial-onset seizures (ICD-10 Group G40.1, Group G40.2)?

   If yes, continue to #2.
   If no, continue to #4.

2. Will Subvenite be used as adjunctive therapy and the patient meets **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - The patient has a contraindication to or is unable to swallow lamotrigine tablets

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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LAMOTRIGINE

GUIDELINES FOR USE (CONTINUED)

3. Will Subvenite be used as monotherapy and the patient meets **ALL** of the following criteria?
   - The patient is 16 years of age or older
   - The patient is receiving treatment with carbamazepine, phenytoin, phenobarbital, primidone, or valproate as the single antiepileptic drug (AED) but will be switched to Subvenite
   - The patient has a contraindication to or is unable to swallow lamotrigine tablets

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient have a diagnosis of primary generalized tonic-clonic (PGTC) seizures (ICD-10 Group G40.3) or generalized seizures of Lennox-Gastaut syndrome (ICD-10 Group G40.81), and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Subvenite will be used as adjunctive therapy
   - The patient has a contraindication to or is unable to swallow lamotrigine tablets

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Does the patient have a diagnosis of bipolar I disorder (ICD-10 Group F31 except Group F31.8) and meet **ALL** of the following criteria?
   - Subvenite will be used for maintenance treatment
   - The patient is receiving treatment with standard therapy (e.g., olanzapine, valproate, lithium) for acute mood episodes (depression, mania, hypomania, mixed episodes)
   - The patient has a contraindication to or is unable to swallow lamotrigine tablets

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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LAMOTRIGINE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LAMOTRIGINE (Subvenite)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Partial-onset seizures (a type of seizure)
   2. Primary generalized tonic-clonic (PGTC) seizures (a type of seizure)
   3. Generalized seizures of Lennox-Gastaut syndrome (a type of seizure disorder in young children)
   4. Bipolar I disorder (a type of mood disorder)

B. If you have partial-onset seizures, approval also requires ONE of the following:
   1. You will use Subvenite as adjunctive (add-on) therapy and meet ALL of the following:
      a. You are 2 years of age or older
      b. You have a contraindication to (harmful for you to use) or are unable to swallow lamotrigine tablets
   2. You will use Subvenite as monotherapy (one medication treatment) and meet ALL of the following:
      a. You are 16 years of age or older
      b. You are receiving treatment with carbamazepine, phenytoin, phenobarbital, primidone, or valproate as a single antiepileptic medication (a type of medication used to treat epilepsy or seizures) but you will switch to Subvenite
      c. You have a contraindication to (harmful for you to use) or are unable to swallow lamotrigine tablets

C. If you have primary generalized tonic-clonic seizures or generalized seizures, approval also requires:
   1. You are 2 years of age or older
   2. You will use Subvenite as adjunctive (add-on) therapy
   3. You have a contraindication to (harmful for you to use) or are unable to swallow lamotrigine tablets

D. If you have bipolar I disorder, approval also requires:
   1. You will use Subvenite for maintenance treatment
   2. You are receiving treatment with standard therapy (such as olanzapine, valproate, lithium) for acute mood episodes (depression, mania, hypomania, mixed episodes [types of mood disorders])
   3. You have a contraindication to (harmful for you to use) or are unable to swallow lamotrigine tablets

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LAMOTRIGINE (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Subvenite.

REFERENCES

Subvenite [Prescribing Information]. Lisle, IL: OWP Pharmaceuticals Inc.; September 2025.

For Part D use only:

LAMOTRIGINE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	ALL INDICATIONS: CONTRAINDICATION TO OR UNABLE TO SWALLOW LAMOTRIGINE TABLETS.

Created: 01/26
Effective: 01/26/26 Client Approval: 01/26 P&T Approval: 01/26

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LANADELUMAB-FLYO (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LANADELUMAB-FLYO	TAKHZYRO	45177		GPI-10 (8584204020)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hereditary angioedema (HAE) (ICD-10 D84.1) and meet **ALL** of the following criteria?
- The patient is 2 years of age or older
- Takhzyro will be used for prophylaxis against HAE attacks
- Therapy is prescribed by or in consultation with an allergist, immunologist, hematologist, or pulmonologist
- Takhzyro will NOT be used concurrently with an alternative prophylactic agent for HAE attacks (e.g., Cinryze [C1 esterase inhibitor], Haegarda [C1 esterase inhibitor], danazol, Orladeyo [berotralstat], Andembry [garadacimab-gxii])

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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LANADELUMAB-FLYO (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient meet **ONE** of the following criteria?
   - The patient has Type I or II HAE, as confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q
   - The patient has Type III HAE

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LANADELUMAB-FLYO (Takhzyro)** requires the following rule(s) be met for approval:
   A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
   B. You are 2 years of age or older
   C. Takhzyro will be used for the prevention of hereditary angioedema attacks
   D. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), immunologist (a type of immune system doctor), hematologist (a type of blood doctor), or pulmonologist (lung/breathing doctor)
   E. You will NOT use Takhzyro concurrently (at the same time) with an alternative preventive medication for HAE attacks (such as Cinryze [C1 esterase inhibitor], Haegarda [C1 esterase inhibitor], danazol, Orladeyo [berotralstat], Andembry [garadacimab-gxii])
   F. You meet ONE of the following:
      1. You have Type I or II hereditary angioedema (a type of gene condition with severe body swelling), as confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q (types of lab tests)
      2. You have Type III hereditary angioedema (a type of gene condition with severe body swelling)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LANADELUMAB-FLYO (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary angioedema (HAE) (ICD-10 D84.1) **AND** meet the following criterion?
   - Takhzyro will NOT be used concurrently with an alternative prophylactic agent for HAE attacks (e.g., Cinryze [C1 esterase inhibitor], Haegarda [C1 esterase inhibitor], danazol, Orladeyo [berotralstat], Andembry [garadacimab-gxii])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LANADELUMAB-FLYO (Takhzyro)** requires the following rule(s) be met for renewal:
   A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
   B. You will NOT use Takhzyro concurrently (at the same time) with an alternative preventive medication for HAE attacks (such as Cinryze [C1 esterase inhibitor], Haegarda [C1 esterase inhibitor], danazol, Orladeyo [berotralstat], Andembry [garadacimab-gxii])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Takhzyro.

REFERENCES
Takhzyro [Prescribing Information]. Lexington, MA: Dyax Corp.; January 2025.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LANADELUMAB-FLYO (PART D)

For Part D use only:

LANADELUMAB-FLYO (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	HEREDITARY ANGIOEDEMA (HAE): INITIAL: 1) TYPE III HAE, OR 2) TYPE I OR II HAE CONFIRMED BY ONE OF THE FOLLOWING COMPLEMENT TESTS: C1-INH PROTEIN LEVELS, C4 PROTEIN LEVELS, C1-INH FUNCTIONAL LEVELS, C1Q.
Age Restrictions	N/A
Prescriber Restrictions	HAE: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH AN ALLERGIST, IMMUNOLOGIST, HEMATOLOGIST OR PULMONOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS
Other Criteria	HAE: INITIAL/RENEWAL: NO CONCURRENT USE WITH AN ALTERNATIVE PROPHYLACTIC AGENT FOR HAE ATTACKS.

Created: 09/18
Effective: 03/01/26 Client Approval: 02/26 P&T Approval: 07/24

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LANREOTIDE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LANREOTIDE ACETATE	SOMATULINE DEPOT, LANREOTIDE ACETATE	10781		GPI-10 (3017005010)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of acromegaly (ICD-10 E22.0) and meet **ALL** of the following criteria?
   - The patient had an inadequate response to surgery or radiation OR these therapies arenot appropriate
   - Therapy is prescribed by or in consultation with an endocrinologist

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

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LANREOTIDE (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of gastroenteropancreatic neuroendocrine tumors (GEP-NETs) (ICD-10 Group C7A) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has unresectable, well or moderately differentiated, locally advanced or metastatic GEP-NETs

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Does the patient have a diagnosis of carcinoid syndrome (ICD-10 E34.0) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LANREOTIDE (Somatuline Depot)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Acromegaly (a type of hormone disorder)
      2. Gastroenteropancreatic neuroendocrine tumors (GEP-NETs: a rare type of tumor)
      3. Carcinoid syndrome (a set of symptoms caused by a type of tumor that releases substances into the body)

   B. If you have acromegaly, approval also requires:
      1. You had an inadequate response (did not work) to surgery or radiation, OR these therapies are not appropriate for you
      2. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)

   (Initial denial text continued on next page)

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LANREOTIDE (PART D)

INITIAL CRITERIA (CONTINUED)

C. If you have gastroenteropancreatic neuroendocrine tumors, approval also requires:
1. You are 18 years of age or older
2. You have unresectable (unable to remove by surgery), well or moderately differentiated, locally advanced (cancer that has spread from where it started to nearby tissue or lymph nodes) or metastatic (cancer that has spread to other parts of the body) gastroenteropancreatic neuroendocrine tumors

D. If you have carcinoid syndrome, approval also requires:
1. You are 18 years of age or older

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LANREOTIDE (PART D)

RENEWAL CRITERIA

NOTE: For the diagnosis of GEP-NETs (gastroenteropancreatic neuroendocrine tumors) or carcinoid syndrome, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of acromegaly (ICD-10 E22.0) and meet **ALL** of the following criteria?
   - The patient has experienced a reduction, normalization, or maintenance of IGF-1 levels based on age and gender
   - The patient has shown improvement or sustained remission of clinical symptoms of acromegaly

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LANREOTIDE (Somatuline Depot)** requires the following rule(s) be met for renewal:
   A. You have acromegaly (a type of hormone disorder)
   B. You have experienced a reduction, normalization, or maintenance of insulin-like growth factor 1 (IGF-1: a type of hormone) levels based on your age and gender
   C. You have shown improvement or sustained remission (symptoms have gone away) of clinical symptoms of acromegaly

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Somatuline Depot and lanreotide acetate.

REFERENCES

Somatuline Depot [Prescribing Information]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.; February 2023.
Lanreotide acetate [Prescribing Information]. Warren, NJ: Cipla USA Inc.; September 2023.

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LANREOTIDE (PART D)

LANREOTIDE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	ACROMEGALY: INITIAL: THERAPY IS PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST.
Coverage Duration	ACROMEGALY: INITIAL/RENEWAL: 12 MOS. GEP-NETS, CARCINOID SYNDROME: 12 MOS.
Other Criteria	ACROMEGALY: RENEWAL: 1) REDUCTION, NORMALIZATION, OR MAINTENANCE OF IGF-1 LEVELS BASED ON AGE AND GENDER, AND 2) IMPROVEMENT OR SUSTAINED REMISSION OF CLINICAL SYMPTOMS.

Created: 10/10
Effective: 01/01/26 Client Approval: 12/25 P&T Approval: 10/25

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LAPATINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LAPATINIB DITOSYLATE	TYKERB, LAPATINIB	34541		GPI-10 (2153302610)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of breast cancer (ICD-10 Group C50) **AND** meet the following criterion?
   - The patient's breast cancer is human epidermal growth factor receptor 2 (HER2) positive

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See denial text at the end of the guideline.

2. Does the patient have advanced or metastatic breast cancer and meet **ALL** of the following criteria?
   - The requested medication will be used in combination with Xeloda (capecitabine)
   - The patient has received prior therapy with Herceptin (trastuzumab), an anthracycline (e.g., daunorubicin, doxorubicin, epirubicin, idarubicin), AND a taxane (e.g., paclitaxel, docetaxel)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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LAPATINIB (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have metastatic breast cancer and meet **ALL** of the following criteria?
   - The patient's tumor is hormone receptor-positive
   - The requested medication will be used in combination with Femara (letrozole)
   - The patient is a postmenopausal woman

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LAPATINIB (Tykerb)** requires the following rule(s) be met for approval:
   A. You have advanced or metastatic breast cancer (breast cancer that has progressed or has spread to other parts of your body)
   B. Your breast cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive
   C. If you have advanced breast cancer, approval also requires:
      1. The requested medication will be used in combination with Xeloda (capecitabine)
      2. You have previously received treatment with Herceptin (trastuzumab), an anthracycline (such as daunorubicin, doxorubicin, epirubicin, idarubicin), AND a taxane (such as paclitaxel, docetaxel)
   D. If you have metastatic breast cancer, approval also requires ONE of the following:
      1. The requested medication will be used in combination with Xeloda (capecitabine), AND you have previously received treatment with Herceptin (trastuzumab), an anthracycline (such as daunorubicin, doxorubicin, epirubicin, idarubicin), AND a taxane (such as paclitaxel, docetaxel)
      2. The requested medication will be used in combination with Femara (letrozole), your tumor is hormone receptor (HR: a type of protein)-positive, and you are a postmenopausal (after menopause) woman

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LAPATINIB (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tykerb.

REFERENCES

Tykerb [Prescribing Information]. East Hanover, New Jersey. Novartis; March 2022.

LAPATINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 10/19
Effective: 07/01/25 Client Approval: 05/25 P&T Approval: 05/19

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LAROTRECTINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LAROTRECTINIB SULFATE	VITRAKVI	45494		GPI-10 (2153383520)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a solid tumor and meet **ALL** of the following criteria?
   - The patient's tumor has a neurotrophic receptor tyrosine kinase (*NTRK*) gene fusion without a known acquired resistance mutation, as detected by an FDA-approved test
   - The patient's tumor is metastatic or surgical resection is likely to result in severe morbidity
   - The patient has no satisfactory alternative treatments or has progressed following treatment

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the request for Vitrakvi oral solution and the patient meets **ONE** of the following criteria?
   - The patient had a trial of Vitrakvi capsules
   - The patient is unable to take the capsule formulation

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, **approve for 12 months by GPID or GPI-14 for all of the following:**
   - **25mg capsule.**
   - **100mg capsule.**

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LAROTRECTINIB (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LAROTRECTINIB (Vitrakvi)** requires the following rule(s) be met for approval:

A. You have a solid tumor (abnormal mass)
B. Your tumor has a neurotrophic receptor tyrosine kinase (NTRK: type of enzyme) gene fusion without a known acquired resistance mutation (you have a type of enzyme that does not have a mutation), as detected by a Food and Drug Administration (FDA)-approved test
C. Your tumor is metastatic (spread to another part of body) or surgical resection (removal) is likely to result in severe morbidity (illness)
D. You have no satisfactory alternative treatments or your condition has gotten worse after treatment
E. If the request is for Vitrakvi oral solution, approval also requires ONE of the following:
    1. You have tried Vitrakvi capsules
    2. You are unable to take the capsule formulation

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vitrakvi.

REFERENCES

Vitrakvi [Prescribing Information]. Stamford, CT: Loxo Oncology, Inc: November 2023.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LAROTRECTINIB (PART D)

For Part D use only:

LAROTRECTINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	VITRAKVI ORAL SOLUTION: 1) TRIAL OF VITRAKVI CAPSULES, OR 2) UNABLE TO TAKE CAPSULE FORMULATION.

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 01/19
Client Approval: 06/24
P&T Approval: 01/19

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LASMIDITAN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LASMIDITAN SUCCINATE	REYVOW	46082		GPI-10 (6740654060)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for acute treatment of migraines (ICD Group G43 except G43.7 and G43.E) and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to ONE triptan (e.g., Maxalt [rizatriptan], Imitrex [sumatriptan])
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Ubrelvy (ubrogepant), Nurtec ODT (rimegepant)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LASMIDITAN (Reyvow)** requires the following rule(s) be met for approval:
   A. The request is for acute (quick onset) treatment of migraines (a type of headache)
   B. You are 18 years of age or older
   C. You have tried or have a contraindication to (harmful for you to use) ONE triptan (such as Maxalt [rizatriptan], Imitrex [sumatriptan])
   D. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Ubrelvy (ubrogepant), Nurtec ODT (rimegepant)

   (Initial denial text continued on next page)

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LASMIDITAN (PART D)

INITIAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LASMIDITAN (PART D)

RENEWAL CRITERIA

1. Is the request for the acute treatment of migraines (ICD Group G43 except G43.7 and G43.E) and the patient meets **ONE** of the following criteria?
   - The patient has experienced an improvement from baseline in a validated acute treatment patient-reported outcome questionnaire (e.g., Migraine Assessment of Current Therapy [Migraine-ACT])
   - Therapy works consistently in majority of migraine attacks

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LASMIDITAN (Reyvow)** requires the following rule(s) be met for renewal:
   A. The request is for acute (quick onset) treatment of migraines (a type of headache)
   B. You meet ONE of the following:
      1. You have experienced an improvement from baseline in a validated acute treatment patient-reported outcome questionnaire (assessment tool used to help guide treatment such as Migraine Assessment of Current Therapy [MIGRAINE-ACT])
      2. Treatment works consistently in majority of migraine attacks

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Reyvow.

REFERENCES
Reyvow [Prescribing Information]. Indianapolis, IN: Lilly USA, LLC; September 2022.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LASMIDITAN (PART D)

For Part D use only:

LASMIDITAN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	ACUTE MIGRAINE TREATMENT: INITIAL: 1) TRIAL OF OR CONTRAINDICATION TO ONE TRIPTAN (E.G., SUMATRIPTAN, RIZATRIPTAN), AND 2) TRIAL OF OR CONTRAINDICATION TO ONE OF THE FOLLOWING PREFERRED AGENTS: UBRELVY OR NURTEC ODT. RENEWAL: 1) IMPROVEMENT FROM BASELINE IN A VALIDATED ACUTE TREATMENT PATIENT-REPORTED OUTCOME QUESTIONNAIRE, OR 2) THERAPY WORKS CONSISTENTLY IN MAJORITY OF MIGRAINE ATTACKS.

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25 Created: 04/20
Commercial Effective: N/A Client Approval: 06/24 P&T Approval: 10/19

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LAZERTINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LAZERTINIB MESYLATE	LAZCLUZE	49822		GPI-10 (2136004830)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Lazcluze will be used in combination with Rybrevant (amivantamab-vmjw) or Rybrevant Faspro (amivantamab-hyaluronidase-lpuj)
   - The patient's tumor has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations, as detected by an FDA-approved test

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LAZERTINIB (Lazcluze)** requires the following rule(s) be met for approval:
   A. You have locally advanced or metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to nearby tissue or lymph nodes or that has spread to other parts of the body)
   (Denial text continued on next page)

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LAZERTINIB (PART D)

GUIDELINES FOR USE (CONTINUED)

B. You are 18 years of age or older
C. Lazcluze will be used in combination with Rybrevant (amivantamab-vmjw) or Rybrevant Faspro (amivantamab-hyaluronidase-lpuj)
D. Your tumor has epidermal growth factor receptor (EGFR: a type of protein) exon 19 deletions or exon 21 L858R substitution mutations (abnormal changes in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lazcluze.

REFERENCES

Lazcluze [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; November 2025.

For Part D use only:

LAZERTINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 08/24
Effective: 01/19/26 Client Approval: 01/26 P&T Approval: 10/24

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEBRIKIZUMAB-LBKZ (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEBRIKIZUMAB-LBKZ	EBGLYSS	49658		GPI-10 (9027304010)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe atopic dermatitis (AD) (ICD-10 Group L20) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient weighs at least 40 kg (88 lbs)
   - Therapy is prescribed by or in consultation with a dermatologist, allergist, or immunologist
   - Ebglyss will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor [e.g.,Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Eucrisa (crisaborole)]) for the treatment of atopic dermatitis
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Dupixent (dupilumab), Rinvoq (upadacitinib)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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LEBRIKIZUMAB-LBKZ (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a trial of or contraindication to **ONE** of the following?
   - High potency topical corticosteroid (e.g., halobetasol propionate 0.01% lotion, triamcinolone acetonide 0.5% cream or ointment) or a super-high potency topical corticosteroid (e.g., fluocinonide 0.1% cream, clobetasol propionate 0.05% cream or ointment)
   - Topical calcineurin inhibitor (e.g., tacrolimus, pimecrolimus)
   - Topical PDE-4 inhibitor (e.g., crisaborole [Eucrisa], Adquey [difamilast], Zoryve [roflumilast])
   - Topical AhR agonist (e.g., Vtama [tapinarof])
   - Topical JAK inhibitor (e.g., ruxolitinib [Opzelura])

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.

   INITIAL DENIAL TEXT: Our guideline named **LEBRIKIZUMAB-LBKZ (Ebglyss)** requires the following rule(s) be met for approval:
   A. You have moderate to severe atopic dermatitis (AD: a type of skin condition)
   B. You are 12 years of age or older
   C. You weigh at least 40 kilograms (88 pounds)
   D. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
   E. You will NOT use Ebglyss concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Eucrisa (crisaborole)]) for the treatment of atopic dermatitis
   F. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Dupixent (dupilumab), Rinvoq (upadacitinib)
   G. You have tried or have a contraindication to (harmful for you to use) ONE of the following:
      1. High potency topical corticosteroid (such as halobetasol propionate 0.01% lotion, triamcinolone acetonide 0.5% cream or ointment) or a super-high potency topical corticosteroid (such as fluocinonide 0.1% cream, clobetasol propionate 0.05% cream or ointment)
      2. Topical calcineurin inhibitor (such as tacrolimus, pimecrolimus)
      3. Topical PDE-4 inhibitor (such as crisaborole [Eucrisa], Adquey [difamilast], Zoryve [roflumilast])
      4. Topical aryl hydrocarbon receptor (AhR) agonist (such as Vtama [tapinarof])
      5. Topical JAK inhibitor (such as ruxolitinib [Opzelura])

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEBRIKIZUMAB-LBKZ (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe atopic dermatitis (AD) (ICD-10 Group L20) and meet **ALL** of the following criteria?
   - The patient has shown improvement while on Ebglyss
   - Ebglyss will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Eucrisa (crisaborole)]) for the treatment of atopic dermatitis

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: Our guideline named **LEBRIKIZUMAB-LBKZ (Ebglyss)** requires the following rule(s) be met for renewal:
   A. You have moderate to severe atopic dermatitis (AD: a type of skin condition)
   B. You have shown improvement while on Ebglyss
   C. You will NOT use Ebglyss concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Eucrisa (crisaborole)]) for the treatment of atopic dermatitis

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ebglyss.

REFERENCES

Ebglyss [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; October 2025.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEBRIKIZUMAB-LBKZ (PART D)

For Part D use only:

LEBRIKIZUMAB-LBKZ (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	AD: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST, ALLERGIST, OR IMMUNOLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	AD: INITIAL: 1) TRIAL OF OR CONTRAINDICATION TO ONE OF THE FOLLOWING: (A) HIGH OR SUPER-HIGH POTENCY TOPICAL CORTICOSTEROID, (B) TOPICAL CALCINEURIN INHIBITOR, (C) TOPICAL PDE4 INHIBITOR, (D) TOPICAL AHR AGONIST OR (E) TOPICAL JAK INHIBITOR, AND 2) TRIAL OF OR CONTRAINDICATION TO ONE OF THE FOLLOWING PREFERRED AGENTS: DUPIXENT, RINVOQ. INITIAL/RENEWAL: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AD. RENEWAL: IMPROVEMENT WHILE ON THERAPY.

Created: 09/24
Effective: 08/01/26 Client Approval: 07/26 DMC Approval: 06/30/26

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LECANEMAB-IRMB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LECANEMAB-IRMB	LEQEMBI IQLIK	48590		GPI-10 (6205054530)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Alzheimer's disease (ICD-10 Group G30) and meet **ALL** of the following criteria?
   - The patient has mild cognitive impairment or mild dementia
   - Therapy is prescribed by or in consultation with a neurologist, geriatrician, or psychiatrist
   - The patient has the presence of amyloid-beta plaques
   - The patient has a Clinical Dementia Rating (CDR) global score of 0.5 or 1.0, OR aMini Mental Status Exam (MMSE) score of 22-30
   - The patient had a baseline brain MRI within one year prior to treatment
   - The patient does NOT have a history of a clotting disorder
   - The patient is NOT concurrently using any anticoagulant or antiplatelet therapy (e.g., Xarelto [rivaroxaban], Pradaxa [dabigatran], Plavix [clopidogrel], Effient [prasugrel]), except for aspirin at 81mg daily or less

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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LECANEMAB-IRMB (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LECANEMAB-IRMB (Leqembi IGLIK)** requires the following rule(s) be met for approval:

A. You have Alzheimer's disease (a progressive brain disorder that slowly destroys memory and thinking skills)
B. You have mild cognitive impairment (decreased ability to process, understand, store and remember information) or mild dementia (a type of memory disorder) due to Alzheimer's disease
C. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor), geriatrician (a doctor who specializes in the health care of elderly individuals), or psychiatrist (a type of mental health doctor)
D. You have the presence of amyloid-beta plaques (an indicator of Alzheimer's disease)
E. You have a Clinical Dementia Rating (CDR: a tool for evaluating memory loss) global score of 0.5 or 1.0, OR a Mini Mental Status Exam (MMSE: a test used to evaluate memory, thinking, and understanding) score of 22 to 30
F. You have had a baseline brain MRI (magnetic resonance imaging) within one year prior to treatment
G. You do NOT have a history of a clotting disorder (condition that interferes with the blood's ability to clot)
H. You are NOT concurrently (at the same time) using any anticoagulant or antiplatelet therapy (such as Xarelto [rivaroxaban], Pradaxa [dabigatran], Plavix [clopidogrel], Effient [prasugrel]), except for aspirin at 81mg daily or less

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LECANEMAB-IRMB (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Alzheimer's disease (ICD-10 Group G30) and meet **ALL** of the following criteria?
   - The patient has mild cognitive impairment or mild dementia
   - The patient's cognitive decline has slowed or stopped
   - The patient is NOT experiencing any severe, unstable, or symptomatic amyloid-related imaging abnormalities (ARIA)
   - The patient is NOT concurrently using any anticoagulant or antiplatelet therapy (e.g., Xarelto [rivaroxaban], Pradaxa [dabigatran], Plavix [clopidogrel], Effient [prasugrel]), except for aspirin at 81mg daily or less

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LECANEMAB-IRMB (Leqembi IQLIK)** requires the following rule(s) be met for renewal:
   A. You have Alzheimer's disease (a progressive brain disorder that slowly destroys memory and thinking skills)
   B. You have mild cognitive impairment (decreased ability to process, understand, store and remember information) or mild dementia (a type of memory disorder) due to Alzheimer's disease
   C. Your cognitive decline has slowed or stopped
   D. You are NOT experiencing any severe, unstable, or symptomatic amyloid-related imaging abnormalities (ARIA: abnormal differences seen on magnetic resonance imaging [MRI: a type of imaging] of the brain)
   E. You are NOT concurrently (at the same time) using any anticoagulant or antiplatelet therapy (such as Xarelto [rivaroxaban], Pradaxa [dabigatran], Plavix [clopidogrel], Effient [prasugrel]), except for aspirin at 81mg daily or less

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LECANEMAB-IRMB (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Leqembi IQLIK.

REFERENCES

Leqembi IQLIK [Prescribing Information]. Nutley, NJ: Eisai Inc.; August 2025.

For Part D use only:

LECANEMAB-IRMB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	ALZHEIMER'S DISEASE: INITIAL: 1) CLINICAL DEMENTIA RATING GLOBAL SCORE OF 0.5 OR 1.0, OR 2) MINI MENTAL STATUS EXAM SCORE OF 22-30.
Age Restrictions	N/A
Prescriber Restrictions	ALZHEIMER'S DISEASE: INITIAL: THERAPY IS PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST, GERIATRICIAN, OR PSYCHIATRIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	ALZHEIMER'S DISEASE: INITIAL: 1) PRESENCE OF AMYLOID-BETA PLAQUES, 2) BASELINE BRAIN MRI WITHIN ONE YEAR PRIOR TO TREATMENT, 3) NO HISTORY OF A CLOTTING DISORDER, AND 4) NO CONCURRENT USE WITH ANY ANTICOAGULANT OR ANTIPLATELET THERAPY EXCEPT FOR ASPIRIN AT 81MG DAILY OR LESS. RENEWAL: 1) COGNITIVE DECLINE HAS SLOWED OR STOPPED, 2) NOT EXPERIENCING ANY SEVERE, UNSTABLE, OR SYMPTOMATIC AMYLOID-RELATED IMAGING ABNORMALITIES, AND 3) NO CONCURRENT USE WITH ANY ANTICOAGULANT OR ANTIPLATELET THERAPY EXCEPT FOR ASPIRIN AT 81MG DAILY OR LESS.

Created: 09/25
Effective: 10/01/25 Client Approval: 09/25 P&T Approval: 10/22

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEDIPASVIR/SOFOSBUVIR (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEDIPASVIR/ SOFOSBUVIR	HARVONI	41457		GPI-10 (1235990240)	BRAND ONLY

Do not review this guideline with physicians; if the caller wishes to initiate a request, then a MRF must be completed (see the MedImpact Standard MRF for HepC).

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic hepatitis C virus (HCV) (ICD-10 B18.2) and meet **ALL** of the following criteria?
- The patient is 3 years of age or older
- The patient has genotype 1, 4, 5, or 6 infection

If yes, continue to #2.
If no, continue to #10.

2. Does the patient have an HCV RNA level within the past 6 months?

If yes, continue to #3.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

3. Will Harvoni be used concurrently with **ANY** of the following medications?
- Carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, Priftin (rifapentine), rosuvastatin, Aptivus (tipranavir)/ritonavir, Sovaldi (sofosbuvir; as a single agent), Epclusa (velpatasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir), Mavyret (pibrentasvir/glecaprevir), or Vosevi (velpatasvir/sofosbuvir/voxilaprevir)

If yes, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

If no, continue to #4.

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LEDIPASVIR/SOFOSBUVIR (PART D)

GUIDELINES FOR USE (CONTINUED)

4. Is the patient treatment-naïve and meets **ALL** of the following criteria?
   - The patient has genotype 1 or 4
   - The patient does not have cirrhosis
   - The patient has an HCV RNA level of less than 6 million IU/mL

   If yes, **approve for 8 weeks by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Is the patient treatment-naïve and meets **ONE** of the following criteria?
   - The patient does not have cirrhosis
   - The patient has compensated cirrhosis (Child-Pugh A)
   - The patient has decompensated cirrhosis (Child-Pugh B or C) AND Harvoni will be used with ribavirin
   - The patient has genotype 1 or 4 infection, is post-liver transplant, does not have cirrhosis, AND Harvoni will be used with ribavirin
   - The patient has genotype 1 or 4 infection, is post-liver transplant, has compensated cirrhosis (Child-Pugh A), AND Harvoni will be used with ribavirin

   If yes, **approve for 12 weeks by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #6.

6. Does the patient have genotype 1 infection and meet **ALL** of the following criteria?
   - The patient is treatment-experienced (previously failed a peginterferon alfa-based regimen)
   - The patient has compensated cirrhosis (Child-Pugh A)

   If yes, **approve for 24 weeks by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #7.

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LEDIPASVIR/SOFOSBUVIR (PART D)

GUIDELINES FOR USE (CONTINUED)

7. Is the patient treatment-experienced (previously failed a peginterferon alfa-based regimen) and meets **ONE** of the following criteria?
   - The patient does not have cirrhosis
   - The patient has genotype 4, 5, or 6 infection AND has compensated cirrhosis (Child-Pugh A)
   - The patient has genotype 1 or 4 infection, is post-liver transplant, does not have cirrhosis, AND Harvoni will be used with ribavirin
   - The patient has genotype 1 or 4 infection, is post-liver transplant, has compensated cirrhosis (Child-Pugh A), AND Harvoni will be used with ribavirin

   If yes, **approve for 12 weeks by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #8.

8. Is the patient treatment-experienced and meets **ALL** of the following criteria?
   - The patient has decompensated cirrhosis (Child-Pugh B or C)
   - Harvoni will be used with ribavirin

   If yes, **approve for 12 weeks by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #9.

9. Does the patient have decompensated cirrhosis and meet **ONE** of the following criteria?
   - The patient has a contraindication to ribavirin (ribavirin ineligible)
   - The patient failed prior treatment with a sofosbuvir-based regimen (e.g., Epclusa [sofosbuvir/velpatasvir]) AND Harvoni will be used with ribavirin
   - The patient is post-liver transplant, treatment-experienced, AND Harvoni will be used with ribavirin

   If yes, **approve for 24 weeks by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #10.

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LEDIPASVIR/SOFOSBUVIR (PART D)

GUIDELINES FOR USE (CONTINUED)

10. Is the requested regimen recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment?

    If yes, **approve as indicated per guidance in AASLD/IDSA.**
    If no, do not approve.

    DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

    Our guideline named **LEDIPASVIR/SOFOSBUVIR (Harvoni)** requires the following rule(s) be met for approval:

    A. You have chronic hepatitis C virus, (HCV: liver inflammation caused by a type of virus)
    B. You are 3 years of age or older
    C. You have genotype 1, 4, 5, or 6 hepatitis C infection (types of hepatitis C virus)
    D. You have an HCV RNA level (a measure of the amount of hepatitis C virus in the blood) within the past 6 months
    E. You will NOT use Harvoni concurrently (at the same time) with any of the following medications: carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, Priftin (rifapentine), rosuvastatin, Aptivus (tipranavir)/ritonavir, Sovaldi (sofosbuvir; as a single agent), Epclusa (velpatasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir), Mavyret (pibrentasvir/glecaprevir), or Vosevi (velpatasvir/sofosbuvir/voxilaprevir)
    F. If you are treatment-naïve (no prior treatment), approval also requires ONE of the following:
        1. You do not have cirrhosis (liver damage and scarring)
        2. You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage)
        3. You have decompensated cirrhosis (a condition where there is liver damage and scarring with major symptoms) (Child-Pugh B or C: a score that evaluates the severity of liver damage) AND Harvoni will be used with ribavirin unless you have a contraindication to (harmful for you to use) ribavirin
        4. You have genotype 1 or 4, received a liver transplant (replaced your liver), do not have cirrhosis, AND Harvoni will be used with ribavirin
        5. You have genotype 1 or 4, received a liver transplant, have compensated cirrhosis (Child-Pugh A), AND Harvoni will be used with ribavirin

    (Denial text continued on next page)

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LEDIPASVIR/SOFOSBUVIR (PART D)

GUIDELINES FOR USE (CONTINUED)

G. If you are treatment-experienced (failed prior treatment), approval also requires ONE of the following:

1. You do not have cirrhosis (liver damage and scarring) AND were previously treated with a peginterferon alfa-based regimen
2. You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage) AND were previously treated with a peginterferon alfa-based regimen
3. You have decompensated cirrhosis (a condition where there is liver damage and scarring with major symptoms) (Child-Pugh B or C: a score that evaluates the severity of liver damage) AND Harvoni will be used with ribavirin, unless you have a contraindication to (harmful for you to use) ribavirin
4. You have genotype 1 or 4 infection, received a liver transplant (replaced your liver), do not have cirrhosis, had prior treatment with a peginterferon alfa-based regimen, AND Harvoni will be used with ribavirin
5. You have genotype 1 or 4 infection, received a liver transplant, have compensated cirrhosis (Child-Pugh A), had prior treatment with a peginterferon alfa-based regimen, AND Harvoni will be used with ribavirin
6. You have decompensated cirrhosis, failed prior treatment with a sofosbuvir-based regimen (such as Epclusa [sofosbuvir/velpatasvir]) AND Harvoni will be used with ribavirin
7. You have received a liver transplant, have decompensated cirrhosis, AND Harvoni will be used with ribavirin

H. Harvoni will also be approved for any other regimen/condition not listed above that is recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LEDIPASVIR/SOFOSBUVIR (PART D)

RATIONALE

For further information, please refer to the prescribing information and/or drug monograph for Harvoni.

REFERENCES

Guidance from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) Recommendations for Testing, Managing, and Treating hepatitis C. Available online at http://www.hcvguidelines.org/full-report-view Accessed November 28, 2023.

Harvoni [Prescribing Information]. Foster City, CA: Gilead Sciences; March 2020.

For Part D use only:

LEDIPASVIR-SOFOSBUVIR (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	HCV RNA LEVEL WITHIN PAST 6 MONTHS.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	CRITERIA WILL BE APPLIED CONSISTENT WITH CURRENT AASLD/IDSA GUIDANCE.
Other Criteria	1) CRITERIA WILL BE APPLIED CONSISTENT WITH CURRENT AASLD/IDSA GUIDANCE, AND 2) NOT CONCURRENTLY TAKING ANY OF THE FOLLOWING: CARBAMAZEPINE, PHENYTOIN, PHENOBARBITAL, OXCARBAZEPINE, RIFAMPIN, RIFABUTIN, RIFAPENTINE, ROSUVASTATIN, TIPRANAVIR/RITONAVIR, SOFOSBUVIR (AS A SINGLE AGENT), EPCLUSA, ZEPATIER, MAVYRET, OR VOSEVI.

Created: 11/14
Effective: 08/01/25 Client Approval: 07/25 P&T Approval: 04/24

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEFAMULIN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEFAMULIN ACETATE	XENLETA		46826	GPI-14 (16240040100320)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of community-acquired bacterial pneumonia (CABP) (ICD-10 J15.9) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's CABP infection is caused by any of the following susceptible microorganisms: *Streptococcus pneumoniae, Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae, Legionella pneumophila, Mycoplasma pneumoniae,* or *Chlamydophila pneumoniae*

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is therapy prescribed by or in consultation with an infectious disease (ID) specialist?

   If yes, **approve for 1 month by HICL or GPI-10 for one fill.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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LEFAMULIN (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Has an antimicrobial susceptibility test been performed that meets **ALL** of the following criteria?
   - The results from the infection site culture indicate pathogenic organism(s) with resistance to TWO standard of care agents for CABP (e.g., azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid)
   - The results from the infection site culture indicate pathogenic organism(s) with susceptibility to Xenleta

   If yes, **approve for 1 month by HICL or GPI-10 for one fill.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

4. Does the patient meet **ALL** of the following criteria?
   - Antimicrobial susceptibility results are unavailable
   - The patient had a trial of or contraindication to TWO standard of care agents for CABP (e.g., azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid)

   If yes, **approve for 1 month by HICL or GPI-10 for one fill.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LEFAMULIN (Xenleta)** requires the following rule(s) be met for approval:
   A. You have community-acquired bacterial pneumonia (type of lung infection)
   B. You are 18 years of age or older
   C. Your infection is caused by any of the following susceptible microorganisms (bacteria that the drug can kill): *Streptococcus pneumoniae, Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae, Legionella pneumophila, Mycoplasma pneumoniae,* or *Chlamydophila pneumoniae*

   (Denial text continued on next page)

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LEFAMULIN (PART D)

GUIDELINES FOR USE (CONTINUED)

D. You meet ONE of the following criteria:
   1. Therapy is prescribed by or in consultation with an infectious disease specialist (a doctor who specializes in the treatment of infections)
   2. Your antimicrobial susceptibility test (lab test that shows what drugs work on which bacteria) shows ALL of the following:
      a. The bacteria at the infection site are resistant (drug will not work for that organism) to TWO standard of care medications for community-acquired bacterial pneumonia (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid)
      b. Xenleta will work against the bacteria
   3. If antimicrobial susceptibility results (lab test that shows what drugs work on which bacteria) are not available, we require you have tried or have a contraindication to (harmful for you to use) TWO standard of care medications for community-acquired bacterial pneumonia (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xenleta.

REFERENCES

Xenleta [Prescribing Information]. Ireland DAC: Nabriva Therapeutics US, Inc.; June 2021.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEFAMULIN (PART D)

For Part D use only:

LEFAMULIN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	ONE MONTH
Other Criteria	COMMUNITY-ACQUIRED BACTERIAL PNEUMONIA (CABP): 1) PRESCRIBED BY OR IN CONSULTATION WITH AN INFECTIOUS DISEASE SPECIALIST, 2) ANTIMICROBIAL SUSCEPTIBILITY TESTING SHOWS SUSCEPTIBILITY TO XENLETA AND RESISTANCE TO TWO STANDARD OF CARE AGENTS FOR CABP (E.G., AZITHROMYCIN, DOXYCYCLINE, LEVOFLOXACIN, MOXIFLOXACIN, AMOXICILLIN, CEFTRIAXONE, LINEZOLID), OR 3) IF SENSITIVITY RESULTS ARE UNAVAILABLE: TRIAL OF OR CONTRAINDICATION TO TWO STANDARD OF CARE AGENTS FOR CABP (E.G., AZITHROMYCIN, DOXYCYCLINE, LEVOFLOXACIN, MOXIFLOXACIN, AMOXICILLIN, CEFTRIAXONE, LINEZOLID).

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25 Created: 11/19
Commercial Effective: N/A Client Approval: 06/24 P&T Approval: 07/19

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LENALIDOMIDE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LENALIDOMIDE	REVLIMID, LENALIDOMIDE	33412		GPI-10 (9939405000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of multiple myeloma (MM) (ICD-10 Group C90.0) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of anemia due to a myelodysplastic syndrome (MDS) (ICD-10 Group D46) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's myelodysplastic syndrome (MDS) is associated with a deletion 5q abnormality

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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LENALIDOMIDE (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of mantle cell lymphoma (MCL) (ICD-10 Group C83.1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has relapsed or progressed after two prior therapies, one of which included Velcade (bortezomib)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

4. Does the patient have a diagnosis of follicular lymphoma (FL) (ICD-10 Group C82) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has previously been treated for follicular lymphoma (FL)
   - The requested medication will be used in combination with a rituximab product

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Does the patient have a diagnosis of marginal zone lymphoma (MZL) (ICD-10 Group C83.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has previously been treated for marginal zone lymphoma (MZL)
   - The requested medication will be used in combination with a rituximab product

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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LENALIDOMIDE (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LENALIDOMIDE (Revlimid)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Multiple myeloma (a type of blood cancer)
   2. Anemia due to a myelodysplastic syndrome (a type of blood cancer)
   3. Mantle cell lymphoma (a type of blood cancer)
   4. Follicular lymphoma (a type of blood cancer)
   5. Marginal zone lymphoma (a type of blood cancer)

B. If you have multiple myeloma, approval also requires:
   1. You are 18 years of age or older

C. If you have myelodysplastic syndrome, approval also requires:
   1. You are 18 years of age or older
   2. Your myelodysplastic syndrome is associated with a deletion 5q abnormality (a type of gene mutation)

D. If you have mantle cell lymphoma, approval also requires:
   1. You are 18 years of age or older
   2. You have relapsed or progressed (disease has returned or worsened) after two prior therapies, one of which included Velcade (bortezomib)

E. If you have follicular lymphoma, approval also requires:
   1. You are 18 years of age or older
   2. You have previously been treated for follicular lymphoma
   3. The requested medication will be used in combination with a rituximab product (type of cancer drug)

F. If you have marginal zone lymphoma, approval also requires:
   1. You are 18 years of age or older
   2. You have previously been treated for marginal zone lymphoma
   3. The requested medication will be used in combination with a rituximab product (type of cancer drug)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LENALIDOMIDE (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Revlimid.

REFERENCES

Revlimid [Prescribing Information]. Summit, NJ: Celgene Corporation; March 2023.

For Part D use only:

LENALIDOMIDE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25 Created: 11/07
Commercial Effective: N/A Client Approval: 06/24 P&T Approval: 07/19

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LENIOLISIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LENIOLISIB PHOSPHATE	JOENJA	48803		GPI-10 (9939154060)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of activated phosphoinositide 3-kinase delta (PI3Kdelta) syndrome (APDS) (ICD-10 D81.82) **AND** meet the following criterion?
   - The patient is 4 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**

   If no, do not approve.

   DENIAL TEXT:

   Our guideline named **LENIOLISIB (Joenja)** requires the following rule(s) be met for approval:
   A. You have activated phosphoinositide 3-kinase delta (PI3Kdelta) syndrome (APDS: a type of mutation that impacts the immune system)
   B. You are 4 years of age or older

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LENIOLISIB (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Joenja.

REFERENCES
Joenja [Prescribing Information]. Warren, NJ: Pharming Healthcare Inc.; September 2026.

For Part D use only:

LENIOLISIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 04/23
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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LENVATINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LENVATINIB MESYLATE	LENVIMA	41756		GPI-10 (2133505420)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of differentiated thyroid cancer (DTC) (ICD-10 C73) and meet **ALL** of the following criteria? (**NOTE:** Differentiated thyroid cancer (DTC) is classified as papillary (PTC), follicular (FTC), or Hurthle cell)
   - The patient is 18 years of age or older
   - The thyroid cancer is locally recurrent or metastatic
   - The thyroid cancer is progressive
   - The thyroid cancer is refractory to radioactive iodine therapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC) (ICD-10 Groups C64, C65) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #3.
   If no, continue to #4.

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LENVATINIB (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient meet **ONE** of the following criteria?
   - Lenvima will be used in combination with pembrolizumab (Keytruda)
   - Lenvima will be used in combination with everolimus (Afinitor) AND the patient has tried one prior anti-angiogenic therapy (e.g., Sutent [sunitinib], Votrient [pazopanib], Nexavar [sorafenib])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient have a diagnosis of hepatocellular carcinoma (HCC) (ICD-10 C22.0) **AND** meet the following criterion?
   - The patient's cancer is unresectable

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Does the patient have a diagnosis of advanced endometrial carcinoma (EC) (ICD-10 C54.1) and meet **ALL** of the following criteria?
   - Lenvima will be used in combination with pembrolizumab (Keytruda)
   - The patient's cancer is mismatch repair proficient (pMMR) OR is not microsatellite instability-high (MSI-H), as determined by an FDA-approved test
   - The patient has experienced disease progression following prior systemic therapy
   - The patient is not a candidate for curative surgery or radiation

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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LENVATINIB (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LENVATINIB (Lenvima)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Differentiated thyroid cancer (DTC: a type of thyroid cancer)
   2. Advanced renal cell carcinoma (RCC: a type of kidney cancer)
   3. Hepatocellular carcinoma (HCC: a type of liver cancer)
   4. Advanced endometrial carcinoma (EC: a type of uterus cancer)

B. If you have differentiated thyroid cancer, approval also requires:
   1. You are 18 years of age or older
   2. Your thyroid cancer is locally recurrent (re-appears in the same spot) or metastatic (has spread to other parts of the body)
   3. Your thyroid cancer is progressive (getting worse)
   4. Your thyroid cancer is refractory (has not responded) to radioactive iodine therapy

C. If you have advanced renal cell carcinoma, approval also requires:
   1. You are 18 years of age or older
   2. You meet ONE of the following:
      a. Lenvima will be used in combination with pembrolizumab (Keytruda)
      b. Lenvima will be used in combination with everolimus (Afinitor) AND you have tried one prior anti-angiogenic therapy (such as Sutent [sunitinib], Votrient [pazopanib], Nexavar [sorafenib])

D. If you have hepatocellular carcinoma, approval also requires:
   1. Your cancer is unresectable (cannot be removed by surgery)

E. If you have advanced endometrial carcinoma, approval also requires:
   1. Lenvima will be used in combination with pembrolizumab (Keytruda)
   2. Your cancer is mismatch repair proficient (pMMR: your tumor has normal expression of types of protein) OR is not microsatellite instability-high (MSI-H: a type of mutation), as determined by a Food and Drug Administration (FDA)-approved test
   3. You have experienced disease progression (worsening) following prior systemic therapy (treatment that targets the entire body)
   4. You are not a candidate for curative (to cure) surgery or radiation

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LENVATINIB (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Lenvima.

REFERENCES
Lenvima [Prescribing Information]. Nutley, NJ: Eisai, Inc.; January 2025.

For Part D use only:

LENVATINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LETERMOVIR (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LETERMOVIR	PREVYMIS	44622		GPI-10 (1220004500)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the request for prophylaxis of cytomegalovirus (CMV) infection/disease in an allogeneic hematopoietic stem cell transplant (HSCT) recipient and the patient meets **ALL** of the following criteria?
   - The patient is 6 months of age or older AND weighs at least 6 kg (13.2 lbs)
   - The patient is a CMV-seropositive recipient [R+] of an allogeneic HSCT
   - The patient will start or started Prevymis between Day 0 and Day 28 post-transplant (before or after engraftment)

   If yes, continue #2.
   If no, continue to #4.

2. Is the patient not at risk for late CMV infection and disease **AND** meets the following criterion?
   - The patient will not receive Prevymis beyond 100 days post-transplant

   If yes, **approve for 4 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Is the patient at risk for late CMV infection and disease **AND** meets the following criterion?
   - The patient will not receive Prevymis beyond 200 days post-transplant

   If yes, **approve for 7 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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LETERMOVIR (PART D)

GUIDELINES FOR USE (CONTINUED)

4. Is the request for prophylaxis of cytomegalovirus (CMV) disease in a kidney transplant recipient and the patient meets **ALL** of the following criteria?
   - The patient is 12 years of age or older AND weighs at least 40 kg (88 lbs)
   - The patient is at high risk (i.e., donor is CMV seropositive, recipient is CMV seronegative [D+/R-])
   - The patient will start or started Prevymis between Day 0 and Day 7 post-transplant
   - The patient will not receive Prevymis beyond 200 days post-transplant

   If yes, **approve for 7 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LETERMOVIR (Prevymis)** requires the following rule(s) be met for approval:
   A. The request is for ONE of the following:
      1. Prophylaxis (prevention) of cytomegalovirus (CMV: a type of virus) infection/disease in an allogeneic hematopoietic stem cell transplant (HSCT: cells transplanted from a matching donor) recipient
      2. Prophylaxis of cytomegalovirus (CMV) disease in a kidney transplant recipient

   B. If the request is for prophylaxis of cytomegalovirus infection/disease in an allogeneic hematopoietic stem cell transplant recipient, approval also requires:
      1. You are 6 months of age or older AND weigh at least 6 kilograms (13.2 pounds)
      2. You are a CMV-seropositive recipient [R+] of an allogeneic HSCT
      3. You will start or have started Prevymis between Day 0 and Day 28 post-transplant (before or after engraftment [a type of transplant])
      4. You meet ONE of the following:
         a. You are NOT at risk for late CMV infection and disease, AND you will not receive Prevymis beyond 100 days post (after)-transplant
         b. You are at risk for late CMV infection and disease, AND you will not receive Prevymis beyond 200 days post (after)-transplant

   (Denial text continued on next page)

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LETERMOVIR (PART D)

GUIDELINES FOR USE (CONTINUED)

C. If the request is for prophylaxis of cytomegalovirus disease in a kidney transplant recipient, approval also requires:

1. You are 12 years of age or older AND weigh at least 40 kilograms (88 pounds)
2. You are at high risk (donor is CMV seropositive, recipient is CMV seronegative [D+/R-])
3. You will start or have started Prevymis between Day 0 and Day 7 post (after)-transplant
4. You will not receive Prevymis beyond 200 days post-transplant

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Prevymis.

REFERENCES

Prevymis [Prescribing Information]. Rahway, NJ: Merck & Sharp & Dohme LLC; January 2025.

For Part D use only:

LETERMOVIR (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	HSCT: NOT AT RISK FOR LATE CMV: 4 MOS, AT RISK FOR LATE CMV: 7 MOS. KIDNEY TRANSPLANT: 7 MOS.
Other Criteria	HEMATOPOIETIC STEM CELL TRANSPLANT (HSCT): 1) THERAPY WILL BE INITIATED BETWEEN DAY 0 AND DAY 28 POST TRANSPLANT, AND 2) WILL NOT RECEIVE THE MEDICATION BEYOND 100 DAYS POST TRANSPLANT IF NOT AT RISK FOR LATE CYTOMEGALOVIRUS (CMV) INFECTION AND DISEASE, OR BEYOND 200 DAYS POST TRANSPLANT IF AT RISK FOR LATE CMV INFECTION AND DISEASE. KIDNEY TRANSPLANT: 1) THERAPY WILL BE INITIATED BETWEEN DAY 0 AND DAY 7 POST TRANSPLANT, AND 2) WILL NOT RECEIVE THE MEDICATION BEYOND 200 DAYS POST TRANSPLANT.

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LETERMOVIR (PART D)

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEUPROLIDE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEUPROLIDE ACETATE	LEUPROLIDE ACETATE		84597	GPI-14 (21405010106407)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced prostate cancer (ICD-10 C61)?

   If yes, **approve for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LEUPROLIDE** requires the following rule(s) be met for approval:
   A. You have advanced prostate cancer (prostate cancer has spread from the prostate to other parts of the body)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LEUPROLIDE (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for leuprolide acetate.

REFERENCES
Leuprolide acetate [Prescribing Information]. Princeton, NJ: Sandoz Inc.; June 2021.

For Part D use only:

LEUPROLIDE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	PROSTATE CANCER: 12 MONTHS.
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Created: 10/22
Effective: 01/01/25 Client Approval: 08/24 P&T Approval: 10/18

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEUPROLIDE DEPOT BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEUPROLIDE ACETATE	LEUPROLIDE DEPOT, LUTRATE DEPOT		84594	GPI-14 (21405010152230)	

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit).**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #5.

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LEUPROLIDE DEPOT BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

If yes, **Refer to plan. (The health plan makes the final payment determination decision)**

- **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
- **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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LEUPROLIDE DEPOT BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced prostate cancer (ICD-10 C61)?

   If yes, **approve for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LEUPROLIDE DEPOT (Lutrate Depot, Leuprolide Depot)** requires the following rule(s) be met for approval:
   A. You have advanced prostate cancer (prostate cancer that has spread to nearby tissue or organs)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Leuprolide Depot or Lutrate Depot. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

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LEUPROLIDE DEPOT BvD (PART D)

REFERENCES

Leuprolide Depot [Prescribing Information]. Warren, NJ: Cipla USA, Inc.; August 2024.
Lutrate Depot [Prescribing Information]. Parsippany, NJ: Avyxa Pharma, LLC; November 2024.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed April 22, 2025].

For Part D use only:

LEUPROLIDE DEPOT (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 11/22
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 10/18

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEUPROLIDE-ELIGARD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEUPROLIDE ACETATE	ELIGARD, VABRINTY		18155 19219 24301 17377	GPI-14 (21405010156432, 21405010206435, 21405010256445, 21405010106415)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced prostate cancer (ICD-10 C61)?

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LEUPROLIDE-ELIGARD (Vabrinty)** requires the following rule(s) be met for approval:
   A. You have advanced prostate cancer (prostate cancer that has spread from the prostate to other parts of the body)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LEUPROLIDE-ELIGARD (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Eligard or Vabrinty.

REFERENCES

Eligard [Prescribing Information]. Fort Collins, CO: Tolmar Pharmaceuticals, Inc.; February 2025.
Vabrinty [Prescribing Information]. Buffalo Grove, IL: UroNova Pharmaceuticals, Inc.; June 2025.

For Part D use only:

LEUPROLIDE-ELIGARD (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS.
Other Criteria	N/A

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEUPROLIDE-FENSOLVI BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEUPROLIDE ACETATE	FENSOLVI		47996	GPI-14 (30080050256450)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	Yes	No	No	Yes	No	No	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #5.

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LEUPROLIDE-FENSOLVI BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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LEUPROLIDE-FENSOLVI BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of central precocious puberty (CPP) (ICD-10 E30.1) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See initial denial text at the end of the guideline.

2. Is the request for a female patient who meets **ALL** of the following criteria?
   - The patient has an elevated level of luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
   - The patient is younger than 8 years of age at the onset of CPP
   - The patient is at Tanner stage 2 or above for breast development and pubic hair growth

   If yes, **approve for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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LEUPROLIDE-FENSOLVI BvD (PART D)

INITIAL CRITERIA (CONTINUED)

3. Is the request for a male patient who meets **ALL** of the following criteria?
   - The patient has an elevated level of luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
   - The patient is younger than 9 years of age at the onset of CPP
   - The patient is at Tanner stage 2 or above for genital development and pubic hair growth

   If yes, **approve for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LEUPROLIDE-FENSOLVI** requires the following rule(s) be met for approval:
   A. You have central precocious puberty (CPP: early sexual development in children)
   B. You are 2 years of age or older
   C. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
   D. If you are a female, approval also requires:
      1. You have a high level of luteinizing hormone (LH: a type of hormone) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
      2. You are/were younger than 8 years of age when your condition started
      3. You are at Tanner stage 2 or above (scale of physical measurements of development based on external sex characteristics) for breast development and pubic hair growth
   E. If you are a male, approval also requires:
      1. You have a high level of luteinizing hormone (LH: a type of hormone) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
      2. You are/were younger than 9 years of age when your condition started
      3. You are at Tanner stage 2 or above (scale of physical measurements of development based on external sex characteristics) for genital development and pubic hair growth

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEUPROLIDE-FENSOLVI BvD (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of central precocious puberty (CPP) (ICD-10 E30.1) and meet **ALL** of the following criteria?
   - The patient's Tanner staging at initial diagnosis has stabilized or regressed during three separate medical visits in the previous year
   - The patient has not reached the actual age which corresponds to current pubertal age

   If yes, **approve for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LEUPROLIDE-FENSOLVI** requires the following rule(s) be met for renewal:
   A. You have central precocious puberty (CPP: early sexual development in children)
   B. Your Tanner staging (scale of physical measurements of development based on external sex characteristics) at initial diagnosis has stabilized or regressed (lowered) during three separate medical visits in the previous year
   C. You have not reached the actual age which corresponds to your current pubertal age

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Fensolvi. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Fensolvi [Prescribing Information]. Fort Collins, CO: Tolmar, Inc.; September 2025.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed February 3, 2026].

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEUPROLIDE-FENSOLVI BvD (PART D)

For Part D use only:

LEUPROLIDE-FENSOLVI (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	CENTRAL PRECOCIOUS PUBERTY (CPP): INITIAL: FEMALES/MALES: ELEVATED LUTEINIZING HORMONE (LH) LEVEL GREATER THAN 0.2 TO 0.3 MIU/ML AT DIAGNOSIS.
Age Restrictions	N/A
Prescriber Restrictions	CPP: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	CPP: INITIAL: FEMALES: 1) YOUNGER THAN 8 YEARS OF AGE AT ONSET OF CPP, AND 2) AT TANNER STAGE 2 OR ABOVE FOR BREAST DEVELOPMENT AND PUBIC HAIR GROWTH. MALES: 1) YOUNGER THAN 9 YEARS OF AGE AT ONSET OF CPP, AND 2) AT TANNER STAGE 2 OR ABOVE FOR GENITAL DEVELOPMENT AND PUBIC HAIR GROWTH. RENEWAL: 1) TANNER STAGING AT INITIAL DIAGNOSIS HAS STABILIZED OR REGRESSED DURING THREE SEPARATE MEDICAL VISITS IN THE PREVIOUS YEAR, AND 2) HAS NOT REACHED ACTUAL AGE WHICH CORRESPONDS TO CURRENT PUBERTAL AGE.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEUPROLIDE-LUPRON DEPOT BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEUPROLIDE ACETATE	LUPRON DEPOT	21102		GPI-10 2140501010, 2140501015, 2140501020, 2140501025)	BRAND = LUPRON DEPOT

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 for all strengths under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 for all strengths under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #5.

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LEUPROLIDE-LUPRON DEPOT BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

If yes, **Refer to plan. (The health plan makes the final payment determination decision)**

- **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override)**
- **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

If no, **approve for 12 months by HICL or GPI-10 for all strengths under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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LEUPROLIDE-LUPRON DEPOT BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of advanced prostate cancer (ICD-10 C61)?

   If yes, **approve for 12 months for all strengths as follows:**
   - **Approve by GPID or GPI-14:**
     - **Lupron Depot 7.5 mg**
     - **Lupron Depot 22.5 mg**
     - **Lupron Depot 30 mg**
   - **Approve by NDC or GPI-14:**
     - **Lupron Depot 45 mg**

   If no, continue to #2.

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LEUPROLIDE-LUPRON DEPOT BvD (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of endometriosis (ICD-10 Group N80) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an obstetrician/gynecologist
   - The patient had a trial of or contraindication to a nonsteroidal anti-inflammatory drug (NSAID e.g., ibuprofen, meloxicam, naproxen) AND a progestin-containing preparation (e.g., combination hormonal contraceptive preparation, progestin-only therapy)
   - Lupron Depot will NOT be used concurrently with another GnRH-modulating agent (e.g., Orilissa [elagolix], Zoladex [goserelin], Synarel [nafarelin])
   - The patient has NOT received a total of 12 months of treatment with Lupron Depot per lifetime

   If yes, **approve for 6 months for all strengths as follows:**
   - **Lupron Depot 3.75 mg: Approve by GPID or GPI-14.**
   - **Lupron Depot 11.25 mg: Approve by NDC or GPI-14.**

   If no, continue to #3.

3. Does the patient have a diagnosis of uterine leiomyomata (fibroids) (ICD-10 Group D25) **AND** meet the following criterion?
   - Lupron Depot will be used concomitantly with iron therapy for the preoperative hematologic improvement of anemia caused by fibroids

   If yes, **approve for 3 months for all strengths as follows:**
   - **Lupron Depot 3.75 mg: Approve by GPID or GPI-14.**
   - **Lupron Depot 11.25 mg: Approve by NDC or GPI-14.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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LEUPROLIDE-LUPRON DEPOT BvD (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT:

Our guideline named **LEUPROLIDE-LUPRON DEPOT** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Advanced prostate cancer (prostate cancer that has spread to nearby tissue or organs)
   2. Endometriosis (condition affecting the uterus)
   3. Uterine leiomyomata (fibroids: noncancerous growth of the uterus)

B. If you have endometriosis, approval also requires:
   1. Therapy is prescribed by or in consultation with an obstetrician/gynecologist (a type of women's health doctor)
   2. You have tried or have a contraindication to (harmful for you to use) a nonsteroidal anti-inflammatory drug (NSAID: such as ibuprofen, meloxicam, naproxen) AND a progestin-containing preparation (such as combination hormonal contraceptive preparation, progestin-only therapy)
   3. Lupron Depot will NOT be used at the same time with another gonadotropin-releasing hormone (GnRH)-modulating agent (such as Orilissa [elagolix], Zoladex [goserelin], Synarel [nafarelin])
   4. You have NOT received a total of 12 months of treatment with Lupron Depot per lifetime

C. If you have uterine leiomyomata (fibroids), approval also requires:
   1. Lupron Depot will be used at the same time with iron therapy for the preoperative (before surgery) hematologic (blood) improvement of anemia (a type of blood condition) caused by fibroids (noncancerous growth of the uterus)

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LEUPROLIDE-LUPRON DEPOT BvD (PART D)

RENEWAL CRITERIA

NOTE: For advanced prostate cancer or uterine leiomyomata (fibroids), please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of endometriosis (ICD-10 Group N80) and meet **ALL** of the following criteria?
   - The patient has improvement of pain related to endometriosis while on therapy
   - The patient is receiving concomitant add-back therapy (i.e., combination estrogen-progestin or progestin-only contraceptive preparation)
   - Lupron Depot will NOT be used concurrently with another GnRH-modulating agent (e.g., Orilissa [elagolix], Zoladex [goserelin], Synarel [nafarelin])
   - The patient has NOT received a total of 12 months of treatment with Lupron Depot per lifetime

   If yes, **approve for 6 months for all strengths as follows:**
   - **Lupron Depot 3.75 mg: Approve by GPID or GPI-14.**
   - **Lupron Depot 11.25 mg: Approve by NDC or GPI-14.**

   If no, do not approve.

   RENEWAL DENIAL TEXT:

   Our guideline named **LEUPROLIDE-LUPRON DEPOT** requires the following rule(s) be met for renewal:
   A. You have endometriosis (condition affecting the uterus)
   B. You experienced improvement of pain related to endometriosis while on therapy
   C. You are receiving add-back therapy at the same time (combination estrogen-progestin or progestin-only contraceptive preparation)
   D. Lupron Depot will NOT be used at the same time with another gonadotropin-releasing hormone (GnRH)-modulating agent (such as Orilissa [elagolix], Zoladex [goserelin], Synarel [nafarelin])
   E. You have NOT received a total of 12 months of treatment with Lupron Depot per lifetime

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LEUPROLIDE-LUPRON DEPOT BvD (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lupron Depot. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Lupron Depot [Prescribing Information]. North Chicago, IL: AbbVie Inc.; August 2025.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed August 4, 2026].

For Part D use only:

LEUPROLIDE-LUPRON DEPOT (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: ENDOMETRIOSIS: PRESCRIBED BY OR IN CONSULTATION WITH AN OBSTETRICIAN/GYNECOLOGIST.
Coverage Duration	PROSTATE CA: 12 MOS. UTERINE FIBROIDS: 3 MOS. ENDOMETRIOSIS: INITIAL/RENEWAL: 6 MOS.
Other Criteria	INITIAL: ENDOMETRIOSIS: 1) NO CONCURRENT USE WITH ANOTHER GNRH-MODULATING AGENT, 2) TRIAL OF OR CONTRAINDICATION TO NSAID AND PROGESTIN-CONTAINING PREPARATION, AND 3) HAS NOT RECEIVED A TOTAL OF 12 MONTHS OF TREATMENT PER LIFETIME. RENEWAL: ENDOMETRIOSIS: 1) IMPROVEMENT OF PAIN RELATED TO ENDOMETRIOSIS WHILE ON THERAPY, 2) RECEIVING CONCOMITANT ADD-BACK THERAPY (I.E., COMBINATION ESTROGEN-PROGESTIN OR PROGESTIN-ONLY CONTRACEPTIVE PREPARATION), 3) NO CONCURRENT USE WITH ANOTHER GNRH-MODULATING AGENT, AND 4) HAS NOT RECEIVED A TOTAL OF 12 MONTHS OF TREATMENT PER LIFETIME.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEUPROLIDE-LUPRON DEPOT-PED BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEUPROLIDE ACETATE	LUPRON DEPOT-PED	21102		GPI-10 (3008005010, 3008005015, 3008005025)	BRAND = LUPRON DEPOT-PED

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 for all strengths under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 for all strengths under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #5.

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LEUPROLIDE-LUPRON DEPOT-PED BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

If yes, **Refer to plan. (The health plan makes the final payment determination decision)**

- **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override)**
- **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

If no, **approve for 12 months by HICL or GPI-10 for all strengths under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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LEUPROLIDE-LUPRON DEPOT-PED BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of central precocious puberty (CPP) (ICD-10 E30.1) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with an endocrinologist

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See initial denial text at the end of the guideline.

2. Is the request for a female patient who meets **ALL** of the following criteria?
   - The patient has an elevated level of luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
   - The patient is younger than 8 years of age at the onset of CPP
   - The patient is at Tanner stage 2 or above for breast development and pubic hair growth

   If yes, **approve for 12 months for all strengths as follows:**
   - **Lupron Depot-Ped 7.5 mg: Approve by GPID or GPI-10.**
   - **Lupron Depot-Ped 15 mg: Approve by GPID or GPI-10.**
   - **Lupron Depot-Ped 30 mg: Approve by GPID or GPI-10.**
   - **Lupron Depot-Ped 11.25 mg (1-month kit): Approve by NDC or GPI-10.**
   - **Lupron Depot-Ped 11.25 mg (3-month kit): Approve by GPID or GPI-10.**
   - **Lupron Depot-Ped 45 mg: Approve by NDC or GPI-14.**

   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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LEUPROLIDE-LUPRON DEPOT-PED BvD (PART D)

INITIAL CRITERIA (CONTINUED)

3. Is the request for a male patient who meets **ALL** of the following criteria?
   - The patient has an elevated level of luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
   - The patient is younger than 9 years of age at the onset of CPP
   - The patient is at Tanner stage 2 or above for genital development and pubic hair growth

   If yes, **approve for 12 months for all strengths as follows:**
   - **Lupron Depot-Ped 7.5 mg: Approve by GPID or GPI-10.**
   - **Lupron Depot-Ped 15 mg: Approve by GPID or GPI-10.**
   - **Lupron Depot-Ped 30 mg: Approve by GPID or GPI-10.**
   - **Lupron Depot-Ped 11.25 mg (1-month kit): Approve by NDC or GPI-10.**
   - **Lupron Depot-Ped 11.25 mg (3-month kit): Approve by GPID or GPI-10.**
   - **Lupron Depot-Ped 45 mg: Approve by NDC or GPI-14.**

   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LEUPROLIDE-LUPRON DEPOT-PED** requires the following rule(s) be met for approval:

   A. You have central precocious puberty (CPP: early sexual development in children)
   B. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
   C. If you are a female, approval also requires:
      1. You have a high level of luteinizing hormone (LH: a type of hormone) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
      2. You are/were younger than 8 years of age when your condition started
      3. You are at Tanner stage 2 or above (scale of physical measurements of development based on external sex characteristics) for breast development and pubic hair growth

   (Initial denial text continued on next page)

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LEUPROLIDE-LUPRON DEPOT-PED BvD (PART D)

INITIAL CRITERIA (CONTINUED)

D. If you are a male, approval also requires:

1. You have a high level of luteinizing hormone (LH: a type of hormone) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
2. You are/were younger than 9 years of age when your condition started
3. You are at Tanner stage 2 or above (scale of physical measurements of development based on external sex characteristics) for genital development and pubic hair growth

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LEUPROLIDE-LUPRON DEPOT-PED BvD (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of central precocious puberty (CPP) (ICD-10 E30.1) and meet **ALL** of the following criteria?
   - The patient's Tanner staging at initial diagnosis has stabilized or regressed during three separate medical visits in the previous year
   - The patient has not reached actual age which corresponds to current pubertal age

   If yes, **approve for 12 months for all strengths as follows:**
   - **Lupron Depot-Ped 7.5 mg: Approve by GPID or GPI-10.**
   - **Lupron Depot-Ped 15 mg: Approve by GPID or GPI-10.**
   - **Lupron Depot-Ped 30 mg: Approve by GPID or GPI-10.**
   - **Lupron Depot-Ped 11.25 mg (1-month kit): Approve by NDC or GPI-10.**
   - **Lupron Depot-Ped 11.25 mg (3-month kit): Approve by GPID or GPI-10.**
   - **Lupron Depot-Ped 45 mg: Approve by NDC or GPI-14.**

   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LEUPROLIDE-LUPRON DEPOT-PED** requires the following rule(s) be met for renewal:
   A. You have central precocious puberty (CPP: early sexual development in children)
   B. Your Tanner staging (scale of physical measurements of development based on external sex characteristics) at initial diagnosis has stabilized or regressed (lowered) during three separate medical visits in the previous year
   C. You have not reached your actual age which corresponds to your current pubertal age

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LEUPROLIDE-LUPRON DEPOT-PED BvD (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lupron-Depot-Ped.

The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Lupron Depot-Ped [Prescribing Information]. North Chicago, IL: AbbVie Inc.; April 2023.

Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed July 1, 2024].

For Part D use only:

LEUPROLIDE-LUPRON DEPOT-PED (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	CENTRAL PRECOCIOUS PUBERTY (CPP): INITIAL: FEMALES: ELEVATED LEVEL OF LUTEINIZING HORMONE (LH) LEVEL GREATER THAN 0.2 TO 0.3 MIU/ML AT DIAGNOSIS. MALES: ELEVATED LEVEL OF LH LEVEL GREATER THAN 0.2 TO 0.3 MIU/ML AT DIAGNOSIS.
Age Restrictions	N/A
Prescriber Restrictions	CPP: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	CPP: INITIAL: FEMALES: 1) YOUNGER THAN 8 YEARS OF AGE AT ONSET OF CPP, AND 2) AT TANNER STAGE 2 OR ABOVE FOR BREAST DEVELOPMENT AND PUBIC HAIR GROWTH. MALES: 1) YOUNGER THAN 9 YEARS OF AGE AT ONSET OF CPP, AND 2) AT TANNER STAGE 2 OR ABOVE FOR GENITAL DEVELOPMENT AND PUBIC HAIR GROWTH. RENEWAL: 1) TANNER STAGING AT INITIAL DIAGNOSIS HAS STABILIZED OR REGRESSED DURING THREE SEPARATE MEDICAL VISITS IN THE PREVIOUS YEAR, AND 2) HAS NOT REACHED ACTUAL AGE WHICH CORRESPONDS TO CURRENT PUBERTAL AGE.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEUPROLIDE MESYLATE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEUPROLIDE MESYLATE	CAMCEVI	47414		GPI-10 (2140501055)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced prostate cancer (ICD-10 C61) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LEUPROLIDE MESYLATE (Camcevi)** requires the following rule(s) be met for approval:
   A. You have advanced prostate cancer (prostate cancer that has spread to nearby tissue or organs)
   B. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LEUPROLIDE MESYLATE (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Camcevi.

REFERENCES

Camcevi [Prescribing Information]. Raleigh, NC: Accord BioPharma Inc.; September 2025.

For Part D use only:

LEUPROLIDE MESYLATE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEVACETYLLEUCINE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEVACETYLLEUCINE	AQNEURSA	49883		GPI-10 (6200002300)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Niemann-Pick disease type C (NPC) (ICD-10 E75.242) **AND** meet the following criterion?
- Therapy is prescribed by or in consultation with a neurologist or geneticist

If yes, **approve for 3 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LEVACETYLLEUCINE (Aqneursa)** requires the following rule(s) be met for approval:
A. You have Niemann-Pick disease type C (NPC: a type of genetic condition)
B. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor) or geneticist (a doctor who treats gene disorders)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEVACETYLLEUCINE (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Niemann-Pick disease type C (NPC) (ICD-10 E75.242) **AND** meet the following criterion?
- The patient has experienced improvement or a slowing of disease progression

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LEVACETYLLEUCINE (Aqneursa)** requires the following rule(s) be met for renewal:
A. You have Niemann-Pick disease type C (NPC: a type of genetic condition)
B. You have shown improvement or a slowing of disease progression

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Aqneursa.

REFERENCES
Aqneursa [Prescribing Information]. Austin, TX: IntraBio Inc.; September 2024.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEVACETYLLEUCINE (PART D)

For Part D use only:

LEVACETYLLEUCINE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	NIEMANN-PICK DISEASE TYPE C (NPC): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST OR GENETICIST.
Coverage Duration	INITIAL: 3 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	NPC: RENEWAL: IMPROVEMENT OR SLOWING OF DISEASE PROGRESSION.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEVAMLODIPINE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEVAMLODIPINE MALEATE	CONJUPRI, LEVAMLODIPINE MALEATE	46284		GPI-10 (3400006728)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of hypertension (ICD-10 I10) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - The patient had a trial of or contraindication to one generic dihydropyridine calcium channel blocker (e.g., amlodipine, felodipine, nicardipine)
   - The patient had a trial of or contraindication to one other antihypertensive agent in another class (e.g., hydrochlorothiazide, lisinopril, losartan)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LEVAMLODIPINE (Conjupri)** requires the following rule(s) be met for approval:
   A. You have hypertension (high blood pressure)
   B. You are 6 years of age or older
   C. You have tried or have a contraindication to (harmful for you to use) one generic dihydropyridine calcium channel blocker (such as amlodipine, felodipine, nicardipine)
   D. You have tried or have a contraindication to one other antihypertensive agent in another drug class (such as hydrochlorothiazide, lisinopril, losartan)
   (Denial text continue on next page)

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LEVAMLODIPINE (PART D)

GUIDELINES FOR USE (CONTINUED)

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Conjupri.

REFERENCES

Conjupri [Prescribing Information]. Hong Kong: CSPC Ouyi Pharmaceutical Co., Ltd.; December 2019.

For Part D use only:

LEVAMLODIPINE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	HYPERTENSION: 1) TRIAL OF OR CONTRAINDICATION TO ONE GENERIC DIHYDROPYRIDINE CALCIUM CHANNEL BLOCKER, AND 2) TRIAL OF OR CONTRAINDICATION TO ONE OTHER ANTIHYPERTENSIVE AGENT IN ANOTHER CLASS (E.G., THIAZIDES, ACE INHIBITOR, ARB)

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 05/22
Client Approval: 06/24
P&T Approval: 10/20

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEVODOPA (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEVODOPA	INBRIJA	01897		GPI-10 (7320004000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Parkinson's disease (ICD-10 Group G20) and meet **ALL** of the following criteria?
   - Inbrija will be used for intermittent treatment of OFF episodes associated with Parkinson's disease
   - The patient is currently being treated with carbidopa/levodopa (e.g., Sinemet, Sinemet CR, Parcopa)
   - Therapy is prescribed by or in consultation with a neurologist

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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LEVODOPA (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LEVODOPA (Inbrija)** requires the following rule(s) be met for approval:

A. You have Parkinson's disease (a movement disorder)
B. Inbrija will be used for intermittent treatment of OFF episodes (times when you have symptoms return due to medication wearing off) associated with Parkinson's disease
C. You are currently being treated with carbidopa/levodopa (such as Sinemet, Sinemet Controlled Release [CR], Parcopa)
D. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LEVODOPA (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Parkinson's disease (ICD-10 Group G20) **AND** meet the following criterion?
   - The patient had improvement with motor fluctuations during OFF episodes with the use of Inbrija (e.g., improvement in speech, facial expression, tremor at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LEVODOPA (Inbrija)** requires the following rule(s) be met for renewal:
   A. You have Parkinson's disease (a movement disorder)
   B. You had improvement with motor fluctuations during OFF episodes (times when you have symptoms return due to medication wearing off) with the use of Inbrija (such as improvement in speech, facial expression, tremor at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Inbrija.

REFERENCES

Inbrija [Prescribing Information]. Ardsley, NY: Acorda Therapeutics, Inc., August 2020.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEVODOPA (PART D)

For Part D use only:

LEVODOPA (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	PARKINSONS DISEASE (PD): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS
Other Criteria	PD: RENEWAL: IMPROVEMENT WITH MOTOR FLUCTUATIONS DURING OFF EPISODES WITH THE USE OF INBRIJA.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEVOKETOCONAZOLE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEVOKETOCONAZOLE	RECORLEV	47743		GPI-10 (3002204000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Cushing's syndrome (ICD-10 Group E24) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is not a candidate for surgery or surgery has not been curative
   - Therapy is prescribed by or in consultation with an endocrinologist

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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LEVOKETOCONAZOLE (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LEVOKETOCONAZOLE (Recorlev)** requires the following rule(s) be met for approval:

A. You have Cushing's syndrome (a type of hormone disorder)
B. You are 18 years of age or older
C. You are not a candidate for surgery or surgery has not been curative (to cure)
D. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LEVOKETOCONAZOLE (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis Cushing's syndrome (ICD-10 Group E24) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - The patient maintains tolerability to the medication

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LEVOKETOCONAZOLE (Recorlev)** requires the following rule(s) be met for renewal:
   A. You have Cushing's syndrome (a type of hormone disorder)
   B. You continue to benefit from the medication
   C. You continue to tolerate treatment with the medication

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Recorlev.

REFERENCES

Recorlev [Prescribing Information]. Chicago, IL: Xeris Pharmaceuticals, Inc.; June 2023.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEVOKETOCONAZOLE (PART D)

For Part D use only:

LEVOKETOCONAZOLE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	CUSHINGS SYNDROME (CS): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST.
Coverage Duration	CS: INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS.
Other Criteria	CS: RENEWAL: CONTINUES TO BENEFIT FROM AND MAINTAINS TOLERABILITY TO THE MEDICATION.

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25 Created: 01/22
Commercial Effective: N/A Client Approval: 06/24 P&T Approval: 01/22

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEVOTHYROXINE - ERMEZA (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEVOTHYROXINE SODIUM	ERMEZA		52325	GPI-14 (28100010102024)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of congenital or acquired hypothyroidism (ICD-10 E89.0, Group E03 except for ICD-10 E03.5) **AND** meet the following criterion?
   - The patient had a contraindication to or is unable to swallow levothyroxine tablets or capsules

   If yes, **approve for 12 months by GPID or GPI-14**.
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of thyrotropin-dependent well-differentiated thyroid cancer (ICD-10 C73) and meet **ALL** of the following criteria?
   - Ermeza will be used as an adjunct to surgery and radioiodine therapy
   - The patient had a contraindication to or is unable to swallow levothyroxine tablets or capsules

   If yes, **approve for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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LEVOTHYROXINE - ERMEZA (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LEVOTHYROXINE-ERMEZA** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Congenital (present from birth) or acquired hypothyroidism (low thyroid function)
   2. Thyrotropin (a type of thyroid hormone)-dependent well-differentiated thyroid cancer

B. If you have congenital or acquired hypothyroidism, approval also requires:
   1. You have a contraindication to (harmful for you to use) or are unable to swallow levothyroxine tablets or capsules

C. If you have thyrotropin-dependent well-differentiated thyroid cancer, approval also requires:
   1. Ermeza will be used as adjunct (add-on) to surgery and radioiodine therapy (a type of radiation therapy)
   2. You have a contraindication to (harmful for you to use) or are unable to swallow levothyroxine tablets or capsules

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ermeza.

REFERENCES

Ermeza [Prescribing Information]. Morgantown, WV: Mylan Specialty L.P., April 2022.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEVOTHYROXINE - ERMEZA (PART D)

For Part D use only:

LEVOTHYROXINE - ERMEZA (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	HYPOTHYROIDISM, THYROTROPIN-DEPENDENT WELL-DIFFERENTIATED THYROID CANCER: CONTRAINDICATION TO OR UNABLE TO SWALLOW LEVOTHYROXINE TABLETS OR CAPSULES.

Created: 12/22
Effective: 02/07/26 Client Approval: 02/26 P&T Approval: 04/25

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEVOTHYROXINE-TIROSINT (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEVOTHYROXINE SODIUM	TIROSINT, LEVOTHYROXINE	02849		GPI-10 (2810001010)	DOSAGE FORM = CAPSULE

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of congenital or acquired hypothyroidism (ICD-10 E89.0, Group E03 except for ICD-10 E03.5) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - The patient had a trial and failure of or contraindication to generic levothyroxine tablets

   If yes, **approve all strengths for 12 months by GPID or GPI-14**.
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of thyrotropin-dependent well-differentiated thyroid cancer (ICD-10 C73) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - The requested medication is being used as an adjunct to surgery and radioiodine therapy
   - The patient had a trial and failure of or contraindication to generic levothyroxine tablets

   If yes, **approve all strengths for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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LEVOTHYROXINE-TIROSINT (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LEVOTHYROXINE-TIROSINT** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Congenital (present from birth) or acquired hypothyroidism (low thyroid function)
   2. Thyrotropin (a type of thyroid hormone)-dependent well-differentiated thyroid cancer

B. If you have congenital or acquired hypothyroidism, approval also requires:
   1. You are 6 years of age or older
   2. You have tried and failed (drug did not work) or have a contraindication to (harmful for you to use) generic levothyroxine tablets

C. If you have thyrotropin-dependent well-differentiated thyroid cancer, approval also requires:
   1. You are 6 years of age or older
   2. The requested medication will be used as adjunct (add-on) to surgery and radioiodine therapy (a type of radiation therapy)
   3. You have tried and failed (drug did not work) or have a contraindication to (harmful for you to use) generic levothyroxine tablets

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tirosint.

REFERENCES

Tirosint [Prescribing Information]. Pambio-Noranco, Switzerland: IBSA Institut Biochimique SA, June 2022.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEVOTHYROXINE-TIROSINT (PART D)

For Part D use only:

LEVOTHYROXINE-TIROSINT (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	HYPOTHYROIDISM, THYROTROPIN-DEPENDENT WELL-DIFFERENTIATED THYROID CANCER: TRIAL AND FAILURE OF OR CONTRAINDICATION TO A GENERIC LEVOTHYROXINE TABLET.

Created: 04/23
Effective: 02/07/26 Client Approval: 02/26 P&T Approval: 10/21

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEVOTHYROXINE-TIROSINT-SOL (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEVOTHYROXINE SODIUM	TIROSINT-SOL	02849		GPI-10 (2810001010)	BRAND = TIROSINT-SOL

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of congenital or acquired hypothyroidism (ICD-10 E89.0, Group E03 except for ICD-10 E03.5) **AND** meet the following criterion?
   - The patient had a trial and failure of or contraindication to generic levothyroxine tablets

   If yes, **approve all strengths for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of thyrotropin-dependent well-differentiated thyroid cancer (ICD-10 C73) and meet **ALL** of the following criteria?
   - Tirosint-Sol will be used as an adjunct to surgery and radioiodine therapy
   - The patient had a trial and failure of or contraindication to generic levothyroxine tablets

   If yes, **approve all strengths for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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LEVOTHYROXINE-TIROSINT-SOL (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LEVOTHYROXINE-TIROSINT-SOL** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Congenital (present from birth) or acquired hypothyroidism (low thyroid function)
   2. Thyrotropin (a type of thyroid hormone)-dependent well-differentiated thyroid cancer

B. If you have congenital or acquired hypothyroidism, approval also requires:
   1. You have tried and failed (medication did not work) or have a contraindication to (harmful for you to use) generic levothyroxine tablets

C. If you have thyrotropin-dependent well-differentiated thyroid cancer, approval also requires:
   1. Tirosint-Sol will be used as adjunct (add-on) to surgery and radioiodine therapy (a type of radiation therapy)
   2. You have tried and failed (medication did not work) or have a contraindication to (harmful for you to use) generic levothyroxine tablets

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tirosint-Sol.

REFERENCES

Tirosint-Sol [Prescribing Information]. Pambio-Noranco, Switzerland: IBSA Institut Biochimique SA, November 2023.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEVOTHYROXINE-TIROSINT-SOL (PART D)

For Part D use only:

LEVOTHYROXINE-TIROSINT-SOL (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	HYPOTHYROIDISM, THYROTROPIN-DEPENDENT WELL-DIFFERENTIATED THYROID CANCER: TRIAL AND FAILURE OF OR CONTRAINDICATION TO A GENERIC LEVOTHYROXINE TABLET.

Created: 06/22
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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

L-GLUTAMINE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GLUTAMINE (L-GLUTAMINE)	ENDARI, GLUTAMINE (L-GLUTAMINE)	00856		GPI-10 (8280102000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of sickle cell disease (ICD-10 Group D57) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with a hematologist

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient between 5 and 17 years of age?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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L-GLUTAMINE (PART D)

INITIAL CRITERIA (CONTINUED)

3. Is the patient 18 years of age or older and meets **ONE** of the following criteria?
   - The patient had at least 2 sickle cell crises in the past year (a sickle cell crises is defined as a visit to an emergency room/medical facility for sickle cell disease-related pain which was treated with a parenterally administered narcotic or parenterally administered ketorolac, the occurrence of chest syndrome, priapism, or splenic sequestration)
   - The patient is having sickle-cell associated symptoms (e.g., pain, anemia) which are interfering with activities of daily living
   - The patient has a history of or has recurrent acute chest syndrome (ACS)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **L-GLUTAMINE (Endari)** requires the following rule(s) be met for approval:
   A. You have sickle cell disease (a type of blood disorder)
   B. You are 5 years of age or older
   C. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
   D. If you are 18 years of age or older, approval also requires ONE of the following:
      1. You had at least 2 sickle cell crises in the past year (a sickle cell crisis is defined as a visit to an emergency room/medical facility for sickle cell disease-related pain which was treated with a parenterally administered [injected into the vein] narcotic [a class of drugs used to treat pain] or parenterally administered ketorolac, the occurrence of chest syndrome, priapism [prolonged erection of penis], or splenic sequestration [sickle-shaped blood cells trapped in spleen])
      2. You are having sickle-cell associated symptoms (such as pain, anemia [a type of blood condition]) which are interfering with activities of daily living
      3. You have a history of or have recurrent acute chest syndrome (ACS: chest pain, cough, fever, low oxygen level)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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L-GLUTAMINE (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of sickle cell disease (ICD-10 Group D57) **AND** meet the following criterion?
   - The patient has maintained or experienced a reduction in acute complications of sickle cell disease (SCD) (e.g., number of sickle cell crises, hospitalizations, acute chest syndrome [ACS])

   If yes, **approve for lifetime by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **L-GLUTAMINE (Endari)** requires the following rule(s) be met for renewal:
   A. You have sickle cell disease (a type of blood disorder)
   B. You have maintained or experienced a reduction in acute (short-term) complications of sickle cell disease (such as the number of sickle cell crises, hospitalizations, acute chest syndrome [ACS: chest pain, cough, fever, low oxygen level])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Endari.

REFERENCES
Endari [Prescribing Information]. Torrance, CA: Emmaus Medical, Inc.; July 2024.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

L-GLUTAMINE (PART D)

For Part D use only:

L-GLUTAMINE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	SICKLE CELL DISEASE (SCD): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST
Coverage Duration	INITIAL: 12 MONTHS. RENEWAL: LIFETIME.
Other Criteria	SCD: INITIAL: AGES 18 YEARS OR OLDER: 1) AT LEAST 2 SICKLE CELL CRISES IN THE PAST YEAR, 2) SICKLE-CELL ASSOCIATED SYMPTOMS WHICH ARE INTERFERING WITH ACTIVITIES OF DAILY LIVING, OR 3) HISTORY OF OR HAS RECURRENT ACUTE CHEST SYNDROME. AGES 5 TO 17 YEARS: APPROVED WITHOUT ADDITIONAL CRITERIA. RENEWAL: MAINTAINED OR EXPERIENCED A REDUCTION IN ACUTE COMPLICATIONS OF SCD.

Created: 11/17
Effective: 01/01/26 Client Approval: 01/26 P&T Approval: 10/19

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LIDOCAINE OINTMENT TIRF (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LIDOCAINE	LIDOCAINE		30750	GPI-14 (90850060004210)	

These are TIRF-Like drugs requiring a payment determination for 'Part D' or 'Non-Part D'.

PAYMENT DETERMINATION CRITERIA

1. Does the patient have a diagnosis of end stage renal disease (ESRD) and is on dialysis (ICD-10 N18.6)?

   If yes, please process as follows:

   CSR NOTE: If the caller is a physician, member, and/or AOR, please initiate a verbal PA intake request in MR4. If the caller is a pharmacy, please advise the pharmacy to bill the medication as part of the bundled dialysis facility payment or that the pharmacy contact the provider or member to submit a PA for further review.

   PAC NOTE: Please defer to a pharmacist for denial.

   CLINICAL SPECIALIST NOTE: This medication is included in the bundled dialysis facility payment and is not a Part D eligible drug. Please follow the process within the HQ notes and internal procedures for denial.

   If no, continue to #2.

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LIDOCAINE OINTMENT TIRF (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

2. Is the request for **ONE** of the following?
   - Production of anesthesia of accessible mucous membranes of the oropharynx
   - As an anesthetic lubricant for intubation
   - Temporary relief of pain associated with minor burns, including sunburn, abrasions of the skin, and insect bites

   If yes, **set MCARE_DRUG_DETERM_OVR to 'Y', and approve for 12 months by GPID or GPI-14. Document in the PA comments: Part D Determination Override and diagnosis.** (**NOTE:** If the ESRD_Dialysis attribute is present, select the 'ESRD' Override Type within the PA, which is available in the 'Additional Overrides' section.)

   If no, **do not enter an MCARE override. Then, process as follows:**
   CSR Note:
   - If the caller is a physician, member, and/or AOR, please initiate a verbal PA intake request in MR4.
   - If the caller is a pharmacy, please advise the pharmacy to contact the provider or member to pursue a payment determination and document the diagnosis provided in MedAccess.

   Please follow the clinical authorization process within the HQ notes.

   RPH Note:
   - Review for both FDA and Part D compendial supported off-label indications.
   - If the provided diagnosis is not FDA approved or compendial supported off-label use, **set MCARE_DRUG_DETERM_OVR to 'N' and enter override within the denied PA for 12 months by GPID or GPI-14.**
   - If the diagnosis is UNKNOWN do not enter an MCARE override; follow the criteria for any additional UM and decision the case accordingly. Provide the following PAC instruction: '**PAC: do not enter an MCARE override**.'

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LIDOCAINE OINTMENT TIRF (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LIDOCAINE OINTMENT** requires the following rule(s) be met for approval:

A. You do not have end stage renal disease (ESRD: a type of kidney disease) and are not on dialysis (process of removing excess water, toxins from the blood)
B. The request is for ONE of the following:
    1. Production of anesthesia (numbing) of accessible mucous membranes of the oropharynx (soft, pink, and moist lining at the back of the throat)
    2. As an anesthetic lubricant (a type of numbing, slippery gel) for intubation (placing a breathing tube)
    3. Temporary relief of pain associated with minor burns, including sunburn, abrasions of the skin (minor skin injury), and insect bites

RATIONALE

Prior authorization on lidocaine 5% ointment is required due to a high potential for non-Part D use. Lidocaine 5% ointment should NOT be used for non-medically accepted indications as defined in section 1860D-2(e)(4) of the Act. Patients identified as Part D End Stage Renal Disease (ESRD) undergoing dialysis will be directed to a dialysis treatment center and have their ESRD treatment related drug included in the bundled dialysis facility payment. For further information, please refer to the Prescribing Information and/or Drug Monograph for topical lidocaine ointment.

REFERENCES

Lidocaine ointment [Prescribing Information]. Mahwah, NJ: Glenmark Pharmaceuticals Inc.; January 2020.

Announcement of Calendar Year (CY) 2015 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. April 7, 2014. Section III – Part D: Appropriate Utilization of Prior Authorization Requirements to Determine Part D Drug Status. Page 112 – 114.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LIDOCAINE OINTMENT TIRF (PART D)

For Part D use only:

LIDOCAINE OINTMENT (PART D)	
Covered Uses	ALL MEDICALLY-ACCEPTED INDICATIONS.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 03/23
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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LIDOCAINE PATCH TIRF (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LIDOCAINE	LIDODERM, LIDOCAINE, DERMACINRX LIDOCAN, TRIDACAINE, TRIDACAINE II, III, ZTLIDO		50272 44495	GPI-14 (90850060005930, 90850060005910)	

These are TIRF-Like drugs requiring a payment determination for 'Part D' or 'Non-Part D'.

PAYMENT DETERMINATION CRITERIA

1. Is the request for lidocaine 5% patches (Lidoderm, DermacinRx, Lidocan, Tridacaine, Tridacaine II, Tridacaine III) for **ONE** of the following indications?
   - Relief of pain associated with post-herpetic neuralgia (PHN) (ICD-10 B02.22, B02.29, B02.23)
   - Neuropathy due to diabetes mellitus (ICD-10 Group E11.4)
   - Chronic back pain
   - Osteoarthritis of the knee (ICD-10 Group M17) or hip (ICD-10 Group M16)

   If yes, **set MCARE_DRUG_DETERM_OVR to 'Y' and approve for 12 months by GPID or GPI-14. Document in the PA comments: Part D Determination Override and diagnosis.**

   If no, continue to #2.

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LIDOCAINE PATCH TIRF (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

2. Is the request for ZTlido 1.8% patches for **ONE** of the following indications?
   - Relief of pain associated with post-herpetic neuralgia (PHN) (ICD-10 B02.22, B02.29, B02.23) AND patient is 18 years of age or older
   - Neuropathy due to diabetes mellitus (ICD-10 Group E11.4)
   - Chronic back pain
   - Osteoarthritis of the knee (ICD-10 Group M17) or hip (ICD-10 Group M16)

   If yes, **set MCARE_DRUG_DETERM_OVR to 'Y' and approve for 12 months by GPID or GPI-14. Document in the PA comments: Part D Determination Override and diagnosis.**

   If no, **do not enter an MCARE override. Then, process as follows:**
   CSR Note:
   - If the caller is a physician, member, and/or AOR, please initiate a verbal PA intake request in MR4.
   - If the caller is a pharmacy, please advise the pharmacy to contact the provider or memberto pursue a payment determination and document the diagnosis provided in MedAccess.

   Please follow the clinical authorization process within the HQ notes.

   RPH Note:
   - Review for both FDA and Part D compendial supported off-label indications.
   - If the provided diagnosis is not FDA approved or compendial supported off-label use, **set MCARE_DRUG_DETERM_OVR to 'N' and enter override within the denied PA for 12 months by GPID or GPI-14.**
   - If the diagnosis is UNKNOWN do not enter an MCARE override; follow the criteria for any additional UM and decision the case accordingly. Provide the following PAC instruction: '**PAC: do not enter an MCARE override**.'

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LIDOCAINE PATCH TIRF (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LIDOCAINE PATCH (Lidoderm, DermacinRx Lidocan, Tridacaine, Tridacaine II, Tridacaine III, ZTlido)** requires the following rule(s) be met for approval:

A. If the request is for lidocaine 5% patches (Lidoderm, DermacinRx, Lidocan, Tridacaine, Tridacaine II, Tridacaine III), approval also requires ONE of the following:

1. The request is for relief of pain associated with post-herpetic neuralgia (PHN: nerve pain caused by shingles virus)
2. The request is for neuropathy due to diabetes mellitus (a type of nerve damage caused by high blood sugar)
3. The request is for chronic (long-term) back pain
4. The request is for osteoarthritis (a type of joint condition) of the knee or hip

B. If the request is for ZTlido 1.8% patches, approval also requires ONE of the following:

1. The request is for relief of pain associated with post-herpetic neuralgia (PHN: nerve pain caused by shingles virus) AND you are 18 years of age or older
2. The request is for neuropathy due to diabetes mellitus (a type of nerve damage caused by high blood sugar)
3. The request is for chronic (long-term) back pain
4. The request is for osteoarthritis (a type of joint condition) of the knee or hip

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RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lidoderm, DermacinRx, Lidocan, Tridacaine, Tridacaine II, Tridacaine III, or ZTlido.

Prior authorization on lidocaine is required due to a high potential for non-Part D use. Lidoderm, Lidocan, ZTlido should NOT be used for non-medically accepted indications as defined in section 1860D-2(e)(4) of the Act.

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LIDOCAINE PATCH TIRF (PART D)

REFERENCES

Lidoderm [Prescribing Information]. Malvern, PA: Endo Pharmaceuticals; November 2022.
Lidocan [Prescribing Information]. Panorama City, CA: PureTek Corp; July 2024.
Tridacaine [Prescribing Information]. San Antonio, TX: Trifluent Pharmac; January 2024.
Tridacaine II [Prescribing Information]. San Antonio, TX: Trifluent Pharma; May 2024.
Tridacaine III [Prescribing Information]. San Antonio, TX: Trifluent Pharma; June 2024.
ZTlido [Prescribing Information]. San Diego, CA: Scilex Pharmaceuticals Inc.; April 2021.
Announcement of Calendar Year (CY) 2015 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. April 7, 2014. Section III – Part D: Appropriate Utilization of Prior Authorization Requirements to Determine Part D Drug Status. Page 112 – 114.
Krebs EE, Gravely A, Nugent S, et al: Effect of opioid vs nonopioid medications on pain-related function in patients with chronic back pain or hip or knee osteoarthritis pain: the SPACE randomized clinical trial. JAMA 2018; 319(9):872-882

For Part D use only:

LIDOCAINE PATCH (PART D)	
Covered Uses	ALL MEDICALLY-ACCEPTED INDICATIONS.
Exclusion Criteria	N/A
Required Medical Information	1) PAIN ASSOCIATED WITH POST-HERPETIC NEURALGIA, 2) NEUROPATHY DUE TO DIABETES MELLITUS, 3) CHRONIC BACK PAIN, OR 4) OSTEOARTHRITIS OF THE KNEE OR HIP.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LIDOCAINE SOLUTION TIRF (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LIDOCAINE HCL	LIDOCAINE HCL		11942 97001	GPI-14 (90850060102015, 88350065102045)	

These are TIRF-Like drugs requiring a payment determination for 'Part D' or 'Non-Part D'.

PAYMENT DETERMINATION CRITERIA

1. Is the request for the production of topical anesthesia of accessible mucous membranes of the oral and nasal cavities and proximal portions of the digestive tract, or the respiratory tract?

   If yes, **set MCARE_DRUG_DETERM_OVR to 'Y' and approve for 12 months by GPID or GPI-14. Document in the PA comments: Part D Determination Override and diagnosis.**

   If no, **do not enter an MCARE override. Then, process as follows:**
   CSR Note:
   - If the caller is a physician, member, and/or AOR, please initiate a verbal PA intake request in MR4.
   - If the caller is a pharmacy, please advise the pharmacy to contact the provider or member to pursue a payment determination and document the diagnosis provided in MedAccess.

   Please follow the clinical authorization process within the HQ notes.

   RPH Note:
   - Review for both FDA and Part D compendial supported off-label indications.
   - If the provided diagnosis is not FDA approved or compendial supported off-label use, **set MCARE_DRUG_DETERM_OVR to 'N' and enter override within the denied PA for 12 months by GPID or GPI-14.**
   - If the diagnosis is UNKNOWN do not enter an MCARE override; follow the criteria for any additional UM and decision the case accordingly. Provide the following PAC instruction: '**PAC: do not enter an MCARE override**.'

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LIDOCAINE SOLUTION** requires the following rule(s) be met for approval:
   A. The request is for the production of topical anesthesia (numbing) of accessible mucous membranes (soft, pink, and moist lining inside the body) of the oral and nasal cavities (mouth and nose) and proximal (upper) portions of the digestive tract, or the respiratory tract (airways)

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LIDOCAINE SOLUTION TIRF (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for topical lidocaine solution. Prior authorization on lidocaine is required due to a high potential for non-Part D use.

REFERENCES

Lidocaine hydrochloride solution [Prescribing Information]. Berkeley Heights, NJ: Hikma Pharmaceuticals USA Inc.; May 2023.

Lidocaine hydrochloride solution [Prescribing Information]. South El Monte, CA: International Medication Systems, Ltd; December 2021.

Announcement of Calendar Year (CY) 2015 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. April 7, 2014. Section III – Part D: Appropriate Utilization of Prior Authorization Requirements to Determine Part D Drug Status. Page 112 – 114.

For Part D use only:

LIDOCAINE SOLUTION (PART D)	
Covered Uses	ALL MEDICALLY-ACCEPTED INDICATIONS.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LIDOCAINE-PRILOCAINE TIRF (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LIDOCAINE/PRILOCAINE	LIDOCAINE-PRILOCAINE	16196		GPI-10 (9085990290)	

These are TIRF-Like drugs requiring a payment determination for 'Part D' or 'Non-Part D'.

PAYMENT DETERMINATION CRITERIA

1. Does the patient have a diagnosis of end stage renal disease (ESRD) and is on dialysis (ICD-10 N18.6)?

   If yes, please process as follows:

   CSR Note: If the caller is a physician, member, and/or AOR, please initiate a verbal PA intake request in MR4. If the caller is a pharmacy, please advise the pharmacy to bill the medication as part of the bundled dialysis facility payment or that the pharmacy contact the provider or member to submit a PA for further review.

   PAC Note: Please defer to a pharmacist for denial.

   Clinical specialist note: This medication is included in the bundled dialysis facility payment and is not a Part D eligible drug. Please follow the process within the HQ notes and internal procedures for denial.

   If no, continue to #2.

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LIDOCAINE-PRILOCAINE TIRF (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

2. Does the patient meet **ONE** of the following criteria?
   - The requested medication will be used on normal intact skin for local analgesia
   - The requested medication will be used on genital mucous membranes for superficial minor surgery and as pretreatment for infiltration anesthesia

   If yes, **set MCARE_DRUG_DETERM_OVR to 'Y' and approve for 12 months by HICL or GPI-10. Document in the PA comments: Part D Determination Override and diagnosis.** (**NOTE:** If the ESRD_Dialysis attribute is present, select the 'ESRD' Override Type within the PA, which is available in the 'Additional Overrides' section.)

   If no, **do not enter an MCARE override. Then, process as follows:**
   CSR Note:
   - If the caller is a physician, member, and/or AOR, please initiate a verbal PA intake request in MR4.
   - If the caller is a pharmacy, please advise the pharmacy to contact the provider or member to pursue payment determination and document the diagnosis provided in MedAccess.

   Please follow the clinical authorization process within the HQ notes.

   RPH Note:
   - Review for both FDA and Part D compendial supported off-label indications.
   - If the provided diagnosis is not FDA approved or compendial supported off-label use, **set MCARE_DRUG_DETERM_OVR to 'N' and enter override within the denied PA for 12 months by HICL or GPI-10.**
   - If the diagnosis is UNKNOWN do not enter an MCARE override; follow the criteria for any additional UM and decision the case accordingly. Provide the following PAC instruction: '**PAC: do not enter an MCARE override**.'

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LIDOCAINE-PRILOCAINE** requires the following rule(s) be met for approval:
   A. You do not have end stage renal disease (ESRD: a type of kidney disease) and are not on dialysis (process of removing excess water, toxins from the blood)
   B. You meet ONE of the following:
      1. The requested medication will be used on normal intact (unbroken) skin for local analgesia (pain relief in a small area)
      2. The requested medication will be used on genital mucous membranes (soft, moist, pink, or red lining of the genital area) for superficial minor surgery (a type of simple procedure done on the top layers of the tissue) and as pretreatment (before treatment) for infiltration anesthesia (injection of medication to numb the treatment area)

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LIDOCAINE-PRILOCAINE TIRF (PART D)

RATIONALE

Prior authorization on lidocaine-prilocaine cream is required due to a high potential for non-Part D use. Lidocaine-prilocaine cream should NOT be used for non-medically accepted indications as defined in section 1860D-2(e)(4) of the Act.
Patients identified as Part D End Stage Renal Disease (ESRD) undergoing dialysis will be directed to a dialysis treatment center and have their ESRD treatment related drug included in the bundled dialysis facility payment. For further information, please refer to the prescribing information for lidocaine-prilocaine cream.

REFERENCES

Announcement of Calendar Year (CY) 2015 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. April 7, 2014. Section III – Part D: Appropriate Utilization of Prior Authorization Requirements to Determine Part D Drug Status. Page 112 – 114.
Lidocaine and prilocaine cream [Prescribing Information]. Melville, NY: E. Fougera & Co.; January 2024.

For Part D use only:

LIDOCAINE PRILOCAINE (PART D)	
Covered Uses	ALL MEDICALLY-ACCEPTED INDICATIONS.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LINVOSELTAMAB-GCPT (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LINVOSELTAMAB-GCPT	LYNOZYFIC	50677		GPI-10 (2135204500)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory multiple myeloma (ICD-10 Group C90.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received at least FOUR prior lines of therapy, including a proteasome inhibitor (e.g., Velcade [bortezomib], Kyprolis [carfilzomib], Ninlaro [ixazomib]), an immunomodulatory agent (e.g., Revlimid [lenalidomide], Pomalyst [pomalidomide]), and an anti-CD38 monoclonal antibody [e.g., Darzalex [daratumumab])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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LINVOSELTAMAB-GCPT (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LINVOSELTAMAB-GCPT (Lynozyfic)** requires the following rule(s) be met for approval:

A. You have relapsed or refractory multiple myeloma (a type of blood cancer that has returned or did not respond to treatment)
B. You are 18 years of age or older
C. You have received at least FOUR prior lines of therapy, including a proteasome inhibitor (such as Velcade [bortezomib], Kyprolis [carfilzomib], Ninlaro [ixazomib]), an immunomodulatory agent (such as Revlimid [lenalidomide], Pomalyst [pomalidomide]), and an anti-CD38 monoclonal antibody [such as Darzalex [daratumumab])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lynozyfic.

REFERENCES

Lynozyfic [Prescribing Information]. Cambridge, MA: Takeda Pharmaceuticals; July 2025.

For Part D use only:

LINVOSELTAMAB-GCPT (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LISDEXAMFETAMINE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LISDEXAMFETAMINE DIMESYLATE	VYVANSE, LISDEXAMFETAMINE DIMESYLATE	34486		GPI-10 (6110002510)	BRAND ≠ ARYNTA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe binge eating disorder (ICD-10 F50.81)and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a psychiatrist
   - The patient has had at least 3 binge eating episodes per week for at least 3 months

   If yes, **approve all strengths for 3 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of attention deficit hyperactivity disorder (ADHD) (ICD-10 Group F90) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - The patient had a trial of or contraindication to ONE of the following long-acting stimulants: dextroamphetamine/amphetamine extended release (ER, XR) capsules, methylphenidate controlled delivery (CD) capsules, methylphenidate long acting (LA) capsules, methylphenidate ER tablets

   If yes, **approve all strengths for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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LISDEXAMFETAMINE (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LISDEXAMFETAMINE (Vyvanse)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Attention deficit hyperactivity disorder (ADHD: a type of mental health disorder)
   2. Moderate to severe binge eating disorder (a type of eating disorder)

B. If you have attention deficit hyperactivity disorder, approval also requires:
   1. You are 6 years of age or older
   2. You have tried or have a contraindication to (harmful for you to use) ONE of the following long-acting stimulants: dextroamphetamine/amphetamine extended release (ER, XR) capsules, methylphenidate controlled delivery (CD) capsules, methylphenidate long acting (LA) capsules, methylphenidate ER tablets

C. If you have moderate to severe binge eating disorder, approval also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a psychiatrist (a type of mental health doctor)
   3. You have had at least 3 binge eating events (episodes) per week for at least 3 months

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LISDEXAMFETAMINE (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe binge eating disorder (ICD-10 F50.81) **AND** meet the following criterion?
   - The requested drug has been effective in reducing the number of binge eating episodes per week from the patient's baseline

   If yes, **approve all strengths for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of attention deficit hyperactivity disorder (ADHD) (ICD-10 Group F90)?

   If yes, **approve all strengths for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LISDEXAMFETAMINE (Vyvanse)** requires the following rules be met for renewal:
   A. You have ONE of the following:
      1. Attention deficit hyperactivity disorder (ADHD: a type of mental health disorder)
      2. Moderate to severe binge eating disorder (a type of eating disorder)
   B. If you have moderate to severe binge eating disorder, renewal also requires:
      1. You have had a decrease in the number of binge eating events per week from when you first started the requested medication

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LISDEXAMFETAMINE (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vyvanse and lisdexamfetamine dimesylate.

REFERENCES

Vyvanse [Prescribing Information]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; October 2023.

lisdexamfetamine dimesylate. [Prescribing Information]. Berkeley Heights, NJ: Hikma Pharmaceuticals USA Inc.; January 2024.

For Part D use only:

LISDEXAMFETAMINE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	BINGE EATING DISORDER (BED): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A PSYCHIATRIST.
Coverage Duration	INITIAL: BED: 3 MOS, ADHD: 12 MOS. RENEWAL: ALL INDICATIONS: 12 MOS.
Other Criteria	INITIAL: BED: HAS AT LEAST 3 BINGE EATING EPISODES PER WEEK FOR AT LEAST 3 MONTHS. ADHD: TRIAL OF OR CONTRAINDICATION TO ONE OF THE FOLLOWING LONG-ACTING STIMULANTS: DEXTROAMPHETAMINE/AMPHETAMINE ER OR XR CAPSULES, METHYLPHENIDATE CD CAPSULES, METHYLPHENIDATE LA CAPSULES, METHYLPHENIDATE ER TABLETS. RENEWAL: BED: REDUCTION IN THE NUMBER OF BINGE EATING EPISODES PER WEEK FROM BASELINE.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LISDEXAMFETAMINE SOLUTION (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LISDEXAMFETAMINE DIMESYLATE	ARYNTA	34486		GPI-10 (6110002510)	BRAND = ARYNTA

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of attention deficit hyperactivity disorder (ADHD) (ICD-10 Group F90) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - The patient has a contraindication to or is unable to swallow lisdexamfetamine capsules or chewable tablets

   If yes, **approve for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe binge eating disorder (ICD-10 F50.81) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a contraindication to or is unable to swallow lisdexamfetamine capsules or chewable tablets

   If yes, **approve for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LISDEXAMFETAMINE SOLUTION (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LISDEXAMFETAMINE SOLUTION (Arynta)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Attention deficit hyperactivity disorder (ADHD: a type of mental health disorder)
   2. Moderate to severe binge eating disorder (a type of eating disorder)

B. If you have attention deficit hyperactivity disorder, approval also requires:
   1. You are 6 years of age or older
   2. You have a contraindication to (harmful for you to use) or are unable toswallow lisdexamfetamine capsules or chewable tablets

C. If you have moderate to severe binge eating disorder, approval also requires:
   1. You are 18 years of age or older
   2. You have a contraindication to (harmful for you to use) or are unable toswallow lisdexamfetamine capsules or chewable tablets

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Arynta.

REFERENCES

Arynta [Prescribing Information]. Woburn, MA: Azurity Pharmaceuticals, Inc.; June 2025.

For Part D use only:

LISDEXAMFETAMINE SOLUTION (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	ATTENTION DEFICIT HYPERACTIVITY DISORDER (ADHD), BINGE EATING DISORDER (BED): CONTRAINDICATION TO OR UNABLE TO SWALLOW LISDEXAMFETAMINE CAPSULES OR CHEWABLE TABLETS.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LISINOPRIL (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LISINOPRIL	QBRELIS	00132		GPI-10 (3610003000)	BRAND = QBRELIS

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of hypertension (ICD-10 I10) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - The patient has a contraindication to or is unable to swallow lisinopril tablets

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of heart failure (ICD-10 Group I50) and meet **ALL** of the following criteria?
   - Qbrelis will be used as adjunct therapy
   - The patient has a contraindication to or is unable to swallow lisinopril tablets

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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LISINOPRIL (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of acute myocardial infarction (ICD-10 Group I21) **AND** meet the following criterion?
   - The patient has a contraindication to or is unable to swallow lisinopril tablets

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LISINOPRIL (Qbrelis)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Hypertension (high blood pressure)
      2. Heart failure (a type of heart condition)
      3. Acute myocardial infarction (heart attack)

   B. If you have hypertension, approval also requires:
      1. You are 6 years of age or older
      2. You have a contraindication to (harmful for you to use) or are unable to swallow lisinopril tablets

   C. If you have heart failure, approval also requires:
      1. Qbrelis will be used as adjunct (add-on) therapy
      2. You have a contraindication to (harmful for you to use) or are unable to swallow lisinopril tablets

   D. If you have acute myocardial infarction, approval also requires:
      1. You have a contraindication to (harmful for you to use) or are unable to swallow lisinopril tablets

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Qbrelis.

REFERENCES
Qbrelis [Prescribing Information]. Woburn, MA: Azurity Pharmaceuticals, Inc.; April 2023.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LISINOPRIL (PART D)

For Part D use only:

LISINOPRIL (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	ALL INDICATIONS: CONTRAINDICATION TO OR UNABLE TO SWALLOW LISINOPRIL TABLETS.

Created: 10/25
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 07/25

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LOMITAPIDE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LOMITAPIDE MESYLATE	JUXTAPID	39883		GPI-10 (3948005020)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of homozygous familial hypercholesterolemia (HoFH) (ICD-10 E78.01) as determined by meeting **ONE** of the following criteria?
   - Simon Broome diagnostic criteria (definite)
   - Dutch Lipid Network criteria with a score of at least 8
   - A clinical diagnosis based on a history of an untreated LDL-cholesterol level greater than 500 mg/dL AND the patient has either xanthoma before 10 years of age or evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a cardiologist, endocrinologist, or lipidologist
   - The patient has an LDL-cholesterol level of at least 70 mg/dL while on maximally tolerated drug treatment

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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LOMITAPIDE (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient meet **ONE** of the following criteria?
   - The patient is 2 to 9 years of age
   - The patient is 10 years of age or older AND had a trial of Repatha (evolocumab)
   - The patient lacks functioning LDL receptors

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient meet **ONE** of the following criteria?
   - The patient is currently taking a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) AND has been taking it for a duration of at least 8 weeks
   - Given that the patient cannot tolerate a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily), the patient is currently taking a maximally tolerated dose of any statin AND has been taking it for a duration of at least 8 weeks
   - The patient has an absolute contraindication to statin therapy (e.g., age, active decompensated liver disease, nursing female, pregnancy or plans to become pregnant, hypersensitivity reaction)
   - The patient has statin intolerance
   - The patient has tried rosuvastatin, atorvastatin, or statin therapy at any dose and has experienced skeletal-muscle related symptoms (e.g., myopathy)

   If yes, **approve for 12 months by HICL or GPI-10.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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LOMITAPIDE (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT:

Our guideline named **LOMITAPIDE (Juxtapid)** requires the following rule(s) be met for approval:

A. You have homozygous familial hypercholesterolemia (HoFH: type of inherited high cholesterol)
B. You are 2 years of age or older
C. Your diagnosis is determined by meeting ONE of the following:
    1. Simon Broome diagnostic criteria (definite) (a tool for diagnosing homozygous familial hypercholesterolemia)
    2. Dutch Lipid Network (a tool for diagnosing homozygous familial hypercholesterolemia) criteria with a score of at least 8
    3. A clinical diagnosis based on a history of an untreated low density lipoprotein (LDL: bad cholesterol)-cholesterol level greater than 500 mg/dL AND you have either xanthoma (a type of skin condition) before 10 years of age or there is evidence of heterozygous familial hypercholesterolemia (HeFH: type of inherited high cholesterol) in both parents
D. Therapy is prescribed by or in consultation with a cardiologist (heart doctor), endocrinologist (hormone doctor), or lipidologist (cholesterol management doctor)
E. You have a low density lipoprotein cholesterol (LDL-C: bad cholesterol) level of at least 70 mg/dL while on maximally tolerated drug treatment
F. You meet ONE of the following:
    1. You are 2 to 9 years of age
    2. You are 10 years of age or older AND have tried Repatha (evolocumab)
    3. You do NOT have functional LDL (low density lipoprotein)-receptors (a type of protein)
G. You meet ONE of the following:
    1. You are currently taking a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) AND have been taking it for a duration of at least 8 weeks
    2. You did not tolerate a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily), but you are currently taking a maximally tolerated dose of any statin AND have been taking it for a duration of at least 8 weeks
    3. You have an absolute contraindication to (harmful for you to use) statin therapy (such as age, active decompensated liver disease [symptoms related to liver damage], nursing female, pregnancy or plans to become pregnant, hypersensitivity [allergic] reaction)
    4. You have statin intolerance (side effect)
    5. You have tried rosuvastatin, atorvastatin, or statin therapy at any dose andexperienced skeletal-muscle related symptoms (such as myopathy [muscle disease])

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LOMITAPIDE (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Juxtapid.

REFERENCES
Juxtapid [Prescribing Information]. Parma, Italy: Chiesi Farmaceutici S.p.A.; February 2026.

For Part D use only:

LOMITAPIDE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (HOFH): 1) DIAGNOSIS DETERMINED BY: (A) DEFINITE SIMON BROOME DIAGNOSTIC CRITERIA, (B) DUTCH LIPID NETWORK CRITERIA SCORE OF AT LEAST 8, OR (C) CLINICAL DIAGNOSIS BASED ON A HISTORY OF AN UNTREATED LDL-C CONCENTRATION GREATER THAN 500 MG/DL TOGETHER WITH EITHER XANTHOMA BEFORE 10 YEARS OF AGE OR EVIDENCE OF HEFH IN BOTH PARENTS, AND 2) LDL-C LEVEL OF AT LEAST 70MG/DL WHILE ON MAXIMALLY TOLERATED DRUG TREATMENT.
Age Restrictions	N/A
Prescriber Restrictions	HOFH: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST, ENDOCRINOLOGIST OR LIPIDOLOGIST.
Coverage Duration	12 MONTHS
Other Criteria	HOFH: 1) TRIAL OF REPATHA, WHERE AGES ALIGN, UNLESS THE PATIENT HAS NON-FUNCTIONING LDL RECEPTORS, AND 2) ONE OF THE FOLLOWING: (A) TAKING A HIGH-INTENSITY STATIN (I.E., ATORVASTATIN 40-80MG DAILY, ROSUVASTATIN 20-40MG DAILY) FOR A DURATION OF AT LEAST 8 WEEKS, (B) TAKING A MAXIMALLY TOLERATED DOSE OF ANY STATIN FOR A DURATION OF AT LEAST 8 WEEKS GIVEN THAT THE PATIENT CANNOT TOLERATE A HIGH-INTENSITY STATIN, (C) ABSOLUTE CONTRAINDICATION TO STATIN THERAPY (E.G., AGE, ACTIVE DECOMPENSATED LIVER DISEASE, NURSING FEMALE, PREGNANCY OR PLANS TO BECOME PREGNANT, HYPERSENSITIVITY REACTIONS), (D) STATIN INTOLERANCE, OR (E) TRIAL OF ROSUVASTATIN, ATORVASTATIN, OR STATIN THERAPY AT ANY DOSE AND HAS EXPERIENCED SKELETAL-MUSCLE RELATED SYMPTOMS (E.G., MYOPATHY).

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LONAFARNIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LONAFARNIB	ZOKINVY	46991		GPI-10 (9946304500)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Hutchinson-Gilford Progeria Syndrome (HGPS) (ICD-10 E34.8) and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - The patient has a body surface area (BSA) of 0.39m(2) or above

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of processing-deficient Progeroid Laminopathies and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - The patient has a body surface area (BSA) of 0.39m(2) or above
   - The patient has a heterozygous LMNA mutation with progerin-like protein accumulation OR homozygous or compound heterozygous ZMPSTE24 mutations

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See denial text at the end of the guideline.

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LONAFARNIB (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LONAFARNIB (Zokinvy)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Hutchinson-Gilford Progeria Syndrome (HGPS: a rare genetic disorder)
   2. Processing-deficient Progeroid Laminopathies (a rare genetic disorder)
B. You are 1 year of age or older
C. You have a body surface area (BSA) of 0.39 meters squared or more
D. If you have processing-deficient Progeroid Laminopathies, approval also requires you have ONE of the following:
   1. Heterozygous LMNA (type of gene) mutation with progerin-like protein accumulation
   2. Homozygous or compound heterozygous ZMPSTE24 (type of gene) mutations

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zokinvy.

REFERENCES

Zokinvy[Prescribing Information]. Palo Alto, CA: Eiger BioPharmaceuticals, Inc.; November 2020.

For Part D use only:

LONAFARNIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LONAFARNIB (PART D)

Core	Advantage	Plus
No	No	Yes

Created: 12/20
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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LONAPEGSOMATROPIN-TCGD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LONAPEGSOMATROPIN-TCGD	SKYTROFA	47565		GPI-10 (3010000380)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the requested medication being used for **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.
   If no, continue to #2.

2. Is the request for a pediatric patient with a diagnosis of growth failure due to inadequate secretion of endogenous growth hormone (GH) (ICD-10 Group E34.3), and does the patient meet **ALL** of the following criteria?
   - The patient is 1 to 17 years of age and weighs at least 11.5 kg (25.3 lbs)
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has open epiphyses (as confirmed by radiograph of the wrist and hand)
   - The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   - Skytrofa will NOT be used concurrently with Increlex (mecasermin)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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LONAPEGSOMATROPIN-TCGD (PART D)

INITIAL CRITERIA (CONTINUED)

3. Is the request for an adult patient with a diagnosis of growth hormone deficiency (GHD) (ICD-10 Group E34.3, E23.0), and does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist
   - Skytrofa will NOT be used concurrently with Increlex (mecasermin)

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Is the patient's GHD caused by a congenital, genetic, or organic disease (e.g., craniopharyngioma [tumor], pituitary hypoplasia, ectopic posterior pituitary, previous cranial irradiation)?

   If yes, **approve for 12 months by HICL or GPI-10**.
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Is the patient's GHD confirmed by **ONE** of the following growth hormone stimulation tests?
   - Insulin tolerance test (peak growth hormone of 5 ng/mL or less)
   - Glucagon-stimulation test (peak response of 3 ng/mL or less AND the patient's BMI is less than 25 kg/m2; OR peak response of 3 ng/mL or less AND the patient's BMI is between 25 and 30 kg/m2 with a high pre-test probability; OR peak response of 1 ng/mL or less AND the patient's BMI is between 25 and 30 kg/m2 with a low test probability; OR peak response of 1 ng/mL or less AND the patient's BMI is greater than 30 kg/m2)
   - Macimorelin test (peak growth hormone of 2.8 ng/mL or less)

   If yes, **approve for 12 months by HICL or GPI-10**.
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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LONAPEGSOMATROPIN-TCGD (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LONAPEGSOMATROPIN-TCGD (Skytrofa)** requires the following rule(s) be met for approval:

A. You meet ONE of the following:
   1. You are a pediatric patient with growth failure due to inadequate secretion of endogenous (produced inside the body) growth hormone (GH)
   2. You are an adult patient with growth hormone deficiency (GHD: a type of hormone disorder with low growth hormone)

B. Skytrofa is NOT being used for any of the following:
   1. Athletic enhancement (to perform better in sports)
   2. Anti-aging purposes

C. If you are a pediatric patient with growth failure due to inadequate secretion of endogenous growth hormone, approval also requires:
   1. You are 1 to 17 years of age and weigh at least 11.5 kg (25.3 pounds)
   2. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
   3. You have open epiphyses (end part of long bone) as confirmed by radiograph (type of imaging test) of the wrist and hand
   4. Your height is at least 2 standard deviations (SD: a measure of variation from the average) below the mean (average) height for children of the same age and gender
   5. You will NOT use Skytrofa concurrently (at the same time) with Increlex (mecasermin)

(Initial denial text continued on next page)

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LONAPEGSOMATROPIN-TCGD (PART D)

INITIAL CRITERIA (CONTINUED)

D. If you are an adult patient with growth hormone deficiency, approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
3. You will NOT use Skytrofa concurrently (at the same time) with Increlex (mecasermin)
4. You meet ONE of the following:
   a. Your diagnosis is caused by a congenital (at birth), genetic, or organic disease (such as craniopharyngioma [tumor], pituitary hypoplasia [a type of brain condition], ectopic posterior pituitary [a type of brain condition], previous cranial irradiation [radiation to the brain])
   b. Your diagnosis is confirmed by ONE of the following growth hormone stimulation tests (tests that measure the body's ability to produce growth hormone):
      i. Insulin tolerance test (peak growth hormone of 5 ng/mL or less)
      ii. Glucagon-stimulation test (peak response of 3 ng/mL or less AND your body mass index [BMI: a tool for evaluating body fat] is less than 25 kg/m2; OR peak response of 3 ng/mL or less AND your BMI is between 25 and 30 kg/m2 with a high pre-test probability; OR peak response of 1 ng/mL or less AND your BMI is between 25 and 30 kg/m2 with a low test probability; OR peak response of 1 ng/mL or less AND your BMI is greater than 30 kg/m2)
      iii. Macimorelin test (peak growth hormone of 2.8 ng/mL or less)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LONAPEGSOMATROPIN-TCGD (PART D)

RENEWAL CRITERIA

1. Is the requested medication being used for **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.
   If no, continue to #2.

2. Is the request for a pediatric patient with a diagnosis of growth failure due to inadequate secretion of endogenous growth hormone (GH) (ICD-10 Group E34.3), and does the patient meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has open epiphyses (as confirmed by radiograph of the wrist and hand) OR the patient has not completed prepubertal growth
   - The patient has shown improvement (increased height or increased growth velocity) while on therapy
   - Skytrofa will NOT be used concurrently with Increlex (mecasermin)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Is the request for an adult patient with a diagnosis of growth hormone deficiency (GHD) (ICD-10 Group E34.3, E23.0), and does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has achieved or maintained a response to therapy as evidenced by clinical treatment goals (e.g., improved body composition, lipid panel, bone health)
   - Skytrofa will NOT be used concurrently with Increlex (mecasermin)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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LONAPEGSOMATROPIN-TCGD (PART D)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LONAPEGSOMATROPIN-TCGD (Skytrofa)** requires the following rule(s) be met for renewal:

A. You meet ONE of the following:
   1. You are a pediatric patient with growth failure due to inadequate secretion of endogenous (produced inside the body) growth hormone (GH)
   2. You are an adult patient with growth hormone deficiency (GHD: a type of hormone disorder with low growth hormone)

B. Skytrofa is NOT being used for the treatment of any of the following conditions:
   1. Athletic enhancement (to perform better in sports)
   2. Anti-aging purposes

C. If you are a pediatric patient with growth failure due to inadequate secretion of endogenous growth hormone, renewal also requires:
   1. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
   2. You have open epiphyses (end part of long bone) as confirmed by radiograph (type of imaging test) of the wrist and hand OR you have not completed prepubertal growth
   3. You have shown improvement (increased height or increased growth velocity [rate]) while on therapy
   4. You will NOT use Skytrofa concurrently (at the same time) with Increlex (mecasermin)

D. If you are an adult patient with growth hormone deficiency, renewal also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an endocrinologist (type of hormone doctor)
   3. You have achieved or maintained a response to therapy as evidenced by clinical treatment goals (such as improved body composition, lipid [fat] panel, bone health)
   4. You will NOT use Skytrofa concurrently (at the same time) with Increlex (mecasermin)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Skytrofa.

REFERENCES

Skytrofa [Prescribing Information]. Princeton, NJ: Ascendis Pharma Endocrinology, Inc.; July 2025.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LONAPEGSOMATROPIN-TCGD (PART D)

For Part D use only:

LONAPEGSOMATROPIN-TCGD (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	INITIAL/RENEWAL: ATHLETIC ENHANCEMENT, ANTI-AGING PURPOSES.
Required Medical Information	INITIAL: PEDIATRIC GROWTH HORMONE DEFICIENCY (GHD): HEIGHT IS AT LEAST 2 STANDARD DEVIATIONS (SD) BELOW THE MEAN HEIGHT FOR CHILDREN OF THE SAME AGE AND GENDER. ADULT GHD: 1) HAS A CONGENITAL, GENETIC, OR ORGANIC DISEASE (E.G., CRANIOPHARYNGIOMA, PITUITARY HYPOPLASIA, ECTOPIC POSTERIOR PITUITARY, PREVIOUS CRANIAL IRRADIATION), OR 2) GHD CONFIRMED BY ONE OF THE FOLLOWING GROWTH HORMONE (GH) STIMULATION TESTS: (A) INSULIN TOLERANCE TEST (PEAK GH OF 5 NG/ML OR LESS), (B) GLUCAGON-STIMULATION TEST (ONE OF THE FOLLOWING: (I) PEAK RESPONSE OF 3 NG/ML OR LESS AND BMI LESS THAN 25 KG/M2, (II) PEAK RESPONSE OF 3 NG/ML OR LESS AND BMI IS BETWEEN 25 AND 30 KG/M2 WITH A HIGH PRE-TEST PROBABILITY, (III) PEAK RESPONSE OF 1 NG/ML OR LESS AND BMI IS BETWEEN 25 AND 30 KG/M2 WITH LOW TEST PROBABILITY, OR (IV) PEAK RESPONSE OF 1 NG/ML OR LESS AND BMI IS GREATER THAN 30 KG/M2), OR (C) MACIMORELIN TEST (PEAK GH OF 2.8 NG/ML OR LESS).
Age Restrictions	N/A
Prescriber Restrictions	INITIAL/RENEWAL: PEDIATRIC/ADULT GHD: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS
Other Criteria	INITIAL: PEDIATRIC GHD: OPEN EPIPHYSES AS CONFIRMED BY RADIOGRAPH OF WRIST AND HAND. INITIAL/RENEWAL: PEDIATRIC GHD, ADULT GHD: NO CONCURRENT USE WITH INCRELEX. RENEWAL: PEDIATRIC GHD: 1) OPEN EPIPHYSES AS CONFIRMED BY RADIOGRAPH OF WRIST AND HAND OR PATIENT HAS NOT COMPLETED PREPUBERTAL GROWTH, AND 2) IMPROVEMENT ON THERAPY (INCREASED HEIGHT OR INCREASED GROWTH VELOCITY). ADULT GHD: ACHIEVED OR MAINTAINED A RESPONSE TO THERAPY (E.G., IMPROVED BODY COMPOSITION, LIPID PANEL, BONE HEALTH).

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LONCASTUXIMAB TESIRINE-LPYL (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LONCASTUXIMAB TESIRINE-LPYL	ZYNLONTA	47312		GPI-10 (2135164050)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory large B-cell lymphoma (ICD-10 Groups C83.3, C85.2), including diffuse large B-cell lymphoma (DLBCL) (ICD-10 Group C83.3), DLBCL arising from low grade lymphoma, and high-grade B-cell lymphoma and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received two or more lines of systemic therapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LONCASTUXIMAB TESIRINE-LPYL (Zynlonta)** requires the following rule(s) be met for approval:
   A. You have relapsed or refractory large B-cell lymphoma (type of white blood cell cancer that has returned or is not responding to treatment), including diffuse large B-cell lymphoma (DLBCL), DLBCL arising from low grade lymphoma, and high-grade B-cell lymphoma
   B. You are 18 years of age or older
   C. You have received two or more lines of systemic therapy (treatment that travels throughout the body)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LONCASTUXIMAB TESIRINE-LPYL (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zynlonta.

REFERENCES

Zynlonta [Prescribing Information]. Epalinges, Switzerland: ADC Therapeutics SA; October 2022.

For Part D use only:

LONCASTUXIMAB TESIRINE-LPYL (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LORLATINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LORLATINIB	LORBRENA	45448		GPI-10 (2153055600)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's tumors are anaplastic lymphoma kinase (ALK)-positive, as detected by an FDA-approved test

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LORLATINIB (Lorbrena)** requires the following rule(s) be met for approval:
   A. You have metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body)
   B. You are 18 years of age or older
   C. Your tumors are anaplastic lymphoma kinase (ALK: type of enzyme)-positive, as detected by a Food and Drug Administration (FDA)-approved test

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LORLATINIB (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lorbrena.

REFERENCES

Lorbrena [Prescribing Information]. New York, NY: Pfizer, Inc. ; March 2021.

For Part D use only:

LORLATINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LOSARTAN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LOSARTAN POTASSIUM	ARBLI	09829		GPI-10 (3615004020)	BRAND = ARBLI

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of hypertension (ICD-10 I10) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - The patient has a contraindication to or is unable to swallow losartan tablets

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of hypertension (ICD-10 I10) with left ventricular hypertrophy (ICD-10 I51.7) **AND** meet the following criterion?
   - The patient has a contraindication to or is unable to swallow losartan tablets

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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LOSARTAN (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of type 2 diabetes with diabetic nephropathy (ICD-10 E11.21) and meet **ALL** of the following criteria?
   - The patient has a history of hypertension
   - The patient has an elevated serum creatinine level and proteinuria (urinary albumin to creatinine ratio of at least 300mg/g)
   - The patient has a contraindication to or is unable to swallow losartan tablets

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LOSARTAN (Arbli)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Hypertension (high blood pressure)
      2. Hypertension with left ventricular hypertrophy (a type of heart condition)
      3. Type 2 diabetes (a disorder with high blood sugar) with diabetic nephropathy (a type of kidney disease caused by high blood sugar)

   B. If you have hypertension, approval also requires:
      1. You are 6 years of age or older
      2. You have a contraindication to (harmful for you to use) or are unable to swallow losartan tablets

   C. If you have hypertension with left ventricular hypertrophy, approval also requires:
      1. You have a contraindication to (harmful for you to use) or are unable to swallow losartan tablets

   D. If you have type 2 diabetes with diabetic nephropathy, approval also requires:
      1. You have a history of hypertension (high blood pressure)
      2. You have an elevated serum creatinine level (a type of lab test to measure kidney function) and proteinuria (a condition with high levels of protein in the urine) (urinary albumin to creatinine ratio of at least 300mg/g)
      3. You have a contraindication to (harmful for you to use) or are unable to swallow losartan tablets

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LOSARTAN (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Arbli.

REFERENCES
Arbli [Prescribing Information]. Commack, NY: Scienture LLC; March 2025.

For Part D use only:

LOSARTAN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	HYPERTENSION, HYPERTENSION WITH LEFT VENTRICULAR HYPERTROPHY, TYPE 2 DIABETES WITH DIABETIC NEPHROPATHY: CONTRAINDICATION TO OR UNABLE TO SWALLOW LOSARTAN TABLETS.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LOTILANER (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LOTILANER	XDEMVY	45544		GPI-10 (8610605000)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Demodex blepharitis (ICD-10 Group H01.00) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 6 weeks by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LOTILANER (Xdemvy)** requires the following rule(s) be met for approval:
   A. You have Demodex blepharitis (a type of inflammatory eye condition)
   B. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LOTILANER (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xdemvy.

REFERENCES

Xdemvy [Prescribing Information]. Irvine, CA: Tarsus Pharmaceuticals, Inc.; July 2023.

For Part D use only:

LOTILANER (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	DEMODEX BLEPHARITIS: 18 YEARS OF AGE OR OLDER
Prescriber Restrictions	N/A
Coverage Duration	6 WEEKS
Other Criteria	N/A

Created: 06/24
Effective: 01/01/25 Client Approval: 06/24 P&T Approval: 10/23

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LUMACAFTOR-IVACAFTOR (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LUMACAFTOR/IVACAFTOR	ORKAMBI	42235		GPI-10 (4530990230)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of cystic fibrosis (CF) (ICD-10 Group E84) and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - Therapy is prescribed by or in consultation with a pulmonologist or cystic fibrosis expert
   - Orkambi will NOT be used concurrently with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (e.g., medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)
   - The patient is homozygous for the *F508del* mutation in the CFTR gene

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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LUMACAFTOR-IVACAFTOR (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LUMACAFTOR-IVACAFTOR (Orkambi)** requires the following rule(s) be met for approval:

A. You have cystic fibrosis (CF: a type of lung disorder)
B. You are 1 year of age or older
C. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or cystic fibrosis expert
D. You will NOT use Orkambi concurrently (at the same time) with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (such as medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)
E. You are homozygous (have two copies of the same gene) for the F508del mutation in the CFTR gene (abnormal change in a type of gene)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LUMACAFTOR-IVACAFTOR (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of cystic fibrosis (CF) (ICD-10 Group E84) and meet **ALL** of the following criteria?
   - The patient has experienced an improvement in clinical status
   - Orkambi will NOT be used concurrently with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (e.g., medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)

   If yes, **approve for lifetime by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LUMACAFTOR-IVACAFTOR (Orkambi)** requires the following rule(s) be met for renewal:
   A. You have cystic fibrosis (CF: a type of lung disorder)
   B. You have experienced an improvement in your clinical status
   C. You will NOT use Orkambi concurrently (at the same time) with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (such as medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LUMACAFTOR-IVACAFTOR (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Orkambi.

REFERENCES

Orkambi [Prescribing Information]. Boston, MA: Vertex Pharmaceuticals Incorporated; December 2024.

For Part D use only:

LUMACAFTOR-IVACAFTOR (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	CYSTIC FIBROSIS (CF): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A PULMONOLOGIST OR CF EXPERT.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: LIFETIME.
Other Criteria	CF: INITIAL: NO CONCURRENT USE WITH ANOTHER CYSTIC FIBROSIS TRANSMEMBRANE CONDUCTANCE REGULATOR (CFTR) MODULATOR. RENEWAL: 1) IMPROVEMENT IN CLINICAL STATUS, AND 2) NO CONCURRENT USE WITH ANOTHER CFTR MODULATOR.

Created: 07/15
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 01/25

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LUMASIRAN BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LUMASIRAN SODIUM	OXLUMO	46999		GPI-10 (5662604020)	

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #5.

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LUMASIRAN BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LUMASIRAN BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of primary hyperoxaluria type 1 (PH1) (ICD-10 E72.53)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LUMASIRAN (Oxlumo)** requires the following rule(s) be met for approval:
   A. You have primary hyperoxaluria type 1 (PH1: a rare disorder that affects the kidneys)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Oxlumo. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LUMASIRAN BvD (PART D)

REFERENCES

Oxlumo [Prescribing Information]. Cambridge, MA: Alynlam Pharmaceuticals, Inc.; September 2023.

Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed July 1, 2024].

For Part D use only:

LUMASIRAN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LURBINECTEDIN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LURBINECTEDIN	ZEPZELCA	46626		GPI-10 (2110002400)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of small cell lung cancer (SCLC) (ICD-10 Group C34) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have extensive-stage small cell lung cancer (ES-SCLC) and meet **ALL** of the following criteria?
   - Zepzelca will be used in combination with Tecentriq (atezolizumab) or Tecentriq Hybreza (atezolizumab and hyaluronidase-tqjs)
   - The patient's disease has not progressed after first-line induction therapy with Tecentriq (atezolizumab) or Tecentriq Hybreza (atezolizumab and hyaluronidase-tqjs), carboplatin, and etoposide

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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LURBINECTEDIN (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Is the patient's cancer metastatic **AND** the patient meets the following criterion?
   - The patient had disease progression on or after platinum-based chemotherapy (e.g., carboplatin, cisplatin)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LURBINECTEDIN (Zepzelca)** requires the following rule(s) be met for approval:
   A. You have small cell lung cancer (SCLC: a type of lung cancer)
   B. You are 18 years of age or older
   C. You meet ONE of the following:
      1. You have extensive-stage small cell lung cancer (ES-SCLC: a type of lung cancer); Zepzelca will be used in combination with Tecentriq (atezolizumab) or Tecentriq Hybreza (atezolizumab and hyaluronidase-tqjs); AND your disease has not progressed (worsened) after first-line induction therapy (start of treatment) with Tecentriq (atezolizumab) or Tecentriq Hybreza (atezolizumab and hyaluronidase-tqjs), carboplatin, and etoposide
      2. Your cancer is metastatic (has spread to other parts of the body); AND you had disease progression (worsening) on or after platinum-based chemotherapy (a type of cancer treatment such as carboplatin or cisplatin)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LURBINECTEDIN (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zepzelca.

REFERENCES

Zepzelca [Prescribing Information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; October 2025.

For Part D use only:

LURBINECTEDIN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 06/20
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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LUSPATERCEPT-AAMT (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LUSPATERCEPT-AAMT	REBLOZYL	46196		GPI-10 (8240054010)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of beta thalassemia (ICD-10 D56.1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient requires regular red blood cell (RBC) transfusions
   - Reblozyl will be used for the treatment of anemia

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of very low- to intermediate-risk myelodysplastic syndrome (MDS) (ICD-10 Group D46) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is erythropoiesis stimulating agent (ESA)-naïve (has not previously used an ESA such as Epogen [epoetin alfa])
   - Reblozyl will be used for the treatment of anemia

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue #3.

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LUSPATERCEPT-AAMT (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have **ONE** of the following diagnoses?
   - Very low- to intermediate-risk myelodysplastic syndrome with ring sideroblasts (MDS-RS) (ICD-10 D46.B, D46.1)
   - Myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T) (ICD-10 D46.B and D46.1 and D47.1 and Group D75.83)

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is failing an erythropoiesis stimulating agent (ESA) (e.g., Epogen [epoetin alfa]) AND requires at least 2 red blood cell (RBC) units over 8 weeks
   - Reblozyl will be used for the treatment of anemia

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.***

   Our guideline named **LUSPATERCEPT-AAMT (Reblozyl)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Beta thalassemia (a type of blood condition)
      2. Very low- to intermediate-risk myelodysplastic syndrome (MDS: a type of blood cancer)
      3. Very low- to intermediate-risk myelodysplastic syndrome with ring sideroblasts (MDS-RS: a type of blood cancer)
      4. Myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T: a type of blood cancer)

   B. If you have beta thalassemia, approval also requires:
      1. You are 18 years of age or older
      2. You require regular red blood cell (RBC) transfusions (adding blood to your body)
      3. Reblozyl will be used for the treatment of anemia (a type of blood condition)

   (Denial text continued on next page)

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LUSPATERCEPT-AAMT (PART D)

GUIDELINES FOR USE (CONTINUED)

C. If you have very low-to intermediate-risk myelodysplastic syndrome, approval also requires:
1. You are 18 years of age or older
2. You are erythropoiesis stimulating agent (ESA)-naïve (you have not previously used a type of medication that increases the production of red blood cells such as Epogen [epoetin alfa])
3. Reblozyl will be used for the treatment of anemia (a type of blood condition)

D. If you have very low- to intermediate-risk myelodysplastic syndrome with ring sideroblasts OR with myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis, approval also requires:
1. You are 18 years of age or older
2. You are failing an erythropoiesis stimulating agent (ESA: a type of medication that increases the production of red blood cells such as Epogen [epoetin alfa])
3. You require at least 2 red blood cell (RBC) units over 8 weeks
4. Reblozyl will be used for the treatment of anemia (a type of blood condition)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Reblozyl.

REFERENCES
Reblozyl [Prescribing Information]. Summit, NJ: Celgene Corporation; May 2024.

For Part D use only:

LUSPATERCEPT-AAMT (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 11/19
Effective: 01/19/26 Client Approval: 01/26 P&T Approval: 10/23

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LUSUTROMBOPAG (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LUSUTROMBOPAG	MULPLETA	45127		GPI-10 (8240504500)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of thrombocytopenia (ICD-10 D69.6) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has chronic liver disease
   - The patient is scheduled to undergo a procedure 8 to 14 days after starting Mulpleta therapy
   - Therapy is prescribed by or in consultation with a hematologist, gastroenterologist, hepatologist, immunologist, endocrinologist, or surgeon
   - Mulpleta will NOT be used concurrently with other thrombopoietin receptor agonists [TPO-RAs] (e.g., Doptelet [avatrombopag], Nplate [romiplostim], Promacta [eltrombopag])

   If yes, **approve for 1 month by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LUSUTROMBOPAG (Mulpleta)** requires the following rule(s) be met for approval:
   A. You have thrombocytopenia (a type of blood disorder)
   B. You are 18 years of age or older
   C. You have chronic (long-term) liver disease
   D. You are scheduled to undergo a procedure 8 to 14 days after starting Mulpleta therapy
   (Denial text continued on next page)

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LUSUTROMBOPAG (PART D)

GUIDELINES FOR USE (CONTINUED)

E. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor), gastroenterologist (a type of doctor who treats digestive conditions), hepatologist (a type of liver doctor), immunologist (a type of immune system doctor), endocrinologist (a type of hormone doctor), or surgeon
F. You will NOT use Mulpleta concurrently (at the same time) with other thrombopoietin receptor agonists [TPO-RAs] (such as Doptelet [avatrombopag], Nplate [romiplostim], Promacta [eltrombopag])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Mulpleta.

REFERENCES

Mulpleta [Prescribing Information]. Florham Park, NJ: Shionogi & Co, Ltd.; April 2020.

For Part D use only:

LUSUTROMBOPAG (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	THROMBOCYTOPENIA: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST, GASTROENTEROLOGIST, HEPATOLOGIST, IMMUNOLOGIST, ENDOCRINOLOGIST, OR SURGEON.
Coverage Duration	1 MONTH
Other Criteria	THROMBOCYTOPENIA: 1) HAS A PLANNED PROCEDURE 8 TO 14 DAYS AFTER INITIATION OF MULPLETA, AND 2) NO CONCURRENT USE WITH OTHER THROMBOPOIETIN RECEPTOR AGONISTS.

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 08/18
Client Approval: 06/24
P&T Approval: 12/18

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ADVANTAGE AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MACITENTAN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MACITENTAN	MACITENTAN	40677		GPI-10 (4016005000)	BRAND ≠ OPSUMIT

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (World Health Organization Group 1) (ICD-10 I27.0, Group I27.2) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of 15 mmHg or less
   - Pulmonary vascular resistance (PVR) greater than 2 Wood units

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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MACITENTAN (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **MACITENTAN (Opsumit)** requires the following rule(s) be met for approval:

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization Group 1: a way to classify the severity of disease)
B. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
C. Your pulmonary arterial hypertension diagnosis is confirmed by right heart catheterization (a test used to measure how well the heart is pumping) with ALL of the following lab values:
    1. Mean pulmonary artery pressure (PAP: a type of measurement for pulmonary arterial hypertension) greater than 20 mmHg
    2. Pulmonary capillary wedge pressure (PCWP: a type of measurement for pulmonary arterial hypertension) of 15 mmHg or less
    3. Pulmonary vascular resistance (PVR: a type of measurement for pulmonary arterial hypertension) greater than 2 Wood units

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MACITENTAN (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (World Health Organization Group 1) (ICD-10 I27.0, Group I27.2)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MACITENTAN (Opsumit)** requires the following rule(s) be met for renewal:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization Group 1: a way to classify the severity of disease)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph(s) for Opsumit.

REFERENCES
Opsumit [Prescribing Information]. Titusville, NJ: Actelion Pharmaceuticals US, Inc; April 2025.

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ADVANTAGE AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MACITENTAN (PART D

For Part D use only:

MACITENTAN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	PULMONARY ARTERIAL HYPERTENSION (PAH): INITIAL: DIAGNOSIS CONFIRMED BY RIGHT HEART CATHETERIZATION WITH THE FOLLOWING PARAMETERS: 1) MEAN PULMONARY ARTERY PRESSURE (PAP) GREATER THAN 20 MMHG, 2) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF 15 MMHG OR LESS, AND 3) PULMONARY VASCULAR RESISTANCE (PVR) GREATER THAN 2 WOOD UNITS.
Age Restrictions	N/A
Prescriber Restrictions	PAH: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	N/A

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MACITENTAN-TADALAFIL TIRF (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MACITENTAN/ TADALAFIL	OPSYNVI	47644		GPI-10 (4099550250)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

These are TIRF-Like drugs requiring a payment determination for "Part D" or "Non-Part D".

PAYMENT DETERMINATION CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (ICD-10 I27.0, Group I27.2) (World Health Organization Group 1)?

   If yes, **set MCARE_DRUG_DETERM_OVR to 'Y' and approve for 12 months by HICL or GPI-10. Document in the PA comments: Part D Determination Override and diagnosis.**

   If no, **do not enter an MCARE override. Then, process as follows:**
   CSR Note:
   - If the caller is a physician, member, and/or AOR, please initiate a verbal PA intake request in MR3.
   - If the caller is a pharmacy, please advise the pharmacy to contact the provider or member to pursue a payment determination and document the diagnosis provided in MedAccess.

   Please follow the clinical authorization process within the HQ notes.

   RPH Note:
   - Review for both FDA and Part D compendial supported off-label indications.
   - If the provided diagnosis is not FDA approved or compendial supported off-label use, **set MCARE_DRUG_DETERM_OVR to 'N' and enter override within the denied PA for 12 months by HICL or GPI-10.**
   - If the diagnosis is UNKNOWN do not enter an MCARE override; follow the criteria for any additional UM and decision the case accordingly. Provide the following PAC instruction**:** '**PAC: do not enter an MCARE override**.'

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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MACITENTAN-TADALAFIL TIRF (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (ICD-10 I27.0, Group I27.2) (World Health Organization Group 1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has WHO Functional Class II-III symptoms
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   - The patient is NOT concurrently or intermittently taking oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
   - Opsynvi will NOT be used concurrently with guanylate cyclase (GC) stimulators (e.g., Adempas [riociguat])

   If yes, continue to #2.
   If no, do not approve.
   If not a Part D indication: Set MCARE_DRUG_DETERM_OVR to 'N' and enter override within the denied PA for 12 months by HICL or GPI-10.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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MACITENTAN-TADALAFIL TIRF (PART D)

INITIAL CRITERIA (CONTINUED)

2. Is the PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of 15 mmHg or less
   - Pulmonary vascular resistance (PVR) of greater than 2 Wood units

   If yes, **approve for 12 months by HICL or GPI-10. NOTE: If the claim rejects for payment determination after analyzing, then follow the above TIRF-Like determination criteria.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   If indication is Part D, but other criteria not met: Set MCARE_DRUG_DETERM_OVR to 'Y' and enter override within the partially denied PA for 12 months by HICL or GPI-10.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MACITENTAN-TADALAFIL (Opsynvi)** requires the following rule(s) be met for approval:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization Group 1: a way to classify the severity of disease)
   B. You are 18 years of age or older
   C. You have WHO Functional Class II-III symptoms (a way to classify how limited physical activity is)
   D. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   E. You are NOT concurrently (at the same time) or intermittently (off and on) taking oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
   F. You will NOT use Opsynvi concurrently (at the same time) with guanylate cyclase stimulators (drugs that also treat pulmonary hypertension such as Adempas [riociguat])

   (Initial denial text continued on next page)

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MACITENTAN-TADALAFIL TIRF (PART D)

INITIAL CRITERIA (CONTINUED)

G. Your pulmonary arterial hypertension diagnosis is confirmed by right heart catheterization (a test used to measure how well the heart is pumping) with ALL of the following lab values:
   1. Mean pulmonary artery pressure (PAP: a type of measurement for pulmonary arterial hypertension) greater than 20 mmHg
   2. Pulmonary capillary wedge pressure (PCWP: a type of measurement for pulmonary arterial hypertension) of 15 mmHg or less
   3. Pulmonary vascular resistance (PVR: a type of measurement for pulmonary arterial hypertension) greater than 2 Wood units

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MACITENTAN-TADALAFIL TIRF (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (ICD-10 I27.0, Group I27.2) (World Health Organization Group 1) and meet **ALL** of the following criteria?
   - The patient is NOT concurrently or intermittently taking oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
   - Opsynvi will NOT be used concurrently with guanylate cyclase (GC) stimulators (e.g., Adempas [riociguat])

   If yes, **approve for 12 months by HICL or GPI-10. NOTE: If the claim rejects for payment determination after analyzing, then follow the above TIRF-Like determination criteria. APPROVAL TEXT (IF APPLICABLE):** The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   - **If not a Part D indication: Set MCARE_DRUG_DETERM_OVR to 'N' and enter override within the denied PA for 12 months by HICL or GPI-10.**
   - **If indication is Part D, but other criteria not met: Set MCARE_DRUG_DETERM_OVR to 'Y' and enter override within the partially denied PA for 12 months by HICL or GPI-10.**

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MACITENTAN-TADALAFIL (Opsynvi)** requires the following rule(s) be met for renewal:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization Group 1: a way to classify the severity of disease)
   B. You are NOT concurrently (at the same time) or intermittently (off and on) taking oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
   C. You will NOT use Opsynvi concurrently (at the same time) with guanylate cyclase stimulators (drugs that also treat pulmonary hypertension such as Adempas [riociguat])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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MACITENTAN-TADALAFIL TIRF (PART D)

RATIONALE

Prior authorization on these drugs is required due to a high potential for non-Part D use. These drugs should NOT be used for non-medically accepted indications as defined in section 1860D-2(e)(4) of the Act. For further information, please refer to the Prescribing Information and/or Drug Monograph for Opsynvi.

REFERENCES

Opsynvi [Prescribing Information]. Titusville, NJ: Actelion Pharmaceuticals US, Inc.; March 2024.
Announcement of Calendar Year (CY) 2015 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. April 7, 2014. Section III – Part D: Appropriate Utilization of Prior Authorization Requirements to Determine Part D Drug Status. Page 112 – 114.

For Part D use only:

MACITENTAN-TADALAFIL (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	PULMONARY ARTERIAL HYPERTENSION (PAH): INITIAL: DIAGNOSIS CONFIRMED BY RIGHT HEART CATHETERIZATION WITH THE FOLLOWING PARAMETERS: 1) MEAN PULMONARY ARTERY PRESSURE (PAP) GREATER THAN 20 MMHG, 2) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF 15 MMHG OR LESS, AND 3) PULMONARY VASCULAR RESISTANCE (PVR) GREATER THAN 2 WOOD UNITS.
Age Restrictions	N/A
Prescriber Restrictions	PAH: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	PAH: INITIAL/RENEWAL: 1) NOT CONCURRENTLY OR INTERMITTENTLY TAKING ORAL ERECTILE DYSFUNCTION AGENTS (E.G. CIALIS, VIAGRA) OR ANY ORGANIC NITRATES IN ANY FORM, AND 2) NO CONCURRENT USE WITH GUANYLATE CYCLASE STIMULATORS.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MARALIXIBAT (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MARALIXIBAT CHLORIDE	LIVMARLI	47604		GPI-10 (5235005010)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of cholestatic pruritus (ICD-10 L29.81)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient's cholestatic pruritus associated with Alagille syndrome (ALGS) (ICD-10 Q44.71) and the patient meets **ALL** of the following criteria?
   - The patient is 3 months of age or older
   - Therapy is prescribed by or in consultation with a hepatologist, gastroenterologist, or physician who specializes in ALGS cholestasis
   - Livmarli will NOT be used concurrently with another IBAT inhibitor (e.g., Bylvay [odevixibat])

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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MARALIXIBAT (PART D)

INITIAL CRITERIA (CONTINUED)

3. Is the patient's cholestatic pruritus associated with progressive familial intrahepatic cholestasis (PFIC) and the patient meets **ALL** of the following criteria?
   - The patient is 12 months of age or older
   - Therapy is prescribed by or in consultation with a hepatologist, gastroenterologist, or physician who specializes in PFIC cholestasis
   - Livmarli will NOT be used concurrently with another IBAT inhibitor (e.g., Bylvay [odevixibat])

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MARALIXIBAT (Livmarli)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Cholestatic pruritus (itching caused by liver disease) associated with Alagille syndrome (ALGS: a type of genetic disorder)
      2. Cholestatic pruritus associated with progressive familial intrahepatic cholestasis (PFIC: a type of genetic disorder)

   B. If you have cholestatic pruritus associated with Alagille syndrome, approval also requires:
      1. You are 3 months of age or older
      2. Therapy is prescribed by or in consultation with a hepatologist (a type of liver doctor), gastroenterologist (doctor who treats digestive conditions), or physician (doctor) who specializes in ALGS cholestasis
      3. You will NOT use Livmarli concurrently (at the same time) with another ileal bile acid transporter (IBAT) inhibitor (such as Bylvay [odevixibat])

   C. If you have cholestatic pruritus associated with progressive familial intrahepatic cholestasis, approval also requires:
      1. You are 12 months of age or older
      2. Therapy is prescribed by or in consultation with a hepatologist (a type of liver doctor), gastroenterologist (a doctor who treats digestive conditions), or physician (doctor) who specializes in PFIC cholestasis
      3. You will NOT use Livmarli concurrently (at the same time) with another ileal bile acid transporter (IBAT) inhibitor (such as Bylvay [odevixibat])

   (Initial denial text continued on next page)

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MARALIXIBAT (PART D)

INITIAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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MARALIXIBAT (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of cholestatic pruritus (ICD-10 L29.81)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the patient's cholestatic pruritus associated with Alagille syndrome (ALGS) (ICD-10 Q44.71) and the patient meets **ALL** of the following criteria?
   - The patient has shown a clinical response to therapy, defined as improvement in pruritus symptoms AND reduction of serum bile acid from baseline
   - Livmarli will NOT be used concurrently with another IBAT inhibitor (e.g., Bylvay [odevixibat])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Is the patient's cholestatic pruritus associated with progressive familial intrahepatic cholestasis (PFIC) and the patient meets **ALL** of the following criteria?
   - The patient has shown a clinical response to therapy, defined as improvement in pruritus symptoms AND a reduction of serum bile acid from baseline
   - The patient does NOT have PFIC type 2 with specific ABCB11 variants that would result in nonfunctional, or the complete absence of, bile salt export pump (BSEP) protein
   - Livmarli will NOT be used concurrently with another IBAT inhibitor (e.g., Bylvay [odevixibat])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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MARALIXIBAT (PART D)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **MARALIXIBAT (Livmarli)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Cholestatic pruritus (itching caused by liver disease) associated with Alagille syndrome (ALGS: a type of genetic disorder)
   2. Cholestatic pruritus associated with progressive familial intrahepatic cholestasis (PFIC: a type of genetic disorder)

B. If you have cholestatic pruritus associated with Alagille syndrome, renewal also requires:
   1. You have shown a clinical response to therapy defined as improvement in pruritis (itching) symptoms AND a reduction of serum (blood) bile acid from baseline
   2. You will NOT use Livmarli concurrently (at the same time) with another ileal bile acid transporter (IBAT) inhibitor (such as Bylvay [odevixibat])

C. If you have cholestatic pruritus associated with progressive familial intrahepatic cholestasis, renewal also requires:
   1. You have shown a clinical response to therapy defined as improvement in pruritus (itching) symptoms AND a reduction of serum (blood) bile acid from baseline
   2. You do NOT have PFIC type 2 with specific ABCB11 variants (a type of abnormal gene) that would result in nonfunctional (does not work), or the complete absence of, bile salt export pump (BSEP: a type of protein)
   3. You will NOT use Livmarli concurrently (at the same time) with another ileal bile acid transporter (IBAT) inhibitor (such as Bylvay [odevixibat])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Livmarli.

REFERENCES

Livmarli [Prescribing Information]. Foster City, CA: Mirum Pharmaceuticals, Inc.; April 2025.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MARALIXIBAT (PART D)

For Part D use only:

MARALIXIBAT (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: PROGRESSIVE FAMILIAL INTRAHEPATIC CHOLESTASIS (PFIC): PRESCRIBED BY OR IN CONSULTATION WITH A HEPATOLOGIST, GASTROENTEROLOGIST, OR PHYSICIAN WHO SPECIALIZES IN PFIC CHOLESTASIS. ALAGILLE SYNDROME (ALGS): PRESCRIBED BY OR IN CONSULTATION WITH A HEPATOLOGIST, GASTROENTEROLOGIST, OR PHYSICIAN WHO SPECIALIZES IN ALGS CHOLESTASIS.
Coverage Duration	PFIC, ALGS: INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: PFIC, ALGS: NO CONCURRENT USE WITH ANOTHER IBAT INHIBITOR. RENEWAL: PFIC: 1) CLINICAL RESPONSE TO THERAPY DEFINED AS IMPROVEMENT IN PRURITIS SYMPTOMS AND A REDUCTION OF SERUM BILE ACID FROM BASELINE, 2) DOES NOT HAVE PFIC TYPE 2 WITH SPECIFIC ABCB11 VARIANTS THAT WOULD RESULT IN NONFUNCTIONAL, OR THE COMPLETE ABSENCE OF, BILE SALT EXPORT PUMP (BSEP) PROTEIN, AND 3) NO CONCURRENT USE WITH ANOTHER IBAT INHIBITOR. ALGS: 1) CLINICAL RESPONSE TO THERAPY DEFINED AS IMPROVEMENT IN PRURITIS SYMPTOMS AND A REDUCTION OF SERUM BILE ACID FROM BASELINE, AND 2) NO CONCURRENT USE WITH ANOTHER IBAT INHIBITOR.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MARGETUXIMAB-CMKB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MARGETUXIMAB-CMKB	MARGENZA	47037		GPI-10 (2117003420)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic breast cancer (ICD-10 Groups C50, C79.81) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's breast cancer is HER2-positive
   - Margenza will be used in combination with chemotherapy (e.g., Halaven [eribulin], gemcitabine)
   - The patient has received two or more prior anti-HER2 regimens (e.g., Herceptin [trastuzumab], Perjeta [pertuzumab]), at least one of which was for metastatic disease

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MARGETUXIMAB-CMKB (Margenza)** requires the following rule(s) be met for approval:
   A. You have metastatic human epidermal growth factor receptor 2 (HER2: a type of protein)-positive breast cancer (cancer has spread to other parts of the body)
   B. You are 18 years of age or older
   C. Margenza will be used in combination with chemotherapy (such as Halaven [eribulin], gemcitabine)
   D. You have received two or more prior anti-HER2 regimens (such as Herceptin [trastuzumab], Perjeta [pertuzumab]), at least one of which was for metastatic disease

   (Denial text continued on next page)

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MARGETUXIMAB-CMKB (PART D)

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Margenza.

REFERENCES

Margenza [Prescribing Information]. Rockville, MD: MacroGenics, Inc.; May 2023.

For Part D use only:

MARGETUXIMAB-CMKB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 03/21
Client Approval: 06/24
P&T Approval: 04/21

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MARIBAVIR (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MARIBAVIR	LIVTENCITY	47687		GPI-10 (1220005000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of post-transplant cytomegalovirus (CMV) infection (ICD-10 Group B25) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The infection is refractory to prior therapy with ganciclovir, valganciclovir, cidofovir or foscarnet

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MARIBAVIR (Livtencity)** requires the following rule(s) be met for approval:
   A. You have a post-transplant cytomegalovirus (CMV) infection (a type of viral infection)
   B. You are 12 years of age or older
   C. Your infection is refractory (has not responded) to prior therapy with ganciclovir, valganciclovir, cidofovir or foscarnet

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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MARIBAVIR (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Livtencity.

REFERENCES

Livtencity [Prescribing Information]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; November 2021.

For Part D use only:

MARIBAVIR (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 12/21
Effective: 01/01/26 Client Approval: 01/26 P&T Approval: 10/21

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MAVACAMTEN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MAVACAMTEN	CAMZYOS	47972		GPI-10 (4019005000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of symptomatic obstructive hypertrophic cardiomyopathy (HCM) (ICD-10 I42.1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has New York Heart Association (NYHA) class II-III
   - Therapy is prescribed by or in consultation with a cardiologist
   - The patient has a left ventricular outflow track (LVOT) gradient of 50 mmHg or higher
   - The patient had a trial of, contraindication, or intolerance to a beta-blocker (e.g., metoprolol, carvedilol) OR a non-dihydropyridine calcium channel blocker (e.g., verapamil, diltiazem)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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MAVACAMTEN (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **MAVACAMTEN (Camzyos)** requires the following rule(s) be met for approval:

A. You have symptomatic obstructive hypertrophic cardiomyopathy (HCM: a type of heart condition)
B. You are 18 years of age or older
C. You have New York Heart Association (NYHA) class II-III (a way to classify severity of your heart failure symptoms)
D. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor)
E. You have a left ventricular outflow track gradient (a predictor of heart failure and cardiovascular death) of 50 mmHg or higher
F. You have tried, have a contraindication (harmful for you to use), or intolerance to (side effect) a beta-blocker (such as metoprolol, carvedilol) OR a non-dihydropyridine calcium channel blocker (such as verapamil, diltiazem)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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MAVACAMTEN (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of symptomatic obstructive hypertrophic cardiomyopathy (HCM) (ICD-10 I42.1) **AND** meet the following criterion?
   - The patient has experienced continued clinical benefit (e.g., reduction of symptoms, NYHA classification improvement)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MAVACAMTEN (Camzyos)** requires the following rule(s) be met for renewal:
   A. You have symptomatic obstructive hypertrophic cardiomyopathy (HCM: a type of heart condition)
   B. You have experienced continued clinical benefit (such as reduction of symptoms, New York Heart Association [NYHA: a way to classify severity of your heart failure symptoms] classification improvement)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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MAVACAMTEN (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Camzyos.

REFERENCES

Camzyos [Prescribing Information]. Brisbane, CA: MyoKardia, Inc.; June 2023.

For Part D use only:

MAVACAMTEN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	OBSTRUCTIVE HYPERTROPHIC CARDIOMYOPATHY(HCM): INITIAL: LEFT VENTRICULAR OUTFLOW TRACK (LVOT) GRADIENT OF 50 MMHG OR HIGHER
Age Restrictions	N/A
Prescriber Restrictions	OBSTRUCTIVE HCM: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	OBSTRUCTIVE HCM: INITIAL: TRIAL OF, CONTRAINDICATION, OR INTOLERANCE TO A BETA-BLOCKER OR A NON-DIHYDROPYRIDINE CALCIUM CHANNEL BLOCKER. RENEWAL: CONTINUED CLINICAL BENEFIT (E.G., REDUCTION OF SYMPTOMS, NYHA CLASSIFICATION IMPROVEMENT).

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MAVORIXAFOR (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MAVORIXAFOR	XOLREMDI	49557		GPI-10 (8250204600)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of WHIM (warts, hypogammaglobulinemia, infections and myelokathexis) syndrome **AND** meet the following criterion?
   - The patient is 12 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MAVORIXAFOR (Xolremdi)** requires the following rule(s) be met for approval:
   A. You have WHIM (warts, hypogammaglobulinemia [low levels of antibodies in the blood], infections, and myelokathexis [low white blood cell count]) syndrome (a rare genetic disorder of the immune system)
   B. You are 12 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MAVORIXAFOR (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xolremdi.

REFERENCES

Xolremdi [Prescribing Information]. Boston, MA: X4 Pharmaceuticals, Inc.; April 2024.

For Part D use only:

MAVORIXAFOR (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Part D Effective: 05/27/24
Commercial Effective: N/A
Created: 05/24
Client Approval: 05/24
P&T Approval: 07/24

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MECASERMIN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MECASERMIN	INCRELEX	33207		GPI-10 (3016004500)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of growth failure due to **ONE** of the following?
   - Severe primary IGF-1 deficiency (ICD-10 E34.321) (height standard deviation score of -3 or less, basal IGF-1 standard deviation score of-3 or less, and normal or elevated growth hormone)
   - Growth hormone (GH) gene deletion (not growth hormone-deficient short stature) with neutralizing antibodies to GH

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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MECASERMIN (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient meet **ALL** of the following criteria?
   - The patient is 2 to 17 years of age
   - Therapy is prescribed by or in consultation with an endocrinologist or nephrologist
   - The patient has open epiphyses (as confirmed by radiograph of the wrist and hand)
   - Increlex will NOT be used concurrently with another growth hormone medication (somatropin [Genotropin, Humatrope, Norditropin, Nutropin AQ, Omnitrope, Saizen, Serostim, Zomacton], Ngenla [somatrogon-ghla], Sogroya [somapacitan-beco], Skytrofa [lonapegsomatropin-tcgd])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MECASERMIN (Increlex)** requires the following rule(s) be met for approval:
   A. You have growth failure due to ONE of the following:
      1. Severe primary insulin growth-like factor 1 (IGF-1: a type of hormone) deficiency (your height standard deviation score [a measure of variation from the average] is -3 or less, your basal IGF-1 standard deviation score is -3 or less, and you have normal or elevated growth hormone)
      2. Growth hormone (GH) gene deletion (not growth hormone-deficient short stature) with neutralizing antibodies to growth hormone
   B. You are 2 to 17 years of age or older
   C. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor) or nephrologist (a type of kidney doctor)
   D. You have open epiphyses (end part of long bone) as confirmed by radiograph (type of imaging test) of the wrist and hand
   E. You will NOT use Increlex concurrently (at the same time) with another growth hormone medication (somatropin [Genotropin, Humatrope, Norditropin, Nutropin AQ, Omnitrope, Saizen, Serostim, Zomacton], Ngenla [somatrogon-ghla], Sogroya [somapacitan-beco], Skytrofa [lonapegsomatropin-tcgd])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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MECASERMIN (PART D)

RENEWAL CRITERIA

1. Does the patient meet **ALL** of the following criteria?
   - The patient has shown improvement while on Increlex therapy (increase in height or increase in height velocity)
   - Increlex will NOT be used concurrently with another growth hormone medication (somatropin [Genotropin, Humatrope, Norditropin, Nutropin AQ, Omnitrope, Saizen, Serostim, Zomacton], Ngenla [somatrogon-ghla], Sogroya [somapacitan-beco], Skytrofa [lonapegsomatropin-tcgd])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MECASERMIN (Increlex)** requires the following rule(s) be met for renewal:
   A. You have experienced improvement while on Increlex therapy (increase in height or increase in height velocity)
   B. You will NOT use Increlex concurrently (at the same time) with another growth hormone medication (somatropin [Genotropin, Humatrope, Norditropin, Nutropin AQ, Omnitrope, Saizen, Serostim, Zomacton], Ngenla [somatrogon-ghla], Sogroya [somapacitan-beco], Skytrofa [lonapegsomatropin-tcgd])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Increlex.

REFERENCES

Increlex [Prescribing Information]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.; March 2024.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MECASERMIN (PART D)

For Part D use only:

MECASERMIN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	GROWTH FAILURE: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST OR NEPHROLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	GROWTH FAILURE: INITIAL: OPEN EPIPHYSES AS CONFIRMED BY RADIOGRAPH OF WRIST AND HAND. INITIAL/RENEWAL: NO CONCURRENT USE WITH ANOTHER GROWTH HORMONE MEDICATION. RENEWAL: IMPROVEMENT WHILE ON THERAPY (INCREASE IN HEIGHT OR INCREASE IN HEIGHT VELOCITY).

Created: 06/24
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 04/25

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MECHLORETHAMINE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MECHLORETHAMINE HCL	VALCHLOR	03892		GPI-10 (9037105020)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of stage IA or IB mycosis fungoides-type cutaneous T-cell lymphoma (ICD-10 Group C84.0) **AND** meet the following criterion?
   - The patient has received prior skin-directed therapy (e.g., corticosteroids [betamethasone dipropionate], topical retinoids [Targretin (bexarotene)], imiquimod)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MECHLORETHAMINE (Valchlor)** requires the following rule(s) be met for approval:
   A. You have stage IA or IB mycosis fungoides-type cutaneous T-cell lymphoma (a type of blood cancer and affects the skin)
   B. You have received prior skin-directed treatment (such as corticosteroids [betamethasone dipropionate], topical retinoids [Targretin (bexarotene)], imiquimod)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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MECHLORETHAMINE (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Valchlor.

REFERENCES

Valchlor [Prescribing Information]. Iselin, NJ: Helsinn Therapeutics (U.S.), Inc.; January 2020.

For Part D use only:

MECHLORETHAMINE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Created: 03/23
Effective: 01/01/25 Client Approval: 08/24 P&T Approval: 04/13

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MEPOLIZUMAB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MEPOLIZUMAB	NUCALA	42775		GPI-10 (4460405500)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of severe asthma with an eosinophilic phenotype (ICD-10 J82.83) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a physician specializing in pulmonary medicine or allergy medicine
   - The patient has a blood eosinophil level of at least 150 cells/mcL within the past 12 months
   - Nucala will be used in combination with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (ICS) (e.g., beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (e.g., a long-acting inhaled beta-2-agonist [e.g., salmeterol, formoterol], a long-acting muscarinic antagonist [e.g., Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], leukotriene receptor antagonist [e.g., montelukast, zafirlukast, zileuton], theophylline, an oral corticosteroid [e.g., prednisone])
   - Nucala will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic phenotype asthma

   If yes, continue to #2.
   If no, continue to #4.

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MEPOLIZUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient meet **ONE** of the following criteria?
   - The patient experienced at least ONE asthma exacerbation requiring systemic corticosteroid (e.g., prednisone) burst lasting at least 3 days within the past 12 months
   - The patient experienced at least ONE serious asthma exacerbation requiring hospitalization or ER visit within the past 12 months

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Does the patient have poor symptom control despite current therapy as evidenced by at least **THREE** of the following within the past 4 weeks?
   - Daytime asthma symptoms more than twice per week
   - Any night waking due to asthma
   - Use of a short-acting inhaled beta-2-agonist (SABA) reliever (e.g., albuterol) for symptoms more than twice per week
   - Any activity limitation due to asthma

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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MEPOLIZUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) (ICD-10 Groups J32 and J33) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Nucala will be used as add-on maintenance treatment
   - Therapy is prescribed by or in consultation with an otolaryngologist, allergist, or immunologist
   - There is evidence of nasal polyps by direct examination, endoscopy, or sinus CT scan
   - The patient has inadequately controlled disease
   - The patient had a 56-day trial of ONE topical nasal corticosteroid (e.g., mometasone, fluticasone)
   - Nucala will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CRSwNP

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Does the patient have a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA) (ICD-10 M30.1), also known as Churg-Strauss syndrome, and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Nucala will NOT be used concurrently with another systemic biologic (e.g., Fasenra [benralizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of EGPA

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #6.

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MEPOLIZUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

6. Does the patient have a diagnosis of hypereosinophilic syndrome (HES) (ICD-10 Group D72.11) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient has had HES for at least 6 months without an identifiable non-hematologic secondary cause
   - Nucala will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of HES

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #7.

7. Does the patient have a diagnosis of chronic obstructive pulmonary disease (COPD) (ICD-10 Group J44 except for ICD-10 J44.0 and J44.81) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has an eosinophilic phenotype of COPD
   - Therapy is prescribed by or in consultation with a pulmonologist
   - Nucala will be used in combination with a long-acting muscarinic antagonist (LAMA)/long-acting beta-2-agonist (LABA)/inhaled corticosteroid (ICS) (e.g., Trelegy Ellipta, Breztri Aerosphere, Spiriva with Symbicort)
   - Nucala will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Daliresp (roflumilast)]) for the treatment of eosinophilic phenotype COPD

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIALTEXT: See the initial denial text at the end of the guideline.

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MEPOLIZUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **MEPOLIZUMAB (Nucala)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Severe asthma with an eosinophilic phenotype (a type of lung condition with inflammation)
   2. Chronic rhinosinusitis with nasal polyps (CRSwNP: inflammation of nasal and sinus passages with small growths in the nose)
   3. Eosinophilic granulomatosis with polyangiitis (EGPA), also known as Churg-Strauss syndrome (a type of immune system disorder with inflammation of blood vessels)
   4. Hypereosinophilic syndrome (HES: a type of blood disorder)
   5. Chronic obstructive pulmonary disease (COPD: a type of long-term lung condition)

B. If you have severe asthma with an eosinophilic phenotype, approval also requires:
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a physician specializing in pulmonary (lung/breathing) medicine or allergy medicine
   3. You have a blood eosinophil level (a type of lab test) of at least 150 cells/mcL within the past 12 months
   4. Nucala will be used in combination with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (ICS) (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis), such as a long-acting inhaled beta-2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast, zileuton), theophylline, or an oral corticosteroid (such as prednisone)
   5. You will NOT use Nucala concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic phenotype asthma

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MEPOLIZUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

6. You meet ONE of the following:
   a. You have experienced at least ONE asthma exacerbation (worsening of symptoms) requiring systemic corticosteroid (such as prednisone) burst lasting at least 3 days within the past 12 months
   b. You have experienced at least ONE serious asthma exacerbation requiring a hospitalization or an emergency room visit within the past 12 months
   c. You have poor symptom control despite current therapy as shown by at least THREE of the following within the past 4 weeks:
      i. Daytime asthma symptoms more than twice per week
      ii. Any night waking due to asthma
      iii. Use of a short-acting inhaled beta-2-agonist reliever (SABA) (such as albuterol) for symptoms more than twice per week
      iv. Any activity limitation due to asthma

C. If you have chronic rhinosinusitis with nasal polyps, approval also requires:

1. You are 18 years of age or older
2. Nucala will be used as add-on maintenance treatment (taken on a regular basis)
3. Therapy is prescribed by or in consultation with an otolaryngologist (ear, nose, and throat doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
4. There is evidence of nasal polyps (non-cancerous growths) by direct examination, endoscopy (using a small camera), or sinus computed tomography (CT) scan (a type of imaging test)
5. You have inadequately controlled disease
6. You had a 56-day trial of ONE topical nasal corticosteroid (such as mometasone, fluticasone)
7. You will NOT use Nucala concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic rhinosinusitis with nasal polyps

D. If you have eosinophilic granulomatosis with polyangiitis, approval also requires:

1. You are 18 years of age or older
2. You will NOT use Nucala concurrently (at the same time) with another systemic biologic (such as Fasenra [benralizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic granulomatosis with polyangiitis

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MEPOLIZUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

E. If you have hypereosinophilic syndrome, approval also requires:
1. You are 12 years of age or older
2. You have had hypereosinophilic syndrome (HES) for at least 6 months without an identifiable non-hematologic (not present in the blood) secondary cause (HES is not caused by another condition)
3. You will NOT use Nucala concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK inhibitor, PDE-4 inhibitor) for the treatment of hypereosinophilic syndrome

F. If you have chronic obstructive pulmonary disease, approval also requires:
1. You are 18 years of age or older
2. You have an eosinophilic phenotype of chronic obstructive pulmonary disease (COPD: a type of inflammatory long-term lung condition)
3. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor)
4. Nucala will be used in combination with a long-acting muscarinic antagonist (LAMA)/long-acting beta-2-agonist (LABA)/inhaled corticosteroid (ICS) (such as Trelegy Ellipta, Breztri Aerosphere, Spiriva with Symbicort)
5. You will NOT use Nucala concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Daliresp (roflumilast)]) for the treatment of eosinophilic phenotype COPD

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MEPOLIZUMAB (PART D)

RENEWAL CRITERIA

NOTE: For the diagnosis of hypereosinophilic syndrome (HES), please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of severe asthma with an eosinophilic phenotype (ICD-10 J82.83) and meet **ALL** of the following criteria?
   - The patient will continue to use an inhaled corticosteroid (ICS) (e.g., beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (e.g., a long-acting inhaled beta-2-agonist [e.g., formoterol, salmeterol], a long-acting muscarinic antagonist [e.g., Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], leukotriene receptor antagonist [e.g., montelukast, zafirlukast, zileuton], theophylline, an oral corticosteroid [e.g., prednisone])
   - Nucala will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic phenotype asthma

   If yes, continue to #2.
   If no, continue to #3.

2. Has the patient shown a clinical response as evidenced by **ONE** of the following criteria?
   - Reduction in asthma exacerbations from baseline
   - Decreased utilization of rescue medications (e.g., albuterol)
   - Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing)
   - Increase in percent predicted FEV1 from pre-treatment baseline

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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MEPOLIZUMAB (PART D)

RENEWAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) (ICD-10 Groups J32 and J33) and meet **ALL** of the following criteria?
   - The patient has shown a clinical benefit compared to baseline (e.g., improvements in nasal congestion, sense of smell, size of polyps)
   - Nucala will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of CRSwNP

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

4. Does the patient have a diagnosis of chronic obstructive pulmonary disease (COPD) (ICD-10 Group J44 except for ICD-10 J44.0 and J44.81) and meet **ALL** of the following criteria?
   - The patient has an eosinophilic phenotype of COPD
   - Nucala will be used in combination with a long-acting muscarinic antagonist (LAMA)/long-acting beta-2-agonist (LABA)/inhaled corticosteroid (ICS) (e.g., Trelegy Ellipta, Breztri Aerosphere, Spiriva with Symbicort)
   - Nucala will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Daliresp (roflumilast)]) for the treatment of eosinophilic phenotype COPD

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

5. Has the patient shown a clinical response as evidenced by **ONE** of the following criteria?
   - The patient has a reduction in COPD exacerbations from baseline
   - The patient has a reduction in severity or frequency of COPD-related symptoms (e.g., wheezing, shortness of breath, coughing, sputum production)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #6.

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MEPOLIZUMAB (PART D)

RENEWAL CRITERIA (CONTINUED)

6. Does the patient have a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA) (ICD-10 M30.1), also known as Churg-Strauss syndrome, and meet **ALL** of the following criteria?
   - The patient has shown a reduction in EGPA symptoms compared to baseline OR has been able to reduce/eliminate corticosteroid use
   - Nucala will NOT be used concurrently with another systemic biologic (e.g., Fasenra [benralizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of EGPA

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MEPOLIZUMAB (Nucala)** requires the following rule(s) be met for renewal:

   A. You have ONE of the following:
      1. Severe asthma with an eosinophilic phenotype (a type of lung condition with inflammation)
      2. Chronic rhinosinusitis with nasal polyps (CRSwNP: inflammation of nasal and sinus passages with small growths in the nose)
      3. Chronic obstructive pulmonary disease (COPD: a type of long-term lung condition)
      4. Eosinophilic granulomatosis with polyangiitis (EGPA), also known as Churg-Strauss syndrome (a type of immune system disorder with inflammation of blood vessels)

   B. If you have severe asthma with an eosinophilic phenotype, renewal also requires:
      1. You will continue to use an inhaled corticosteroid (ICS) (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis), such as a long-acting inhaled beta-2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast, zileuton), theophylline, or an oral corticosteroid (such as prednisone)

   (Renewal denial text continued on next page)

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MEPOLIZUMAB (PART D)

RENEWAL CRITERIA (CONTINUED)

2. You will NOT use Nucala concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic phenotype asthma
3. You have shown a clinical response as shown by ONE of the following:
   a. You have experienced a reduction in asthma exacerbations (less sudden and severe worsening of symptoms) from baseline (before starting Nucala)
   b. You have decreased your use of rescue medications (such as albuterol)
   c. You have a decrease in the severity or frequency of asthma-related symptoms (such as wheezing, shortness of breath, coughing)
   d. You have an increase in the percent predicted FEV1 (a type of lung test) from pre-treatment baseline (before starting Nucala)

C. If you have chronic rhinosinusitis with nasal polyps, renewal also requires:

1. You have shown a clinical benefit compared to baseline (before starting Nucala) (such as improvements in nasal congestion, sense of smell, size of polyps)
2. You will NOT use Nucala concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic rhinosinusitis with nasal polyps

D. If you have chronic obstructive pulmonary disease, renewal also requires:

1. You have an eosinophilic phenotype of chronic obstructive pulmonary disease (COPD: a type of inflammatory long-term lung condition)
2. Nucala will be used in combination with a long-acting muscarinic antagonist (LAMA)/long-acting beta-2-agonist (LABA)/inhaled corticosteroid (ICS) (such as Trelegy Ellipta, Breztri Aerosphere, Spiriva with Symbicort)
3. You will NOT use Nucala concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Daliresp (roflumilast)]) for the treatment of eosinophilic phenotype COPD
4. You have shown a clinical response as evidenced by ONE the following:
   a. You have a reduction (decrease) in COPD exacerbations (worsening of symptoms) from baseline (before starting Nucala)
   b. You have a reduction in severity or frequency of COPD-related symptoms (such as wheezing, shortness of breath, coughing, sputum [mucus] production)

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MEPOLIZUMAB (PART D)

RENEWAL CRITERIA (CONTINUED)

E. If you have eosinophilic granulomatosis with polyangiitis, renewal also requires:
1. You have shown a reduction in eosinophilic granulomatosis with polyangiitis (EGPA) symptoms compared to baseline (before starting Nucala), OR you have been able to decrease or eliminate (stop) corticosteroid use
2. You will NOT use Nucala concurrently (at the same time) with another systemic biologic (such as Fasenra [benralizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic granulomatosis with polyangiitis

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Nucala.

REFERENCES
Nucala [Prescribing Information]. Philadelphia, PA: GlaxoSmithKline, LLC; August 2025.

For Part D use only:

MEPOLIZUMAB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	INITIAL: ASTHMA: BLOOD EOSINOPHIL LEVEL OF AT LEAST 150 CELLS/MCL WITHIN THE PAST 12 MONTHS.
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: ASTHMA: PRESCRIBED BY OR IN CONSULTATION WITH A PHYSICIAN SPECIALIZING IN PULMONARY OR ALLERGY MEDICINE. CRSWNP: PRESCRIBED BY OR IN CONSULTATION WITH AN OTOLARYNGOLOGIST, ALLERGIST OR IMMUNOLOGIST. EOSINOPHILIC COPD: PRESCRIBED BY OR IN CONSULTATION WITH A PULMONOLOGIST.
Coverage Duration	INITIAL: CRSWNP: 6 MO. OTHERS: 12 MO. RENEWAL: CRSWNP, ASTHMA, COPD, EGPA, HES: 12 MO.
Other Criteria	INITIAL: ALL INDICATIONS: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION. ASTHMA: 1) CONCURRENT THERAPY WITH A MEDIUM, HIGH-DOSE OR MAXIMALLY TOLERATED DOSE OF AN INHALED CORTICOSTEROID (ICS) AND AT LEAST ONE OTHER MAINTENANCE MEDICATION, AND 2) ONE OF THE FOLLOWING: (A) AT LEAST ONE ASTHMA EXACERBATION REQUIRING SYSTEMIC CORTICOSTEROID BURST LASTING AT LEAST 3 DAYS WITHIN THE PAST 12 MONTHS OR AT LEAST ONE SERIOUS

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	EXACERBATION REQUIRING HOSPITALIZATION OR ER VISIT WITHIN THE PAST 12 MONTHS, OR (B) POOR SYMPTOM CONTROL DESPITE CURRENT THERAPY AS EVIDENCED BY AT LEAST THREE OF THE FOLLOWING WITHIN THE PAST 4 WEEKS: DAYTIME ASTHMA SYMPTOMS MORE THAN TWICE/WEEK, ANY NIGHT WAKING DUE TO ASTHMA, SABA RELIEVER FOR SYMPTOMS MORE THAN TWICE/WEEK, ANY ACTIVITY LIMITATION DUE TO ASTHMA. CHRONIC RHINOSINUSITIS WITH NASAL POLYPS (CRSWNP): 1) A 56 DAY TRIAL OF ONE TOPICAL NASAL CORTICOSTEROID, 2) EVIDENCE OF NASAL POLYPS BY DIRECT EXAMINATION, ENDOSCOPY, OR SINUS CT SCAN, AND 3) INADEQUATELY CONTROLLED DISEASE. EOSINOPHILIC COPD: USED IN COMBINATION WITH A LAMA/LABA/ICS. RENEWAL: ASTHMA: 1) CONTINUED USE OF ICS AND AT LEAST ONE OTHER MAINTENANCE MEDICATION, 2) CLINICAL RESPONSE AS EVIDENCED BY: (A) REDUCTION IN ASTHMA EXACERBATIONS FROM BASELINE, (B) DECREASED UTILIZATION OF RESCUE MEDICATIONS, (C) REDUCTION IN SEVERITY OR FREQUENCY OF ASTHMA-RELATED SYMPTOMS, OR (D) INCREASE IN PERCENT PREDICTED FEV1 FROM PRETREATMENT BASELINE, AND 3) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR THE SAME INDICATION. CRSWNP: 1) CLINICAL BENEFIT COMPARED TO BASELINE, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR THE SAME INDICATION. EOSINOPHILIC GRANULOMATOSIS WITH POLYANGIITIS (EGPA): 1) REDUCTION IN EGPA SYMPTOMS COMPARED TO BASELINE OR ABILITY TO REDUCE/ELIMINATE CORTICOSTEROID USE, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR THE SAME INDICATION. EOSINOPHILIC COPD: 1) USED IN COMBINATION WITH A LAMA/LABA/ICS, 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR THE SAME INDICATION, AND 3) CLINICAL RESPONSE AS EVIDENCED BY: (A) REDUCTION IN COPD EXACERBATIONS FROM BASELINE, OR (B) REDUCTION IN SEVERITY OR FREQUENCY OF COPD-RELATED SYMPTOMS.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

METHAMPHETAMINE DvE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
METHAMPHETAMINE HCL	DESOXYN, METHAMPHETAMINE HCL	02067		GPI-10 (6110003010)	

These are DvE drugs requiring a payment determination for "Part D" or "Non-Part D".

PAYMENT DETERMINATION CRITERIA

1. Is the medication being requested for obesity (ICD-10 Group E66)?

   If yes, **set CMS_DVE_OVR to 'E' and approve for 12 months by HICL or GPI-10. Document in the PA comments: Payment Determination Override. This is not a Part D indication.**

   If no, continue to #2.

2. Does the patient have a diagnosis of attention deficit hyperactivity disorder (ADHD) (ICD-10 Group F90) **AND** meet the following criterion?
   - The patient is 6 years of age or older

   If yes, **set CMS_DVE_OVR to 'D' and approve for 12 months by HICL or GPI-10. Document in the PA comments: Part D Determination Override.**

   If no, **set CMS_DVE_OVR to 'E' and approve for 12 months by HICL or GPI-10. Document in the PA comments: Payment Determination Override. This is not a Part D indication.**

   NOTE: If the claim rejects after analyzing, then follow the clinical authorization process within HQ notes.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **METHAMPHETAMINE (Desoxyn)** requires the following rule(s) be met for approval:
   A. You have attention deficit hyperactivity disorder (ADHD: a type of mental health disorder)
   B. You are 6 years of age or older

   Note: The requested medication will NOT be approved if the request is for obesity (a condition of higher than normal body fat)

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METHAMPHETAMINE DvE (PART D)

RATIONALE

To limit the coverage of Desoxyn to the Medicare Part D covered indication of attention deficit hyperactivity disorder (ADHD), and exclude coverage for the treatment of obesity. For further information, please refer to the Prescribing Information and/or Drug Monograph for Desoxyn.

REFERENCES

Desoxyn [Prescribing information]. Lebanon, NJ: Recordati Rare Diseases, Inc.; September 2024.
Methamphetamine hydrochloride [Prescribing information]. Berkeley Heights, NJ: Hikma Pharmaceuticals USA Inc.; September 2024.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements. Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf. [Accessed March 2026].

For Part D use only:

METHAMPHETAMINE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	TREATMENT OF OBESITY
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS.
Other Criteria	N/A

Created: 10/19
Effective: 03/09/26 Client Approval: 03/26 P&T Approval: 08/13

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

METHOCARBAMOL (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
METHOCARBAMOL	ATMEKSI		58157	GPI-14 (75100070001820)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of an acute, painful musculoskeletal condition and meet **ALL** of the following criteria?
   - The patient is 16 years of age or older
   - The patient has a contraindication to or is unable to swallow generic methocarbamol tablets

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **METHOCARBAMOL (Atmeksi)** requires the following rule(s) be met for approval:
   A. You have an acute, painful musculoskeletal condition (sudden and severe pain relating to muscles and bones)
   B. You are 16 years of age or older
   C. You have a contraindication to (harmful for you to use) or are unable to swallow generic methocarbamol tablets

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

METHOCARBAMOL (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Atmeksi.

REFERENCES
Atmeksi [Prescribing Information]. Watkinsville, GA: Rosemont Pharmaceuticals, Inc; July 2025.

For Part D use only:

METHOCARBAMOL (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS.
Other Criteria	ACUTE, PAINFUL MUSCULOSKELETAL CONDITION: CONTRAINDICATION TO OR UNABLE TO SWALLOW GENERIC METHOCARBAMOL TABLETS.

Created: 04/26
Effective: 04/11/26 Client Approval: 04/26 P&T Approval: 04/26

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

METHOTREXATE BVD DETERMINATION (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
METHOTREXATE SODIUM	TREXALL, METHOTREXATE	03905		GPI-10 (2130005010)	ROUTE = ORAL
METHOTREXATE	JYLAMVO, XATMEP	03906		GPI-10 (2130005000)	ROUTE = ORAL

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request then a verbal MRF must be completed. Please check the applicable CS note for processing.

NOTE: For oral methotrexate, this PA is for administrative Step Override purposes to determine Medicare Part B versus Medicare Part D funding.

GUIDELINES FOR USE

1. Is the drug being used to treat a cancerous condition?

   If yes, **approve for lifetime by GPID or GPI-14 for all strengths and forms under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, **approve for 12 months by GPID or GPI-14 for all strengths and forms under Part D as follows:**
   - **Populate the B vs. D field with a 'D' in the PA override field AND**
   - **Override the administrative step therapy required restriction**

RATIONALE

This drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. To determine whether methotrexate is being used to treat a medical condition other than those for which it's use qualifies for coverage under Medicare Part B. When methotrexate is used as a chemotherapeutic drug, it is covered by Part B.

REFERENCES

Medicare Prescription Drug Benefit Manual Chapter 6 – Part D Drugs and Formulary Requirements, Appendix C- Summary of Coverage Policy Medicare Part B Versus Part DCoverage Issues. Rev 10, 02-19-10. Available at: http://www.cms.gov/PrescriptionDrugCovContra/12_PartDManuals.asp. [Accessed July 15, 2024].

Medicare Prescription Drug Benefit Manual – Chapter 14: Coordination of Benefits (Rev 18, 09-17-18). Available at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter-14-Coordination-of-Benefits-v09-14-2018.pdf [Accessed July 15, 2024].

Prior Authorization for Methotrexate Prescriptions. Available at: https://www.cms.gov/Outreach-and-Education/Outreach/PRIT/Active-PRIT-Issues-Items/CMS1256592.html. [Accessed 12/21/2018].

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

METHOTREXATE BVD DETERMINATION (PART D)

For Part D use only:

METHOTREXATE BVD DETERMINATION (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	PART D DOES NOT COVER THIS DRUG WHEN USED FOR CANCER.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	PART B:LIFETIME, PART D: 12 MONTHS
Other Criteria	N/A

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

METHOXY PEG-EPOETIN BETA (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
METHOXY PEG-EPOETIN BETA	MIRCERA	35005		GPI-10 (8240104010)	

PAYMENT DETERMINATION CRITERIA

1. Does the patient have a diagnosis of end stage renal disease (ESRD) and is on dialysis (ICD-10 N18.6)?

   If yes, **do NOT approve under Part D. Finalize as follows:**

   PAC NOTE: Please defer to a pharmacist for denial.

   CLINICAL SPECIALIST NOTE: This medication is included in the bundled dialysis facility payment which is paid under Medicare Part B and is not a Part D eligible drug. Please follow your internal procedures for denial.

   If no, review the clinical criteria for Part D coverage below if applicable.
   (**NOTE**: If the ESRD_Dialysis attribute is present, select the 'ESRD' Override Type within the PA, which is available in the 'Additional Overrides' section.)

Guideline interpretation beyond this point requires Clinical/Technician review.

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METHOXY PEG-EPOETIN BETA (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of anemia associated with chronic kidney disease (CKD) (ICD-10 D63.1)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of guideline.

2. Is the patient between 3 months and 17 years of age **AND** meet the following criterion?
   - The patient is converting from another erythropoiesis-stimulating agent (ESA) (e.g. Epogen [epoetin alfa], Aranesp [darbepoetin alfa]) after hemoglobin level has been stabilized with the ESA

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Is the patient 18 years of age or older and meet **ALL** of the following?
   - The patient had a trial of or contraindication to the preferred agent: Retacrit (epoetin alfa-epbx)
   - The patient's hemoglobin level is less than 10g/dL

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of guideline.

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METHOXY PEG-EPOETIN BETA (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **METHOXY PEG-EPOETIN BETA (Mircera)** requires the following rule(s) be met for approval:

A. You have anemia (low amount of healthy red blood cells) associated with chronic kidney disease (CKD)

B. If you are between 3 months and 17 years of age, approval also requires:

1. You are changing from another erythropoiesis-stimulating agent (ESA, such as Epogen [epoetin alfa], Aranesp [darbepoetin alfa]) after your hemoglobin level (type of blood test) has been stabilized with the ESA

C. If you are 18 years of age or older, approval also requires:

1. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Retacrit (epoetin alfa-epbx)
2. Your hemoglobin level (type of blood test) is less than 10g/dL

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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METHOXY PEG-EPOETIN BETA (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of anemia associated with chronic kidney disease (CKD) (ICD-10 D63.1) **AND** meet the following criterion?
   - The patient is NOT receiving dialysis treatment
     [Note: If the patient is currently receiving dialysis treatment, the requested medication is included in the bundle dialysis facility payment which is paid under Medicare Part B]. Please refer to CRITERIA FOR PART B vs PART D DETERMINATION above.

     If yes, continue to #2.
     If no, do not approve.
     DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the patient between 3 months and 17 years of age and meets **ONE** of the following criteria?
   - The patient's hemoglobin level is less than 12g/dL
   - The patient's hemoglobin level has reached 12g/dL and the dose is being or has been reduced/interrupted to decrease the need for blood transfusions

     If yes, **approve for 12 months by HICL or GPI-10.**
     APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

     If no, continue to #3.

3. Is the patient 18 years of age or older and meets **ONE** of the following criteria?
   - The patient's hemoglobin level is less than 10g/dL
   - The patient's hemoglobin level has reached 10g/dL and the dose is being or has been reduced/interrupted to decrease the need for blood transfusions

     If yes, **approve for 12 months by HICL or GPI-10.**
     APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

     If no, do not approve.
     DENIAL TEXT: See the renewal denial text at the end of the guideline.

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METHOXY PEG-EPOETIN BETA (PART D)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **METHOXY PEG-EPOETIN BETA (Mircera)** requires the following rule(s) be met for renewal:

A. You have anemia (low amount of healthy red blood cells) associated with chronic kidney disease (CKD)

B. If you are between 3 months and 17 years of age, renewal also requires:
1. You are NOT receiving dialysis treatment (process of removing excess water, toxins from the blood)
2. You meet ONE of the following:
   a. Your hemoglobin level (type of blood test) is less than 12g/dL
   b. Your hemoglobin level has reached 12g/dL and your dose is being or has been reduced/interrupted to decrease the need for blood transfusions

C. If you are 18 years of age or older, renewal also requires:
1. You are NOT receiving dialysis treatment (process of removing excess water, toxins from the blood)
2. You meet ONE of the following:
   a. Your hemoglobin level (type of blood test) is less than 10g/dL
   b. Your hemoglobin level (type of blood test) has reached 10g/dL and your dose is being or has been reduced/interrupted to decrease the need for blood transfusions

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Patients identified as Part D (ESRD) undergoing dialysis will be directed to a dialysis treatment center and have their ESA included in the bundled dialysis facility payment which is paid under Medicare Part B.

For further information, please refer to the Prescribing Information and/or Drug Monograph for Mircera.

REFERENCES

Mircera [Prescribing Information]. St. Gallen, Switzerland: Vifor; June 2024.

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METHOXY PEG-EPOETIN BETA (PART D)

For Part D use only:

METHOXY PEG-EPOETIN BETA (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	INITIAL: CHRONIC KIDNEY DISEASE (CKD) IN ADULTS: HEMOGLOBIN LEVEL IS LESS THAN 10G/DL. RENEWAL: CKD IN ADULTS NOT ON DIALYSIS: 1) HEMOGLOBIN LEVEL IS LESS THAN 10G/DL, OR 2) HEMOGLOBIN LEVEL HAS REACHED 10G/DL AND THE DOSE IS BEING OR HAS BEEN REDUCED/INTERRUPTED TO DECREASE THE NEED FOR BLOOD TRANSFUSIONS. CKD IN PEDIATRIC PATIENTS: 1) HEMOGLOBIN LEVEL IS LESS THAN 12G/DL, OR 2) HEMOGLOBIN LEVEL HAS REACHED 12G/DL AND THE DOSE IS BEING OR HAS BEEN REDUCED/INTERRUPTED TO DECREASE THE NEED FOR BLOOD TRANSFUSIONS.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: CKD: ADULTS: TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT: RETACRIT. RENEWAL: CKD: NOT RECEIVING DIALYSIS TREATMENT. THIS DRUG MAY BE EITHER BUNDLED WITH AND COVERED UNDER END STAGE RENAL DISEASE DIALYSIS RELATED SERVICES OR COVERED UNDER MEDICARE D DEPENDING UPON THE CIRCUMSTANCES.

Created: 10/19
Effective: 05/12/25 Client Approval: 04/25 P&T Approval: 07/24

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

METHYLNALTREXONE INJECTABLE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
METHYLNALTREXONE BROMIDE	RELISTOR		31278 99722 31279	GPI-14 (52580050102020, 5258005010E520, 5258005010E515)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of opioid-induced constipation (OIC) (ICD-10 K59.03) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have chronic non-cancer pain (ICD-10 G89.2), including chronic pain related to prior cancer or its treatment, and meet **ALL** of the following criteria?
   - The patient does NOT require frequent opioid dosage escalation
   - The patient has been taking opioids for at least four weeks
   - The patient had a trial of or contraindication to the preferred agents: naloxegol (Movantik) AND lubiprostone (Amitiza)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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METHYLNALTREXONE INJECTABLE (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have an advanced illness or pain caused by active cancer (ICD-10 G89.3) **AND** meet the following criterion?

- The patient requires opioid dosage escalation for palliative care

If yes, **approve for 6 months by GPID or GPI-14 for all strengths.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **METHYLNALTREXONE INJECTABLE (Relistor)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Opioid-induced constipation (a type of bowel disorder caused by medications used to treat pain) with chronic (long-term) non-cancer pain (including chronic pain related to prior cancer or its treatment)
   2. Opioid-induced constipation (a type of bowel disorder caused by medications used to treat pain) with advanced illness or pain caused by active cancer

B. If you have opioid-induced constipation with chronic non-cancer pain, approval also requires:
   1. You are 18 years of age or older
   2. You do NOT require frequent opioid dosage escalation (increase in dose)
   3. You have been taking opioids for at least four weeks
   4. You have tried or have a contraindication to (harmful for you to use) the preferred medications: naloxegol (Movantik) AND lubiprostone (Amitiza)

C. If you have opioid-induced constipation with advanced illness or pain caused by active cancer, approval also requires:
   1. You are 18 years of age or older
   2. You require opioid dosage escalation (increase in dose) for palliative care (treatment for comfort from symptoms)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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METHYLNALTREXONE INJECTABLE (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Relistor.

REFERENCES

Relistor [Prescribing Information]. Bridgewater, NJ: Salix Pharmaceuticals; May 2025.

For Part D use only:

METHYLNALTREXONE INJECTABLE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	ADVANCED ILLNESS: 6 MONTHS. CHRONIC NON-CANCER PAIN: 12 MONTHS.
Other Criteria	CHRONIC NON-CANCER PAIN: 1) HAS BEEN TAKING OPIOIDS FOR AT LEAST 4 WEEKS, AND 2) TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENTS: NALOXEGOL (MOVANTIK) AND LUBIPROSTONE (AMITIZA)

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

METHYLNALTREXONE ORAL (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
METHYLNALTREXONE BROMIDE	RELISTOR		41923	GPI-14 (52580050100320)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of opioid-induced constipation (OIC) (ICD-10 K59.03, G89.2) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has chronic non-cancer pain, including chronic pain related to prior cancer or its treatment, and does not require frequent opioid dosage escalation
   - The patient has been taking opioids for at least four weeks
   - The patient had a trial of or contraindication to the preferred agents: naloxegol (Movantik) AND lubiprostone (Amitiza)

   If yes, **approve for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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METHYLNALTREXONE ORAL (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **METHYLNALTREXONE ORAL (Relistor)** requires the following rule(s) be met for approval:

A. You have opioid-induced constipation (a type of bowel disorder caused by drugs used to treat pain)
B. You are 18 years of age or older
C. You have chronic non-cancer pain, including chronic pain related to prior cancer or its treatment, and you do not require frequent opioid dosage escalation (increase)
D. You have been taking opioids for at least four weeks
E. You have tried or have a contraindication to (harmful for you to use) the preferred medications: naloxegol (Movantik) AND lubiprostone (Amitiza)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Relistor.

REFERENCES

Relistor [Prescribing Information]. Bridgewater, NJ: Salix Pharmaceuticals. April 2020.

For Part D use only:

METHYLNALTREXONE ORAL (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	OPIOID INDUCED CONSTIPATION WITH CHRONIC NON-CANCER PAIN: 1) HAS BEEN TAKING OPIOIDS FOR AT LEAST 4 WEEKS, AND 2) TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENTS: NALOXEGOL (MOVANTIK) AND LUBIPROSTONE (AMITIZA)

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

METHYLNALTREXONE ORAL (PART D)

Core	Advantage	Plus
No	No	Yes

Created: 07/23
Effective: 01/01/25 Client Approval: 08/24 P&T Approval: 05/18

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

METHYLTESTOSTERONE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
METHYL TESTOSTERONE	METHITEST, METHYLTESTOSTERONE	01404		GPI-10 (2310002000)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	Yes	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for a male patient with a diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) (ICD-10 E29.1) and the patient has **ONE** of the following laboratory values confirming low testosterone levels?
   - At least TWO total serum testosterone levels of less than 300 ng/dL (10.4nmol/L) taken on separate occasions
   - A free serum testosterone level of less than 5 ng/dL (0.17 nmol/L)

   If yes, continue to #2.
   If no, continue to #5.

2. Is the patient 40 years of age or older?

   If yes, continue to #3.
   If no, continue to #4.

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METHYLTESTOSTERONE (PART D)

INITIAL CRITERIA (CONTINUED)

3. Has the patient's prostate specific antigen (PSA) been evaluated for prostate cancer screening?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Has the patient had a trial of or contraindication to **TWO** preferred agents: testosterone 12.5/1.25G, testosterone 20.25/1.25, testosterone 50 mg [1%]?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

5. Is the request for a male patient with a diagnosis of delayed puberty (ICD-10 E30.0) not secondary to a pathological disorder?

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #6.

6. Is the request for a female patient with a diagnosis of metastatic breast cancer (ICD-10 Group C50) who meets **ONE** of the following criteria?
   - The patient is postmenopausal
   - The patient is premenopausal who has benefitted from an oophorectomy AND is considered to have a hormone-responsive tumor

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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METHYLTESTOSTERONE (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **METHYLTESTOSTERONE (Methitest)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Primary or secondary male hypogonadism (hypotestosteronism or low level of testosterone)
   2. Delayed puberty not due to a pathological disorder (disease) in a male
   3. Metastatic breast cancer (cancer that has spread other parts of the body) in a female

B. If you are a male with primary or secondary hypogonadism, approval also requires:
   1. If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated for prostate cancer screening
   2. You have ONE of the following lab values showing you have low testosterone levels:
      a. At least two total serum (blood) testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
      b. Free serum testosterone level of less than 5 ng/dL (0.17 nmol/L)
   3. You have tried or have a contraindication to (harmful for you to use) TWO preferred medications: testosterone 12.5/1.25G, testosterone 20.25/1.25, testosterone 50 mg [1%]

C. If you are a female with metastatic breast cancer, approval also requires ONE of the following:
   1. You are postmenopausal (after menopause)
   2. You are premenopausal (before menopause), you have benefitted from an oophorectomy (surgical removal of the ovaries), and your tumor is hormone-responsive

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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METHYLTESTOSTERONE (PART D)

RENEWAL CRITERIA

NOTE: For the diagnosis metastatic breast cancer, please refer to the Initial Criteria section.

1. Is the request for a male patient with a diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) (ICD-10 E29.1) **AND** the patient meets the following criterion?
   - The patient has improved symptoms compared to baseline and has tolerated treatment

   If yes, continue to #2.
   If no, continue to #4.

2. Is the patient 40 years of age or older?

   If yes, continue to #3.
   If no, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

3. Has the patient's prostate specific antigen (PSA) been evaluated for prostate cancer screening?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Is the request for a male patient with a diagnosis of delayed puberty (ICD-10 E30.0) not secondary to a pathological disorder **AND** meets the following criterion?
   - The patient has not received more than two 6-month courses of testosterone replacement therapy

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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METHYLTESTOSTERONE (PART D)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **METHYLTESTOSTERONE (Methitest)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Primary or secondary male hypogonadism (hypotestosteronism or low level of testosterone)
   2. Delayed puberty not secondary to a pathological disorder (disease) in a male

B. If you are a male with primary or secondary hypogonadism, renewal also requires:
   1. Your symptoms have improved compared to baseline and you have tolerated treatment
   2. If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated for prostate cancer screening

C. If you are a male with delayed puberty not secondary to a pathological disorder, renewal also requires:
   1. You have NOT received more than two 6-month courses of testosterone replacement therapy

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Methitest.

REFERENCES

Methitest [Prescribing Information]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; May 2019.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

METHYLTESTOSTERONE (PART D)

For Part D use only:

METHYLTESTOSTERONE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	MALE HYPOGONADISM: INITIAL: CONFIRMED BY: 1) AT LEAST TWO TOTAL SERUM TESTOSTERONE LEVELS OF LESS THAN 300 NG/DL TAKEN ON SEPARATE OCCASIONS, OR 2) FREE SERUM TESTOSTERONE LEVEL OF LESS THAN 5 NG/DL.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	INITIAL/RENEWAL: MALE DELAYED PUBERTY: 6 MO, MALE HYPOGONADISM: 12 MO. OTHER INDICATIONS: 12 MO.
Other Criteria	INITIAL: MALE HYPOGONADISM: 1) 40 YEARS OR OLDER: PROSTATE SPECIFIC ANTIGEN (PSA) HAS BEEN EVALUATED FOR PROSTATE CANCER SCREENING, AND 2) TRIAL OF OR CONTRAINDICATION TO TWO PREFERRED AGENTS: TESTOSTERONE 12.5/1.25G, TESTOSTERONE 20.25/1.25, TESTOSTERONE 50 MG (1%). RENEWAL: MALE HYPOGONADISM: 1) 40 YEARS OR OLDER: PSA HAS BEEN EVALUATED FOR PROSTATE CANCER SCREENING, AND 2) IMPROVED SYMPTOMS COMPARED TO BASELINE AND TOLERANCE TO TREATMENT. MALE DELAYED PUBERTY: HAS NOT RECEIVED MORE THAN TWO 6-MONTH COURSES OF TESTOSTERONE REPLACEMENT THERAPY.

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Effective: 07/01/25 Client Approval: 05/25 P&T Approval: 01/24

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

METOCLOPRAMIDE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
METOCLOPRAMIDE HCL	GIMOTI		48272	GPI-14 (52300020102080)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of acute and recurrent diabetic gastroparesis (ICD-10 K31.84, E10.43, E11.43) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to TWO generic metoclopramide products (e.g., vial, syringe, tablet, ODT, solution dosage forms)

   If yes, **approve for 3 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **METOCLOPRAMIDE (Gimoti)** requires the following rule(s) be met for approval:
   A. You have acute (short duration) and recurrent (occurring repeatedly) diabetic gastroparesis (a disorder from high blood sugar that causes delayed emptying of food from the stomach)
   B. You are 18 years of age or older
   C. You have tried or have a contraindication to (harmful for you to use) TWO generic metoclopramide products (such as metoclopramide vial, syringe, tablet, orally disintegrating tablet, solution dosage forms)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

METOCLOPRAMIDE (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Gimoti.

REFERENCES
Gimoti [Prescribing Information]. Solana Beach, CA: Evoke Pharma, Inc.; January 2021.

For Part D use only:

METOCLOPRAMIDE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 MONTHS
Other Criteria	TRIAL OF OR CONTRAINDICATION TO TWO GENERIC METOCLOPRAMIDE PRODUCTS

Core	Advantage	Plus
No	No	Yes

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Effective: 01/01/25 Client Approval: 08/24 P&T Approval: 10/20

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

METOPROLOL (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
METOPROLOL TARTRATE	LOPRESSOR		56737	GPI-14 (33200030102020)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of hypertension (ICD-10 I10) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a contraindication to or is unable to swallow metoprolol tartrate tablets

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of angina pectoris (ICD-10 Group I20) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a contraindication to or is unable to swallow metoprolol tartrate tablets

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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METOPROLOL (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of definite or suspected acute myocardial infarction (ICD-10 Group I21) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is hemodynamically stable
   - The patient has a contraindication to or is unable to swallow metoprolol tartrate tablets

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **METOPROLOL (Lopressor)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Hypertension (high blood pressure)
      2. Angina pectoris (a type of heart condition)
      3. Definite or suspected acute myocardial infarction (heart attack)

   B. If you have hypertension, approval also requires:
      1. You are 18 years of age or older
      2. You have a contraindication to (harmful for you to use) or are unable toswallow metoprolol tartrate tablets

   C. If you have angina pectoris, approval also requires:
      1. You are 18 years of age or older
      2. You have a contraindication to (harmful for you to use) or are unable toswallow metoprolol tartrate tablets

   D. If you have definite or suspected acute myocardial infarction, approval also requires:
      1. You are 18 years of age or older
      2. You are hemodynamically stable (blood flow is stable)
      3. You have a contraindication to (harmful for you to use) or are unable toswallow metoprolol tartrate tablets

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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METOPROLOL (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lopressor.

REFERENCES

Lopressor [Prescribing Information]. Parsippany, NJ: Validus Pharmaceuticals LLC; April 2025.

For Part D use only:

METOPROLOL (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	HYPERTENSION, ANGINA PECTORIS, ACUTE MYOCARDIAL INFARCTION: CONTRAINDICATION TO OR UNABLE TO SWALLOW METOPROLOL TARTRATE TABLETS.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

METRELEPTIN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
METRELEPTIN	MYALEPT	41078		GPI-10 (3090605000)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of congenital or acquired generalized lipodystrophy (ICD-10 E88.1) and meet **ALL** of the following criteria?
   - Myalept will be used as an adjunct to diet as replacement therapy to treat the complications of leptin deficiency
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has diabetes mellitus, insulin resistance, OR a fasting hypertriglyceridemia of greater than 200mg/dL

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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METRELEPTIN (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **METRELEPTIN (Myalept)** requires the following rule(s) be met for approval:

A. You have congenital or acquired generalized lipodystrophy (abnormal distribution of fatin the body)
B. Myalept will be used as an adjunct (add-on) to diet as replacement therapy to treat the complications of leptin deficiency (low level of a type of hormone)
C. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
D. You have diabetes mellitus (a disorder with high blood sugar), insulin resistance (a condition where cells in the body do not respond to a type of hormone), OR a fasting hypertriglyceridemia (high levels of fat in the blood) of greater than 200mg/dL

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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METRELEPTIN (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of congenital or acquired generalized lipodystrophy (ICD-10 E88.1) **AND** meet the following criterion?
   - The patient has shown clinical benefit with the use of Myalept (e.g., reduction in glucose levels, reduction of insulin resistance, or reduction of triglycerides)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **METRELEPTIN (Myalept)** requires the following rule(s) be met for renewal:
   A. You have congenital or acquired generalized lipodystrophy (abnormal distribution of fatin the body)
   B. You have shown clinical benefit (improvement) with the use of Myalept (such as areduction in glucose levels [lower level of blood sugar], reduction of insulin resistance [cells in the body are more responsive to a type of hormone], or reduction of triglycerides [lower level of fat in the blood])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Myalept.

REFERENCES
Myalept [Prescribing Information]. Cambridge, MA: Aegerion Pharmaceuticals, Inc.; February 2022.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

METRELEPTIN (PART D)

For Part D use only:

METRELEPTIN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	LIPODYSTROPHY: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS
Other Criteria	LIPODYSTROPHY: INITIAL: HAS DIABETES MELLITUS, INSULIN RESISTANCE, OR A FASTING HYPERTRIGLYCERIDEMIA OF GREATER THAN 200MG/DL. RENEWAL: HAS SHOWN CLINICAL BENEFIT (E.G., REDUCTION IN GLUCOSE LEVELS, REDUCTION OF INSULIN RESISTANCE, OR REDUCTION OF TRIGLYCERIDES).

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

METRONIDAZOLE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
METRONIDAZOLE	LIKMEZ	04157		GPI-10 (1600003500)	BRAND = LIKMEZ

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of trichomoniasis (ICD-10 Group A59) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a contraindication to OR inability to swallow generic metronidazole tablets

   If yes, **approve for 30 days by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of acute intestinal amebiasis (amoebic dysentery) (ICD-10 A06.0) or amebic liver abscess (ICD-10 A06.4) and meet **ALL** of the following criteria?
   - The patient has a contraindication to OR inability to swallow generic metronidazole tablets

   If yes, **approve for 30 days by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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METRONIDAZOLE (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Is the request for the treatment of serious infections caused by susceptible anaerobic bacteria (e.g., *Bacteroides* species, *Clostridium* species, *Peptococcus* species) and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a contraindication to OR inability to swallow generic metronidazole tablets

   If yes, **approve for 30 days by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **METRONIDAZOLE (Likmez)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Trichomoniasis (a type of infection caused by a parasite)
      2. Acute intestinal amebiasis (amoebic dysentery: a type of infection of the intestines) OR amebic liver abscess (a collection of pus in the liver caused by a parasite)
      3. Serious infections caused by susceptible anaerobic bacteria, such as *Bacteroides* species, *Clostridium* species, *Peptococcus* species (infections caused by types of bacteria that can be treated with Likmez)
   B. You have a contraindication to (harmful for you to use) OR are unable to swallow generic metronidazole tablets
   C. For the treatment of trichomoniasis or serious infections caused by susceptible anaerobic bacteria, approval also requires:
      1. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

METRONIDAZOLE (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Likmez.

REFERENCES

Likmez [Prescribing Information]. Hauppauge, NY: Saptalis Pharmaceuticals LLC; December 2024.

For Part D use only:

METRONIDAZOLE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	30 DAYS
Other Criteria	TRICHOMONIASIS, ACUTE INTESTINAL AMEBIASIS (AMOEBIC DYSENTERY) OR AMEBIC LIVER ABSCESS, SERIOUS INFECTIONS CAUSED BY SUSCEPTIBLE ANAEROBIC BACTERIA: CONTRAINDICATION TO OR INABILITY TO SWALLOW GENERIC METRONIDAZOLE TABLETS.

Created: 01/25
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 01/24

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

METYROSINE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
METYROSINE	DEMSER, METYROSINE	00138		GPI-10 (3630002500)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
Yes	Yes	No	Yes	Yes	No	Yes	Yes	No	Yes	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pheochromocytoma (ICD-10 Groups D35.0, C74.1) and the requested medication will be used for **ONE** of the following?
   - Preoperative preparation for surgery
   - Management of malignant pheochromocytoma when surgery is contraindicated
   - Chronic treatment of patients with malignant pheochromocytoma

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following?
   - The patient has a non-metastatic pheochromocytoma
   - Therapy is prescribed by or in consultation with an endocrinologist, an endocrine surgeon, or a hematologist-oncologist

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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METYROSINE (PART D)

INITIAL CRITERIA (CONTINUED)

3. Is the patient awaiting surgery?

   If yes, continue to #4.
   If no, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

4. Will the requested medication be used in combination with an alpha-adrenergic receptor blocker (e.g., doxazosin, terazosin, prazosin, phenoxybenzamine)?

   If yes, **approve for 30 days by HICL or GPI-10 for one fill.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **METYROSINE (Demser)** requires the following rule(s) be met for approval:
   A. You have pheochromocytoma (a type of rare tumor)
   B. You will be using the requested medication for ONE of the following:
      1. Preoperative (before surgery) preparation of surgery
      2. Management of malignant (cancerous) pheochromocytoma when surgery is contraindicated (harmful for you to have)
      3. Chronic (long term) treatment of malignant pheochromocytoma
   C. You have a non-metastatic pheochromocytoma (tumor has not spread to other parts of the body)
   D. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor), an endocrine surgeon (surgeon specializing in removal of glands such as adrenal glands), or a hematologist-oncologist (a type of cancer doctor)
   E. If you are awaiting surgery, approval also requires:
      1. The requested medication will be in combination with an alpha-adrenergic receptor blocker (such as doxazosin, terazosin, prazosin, phenoxybenzamine)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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METYROSINE (PART D)

RENEWAL CRITERIA

NOTE: For the request of preoperative preparation for surgery, please refer to the initial criteria section.

1. Does the patient have a diagnosis of pheochromocytoma (ICD-10 Groups D35.0, C74.1) and the requested medication will be used for **ONE** of the following?
   - Management of malignant pheochromocytoma when surgery is contraindicated
   - Chronic treatment of patients with malignant pheochromocytoma

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the patient stable or has shown clinical improvement while on therapy?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **METYROSINE (Demser)** requires the following rule(s) be met for renewal:
   A. You have pheochromocytoma (a type of rare tumor)
   B. You will be using the requested medication for ONE of the following:
      1. Management of malignant (cancerous) pheochromocytoma when surgery is contraindicated (harmful for you to have)
      2. Chronic (long term) treatment of malignant pheochromocytoma
   C. You are stable or have shown clinical improvement while on therapy (treatment)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Demser.

REFERENCES

Demser [Prescribing Information]. Steinbach, MB R5G 1Z7, Canada: Bausch Health Companies, Inc.; July 2021.

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METYROSINE (PART D)

For Part D use only:

METYROSINE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	PHEOCHROMOCYTOMA: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST, ENDOCRINE SURGEON, OR HEMATOLOGIST-ONCOLOGIST.
Coverage Duration	PREOPERATIVE PREPARATION FOR SURGERY: 30 DAYS. MALIGNANT PHEOCHROMOCYTOMA: INITIAL/RENEWAL:12 MOS.
Other Criteria	PHEOCHROMOCYTOMA: INITIAL: HAS NON-METASTATIC PHEOCHROMOCYTOMA. PREOPERATIVE PREPARATION FOR SURGERY: USE IN COMBINATION WITH AN ALPHA-ADRENERGIC RECEPTOR BLOCKER. RENEWAL: MALIGNANT PHEOCHROMOCYTOMA: STABLE OR CLINICAL IMPROVEMENT WHILE ON THERAPY.

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Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 04/25

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MIDOSTAURIN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MIDOSTAURIN	RYDAPT	44227		GPI-10 (2153303000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have acute myeloid leukemia (AML) (ICD Group C92.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has newly diagnosed AML
   - The patient's cancer is FLT3 mutation-positive, as detected by an FDA-approved test
   - Rydapt will be used in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation chemotherapy

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of aggressive systemic mastocytosis (ASM) (ICD-10 C96.21), systemic mastocytosis with associated hematological neoplasm (SM-AHN) (ICD-10 D47.02), or mast cell leukemia (MCL) (ICD Group C94.3) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text on the next page.

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MIDOSTAURIN (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **MIDOSTAURIN (Rydapt)** requires the following rules to be met for approval:

A. You have ONE of the following:
   1. Acute myeloid leukemia (AML: a type of blood cancer)
   2. Aggressive systemic mastocytosis (ASM: a type of blood disorder)
   3. Systemic mastocytosis with associated hematological neoplasm (SM-AHN: a type of blood cancer)
   4. Mast cell leukemia (MCL: a type of blood cancer)

B. If you have acute myeloid leukemia, approval also requires:
   1. You are 18 years of age or older
   2. You have newly diagnosed acute myeloid leukemia
   3. You are FLT3 (type of gene) mutation-positive, as detected by a Food and Drug Administration (FDA)-approved test
   4. Rydapt will be used in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation chemotherapy (cancer drugs)

C. If you have aggressive systemic mastocytosis, systemic mastocytosis with associated hematological neoplasm, or mast cell leukemia, approval also requires:
   1. You are 18 years of age or older

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the prescribing information and/or drug monograph for Rydapt.

REFERENCES

Rydapt [Prescribing Information]. East Hanover, New Jersey: Novartis Pharmaceuticals; May 2023.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MIDOSTAURIN (PART D)

For Part D use only:

MIDOSTAURIN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	ACUTE MYELOID LEUKEMIA: 6 MONTHS. ADVANCED SYSTEMIC MASTOCYTOSIS: 12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25 Created: 05/17
Commercial Effective: N/A Client Approval: 06/24 P&T Approval: 07/17

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MIFEPRISTONE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MIFEPRISTONE	KORLYM, MIFEPRISTONE	07325		GPI-10 (2730405000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of endogenous Cushing's syndrome (CS) (ICD-10 Group E24 except ICD-10 E24.2 and E24.4) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient also has a diagnosis of type 2 diabetes mellitus (ICD-10 Groups E08, E09, E11, E13) OR glucose intolerance
   - The patient has failed surgical treatment for Cushing's syndrome OR is not a candidate for surgery
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's hypercortisolism is NOT a result of chronic glucocorticoids (e.g., prednisone)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Has the diagnosis of endogenous Cushing's syndrome been confirmed by **ONE** of the following tests?
   - 24-hour urine free cortisol (at least 2 tests to confirm)
   - Overnight 1mg dexamethasone test
   - Late-night salivary cortisol (at least 2 tests to confirm)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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MIFEPRISTONE (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **MIFEPRISTONE (Korlym)** requires the following rule(s) be met for approval:

A. You have endogenous Cushing's syndrome (CS: a type of hormone disorder)
B. You are 18 years of age or older
C. You also have type 2 diabetes mellitus (a disorder with high blood sugar) OR glucose intolerance (a condition that results in high blood sugar)
D. You have failed surgical treatment (surgery did not work) for Cushing's syndrome OR you are NOT a candidate for surgery
E. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
F. Your diagnosis is confirmed by ONE of the following:
    1. 24-hour urine free cortisol (a type of test that measures the amount of cortisol in the urine) (at least 2 tests to confirm)
    2. Overnight 1mg dexamethasone test (a type of diagnostic test)
    3. Late-night salivary cortisol (a type of test that measures the amount of cortisol in the saliva at night) (at least 2 tests to confirm)
G. Your hypercortisolism (high levels of cortisol) is NOT due to chronic glucocorticoids (long-term use of a class of drugs that consists of steroids, such as prednisone)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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MIFEPRISTONE (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of endogenous Cushing's syndrome (CS) (ICD-10 Group E24 except ICD-10 E24.2 and E24.4) and meet **ALL** of the following criteria?
   - The patient continues to have improvement of glucose tolerance or stable glucose tolerance (e.g., reduced A1C, improved fasting glucose)
   - The patient continues to have tolerability to therapy
   - The patient continues to not be a candidate for surgical treatment for Cushing's syndrome OR has failed surgery

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MIFEPRISTONE (Korlym)** requires the following rule(s) be met for renewal:
   A. You have endogenous Cushing's syndrome (CS: a type of hormone disorder)
   B. You continue to have improvement of glucose tolerance or stable glucose tolerance (such as reduced hemoglobin A1C level [a type of lab test], improved fasting glucose)
   C. You continue to tolerate treatment
   D. You are NOT a candidate for surgery OR you have failed surgery (surgery did not work) for Cushing's syndrome

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Korlym.

REFERENCE

Korlym [Prescribing Information]. Menlo Park, CA: Corcept Therapeutics Incorporated; January 2025.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MIFEPRISTONE (PART D)

For Part D use only:

MIFEPRISTONE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	CUSHINGS SYNDROME (CS): INITIAL: DIAGNOSIS CONFIRMED BY: 1) 24-HR URINE FREE CORTISOL (AT LEAST 2 TESTS TO CONFIRM), 2) OVERNIGHT 1MG DEXAMETHASONE TEST, OR 3) LATE NIGHT SALIVARY CORTISOL (AT LEAST 2 TESTS TO CONFIRM).
Age Restrictions	N/A
Prescriber Restrictions	CS: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS
Other Criteria	CS: INITIAL: HYPERCORTISOLISM IS NOT A RESULT OF CHRONIC GLUCOCORTICOIDS. RENEWAL: 1) CONTINUES TO HAVE IMPROVEMENT OF GLUCOSE TOLERANCE OR STABLE GLUCOSE TOLERANCE (E.G., REDUCED A1C, IMPROVED FASTING GLUCOSE), 2) CONTINUES TO HAVE TOLERABILITY TO THERAPY, AND 3) CONTINUES TO NOT BE A CANDIDATE FOR SURGICAL TREATMENT OR HAS FAILED SURGERY.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MIGALASTAT (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MIGALASTAT HCL	GALAFOLD	44433		GPI-10 (3090365010)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Fabry disease (ICD-10 E75.21) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a nephrologist, cardiologist, or specialist in genetics or inherited metabolic disorders
   - The patient has an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data that is interpreted by a clinical genetics professional as pathogenic or likely pathogenic (i.e., patient does not have a benign amenable GLA variant)
   - Galafold will NOT be used concurrently with another Fabry disease therapy (e.g., Fabrazyme [agalsidase beta], Elfabrio [pegunigalsidase alfa-iwxj])

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the request for a female patient who meets the following criterion?
   - The patient has a galactosidase alpha (GLA) gene mutation via genetic testing

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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MIGALASTAT (PART D)

INITIAL CRITERIA (CONTINUED)

3. Is the request for a male patient who meets **ONE** of the following criteria?
   - The patient has an alpha galactosidase A (a-Gal A) deficiency as indicated by an enzyme assay
   - The patient has a galactosidase alpha (GLA) gene mutation via genetic testing

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MIGALASTAT (Galafold)** requires the following rule(s) be met for approval:

   A. You have Fabry disease (a rare genetic disease)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with a nephrologist (kidney doctor), cardiologist (heart doctor), or specialist in genetics or inherited metabolic disorders
   D. You have an amenable (responsive) galactosidase alpha (GLA: a type of gene) gene variant based on in vitro assay data (information from a type of lab test) that is interpreted by a clinical genetics professional as the cause of disease (pathogenic or likely pathogenic)
   E. You will NOT use Galafold concurrently (at the same time) with another Fabry disease medication (such as Fabrazyme [agalsidase beta], Elfabrio [pegunigalsidase alfa-iwxj])
   F. If you are a female, approval also requires:
      1. You have a galactosidase alpha (GLA: a type of gene) gene mutation by genetic testing
   G. If you are a male, approval also requires ONE of the following:
      1. You do not have enough alpha galactosidase A (a-Gal A: a type of protein) as indicated by an enzyme assay (a type of lab test)
      2. You have a galactosidase alpha (GLA: a type of gene) gene mutation by genetic testing

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MIGALASTAT (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Fabry disease (ICD-10 E75.21) and meet **ALL** of the following criteria?
   - The patient has demonstrated improvement or stabilization
   - Galafold will NOT be used concurrently with another Fabry disease therapy (e.g., Fabrazyme [agalsidase beta], Elfabrio [pegunigalsidase alfa-iwxj])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MIGALASTAT (Galafold)** requires the following rule(s) be met for renewal:

   A. You have Fabry disease (a rare genetic disease)
   B. You have demonstrated improvement or stabilization while on therapy
   C. You will NOT use Galafold concurrently (at the same time) with another Fabry disease medication (such as Fabrazyme [agalsidase beta], Elfabrio [pegunigalsidase alfa-iwxj])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Galafold.

REFERENCES

Galafold [Prescribing Information]. Philadelphia, PA: Amicus Therapeutics; June 2024.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MIGALASTAT (PART D)

For Part D use only:

MIGALASTAT (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D
Exclusion Criteria	N/A
Required Medical Information	FABRY DISEASE: INITIAL: 1) HAS AN AMENABLE GALACTOSIDASE ALPHA GENE (GLA) VARIANT BASED ON IN VITRO ASSAY DATA THAT IS INTERPRETED BY A CLINICAL GENETICS PROFESSIONAL AS PATHOGENIC OR LIKELY PATHOGENIC, AND 2) ONE OF THE FOLLOWING: (A) FEMALES: GLA GENE MUTATION VIA GENETIC TESTING, OR (B) MALES: ENZYME ASSAY INDICATING ALPHA GALACTOSIDASE A DEFICIENCY OR GLA GENE MUTATION VIA GENETIC TESTING.
Age Restrictions	N/A
Prescriber Restrictions	FABRY DISEASE: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEPHROLOGIST, CARDIOLOGIST, OR SPECIALIST IN GENETICS OR INHERITED METABOLIC DISORDERS.
Coverage Duration	INITIAL: 6 MOS. RENEWAL: 12 MOS.
Other Criteria	FABRY DISEASE: INITIAL: NO CONCURRENT USE WITH ANOTHER FABRY DISEASE THERAPY. RENEWAL: 1) DEMONSTRATED IMPROVEMENT OR STABILIZATION, AND 2) NO CONCURRENT USE WITH ANOTHER FABRY DISEASE THERAPY.

Created: 08/18
Effective: 01/01/26 Client Approval: 01/26 P&T Approval: 07/23

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MIGLUSTAT-OPFOLDA (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MIGLUSTAT	OPFOLDA		54801	GPI-10 (3090776000)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) (ICD-10 E74.02) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient weighs at least 40 kg (88 lbs.)
   - The patient is not improving on their current enzyme replacement therapy (ERT) (e.g., Lumizyme [alglucosidase alfa])
   - Opfolda will be used in combination with Pombiliti (cipaglucosidase alfa-atga)

   If yes, **approve for lifetime by GPID or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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MIGLUSTAT-OPFOLDA (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **MIGLUSTAT-OPFOLDA** requires the following rule(s) be met for approval:

A. You have late-onset Pompe disease (a type of genetic disorder) due to lysosomal acid alpha-glucosidase (GAA: a type of enzyme) deficiency
B. You are 18 years of age or older
C. You weigh at least 40 kilograms (88 pounds)
D. You are not improving on your current enzyme replacement therapy (ERT) such as Lumizyme (alglucosidase alfa)
E. Opfolda will be used in combination with Pombiliti (cipaglucosidase alfa-atga)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Opfolda.

REFERENCES

Opfolda [Prescribing Information]. Philadelphia, PA: Amicus Therapeutics US, LLC; September 2023.

For Part D use only:

MIGLUSTAT-OPFOLDA (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	LIFETIME
Other Criteria	N/A

Created: 10/23
Effective: 01/01/25 Client Approval: 08/24 P&T Approval: 01/24

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MIGLUSTAT-ZAVESCA (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MIGLUSTAT	ZAVESCA, YARGESA, MIGLUSTAT		19453	GPI-10 (8270007000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of mild to moderate type 1 Gaucher disease (ICD-10 E75.22) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The requested medication will be used as monotherapy
   - Enzyme replacement therapy is not a therapeutic option for this patient (e.g., due to allergy, hypersensitivity, poor venous access)

   If yes, **approve for 12 months by GPID or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MIGLUSTAT-ZAVESCA (Yargesa)** requires the following rule(s) be met for approval:
   A. You have mild to moderate type 1 Gaucher disease (a type of genetic condition)
   B. You are 18 years of age or older
   C. The requested medication will be used as monotherapy (one drug treatment)
   D. Enzyme replacement therapy (a type of treatment) is not a therapeutic option for you (due to reasons such as allergy, hypersensitivity [allergic reaction], poor access to veins)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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MIGLUSTAT-ZAVESCA (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zavesca and Yargesa.

REFERENCES

Zavesca [Prescribing Information]. Titusville, NJ: Actelion Pharmaceuticals US, Inc.; August 2022.
Yargesa [Prescribing Information]. Parsippany, NJ: Edenbridge Pharmaceuticals, LLC; October 2023.

MIGLUSTAT-ZAVESCA (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 10/19
Client Approval: 06/24
P&T Approval: 02/11

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ADVANTAGE AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MILTEFOSINE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MILTEFOSINE	IMPAVIDO	16200		GPI-10 (1600003600)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have **ONE** of the following diagnoses?
   - Visceral leishmaniasis (ICD-10 B55.0) caused by *Leishmania donovani*
   - Cutaneous leishmaniasis (ICD-10 B55.1) caused by *Leishmania braziliensis*, *Leishmania guyanensis*, or *Leishmania panamensis*
   - Mucosal leishmaniasis (ICD-10 B55.2) caused by *Leishmania braziliensis*

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient is 12 years of age or older weighing at least 30kg (66lbs)
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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MILTEFOSINE (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline for **MILTEFOSINE (Impavido)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Visceral leishmaniasis caused by *Leishmania donovani* (type of parasitic disease that affects your organs)
   2. Cutaneous leishmaniasis caused by *Leishmania braziliensis, Leishmania guyanensis, or Leishmania panamensis* (type of parasitic disease that affects your skin)
   3. Mucosal leishmaniasis caused by *Leishmania braziliensis* (type of parasitic disease that affects inside mouth, throat and nose)

B. You meet ONE of the following:
   1. You are 12 years of age or older weighing at least 30kg (66lbs)
   2. You are 18 years of age or older

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Impavido.

REFERENCES

Impavido [Prescribing Information]. Orlando, FL: Profounda, Inc.; May 2021.

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ADVANTAGE AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MILTEFOSINE (PART D)

For Part D use only:

MILTEFOSINE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
No	Yes	Yes

Part D Effective: 01/01/25 Created: 11/16
Commercial Effective: N/A Client Approval: 10/24 P&T Approval: 11/16

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MIRDAMETINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MIRDAMETINIB	GOMEKLI	50277		GPI-10 (2153355000)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of neurofibromatosis type 1 (NF1) (ICD-10 Q85.01) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - The patient has symptomatic plexiform neurofibromas (PN) that cannot be completely resected

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MIRDAMETINIB (Gomekli)** requires the following rule(s) be met for approval:
   A. You have neurofibromatosis type 1 (NF1: a type of skin and nervous system disorder)
   B. You are 2 years of age or older
   C. You have symptomatic plexiform neurofibromas (PN: tumors that grow along the nerves) that cannot be completely resected (cannot be completely removed by surgery)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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MIRDAMETINIB (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Gomekli.

REFERENCES

Gomekli [Prescribing Information]. Stamford, CT: SpringWorks Therapeutics, Inc.; February 2025.

For Part D use only:

MIRDAMETINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 02/25
Effective: 03/10/25 Client Approval: 02/25 P&T Approval: 04/25

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MIRIKIZUMAB-MRKZ SQ (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MIRIKIZUMAB-MRKZ	OMVOH	49282		GPI-10 (5250405040)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Omvoh will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Selarsdi /Yesintek /ustekinumab-aauz
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Skyrizi (risankizumab-rzaa)
     - Tremfya (guselkumab)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

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MIRIKIZUMAB-MRKZ SQ (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Omvoh will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Selarsdi /Yesintek /ustekinumab-aauz
     - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Skyrizi (risankizumab-rzaa)
     - Tremfya (guselkumab)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MIRIKIZUMAB-MRKZ SQ (Omvoh)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
      2. Moderate to severe Crohn's disease (CD: a type of bowel disorder)

   (Initial denial text continued on next page)

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MIRIKIZUMAB-MRKZ SQ (PART D)

INITIAL CRITERIA (CONTINUED)

B. If you have moderate to severe ulcerative colitis, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
3. You will NOT use Omvoh concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis
4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Selarsdi /Yesintek /ustekinumab-aauz
   b. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
   c. Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
   d. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
   e. Skyrizi (risankizumab-rzaa)
   f. Tremfya (guselkumab)

C. If you have moderate to severe Crohn's disease, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
3. You will NOT use Omvoh concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn’s disease
4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Selarsdi /Yesintek /ustekinumab-aauz
   b. Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
   c. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
   d. Skyrizi (risankizumab-rzaa)
   e. Tremfya (guselkumab)

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MIRIKIZUMAB-MRKZ SQ (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) **AND** meet the following criterion?
   - Omvoh will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) **AND** meet the following criterion?
   - Omvoh will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MIRIKIZUMAB-MRKZ SQ (Omvoh)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
      2. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   B. If you have moderate to severe ulcerative colitis, renewal also requires:
      1. You will NOT use Omvoh concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

   (Renewal denial text continued on next page)

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MIRIKIZUMAB-MRKZ SQ (PART D)

RENEWAL CRITERIA (CONTINUED)

C. If you have moderate to severe Crohn's disease, renewal also requires:

1. You will NOT use Omvoh concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Omvoh.

REFERENCES

Omvoh [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; November 2025.

For Part D use only:

MIRIKIZUMAB-MRKZ SQ (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: ULCERATIVE COLITIS (UC), CROHNS DISEASE (CD): PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: UC: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: SELARSDI/YESINTEK/USTEKINUMAB-AAUZ, XELJANZ, HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, RINVOQ, SKYRIZI, TREMFYA. CD: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: SELARSDI/YESINTEK/USTEKINUMAB-AAUZ, HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, RINVOQ, SKYRIZI, TREMFYA. INITIAL/RENEWAL: ALL INDICATIONS: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION.

Created: 11/23
Effective: 05/01/26 Client Approval: 04/26 P&T Approval: 04/25

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MIRVETUXIMAB SORAVTANSINE-GYNX BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MIRVETUXIMAB SORAVTANSINE-GYNX	ELAHERE	48453		GPI-10 (2135503020)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	Yes	No	Yes	Yes	No	Yes	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is the drug administered via an implantable pump?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B. (Populate the B vs. D field with 'B' in the PA override field. If MI does not process Part B for the client, refer the caller/request back to the Health plan).**

   If no, continue to #2.

2. Is the drug administered via an external pump?

   If yes, continue to #3.

   If no, **approve for 12 months by HICL or GPI-10 under Part D. (Populate the B vs. D field with 'D' in the PA override field).**

3. Is the drug specifically covered under the applicable Medicare coverage policies (National and/or Local Coverage Policies)?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B. (Populate the B vs. D field with 'B' in the PA override field. If MI does not process Part B for the client, refer the caller/request back to the Health plan).**

   If no, **approve for 12 months by HICL or GPI-10 under Part D. (Populate the B vs. D field with 'D' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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MIRVETUXIMAB SORAVTANSINE-GYNX BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of epithelial ovarian, fallopian tube, or primary peritoneal cancer (ICD-10 Groups C56, C57.0, C48, C79.6) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer is platinum-resistant
   - The patient's tumor is folate receptor-alpha (FRα) positive, as determined by an FDA-approved test
   - The patient has received one to three prior systemic treatment regimen(s) (e.g., bevacizumab, Lynparza [olaparib])
   - The patient will complete an ophthalmic exam, including visual acuity and slit lamp exam, prior to the initiation of Elahere and at the recommended scheduled intervals

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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MIRVETUXIMAB SORAVTANSINE-GYNX BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **MIRVETUXIMAB SORAVTANSINE-GYNX (Elahere)** requires the following rule(s) be met for approval:

A. You have epithelial ovarian, fallopian tube, or primary peritoneal cancer (types of reproductive system cancers)
B. You are 18 years of age or older
C. Your cancer is platinum-resistant (did not respond to a type of cancer treatment such as cisplatin, carboplatin, oxaliplatin)
D. Your tumor is folate receptor-alpha (FRα: a type of protein) positive, as determined by a Food and Drug Administration (FDA)-approved test
E. You have received one to three prior systemic treatment regimen(s) (such as bevacizumab, Lynparza [olaparib])
F. You will complete an ophthalmic (eye) exam, including visual acuity (sharpness of vision) and slit lamp exam (a type of eye exam), before starting Elahere and at the recommended scheduled times

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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MIRVETUXIMAB SORAVTANSINE-GYNX BvD (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Elahere. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs administered by an implantable pump are covered under Part B. Drugs administered via an external pump are covered under Part B if they are included under the local coverage policy of the applicable Medicare coverage policies (National and/or Local Coverage Policies). Drugs administered via an external pump that are not included under the applicable Medicare coverage policies are covered under Part D. A CMS website to assist with National and Local Coverage Determination for B versus D review is http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx

REFERENCES

Elahere [Prescribing Information]. Waltham, MA: ImmunoGen, Inc., October 2024.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: http://www.cms.gov/PrescriptionDrugCovContra/12_PartDManuals.asp. [Accessed February 5, 2025].

For Part D use only:

MIRVETUXIMAB SORAVTANSINE-GYNX (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	EPITHELIAL OVARIAN, FALLOPIAN TUBE, OR PRIMARY PERITONEAL CANCER: AN OPHTHALMIC EXAM, INCLUDING VISUAL ACUITY AND SLIT LAMP EXAM, WILL BE COMPLETED PRIOR TO THE INITIATION OF THERAPY AND AT THE RECOMMENDED SCHEDULED INTERVALS.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 02/25
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 01/23

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MITAPIVAT (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MITAPIVAT SULFATE	PYRUKYND	47840		GPI-10 (8587005070)	BRAND ≠ AQVESME

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hemolytic anemia due to pyruvate kinase (PK) deficiency (ICD-10 D55.21) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve all strengths for 6 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MITAPIVAT (Pyrukynd)** requires the following rule(s) be met for approval:
   A. You have hemolytic anemia (a type of blood condition) due to pyruvate kinase (PK: a type of enzyme) deficiency
   B. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MITAPIVAT (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hemolytic anemia due to pyruvate kinase (PK) deficiency (ICD-10 D55.21) **AND** meet the following criterion?
   - The patient has had clinical benefit while on Pyrukynd

   If yes, **approve all strengths for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MITAPIVAT (Pyrukynd)** requires the following rule(s) be met for renewal:
   A. You have hemolytic anemia (a type of blood condition) due to pyruvate kinase (PK: a type of enzyme) deficiency
   B. You have had clinical benefit while on Pyrukynd

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Pyrukynd.

REFERENCES
Pyrukynd [Prescribing Information]. Cambridge, MA: Agios Pharmaceuticals, Inc.; December 2025.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MITAPIVAT (PART D)

For Part D use only:

MITAPIVAT (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	HEMOLYTIC ANEMIA IN PYRUVATE KINASE (PK) DEFICIENCY: RENEWAL: CLINICAL BENEFIT WHILE ON THERAPY.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MITAPIVAT-AQVESME (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MITAPIVAT SULFATE	AQVESME	47840		GPI-10 (8587005070)	BRAND ≠ PYRUKYND

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of alpha-thalassemia (ICD-10 D56.0) or beta-thalassemia (ICD-10 D56.1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Aqvesme will be used for the treatment of anemia

   If yes, **approve for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MITAPIVAT-AQVESME** requires the following rule(s) be met for approval:
   A. You have alpha-thalassemia or beta-thalassemia (types of blood condition)
   B. You are 18 years of age or older
   C. Aqvesme will be used for the treatment of anemia (a type of blood condition)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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MITAPIVAT-AQVESME (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Aqvesme.

REFERENCES

Aqvesme [Prescribing Information]. Cambridge, MA: Agios Pharmaceuticals, Inc.; December 2025.

For Part D use only:

MITAPIVAT-AQVESME (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 01/26
Effective: 01/19/26 Client Approval: 01/26 P&T Approval: 04/26

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MOMELOTINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MOMELOTINIB DIHYDROCHLORIDE	OJJAARA	49208		GPI-10 (2153754030)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of intermediate or high-risk myelofibrosis (MF) (ICD-10 D75.81), including primary MF (ICD-10 D47.1) or secondary MF (post-polycythemia vera [PV] and post-essential thrombocythemia [ET]), and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has anemia

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MOMELOTINIB (Ojjaara)** requires the following rule(s) be met for approval:
   A. You have intermediate or high-risk myelofibrosis (MF: a type of blood cancer), such as primary MF (MF that developed on its own) or secondary MF (MF that developed from another blood cancer, such as post-polycythemia vera [PV: a type of blood cancer] or post-essential thrombocythemia [ET: a type of blood condition])
   B. You are 18 years of age or older
   C. You have anemia (a type of blood condition)
   (Denial text continued on next page)

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MOMELOTINIB (PART D)

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ojjaara.

REFERENCES

Ojjaara [Prescribing Information]. Durham, NC: GlaxoSmithKline; September 2023.

For Part D use only:

MOMELOTINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MONOMETHYL FUMARATE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MONOMETHYL FUMARATE	BAFIERTAM	46576		GPI-10 (6240555000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), to include clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease, and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to Tecfidera (dimethyl fumarate) AND one of the following preferred agents: Aubagio (teriflunomide), Avonex (interferon beta-1a), Betaseron (interferon beta-1b), Copaxone/Glatopa (glatiramer), Kesimpta (ofatumumab), Plegridy (peginterferon beta-1a), Vumerity (diroximel fumarate)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MONOMETHYL FUMARATE (Bafiertam)** requires the following rule(s) be met for approval:
   A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease returns and goes away), or active secondary progressive disease (advanced disease)

(Denial text continued on next page)

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MONOMETHYL FUMARATE (PART D)

GUIDELINES FOR USE (CONTINUED)

B. You are 18 years of age or older
C. You have tried or have a contraindication to (harmful for you to use) Tecfidera (dimethyl fumarate) AND one of the following preferred medications: Aubagio (teriflunomide), Avonex (interferon beta-1a), Betaseron (interferon beta-1b), Copaxone/Glatopa (glatiramer), Kesimpta (ofatumumab), Plegridy (peginterferon beta-1a), Vumerity (diroximel fumarate)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Bafiertam.

REFERENCES

Bafiertam [Prescribing Information]. High Point, NC: Banner Life Sciences LLC; December 2023.

For Part D use only:

MONOMETHYL FUMARATE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	RELAPSING FORM OF MULTIPLE SCLEROSIS (MS): TRIAL OF OR CONTRAINDICATION TO TECFIDERA AND ONE OF THE PREFERRED AGENTS: AUBAGIO, AVONEX, BETASERON, COPAXONE/GLATOPA, KESIMPTA, PLEGRIDY, VUMERITY.

Core	Advantage	Plus
No	No	Yes

Part D Effective:01/01/25
Commercial Effective: N/A
Created: 09/20
Client Approval: 06/24
P&T Approval: 10/20

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MOSUNETUZUMAB-AXGB BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MOSUNETUZUMAB-AXGB	LUNSUMIO, LUNSUMIO VELO	48556		GPI-10 (2135205010)	

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #5.

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MOSUNETUZUMAB-AXGB BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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MOSUNETUZUMAB-AXGB BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of relapsed or refractory follicular lymphoma (ICD-10 Group C82) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has tried two or more lines of systemic therapy

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MOSUNETUZUMAB-AXGB (Lunsumio, Lunsumio Velo)** requires the following rule(s) be met for approval:
   A. You have relapsed or refractory follicular lymphoma (a type of blood cancer that has returned or does not respond to treatment)
   B. You are 18 years of age or older
   C. You have tried two or more lines of systemic therapy (treatment that targets the entire body)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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MOSUNETUZUMAB-AXGB BvD (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of relapsed or refractory follicular lymphoma (ICD-10 Group C82) and meet **ALL** of the following criteria?
   - The patient has achieved a partial response to treatment
   - The patient has not previously received more than 17 cycles of treatment

   If yes, **approve for 7 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MOSUNETUZUMAB-AXGB (Lunsumio, Lunsumio Velo)** requires the following rule(s) be met for renewal:
   A. You have relapsed or refractory follicular lymphoma (a type of blood cancer that has returned or does not respond to treatment)
   B. You have achieved a partial response to treatment
   C. You have not previously received more than 17 cycles of treatment

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lunsumio and Lunsumio Velo. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Lunsumio [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; December 2025.
Lunsumio Velo [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; December 2025.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed February 2, 2026].

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MOSUNETUZUMAB-AXGB BvD (PART D)

For Part D use only:

MOSUNETUZUMAB-AXGB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	RELAPSED OR REFRACTORY FOLLICULAR LYMPHOMA: INITIAL: 6 MONTHS. RENEWAL: 7 MONTHS.
Other Criteria	RELAPSED OR REFRACTORY FOLLICULAR LYMPHOMA: RENEWAL: 1) HAS ACHIEVED A PARTIAL RESPONSE TO TREATMENT, AND 2) HAS NOT PREVIOUSLY RECEIVED MORE THAN 17 CYCLES OF TREATMENT.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MOXETUMOMAB PASUDOTOX BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MOXETUMOMAB PASUDOTOX-TDFK	LUMOXITI	45363		GPI-10 (2135223650)	

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #5.

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MOXETUMOMAB PASUDOTOX BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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MOXETUMOMAB PASUDOTOX BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory hairy cell leukemia (HCL) (ICD-10 Group C91.4) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received at least two prior systemictherapies, including treatment with a purine nucleoside analog (PNA)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient received 6 cycles of Lumoxiti?

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

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MOXETUMOMAB PASUDOTOX BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **MOXETUMOMAB PASUDOTOX (Lumoxiti)** requires the following rule(s) to be met for approval:

A. You have relapsed (has returned) or refractory (has not responded to treatment) hairy cell leukemia (HCL: a type of blood cancer)
B. You are 18 years of age or older
C. You have received at least two prior systemic therapies (treatment that targets the entire body), including treatment with a purine nucleoside analog (PNA: a type of medication)
D. You have not received 6 cycles of Lumoxiti treatment

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lumoxiti. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Lumoxiti [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; February 2022.

Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed April 4, 2025].

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MOXETUMOMAB PASUDOTOX BvD (PART D)

For Part D use only:

MOXETUMOMAB PASUDOTOX (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 MONTHS
Other Criteria	HAIRY CELL LEUKEMIA (HCL): HAS NOT RECEIVED 6 CYCLES OF LUMOXITI.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MYCOPHENOLATE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MYCOPHENOLATE MOFETIL	MYHIBBIN		55684	GPI-14 (99403030101830)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the request for the prophylaxis of organ rejection and the patient meets **ALL** of the following criteria?
   - The patient is 3 months of age and older
   - The patient has a history of an allogeneic kidney, heart or liver transplant
   - Myhibbin will be used in combination with other immunosuppressants (e.g., cyclosporine)
   - The patient has a contraindication to OR inability to swallow generic mycophenolate mofetil tablets

   If yes, **approve for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MYCOPHENOLATE (Myhibbin)** requires the following rule(s) be met for approval:
   A. You are 3 months of age and older
   B. The request is for the prophylaxis (prevention) of an organ rejection
   C. You have a history of an allogeneic (from a donor) kidney, heart or liver transplant
   D. Myhibbin will be used in combination with other immunosuppressants (such as cyclosporine)
   (Denial text continued on the next page)

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MYCOPHENOLATE (PART D)

GUIDELINES FOR USE (CONTINUED)

E. You have a contraindication to (harmful for you to use) OR are unable to swallow generic mycophenolate mofetil tablets

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Myhibbin.

REFERENCES

Myhibbin [Prescribing Information]. Middlesex, UK: Liqmeds Worldwide Limited; May 2024.

For Part D use only:

MYCOPHENOLATE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	ORGAN TRANSPLANT REJECTION PROPHYLAXIS: CONTRAINDICATION TO OR INABILITY TO SWALLOW GENERIC MYCOPHENOLATE MOFETIL TABLETS.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NAFARELIN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NAFARELIN ACETATE	SYNAREL	21103		GPI-10 (3008005510)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of endometriosis (ICD-10 Group N80) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an obstetrician/gynecologist
   - Synarel will NOT be used concurrently with another GnRH-modulating agent (e.g., Lupron Depot [leuprolide], Zoladex [goserelin])
   - The patient had a trial of or contraindication to a nonsteroidal anti-inflammatory drug (NSAID, e.g., ibuprofen, meloxicam, Naproxen) AND a progestin-containing preparation (e.g., norethindrone, desogestrel, estradiol/norethindrone, desogestrel/ethinyl estradiol)
   - The patient has NOT received a total of 6 months of treatment with Synarel (nafarelin) per lifetime

   If yes, **approve for 6 months per lifetime by HICL or GPI-10.**

   If no, continue to #2.

2. Does the patient have a diagnosis of central precocious puberty (CPP) (ICD-10 E30.1) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with an endocrinologist

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See initial denial text at the end of the guideline.

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NAFARELIN (PART D)

INITIAL CRITERIA (CONTINUED)

3. Is the request for a female patient who meets **ALL** of the following criteria?
   - The patient has elevated levels of luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
   - The patient is younger than 8 years of age at the onset of CPP
   - The patient is at Tanner stage 2 or above for breast development and pubic hair growth

   If yes, **approve for 12 months by HICL or GPI-10.**

   If no, continue to #4.

4. Is the request for a male patient who meets **ALL** of the following criteria?
   - The patient has elevated levels of luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
   - The patient is younger than 9 years of age at the onset of CPP
   - The patient is at Tanner stage 2 or above for genital development and pubic hair growth

   If yes, **approve for 12 months by HICL or GPI-10.**

   If no, do not approve.

   INITIAL DENIAL TEXT:

   Our guideline named **NAFARELIN (Synarel)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Endometriosis (condition affecting the uterus)
      2. Central precocious puberty (CPP: early sexual development in girls and boys)

   (Initial denial text continued on next page)

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NAFARELIN (PART D)

INITIAL CRITERIA (CONTINUED)

B. If you have endometriosis, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with an obstetrician/gynecologist (a type of women's health doctor)
3. You have tried or have a contraindication to (harmful for you to use) a nonsteroidal anti-inflammatory drug (NSAID such as ibuprofen, meloxicam, naproxen) AND a progestin-containing preparation (such as norethindrone, desogestrel, estradiol/norethindrone, desogestrel/ethinyl estradiol)
4. Synarel will NOT be used at the same time with another gonadotropin-releasing hormone (GnRH)-modulating agent (such as Lupron Depot [leuprolide], Zoladex [goserelin])
5. You have NOT received a total of 6 months of treatment with Synarel (nafarelin) per lifetime

C. If you have central precocious puberty, approval also requires:
1. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
2. If you are a female, you meet ALL of the following:
   a. You have high levels of luteinizing hormone (LH: a type of hormone) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
   b. You are/were younger than 8 years of age when your condition started
   c. You are at Tanner stage 2 or above (scale of physical measurements of development based on external sex characteristics) for breast development and pubic hair growth
3. If you are a male, you meet ALL of the following:
   a. You have high levels of luteinizing hormone (LH: a type of hormone) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
   b. You are/were younger than 9 years of age when your condition started
   c. You are at Tanner stage 2 or above (scale of physical measurements of development based on external sex characteristics) for genital development and pubic hair growth

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NAFARELIN (PART D)

RENEWAL CRITERIA

NOTE: For endometriosis, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of central precocious puberty (CPP) (ICD-10 E30.1) and meet **ALL** of the following criteria?
   - The patient's Tanner staging at initial diagnosis has stabilized or regressed
   - The patient has not reached actual age which corresponds to current pubertal age

   If yes, **approve for 12 months by HICL or GPI-10.**

   If no, do not approve.

   RENEWAL DENIAL TEXT:

   Our guideline named **NAFARELIN (Synarel)** requires the following rule(s) be met for renewal:
   A. You have central precocious puberty (CPP: early sexual development in girls and boys)
   B. Your Tanner staging (scale of physical measurements of development based on external sex characteristics) at initial diagnosis has stabilized or regressed (lowered)
   C. You have not reached actual age which corresponds to current pubertal age

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Synarel.

REFERENCES
Synarel [Prescribing Information]. New York, NY: Pfizer Inc.; November 2025.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NAFARELIN (PART D)

For Part D use only:

NAFARELIN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	INITIAL: CENTRAL PRECOCIOUS PUBERTY (CPP): FEMALES: ELEVATED LEVELS OF LUTEINIZING HORMONE (LH) LEVEL GREATER THAN 0.2 TO 0.3 MIU/ML AT DIAGNOSIS. MALES: ELEVATED LEVELS OF LH LEVEL GREATER THAN 0.2 TO 0.3 MIU/ML AT DIAGNOSIS.
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: ENDOMETRIOSIS: PRESCRIBED BY OR IN CONSULTATION WITH AN OBSTETRICIAN/GYNECOLOGIST. CPP: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST.
Coverage Duration	ENDOMETRIOSIS: 6 MONTHS. CPP: INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: ENDOMETRIOSIS: 1) NO CONCURRENT USE WITH ANOTHER GNRH-MODULATING AGENT, 2) TRIAL OF OR CONTRAINDICATION TO NSAID AND PROGESTIN-CONTAINING PREPARATION, AND 3) HAS NOT RECEIVED A TOTAL OF 6 MONTHS OF TREATMENT PER LIFETIME. CPP: FEMALES: 1) YOUNGER THAN 8 YEARS OF AGE AT ONSET OF CPP, AND 2) AT TANNER STAGE 2 OR ABOVE FOR BREAST DEVELOPMENT AND PUBIC HAIR GROWTH. MALES: 1) YOUNGER THAN 9 YEARS OF AGE AT ONSET OF CPP, AND 2) AT TANNER STAGE 2 OR ABOVE FOR GENITAL DEVELOPMENT AND PUBIC HAIR GROWTH. RENEWAL: CPP: 1) TANNER STAGING AT INITIAL DIAGNOSIS HAS STABILIZED OR REGRESSED, AND 2) HAS NOT REACHED ACTUAL AGE WHICH CORRESPONDS TO CURRENT PUBERTAL AGE.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NAPROXEN-ESOMEPRAZOLE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NAPROXEN/ ESOMEPRAZOLE MAG	VIMOVO, NAPROXEN-ESOMEPRAZOLE MAG	36964		GPI-10 (6610990244)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of osteoarthritis (ICD-10 Groups M15, M16, M17, M18, M19, M47), rheumatoid arthritis (ICD-10 M06.9; Groups M05.7, M05.8, M05.9, M06.0, M06.8), or ankylosing spondylitis (ICD-10 Group M45 except Group M45.A), and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The requested medication will be used to decrease the risk of developing gastric ulcers
   - The patient had a trial of ONE of the following generic, prescription-only proton pump inhibitors: omeprazole, lansoprazole, pantoprazole
   - The patient had a trial of generic, prescription-only naproxen

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

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NAPROXEN-ESOMEPRAZOLE (PART D)

GUIDELINES FOR USE (CONTINUED)

2. Does the patient have a diagnosis of juvenile idiopathic arthritis (JIA) (ICD-10 Group M08) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older weighing at least 38 kg (83 lbs)
   - The requested medication will be used to decrease the risk of developing gastric ulcers
   - The patient had a trial of ONE of the following generic, prescription-only proton pump inhibitors: omeprazole, lansoprazole, pantoprazole
   - The patient had a trial of generic, prescription-only naproxen

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NAPROXEN-ESOMEPRAZOLE (Vimovo)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Osteoarthritis (type of joint condition)
      2. Rheumatoid arthritis (type of joint condition)
      3. Ankylosing spondylitis (type of joint condition)
      4. Juvenile idiopathic arthritis (type of joint condition)

   B. If you have osteoarthritis, rheumatoid arthritis, or ankylosing spondylitis, approval also requires:
      1. You are 18 years of age or older
      2. The requested medication will be used to decrease the risk of developing gastric ulcers (type of digestive condition)
      3. You have tried ONE of the following generic, prescription-only proton pump inhibitors: omeprazole, lansoprazole, pantoprazole
      4. You have tried generic, prescription-only naproxen

   (Denial text continued on next page)

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NAPROXEN-ESOMEPRAZOLE (PART D)

GUIDELINES FOR USE (CONTINUED)

C. If you have juvenile idiopathic arthritis, approval also requires:

1. You are 12 years of age or older weighing at least 38 kg (83 pounds)
2. The requested medication will be used to decrease the risk of developing gastric ulcers (type of digestive condition)
3. You have tried ONE of the following generic, prescription-only proton pump inhibitors: omeprazole, lansoprazole, pantoprazole
4. You have tried generic, prescription-only naproxen

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vimovo.

REFERENCES

Vimovo [Prescribing Information]. Lake Forest, IL: Horizon Pharma USA, Inc. July 2023.

For Part D use only:

NAPROXEN- ESOMEPRAZOLE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Medical Required Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	OSTEOARTHRITIS, RHEUMATOID ARTHRITIS, ANKYLOSING SPONDYLITIS, JUVENILE IDIOPATHIC ARTHRITIS: 1) TRIAL OF ONE GENERIC, FEDERAL LEGEND PROTON PUMP INHIBITOR: OMEPRAZOLE, LANSOPRAZOLE, PANTOPRAZOLE, AND 2) TRIAL OF GENERIC, FEDERAL LEGEND NAPROXEN.

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 11/17
Client Approval: 06/24
P&T Approval: 04/17

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NARCOLEPSY AGENTS TIRF (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MODAFINIL	PROVIGIL, MODAFINIL	10865		GPI-10 (6140002400)	
ARMODAFINIL	NUVIGIL, ARMODAFINIL	34868		GPI-10 (6140001000)	

These are TIRF-Like drugs requiring a payment determination for "Part D" or "Non-Part D".

PAYMENT DETERMINATION CRITERIA

1. Does the patient have a diagnosis of excessive sleepiness due to narcolepsy (ICD-10 G47.419), obstructive sleep apnea (OSA) (ICD-10 G47.10, G47.33), or shift work disorder (ICD-10 G47.26) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **set MCARE_DRUG_DETERM_OVR to 'Y' and approve for 12 months by HICL or GPI-10. Document in the PA comments: Part D Determination Override and diagnosis.**

   If no, **do not enter an MCARE override. Then, process as follows:**
   CSR Note:
   - If the caller is a physician, member, and/or AOR, please initiate a verbal PA intake request in MR4.
   - If the caller is a pharmacy, please advise the pharmacy to contact the provider or memberto pursue a payment determination. Document the diagnosis provided in MedAccess.

   Please follow the clinical authorization process within the HQ notes.

   RPH Note:
   - Review for both FDA and Part D compendial supported off-label indications.
   - If the provided diagnosis is not FDA approved or compendial supported off-label use, **set MCARE_DRUG_DETERM_OVR to 'N' and enter override within the denied PA for 12 months by HICL or GPI-10.**
   - If the diagnosis is UNKNOWN do not enter an MCARE override; follow the criteria for any additional UM and decision the case accordingly. Provide the following PAC instruction: '**PAC: do not enter an MCARE override**.'

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NARCOLEPSY AGENTS TIRF (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **NARCOLEPSY AGENTS (Provigil, Nuvigil)** requires the following rule(s) be met for approval:

A. You have excessive sleepiness due to ONE of the following:
   1. Narcolepsy (a type of sleep condition with overwhelming daytime drowsiness)
   2. Obstructive sleep apnea (OSA: a disorder where airflow is blocked during sleep)
   3. Shift work disorder (a type of sleep condition)

B. You are 18 years of age or older

RATIONALE

Prior authorization on these drugs is required due to a high potential for non-Part D use. These drugs should NOT be used for non-medically accepted indications as defined in section 1860D-2(e)(4) of the Act. For further information, please refer to the prescribing information and/or drug monograph for Provigil and Nuvigil.

REFERENCES

Provigil [Prescribing Information]. Parsippany, NJ: Teva Pharmaceuticals; December 2022.
Nuvigil [Prescribing Information]. Parsippany, NJ: Teva Pharmaceuticals; December 2022.
Announcement of Calendar Year (CY) 2015 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. April 7, 2014. Section III – Part D: Appropriate Utilization of Prior Authorization Requirements to Determine Part D Drug Status. Page 112 – 114

For Part D use only:

NARCOLEPSY AGENTS (PART D)	
Covered Uses	ALL MEDICALLY-ACCEPTED INDICATIONS.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 12/18
Effective: 03/09/26 Client Approval: 03/26 P&T Approval: 10/18

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NATALIZUMAB BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NATALIZUMAB	TYSABRI	26750		GPI-10 (6240505000)	

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, continue to #6.
   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, continue to #6.
   If no, continue to #5.

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

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NATALIZUMAB BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

6. Is the drug administered via an implantable pump?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, continue to #7.

7. Is the drug administered using an external pump?

   If yes, continue to #8.
   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

8. Is the drug specifically infused through an external infusion pump covered by Medicare?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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NATALIZUMAB BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Tysabri will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Selarsdi /Yesintek /ustekinumab-aauz, Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima, Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Tremfya (guselkumab)

     If yes, **approve for 6 months by HICL or GPI-10.**
     APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

     If no, continue to #2.

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NATALIZUMAB BvD (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), including clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease, and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Tysabri is being used as monotherapy
   - The patient had a trial of TWO agents indicated for the treatment of MS (e.g., Tecfidera [dimethyl fumarate], Vumerity [diroximel fumarate])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NATALIZUMAB (Tysabri)** requires the following rules be met for approval:
   A. You have ONE of the following:
      1. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
      2. A relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease returns and goes away), or active secondary progressive disease (advanced disease)

   B. If you have moderate to severe Crohn's disease, approval also requires:
      1. You are 18 years of age or older
      2. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
      3. You will NOT use Tysabri concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease
      4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Selarsdi /Yesintek /ustekinumab-aauz, Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima, Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Tremfya (guselkumab)

   (Initial denial text continued on next page)

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NATALIZUMAB BvD (PART D)

INITIAL CRITERIA (CONTINUED)

C. If you have a relapsing form of multiple sclerosis, approval also requires:
1. You are 18 years of age or older
2. Tysabri is being used as monotherapy (one drug treatment)
3. You have tried TWO medications indicated for the treatment of multiple sclerosis (such as Tecfidera [dimethyl fumarate], Vumerity [diroximel fumarate])

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NATALIZUMAB BvD (PART D)

RENEWAL CRITERIA

NOTE: For the diagnosis of a relapsing form of multiple sclerosis (MS), please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) **AND** meet the following criterion?
   - Tysabri will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Has the patient received at least 12 months of therapy with Tysabri **AND** meets the following criterion?
   - The patient has NOT required more than 3 months of corticosteroids use within the past 12 months to control their Crohn's disease while on Tysabri

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Has the patient only received 6 months of therapy with Tysabri **AND** meet the following criterion?
   - The patient has tapered off corticosteroids during the first 24 weeks of Tysabri therapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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NATALIZUMAB BvD (PART D)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **NATALIZUMAB (Tysabri)** requires the following rules be met for renewal:

A. You have moderate to severe Crohn's disease (CD: a type of bowel disorder)
B. You will NOT use Tysabri concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease
C. If you have received at least 12 months of Tysabri therapy, renewal also requires:
   1. You have NOT received more than 3 months of corticosteroid within the past 12 months to control your Crohn's disease while on Tysabri
D. If you have only received 6 months of Tysabri therapy, renewal also requires:
   1. You have tapered off (slowly lowering the dose and stopping) corticosteroids during the first 24 weeks of Tysabri therapy

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tysabri. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B. Drugs administered by an implantable pump are covered under Part B. Drugs administered via an external pump are covered under Part B if they are included under the local coverage policy of the applicable Medicare coverage policies (National and/or Local Coverage Policies). Drugs administered via an external pump that are not included under the applicable Medicare coverage policies are covered under Part D. A CMS website to assist with National and Local Coverage Determination for B versus D review is http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx.

REFERENCES

Tysabri [Prescribing Information]. Cambridge, MA: Biogen Inc.; March 2025.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed March 18, 2026].

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NATALIZUMAB BvD (PART D)

For Part D use only:

NATALIZUMAB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: CROHNS DISEASE (CD): PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST.
Coverage Duration	MULTIPLE SCLEROSIS (MS): 12 MOS. CD: INITIAL: 6 MOS, RENEWAL: 12 MOS.
Other Criteria	INITIAL: MS: TRIAL OF TWO AGENTS INDICATED FOR THE TREATMENT OF MS. CD: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: SELARSDI/YESINTEK/USTEKINUMAB-AAUZ, HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, RINVOQ, SKYRIZI, TREMFYA, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR CD. RENEWAL: CD: 1) ONE OF THE FOLLOWING: (A) RECEIVED AT LEAST 12 MONTHS OF THERAPY WITH TYSABRI AND HAS NOT REQUIRED MORE THAN 3 MONTHS OF CORTICOSTEROID USE WITHIN THE PAST 12 MONTHS TO CONTROL CROHNS DISEASE WHILE ON TYSABRI, OR (B) HAS ONLY RECEIVED 6 MONTHS OF THERAPY WITH TYSABRI AND HAS TAPERED OFF CORTICOSTEROIDS DURING THE FIRST 24 WEEKS OF TYSABRI THERAPY, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR CD.

Created: 08/06
Effective: 05/01/26 Client Approval: 04/26 P&T Approval: 04/25

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NATALIZUMAB-SZTN BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NATALIZUMAB-SZTN	TYRUKO	49170		GPI-10 (6240505070)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	Yes	No	No	Yes	No	No	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, continue to #6.
   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, continue to #6.
   If no, continue to #5.

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NATALIZUMAB-SZTN BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

6. Is the drug administered via an implantable pump?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, continue to #7.

7. Is the drug administered using an external pump?

   If yes, continue to #8.
   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

8. Is the drug specifically infused through an external infusion pump covered by Medicare?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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NATALIZUMAB-SZTN BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Tyruko will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Selarsdi /Yesintek /ustekinumab-aauz, Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima, Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Tremfya (guselkumab)

     If yes, **approve for 6 months by HICL or GPI-10.**
     APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

     If no, continue to #2.

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NATALIZUMAB-SZTN BvD (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), including clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease, and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Tyruko is being used as monotherapy
   - Tyruko will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of a relapsing form of MS
   - The patient had a trial of TWO agents indicated for the treatment of MS (e.g., Tecfidera [dimethyl fumarate], Vumerity [diroximel fumarate])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NATALIZUMAB-SZTN (Tyruko)** requires the following rules be met for approval:
   A. You have ONE of the following:
      1. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
      2. A relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease returns and goes away), or active secondary progressive disease (advanced disease)

   B. If you have moderate to severe Crohn's disease, approval also requires:
      1. You are 18 years of age or older
      2. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
      3. You will NOT use Tyruko concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease
      4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Selarsdi /Yesintek /ustekinumab-aauz, Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima, Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Tremfya (guselkumab)

   (Initial denial text continued on next page)

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NATALIZUMAB-SZTN BvD (PART D)

INITIAL CRITERIA (CONTINUED)

C. If you have a relapsing form of multiple sclerosis, approval also requires:

1. You are 18 years of age or older
2. Tyruko is being used as a monotherapy (one drug treatment)
3. You will NOT use Tyruko concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of a relapsing form of multiple sclerosis
4. You have tried TWO medications indicated for the treatment of multiple sclerosis (such as Tecfidera [dimethyl fumarate], Vumerity [diroximel fumarate])

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NATALIZUMAB-SZTN BvD (PART D)

RENEWAL CRITERIA

NOTE: For the diagnosis of a relapsing form of multiple sclerosis (MS), please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) **AND** meet the following criterion?
   - Tyruko will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Has the patient received at least 12 months of therapy with Tyruko **AND** meets the following criterion?
   - The patient has NOT required more than 3 months of corticosteroids use within the past 12 months to control their Crohn's disease while on Tyruko

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Has the patient only received 6 months of therapy with Tyruko **AND** meet the following criterion?
   - The patient has tapered off corticosteroids during the first 24 weeks of Tyruko therapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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NATALIZUMAB-SZTN BvD (PART D)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **NATALIZUMAB-SZTN (Tyruko)** requires the following rules be met for renewal:

A. You have moderate to severe Crohn's disease (CD: a type of bowel disorder)
B. You will NOT use Tyruko concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease
C. If you have received at least 12 months of Tyruko therapy, renewal also requires:
   1. You have NOT received more than 3 months of corticosteroid within the past 12 months to control your Crohn's disease while on Tyruko
D. If you have only received 6 months of Tyruko therapy, renewal also requires:
   1. You have tapered off (slowly lowering the dose and stopping) corticosteroids during the first 24 weeks of Tyruko therapy

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tyruko. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B. Drugs administered by an implantable pump are covered under Part B. Drugs administered via an external pump are covered under Part B if they are included under the local coverage policy of the applicable Medicare coverage policies (National and/or Local Coverage Policies). Drugs administered via an external pump that are not included under the applicable Medicare coverage policies are covered under Part D. A CMS website to assist with National and Local Coverage Determination for B versus D review is http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx.

REFERENCES

Tyruko [Prescribing Information]. Princeton, NJ: Sandoz Inc.; October 2025.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed March 18, 2026].

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NATALIZUMAB-SZTN BvD (PART D)

For Part D use only:

NATALIZUMAB-SZTN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: CROHNS DISEASE (CD): PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST.
Coverage Duration	MULTIPLE SCLEROSIS (MS): 12 MOS. CD: INITIAL: 6 MOS, RENEWAL: 12 MOS.
Other Criteria	INITIAL: ALL INDICATIONS: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION. MS: TRIAL OF TWO AGENTS INDICATED FOR THE TREATMENT OF MS. CD: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: SELARSDI/YESINTEK/USTEKINUMAB-AAUZ, HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, RINVOQ, SKYRIZI, TREMFYA. RENEWAL: CD: 1) ONE OF THE FOLLOWING: (A) RECEIVED AT LEAST 12 MONTHS OF THERAPY WITH TYRUKO AND HAS NOT REQUIRED MORE THAN 3 MONTHS OF CORTICOSTEROID USE WITHIN THE PAST 12 MONTHS TO CONTROL CROHNS DISEASE WHILE ON TYRUKO, OR (B) HAS ONLY RECEIVED 6 MONTHS OF THERAPY WITH TYRUKO AND HAS TAPERED OFF CORTICOSTEROIDS DURING THE FIRST 24 WEEKS OF TYRUKO THERAPY, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR CD.

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Effective: 05/01/26 Client Approval: 04/26 P&T Approval: 07/24

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NAVEPEGRITIDE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NAVEPEGRITIDE	YUVIWEL	51182		GPI-10 (3095005500)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of achondroplasia (ICD-10 Q77.4) and meet **ALL** of the following criteria?
   - The patient is 2 to 17 years of age
   - The patient has open epiphyses
   - Therapy is prescribed by or in consultation with an endocrinologist, orthopedist, ormedical geneticist
   - Yuviwel will NOT be used concurrently with another C-type natriuretic peptide (CNP)(e.g., Voxzogo [vosoritide]) for the treatment of achondroplasia

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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NAVEPEGRITIDE (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **NAVEPEGRITIDE (Yuviwel)** requires the following rule(s) be met for approval:

A. You have achondroplasia (a type of bone condition)
B. You are 2 to 17 years of age
C. You have open epiphyses (the end part of a long bone)
D. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor), orthopedist (a type of doctor who specializes in bones, joints, muscles, ligaments, tendons and nerves), or medical geneticist (doctor who treats gene disorders)
E. You will NOT use Yuviwel concurrently (at the same time) with another C-type natriuretic peptide (CNP) (such as Voxzogo [vosoritide]) for the treatment of achondroplasia (a type of bone condition)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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NAVEPEGRITIDE (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of achondroplasia (ICD-10 Q77.4) and meet **ALL** of the following criteria?
   - The patient has experienced an improvement in annual growth velocity since baseline
   - The patient's epiphyses remain open
   - Yuviwel will NOT be used concurrently with another C-type natriuretic peptide (CNP) (e.g., Voxzogo [vosoritide]) for the treatment of achondroplasia

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NAVEPEGRITIDE (Yuviwel)** requires the following rule(s) be met for renewal:
   A. You have achondroplasia (a type of bone condition)
   B. You have experienced an improvement in annual growth velocity (rate of growth) since baseline (before treatment with Yuviwel)
   C. Your epiphyses (the end part of a long bone) remain open
   D. You will NOT use Yuviwel concurrently (at the same time) with another C-type natriuretic peptide (CNP) (such as Voxzogo [vosoritide]) for the treatment of achondroplasia (a type of bone condition)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Yuviwel.

REFERENCES

Yuviwel [Prescribing Information]. Princeton, NJ: Ascendis Pharma Endocrinology, Inc.; February 2026.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NAVEPEGRITIDE (PART D)

For Part D use only:

NAVEPEGRITIDE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	ACHONDROPLASIA: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST, ORTHOPEDIST, OR MEDICAL GENETICIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	ACHONDROPLASIA: INITIAL/RENEWAL: NO CONCURRENT USE WITH ANOTHER C-TYPE NATRIURETIC PEPTIDE (CNP) FOR ACHONDROPLASIA. RENEWAL: 1) IMPROVEMENT IN ANNUAL GROWTH VELOCITY SINCE BASELINE, AND 2) EPIPHYSES REMAIN OPEN.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NAXITAMAB-GQGK (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NAXITAMAB-GQGK	DANYELZA	47001		GPI-10 (2135605030)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory high-risk neuroblastoma in the bone or bone marrow and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - Danyelza will be used in combination with a granulocyte-macrophage colony-stimulating factor (GM-CSF) (e.g., Leukine [sargramostim])
   - The patient has demonstrated a partial response, minor response, or stable disease to prior therapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NAXITAMAB-GQGK (Danyelza)** requires the following rule(s) be met for approval:
   A. You have relapsed or refractory high-risk neuroblastoma (a type of rare cancer that has returned or no longer responds to treatment) in the bone or bone marrow
   B. You are 1 year of age or older
   C. Danyelza will be used in combination with a granulocyte-macrophage colony-stimulating factor (GM-CSF: a type of drug used to make more white blood cells, such as Leukine [sargramostim])
   D. You have demonstrated a partial response, minor response, or stable disease to prior therapy
   (Denial text continued on next page)

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NAXITAMAB-GQGK (PART D)

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Danyelza.

REFERENCES

Danyelza [Prescribing Information]. New York, NY: Y-mAbs Therapeutics, Inc.; March 2024.

For Part D use only:

NAXITAMAB-GQGK (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 12/20
Client Approval: 06/24
P&T Approval: 01/21

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NEBULIZER BVD DETERMINATION (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ACETYLCYSTEINE	ACETYLCYSTEINE	00189		GPI-10 (4330001000)	
ALBUTEROL SULFATE	ALBUTEROL SULFATE		41680 14634 14633 41681	GPI-14 (44201010102515, 44201010102555, 44201010102560, 44201010102520)	
ARFORMOTEROL TARTRATE	AFORMOTEROL TARTRATE, BROVANA	34087		GPI-10 (4420101210)	
BUDESONIDE	BUDESONIDE, PULMICORT		17957 17958 62980	GPI-14 (44400015001830, 44400015001840, 44400015001850)	
CROMOLYN SODIUM	CROMOLYN SODIUM		46780	GPI-10 (4415001010)	
DORNASE ALFA	PULMOZYME	08832		GPI-10 (4530402000)	
FORMOTEROL FUMARATE	FORMOTEROL FUMARATE, PERFOROMIST	10747		GPI-10 (4420102710)	
FORMOTEROL FUMARATE/ NEBULIZER	FORMOTEROL FUMARATE-NEBULIZER	49853			
IPRATROPIUM BROMIDE	IPRATROPIUM BROMIDE		42235	GPI-10 (4410003010)	
IPRATROPIUM/ ALBUTEROL SULFATE	IPRATROPIUM-ALBUTEROL SULFATE		13456	GPI-14 (44209902012015)	
LEVALBUTEROL HCL	XOPENEX, XOPENEX CONCENTRATE, LEVALBUTEROL HCL, LEVALBUTEROL CONCENTRATE	19858		GPI-10 (4420104510)	
PENTAMIDINE ISETHIONATE	NEBUPENT,	04162		GPI-10 (1600004500)	

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	PENTAMIDINE ISETHIONATE				
RIBAVIRIN	VIRAZOLE, RIBAVIRIN	04184		GPI-10 (1260407500)	
TOBRAMYCIN	BETHKIS, TOBRAMYCIN	17765		GPI-10 (0700007000)	DOSAGE FORM = NEBU
TOBRAMYCIN IN 0.225% NACL	TOBI, TOBRAMYCIN	16926			
TOBRAMYCIN/ NEBULIZER	TOBRAMYCIN	41620		GPI-10 (0700007000)	BRAND ≠ KITABIS PAK
REVEFENACIN	YUPELRI	45477		GPI-10 (4410007500)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request then a verbal MRF must be completed. Please check the applicable CS note for processing.

NOTE: This PA is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

GUIDELINES FOR USE

1. Is the patient using this medication via a nebulizer?

   If yes, do not approve.
   MEMBER NOTIFICATION LANGUAGE/DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #2.

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NEBULIZER BVD DETERMINATION (PART D)

GUIDELINES FOR USE (CONTINUED)

2. Is the medication being used for a Part D covered indication?

   If yes, **approve for 12 months under Part D as follows (Please enter an override for the 'Nebulizer location override' field):**
   - **Budesonide: Approve all of the following strengths by GPID or GPI-14:**
     - **0.25mg/2mL**
     - **0.5mg/2mL**
     - **1mg/2mL**
   - **All others: Approve by HICL or GPI-10.**

   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   MEMBER NOTIFICATION LANGUAGE/DENIAL TEXT: The guideline named **NEBULIZER BVD DETERMINATION** applies to inhalation drugs that normally require a nebulizer. Medicare Part B (Medical Insurance) covers some medicines used in nebulizers if considered reasonable and necessary. These are covered as Durable Medical Equipment (DME) that your doctor prescribes for use in your home. Approval under Medicare Part D requires that you reside in a nursing or intermediate care facility. If you do not live in such residences, approval under Part D requires the drug be used for a Part D covered indication AND is not used via a nebulizer. Centers for Medicare and Medicaid Services (CMS) has clarified that the Medicare Part B or D coverage for these medicines should be determined by the data submitted by your pharmacy describing the place of residence (home or long term care/nursing home). Future claims for this drug will rely upon the data your pharmacy submits as mentioned above.

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NEBULIZER BVD DETERMINATION (PART D)

RATIONALE

Nebulizer therapy is covered under Part B for patients who are using the medication via a nebulizer in their own home; those who are not using it in their home will be covered under Part D.
50.16.2 – Inhalation Durable Medical Equipment (DME) Supply Drugs (Rev. 18, 09-17-18):
Medicare Part B covers certain inhalation drugs, such as Albuterol and Levalbuterol nebulizer solutions, as supplies under the DME benefit. The DME benefit, however, is not available to beneficiaries residing in long-term care facilities (i.e. Nursing Facilities and Intermediate Care Facilities for Individuals with Intellectual Disabilities). Consequently, if the beneficiary is not on a Part A stay in one of these facilities, these inhalation drugs can be covered under Medicare Part D. CMS permits Part D sponsors to rely on a patient residence code of "3" or "9" on a pharmacy claim for determining when such inhalation drugs may be covered under Part D. Moreover, we expect that sponsors will only pay claims for these products when the pharmacy claim includes these specified patient residence codes regardless of any prior coverage determination based upon a prescriber statement indicating that the beneficiary resides in a long-term care facility (i.e. the prescriber statement and patient residence code must be aligned).

REFERENCES

Medicare Prescription Drug Benefit Manual Chapter 6 – Part D Drugs and Formulary Requirements, Appendix C- Summary of Coverage Policy Medicare Part B Versus Part D Coverage Issues. Rev 18, 01-15-16. Available at: http://www.cms.gov/PrescriptionDrugCovContra/12_PartDManuals.asp. [Accessed September 13, 2024].
Medicare Prescription Drug Benefit Manual Chapter 14 – Coordination of Benefits. 50.16.2 – Inhalation Durable Medical Equipment (DME) Supply Drugs (Rev. 18, 09-17-18). Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter-14-Coordination-of-Benefits-v09-17-2018.pdf [Accessed September 13, 2024].

For Part D use only:

NEBULIZER BVD DETERMINATION (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	PART D DOES NOT COVER THIS DRUG WHEN USED VIA A NEBULIZER AT HOME
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25 Created: 03/11
Commercial Effective: N/A Client Approval: 11/24 P&T Approval: 11/16

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NECITUMUMAB BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NECITUMUMAB	PORTRAZZA	42835		GPI-10 (2136005400)	

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is the drug administered via an implantable pump?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B. (Populate the B vs. D field with 'B' in the PA override field. If MI does not process Part B for the client, refer the caller/request back to the Health plan)**

   If no, continue to #2.

2. Is the drug administered via an external pump?

   If yes, continue to #3.

   If no, **approve for 12 months by HICL or GPI-10 under Part D. (Populate the B vs. D field with 'D' in the PA override field)**

3. Is the drug specifically infused through an external infusion pump covered by Medicare?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B. (Populate the B vs. D field with 'B' in the PA override field. If MI does not process Part B for the client, refer the caller/request back to the Health plan)**

   If no, **approve for 12 months by HICL or GPI-10 under Part D. (Populate the B vs. D field with 'D' in the PA override field)**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NECITUMUMAB BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic squamous non-small cell lung cancer (NSCLC) (ICD-10 Group C34) **AND** meet the following criterion?
   - Portrazza will be used in combination with gemcitabine and cisplatin

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NECITUMUMAB (Portrazza)** requires the following rule(s) be met for approval:
   A. You have metastatic squamous non-small cell lung cancer (a type of lung cancer that has spread to other parts of the body)
   B. Portrazza will be used in combination with gemcitabine and cisplatin

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NECITUMUMAB BvD (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Portrazza. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs administered by an implantable pump are covered under Part B. Drugs administered via an external pump are covered under Part B if they are included under the local coverage policy of the applicable Medicare coverage policies (National and/or Local Coverage Policies). Drugs administered via an external pump that are not included under the applicable Medicare coverage policies are covered under Part D. A CMS website to assist with National and Local Coverage Determination for B versus D review is http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx

REFERENCES

Portrazza [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; November 2015.

Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Appendix C- Summary of Coverage Policy Medicare Part B Versus Part D Coverage Issues. Rev 10, 02-19-10. Available at: http://www.cms.gov/PrescriptionDrugCovContra/12_PartDManuals.asp. [Accessed April 1, 2024].

For Part D use only:

NECITUMUMAB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 12/15
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 02/16

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NEDOSIRAN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NEDOSIRAN SODIUM	RIVFLOZA	49234		GPI-10 (5662605060)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of primary hyperoxaluria type 1 (PH1) (ICD-10 E72.53) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - The patient has relatively preserved kidney function (e.g., eGFR is at least 30mL/min/1.73m[2])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NEDOSIRAN (Rivfloza)** requires the following rule(s) be met for approval:
   A. You have primary hyperoxaluria type 1 (PH1: a type of rare genetic disorder)
   B. You are 2 years of age or older
   C. You have relatively preserved kidney function (such as an estimated glomerular filtration rate [eGFR: a tool for evaluating kidney function] is at least 30mL/min/1.73m[2])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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NEDOSIRAN (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rivfloza.

REFERENCES

Rivfloza [Prescribing Information]. Plainsboro, NJ: Novo Nordisk Inc.; March 2025.

For Part D use only:

NEDOSIRAN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 01/24
Effective: 05/17/25 Client Approval: 05/25 P&T Approval: 07/25

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NEMOLIZUMAB-ILTO (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NEMOLIZUMAB-ILTO	NEMLUVIO	49814		GPI-10 (9079355510)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of prurigo nodularis (PN) (ICD-10 L28.1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist, immunologist, or allergist
   - The patient has a presence of chronic pruritus (i.e., itch lasting longer than 6 weeks), multiple pruriginous lesions (localized or general), and history or sign of a prolonged scratching behavior
   - The patient had a trial of or contraindication to the preferred agent: Dupixent (dupilumab)
   - Nemluvio will NOT be used concurrently with other systemic biologics (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of prurigo nodularis

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, continue to #2.

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NEMOLIZUMAB-ILTO (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of moderate to severe atopic dermatitis (AD) (ICD-10 Group L20) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Nemluvio will be used in combination with a topical corticosteroid (e.g., triamcinolone, clobetasol) and/or calcineurin inhibitor (e.g., tacrolimus, pimecrolimus)
   - Therapy is prescribed by or in consultation with a dermatologist, allergist, or immunologist
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Dupixent (dupilumab), Rinvoq (upadacitinib)
   - Nemluvio will NOT be used concurrently with other systemic biologics (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Eucrisa (crisaborole)]) for the treatment of atopic dermatitis

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Has the patient had a trial of or contraindication to **ONE** of the following?
   - High or super-high potency topical corticosteroid (e.g., clobetasol propionate 0.05% cream or ointment, fluocinonide 0.1% cream, halobetasol propionate 0.01% lotion)
   - Topical calcineurin inhibitor (e.g., tacrolimus, pimecrolimus)
   - Topical PDE-4 inhibitor (e.g., crisaborole [Eucrisa], Adquey [difamilast], Zoryve [roflumilast])
   - Topical AhR agonist (e.g., Vtama [tapinarof])
   - Topical JAK inhibitor (e.g., ruxolitinib [Opzelura])

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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NEMOLIZUMAB-ILTO (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: Our guideline named **NEMOLIZUMAB-ILTO (Nemluvio)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Prurigo nodularis (PN: a type of skin condition)
   2. Moderate to severe atopic dermatitis (AD: a type of skin condition)

B. If you have prurigo nodularis, approval also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor), immunologist (a type of immune system doctor), or allergist (a type of allergy doctor)
   3. You have chronic pruritus (itch lasting longer than 6 weeks), multiple pruriginous lesions (wounds), and a history or sign of a prolonged scratching behavior
   4. You have tried or have a contraindication to the preferred medication: Dupixent (dupilumab)
   5. You will NOT use Nemluvio concurrently (at the same time) with other systemic biologics (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of prurigo nodularis

C. If you have moderate to severe atopic dermatitis, approval also requires:
   1. You are 12 years of age or older
   2. You will use Nemluvio in combination with a topical corticosteroid (such as triamcinolone, clobetasol) and/or calcineurin inhibitor (such as tacrolimus, pimecrolimus)
   3. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
   4. You will NOT use Nemluvio with other systemic biologics (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitors [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Eucrisa (crisaborole)]) for the treatment of atopic dermatitis
   5. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Dupixent (dupilumab), Rinvoq (upadacitinib)
   6. You have tried or have a contraindication to (harmful for you to use) ONE of the following:
      a. High potency topical corticosteroid (such as halobetasol propionate 0.01% lotion, triamcinolone acetonide 0.5% cream or ointment) or a super-high potency topical corticosteroid (such as fluocinonide 0.1% cream, clobetasol propionate 0.05% cream or ointment)
      b. Topical calcineurin inhibitor (such as tacrolimus, pimecrolimus)
      c. Topical PDE-4 inhibitor (such as crisaborole [Eucrisa], Adquey [difamilast], Zoryve [roflumilast])
      d. Topical aryl hydrocarbon receptor (AhR) agonist (such as Vtama [tapinarof])
      e. Topical JAK inhibitor (such as ruxolitinib [Opzelura])

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NEMOLIZUMAB-ILTO (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of prurigo nodularis (PN) (ICD-10 L28.1) and meet **ALL** of the following criteria?
   - The patient has had prurigo nodularis improvement (reduction) of pruritus or pruriginous lesions
   - Nemluvio will NOT be used concurrently with other systemic biologics (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of prurigo nodularis

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe atopic dermatitis (ICD-10 Group L20) and meet **ALL** of the following criteria?
   - The patient has shown improvement while on Nemluvio
   - Nemluvio will NOT be used concurrently with other systemic biologics (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Eucrisa (crisaborole)] for the treatment of atopic dermatitis

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: Our guideline named **NEMOLIZUMAB-ILTO (Nemluvio)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Prurigo nodularis (PN: a type of skin condition)
      2. Moderate to severe atopic dermatitis (AD: a type of skin condition)
   B. If you have prurigo nodularis, renewal also requires:
      1. You have had prurigo nodularis improvement or reduction of pruritus (itching) or pruriginous lesions (wounds)
      2. You will NOT use Nemluvio concurrently (at the same time) with other systemic biologics (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of prurigo nodularis
   C. If you have moderate to severe atopic dermatitis, renewal also requires:
      1. You have shown improvement while on Nemluvio
      2. You will NOT use Nemluvio with other systemic biologics (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitors [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Eucrisa (crisaborole)]) for the treatment of atopic dermatitis

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NEMOLIZUMAB-ILTO (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nemluvio.

REFERENCES

Nemluvio [Prescribing Information]. Dallas, TX: Galderma Laboratories, L.P.; June 2025.

For Part D use only:

NEMOLIZUMAB-ILTO (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	PRURIGO NODULARIS (PN), AD: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST, ALLERGIST OR IMMUNOLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: PN: 1) CHRONIC PRURITUS (ITCH MORE THAN 6 WEEKS), MULTIPLE PRURIGINOUS LESIONS, AND HISTORY OR SIGN OF A PROLONGED SCRATCHING BEHAVIOR, 2) TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT: DUPIXENT, AND 3) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR PN. AD: 1) TRIAL OF OR CONTRAINDICATION TO ONE OF THE FOLLOWING: (A) HIGH OR SUPER-HIGH POTENCY TOPICAL CORTICOSTEROID, (B) TOPICAL CALCINEURIN INHIBITOR, (C) TOPICAL PDE4 INHIBITOR, (D) TOPICAL AHR AGONIST OR (E) TOPICAL JAK INHIBITOR, 2) TRIAL OF OR CONTRAINDICATION TO ONE OF THE FOLLOWING PREFERRED AGENTS: DUPIXENT, RINVOQ, AND 3) NO CONCURRENT USE WITH OTHER SYSTEMIC BIOLOGICS OR TARGETED SMALL MOLECULES FOR AD. RENEWAL: PN: 1) IMPROVEMENT OR REDUCTION OF PRURITUS OR PRURIGINOUS LESIONS, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PN. AD: 1) IMPROVEMENT WHILE ON THERAPY, AND 2) NO CONCURRENT USE WITH OTHER SYSTEMIC BIOLOGICS OR TARGETED SMALL MOLECULES FOR AD.

Created: 08/24
Effective: 08/01/26 Client Approval: 07/26 DMC Approval: 06/30/26

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CORE, ADVANTAGE, PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NERANDOMILAST (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NERANDOMILAST	JASCAYD	50937		GPI-10 (4555505000)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of idiopathic pulmonary fibrosis (IPF) (ICD-10 J84.112) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a pulmonologist
   - The patient has a usual interstitial pneumonia (UIP) pattern as evidenced by high-resolution computed tomography (HRCT) alone or via a combination of surgical lung biopsy and HRCT
   - The patient does NOT have other known causes of interstitial lung disease (ILD) (e.g., connective tissue disease, drug toxicity, asbestos or beryllium exposure, hypersensitivity pneumonitis, systemic sclerosis, rheumatoid arthritis, radiation, sarcoidosis, bronchiolitis obliterans organizing pneumonia, human immunodeficiency virus [HIV] infection, viral hepatitis, cancer)
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Ofev (nintedanib), pirfenidone (Esbriet)

     If yes, **approve for 12 months by HICL or GPI-10.**
     APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

     If no, continue to #2.

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NERANDOMILAST (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of progressive pulmonary fibrosis (PPF) (ICD-10 J84.170) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a pulmonologist or rheumatologist
   - The patient has interstitial lung disease with a progressive phenotype (trait) (PF-ILD)
   - The patient's lung function and respiratory symptoms OR chest imaging has worsened/progressed despite treatment with medications used in clinical practice for ILD (not attributable to comorbidities [e.g., infection, heart failure])
   - The patient has at least 10% fibrosis on a chest high resolution computed tomography (HRCT) (e.g., defined as reticular abnormality with traction bronchiectasis with or without honeycombing)
   - The patient had a trial of or contraindication to the preferred agent: Ofev (nintedanib)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NERANDOMILAST (Jascayd)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Idiopathic pulmonary fibrosis (IPF: a type of lung condition)
      2. Progressive pulmonary fibrosis (PPF: a type of lung condition with gradual scarring of the lungs)

   B. If you have idiopathic pulmonary fibrosis, approval also requires:
      1. You are 18 years of age or older
      2. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor)
      3. You have a usual interstitial pneumonia (UIP) pattern (a specific type of lung scarring) as shown by high-resolution computed tomography (HRCT: type of imaging test) alone or by a combination of surgical lung biopsy (removal of cells or tissue from the lung for examination) and HRCT

   (Initial denial text continued on next page)

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NERANDOMILAST (PART D)

INITIAL CRITERIA (CONTINUED)

4. You do NOT have other known causes of interstitial lung disease (ILD: a type of lung condition) (such as connective tissue disease [a type of autoimmune disorder], drug toxicity, asbestos [a type of mineral that can be toxic] or beryllium [a type of metal that can be toxic] exposure, hypersensitivity pneumonitis [a type of lung condition], systemic sclerosis [a type of autoimmune disorder], rheumatoid arthritis [a type of joint condition], radiation, sarcoidosis [a type of inflammatory disorder], bronchiolitis obliterans organizing pneumonia [a type of lung condition], human immunodeficiency virus infection [HIV: an immune system disease caused by a virus], viral hepatitis [a type of liver inflammation], cancer)
5. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Ofev (nintedanib), pirfenidone (Esbriet)

C. If you have progressive pulmonary fibrosis, approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or rheumatologist (a type of immune system doctor)
3. You have interstitial lung disease with a progressive phenotype (trait) (PF-ILD)
4. Your lung function and respiratory (breathing) symptoms OR chest imaging have worsened/progressed despite treatment with medications used in clinical practice for interstitial lung disease (not caused by comorbidities [additional health conditions] such as infection, heart failure)
5. You have at least 10% fibrosis (tissue scarring) on a chest high resolution computed tomography (HRCT: type of imaging testing) (such as reticular abnormality [a specific pattern on imaging studies] with traction bronchiectasis [a condition where the lungs' airway becomes damaged, widened, and thickened] with or without honeycombing)
6. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Ofev (nintedanib)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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NERANDOMILAST (PART D)

RENEWAL CRITERIA

1. Does the patient have ONE of the following diagnoses?
   - Idiopathic pulmonary fibrosis (IPF) (ICD-10 J84.112)
   - Progressive pulmonary fibrosis (PPF) (ICD-10 J84.170)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Has the patient experienced a clinically meaningful improvement or maintenance in annual rate of decline?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NERANDOMILAST (Jascayd)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Idiopathic pulmonary fibrosis (IPF: a type of lung condition)
      2. Progressive pulmonary fibrosis (PPF: a type of lung condition with gradual scarring of the lungs)
   B. You have experienced a clinically meaningful improvement or maintenance in annual rate of decline

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Jascayd.

REFERENCES
Jascayd [Prescribing Information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; December 2025.

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NERANDOMILAST (PART D)

For Part D use only:

NERANDOMILAST (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	INITIAL: IDIOPATHIC PULMONARY FIBROSIS (IPF): A USUAL INTERSTITIAL PNEUMONIA (UIP) PATTERN AS EVIDENCED BY HIGH-RESOLUTION COMPUTED TOMOGRAPHY (HRCT) ALONE OR VIA A COMBINATION OF SURGICAL LUNG BIOPSY AND HRCT. PROGRESSIVE PULMONARY FIBROSIS (PPF): 1) AT LEAST 10% FIBROSIS ON A CHEST HRCT, AND 2) INTERSTITIAL LUNG DISEASE WITH A PROGRESSIVE PHENOTYPE (PF-ILD).
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: IPF: PRESCRIBED BY OR IN CONSULTATION WITH A PULMONOLOGIST. PPF: PRESCRIBED BY OR IN CONSULTATION WITH A PULMONOLOGIST OR RHEUMATOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: IPF: 1) DOES NOT HAVE OTHER KNOWN CAUSES OF INTERSTITIAL LUNG DISEASE (E.G., CONNECTIVE TISSUE DISEASE, DRUG TOXICITY, ASBESTOS OR BERYLLIUM EXPOSURE, HYPERSENSITIVITY PNEUMONITIS, SYSTEMIC SCLEROSIS, RHEUMATOID ARTHRITIS, RADIATION, SARCOIDOSIS, BRONCHIOLITIS OBLITERANS ORGANIZING PNEUMONIA, HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION, VIRAL HEPATITIS, CANCER), AND 2) TRIAL OF OR CONTRAINDICATION TO ONE OF THE FOLLOWING PREFERRED AGENTS: OFEV, PIRFENIDONE. PPF: 1) LUNG FUNCTION AND RESPIRATORY SYMPTOMS OR CHEST IMAGING HAVE WORSENED/PROGRESSED DESPITE TREATMENT WITH MEDICATIONS USED IN CLINICAL PRACTICE FOR ILD (NOT ATTRIBUTABLE TO COMORBIDITIES SUCH AS INFECTION, HEART FAILURE), AND 2) TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT: OFEV (NINTEDANIB). RENEWAL: IPF, PPF: CLINICAL MEANINGFUL IMPROVEMENT OR MAINTENANCE IN ANNUAL RATE OF DECLINE.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NERATINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NERATINIB MALEATE	NERLYNX	44421		GPI-10 (2153303510)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of breast cancer (ICD-10 Group C50) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's tumor is HER2-positive

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have a diagnosis of early stage (stage I-III) breast cancer and meet **ALL** of the following criteria?
   - Nerlynx will be used as extended adjuvant therapy following trastuzumab based therapy
   - Nerlynx is being requested within 2 years of completing the last trastuzumab dose

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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NERATINIB (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of advanced or metastatic breast cancer and meet **ALL** of the following criteria?
   - Nerlynx will be used in combination with capecitabine
   - The patient has received at least two prior anti-HER2 based regimens in the metastatic setting

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NERATINIB (Nerlynx)** requires the following rule(s) be met for approval:
   A. You have breast cancer
   B. If you have early stage (stage I-III) breast cancer, approval also requires:
      1. You are 18 years of age or older
      2. Your tumor is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive
      3. Nerlynx will be used as extended adjuvant (additional) therapy following trastuzumab based therapy
      4. Nerlynx is being requested within 2 years of completing the last trastuzumab dose
   C. If you have advanced or metastatic breast cancer (cancer has spread from where it started to nearby tissue or lymph nodes or has spread to other parts of the body), approval also requires:
      1. You are 18 years of age or older
      2. Your tumor is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive
      3. Nerlynx will be used in combination with capecitabine
      4. You have received at least two prior anti-HER2 based regimens in the metastatic setting (has spread to other parts of the body)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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NERATINIB (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Nerlynx.

REFERENCES
Nerlynx [Prescribing Information]. Los Angeles, CA: Puma Biotechnology; March 2024.

For Part D use only:

NERATINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	EARLY-STAGE (STAGE I-III) BREAST CANCER: MEDICATION IS BEING REQUESTED WITHIN 2 YEARS OF COMPLETING THE LAST TRASTUZUMAB DOSE. ALL OTHER FDA APPROVED INDICATIONS ARE COVERED WITHOUT ADDITIONAL CRITERIA, EXCEPT THOSE CRITERIA IN THE FDA APPROVED LABEL.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NILOTINIB-DANZITEN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NILOTINIB TARTRATE	DANZITEN	49984		GPI-10 (2153186060)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) (ICD-10 Group C92.1) in chronic phase **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) (ICD-10 Group C92.1) in chronic phase or accelerated phase and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is resistant or intolerant to prior therapy that included imatinib (Gleevec)
   - The patient had a mutational analysis prior to initiation AND therapy is appropriate per the NCCN guideline table for treatment recommendations based on BCR-ABL1 mutation profile *(Please see header CML-5 of the current NCCN guidelines)*

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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NILOTINIB-DANZITEN (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **NILOTINIB-DANZITEN** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML: a type of blood cell cancer) in chronic phase
   2. Previously treated Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase or accelerated phase

B. If you have newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase, approval also requires:
   1. You are 18 years of age or older

C. If you have previously treated Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase or accelerated phase, approval also requires:
   1. You are 18 years of age or older
   2. You are resistant (not responding to treatment) or intolerant (side effect) to prior treatment that included Gleevec (imatinib)
   3. You had a mutational analysis (a type of lab test) prior to the start of treatment AND therapy is appropriate per the National Comprehensive Cancer Network (NCCN) guideline table for treatment recommendations based on BCR-ABL1 mutation (breakpoint cluster region-Abelson murine leukemia 1: a type of abnormal gene) profile

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Danziten.

REFERENCES

Danziten [Prescribing Information]. Woburn, MA: Azurity Pharmaceuticals, Inc.; November 2024.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NILOTINIB-DANZITEN (PART D)

For Part D use only:

NILOTINIB-DANZITEN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	PREVIOUSLY TREATED PHILADELPHIA CHROMOSOME-POSITIVE CHRONIC MYELOID LEUKEMIA (Ph+ CML): 1) PERFORMED MUTATIONAL ANALYSIS PRIOR TO INITIATION OF THERAPY, AND 2) THERAPY IS APPROPRIATE PER NCCN GUIDELINE TABLE FOR TREATMENT RECOMMENDATIONS BASED ON BCR-ABL1 MUTATION PROFILE.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NILOTINIB - TASIGNA (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NILOTINIB HCL	TASIGNA, NILOTINIB HCL	35149		GPI-10 (2153186020)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) (ICD-10 Group C92.1)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the patient newly diagnosed in chronic phase **AND** meet the following criterion?
   - The patient is 1 year of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Is the patient previously treated in chronic phase or accelerated phase **AND** meet the following criterion?
   - The patient had a mutational analysis prior to initiation AND Tasigna is appropriate per the NCCN guideline table for treatment recommendations based on BCR-ABL1 mutation profile *(Please see header CML-5 of the current NCCN guidelines)*

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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NILOTINIB - TASIGNA (PART D)

GUIDELINES FOR USE (CONTINUED)

4. Does the patient meet **ONE** of the following criteria?
   - The patient is 1 to 17 years of age AND is resistant or intolerant to prior therapy with other tyrosine kinase inhibitors (TKI) [e.g., Gleevec (imatinib), Sprycel (dasatinib), Bosulif (bosutinib)]
   - The patient is 18 years of age or older AND is resistant or intolerant to prior therapy that included imatinib (Gleevec)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NILOTINIB - TASIGNA** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML: a type of blood cell cancer) in chronic phase
      2. Previously treated Philadelphia chromosome-positive chronic myeloid leukemia in chronic or accelerated phase

   B. If you have newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase, approval also requires:
      1. You are 1 year of age or older

   C. If you have previously treated Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase or accelerated phase, approval also requires:
      1. You meet ONE of the following:
         a. You are 1 to 17 years of age AND you are resistant (not responding to treatment) or intolerant (side effect) to prior treatment with other tyrosine kinase inhibitors (TKIs, such as Gleevec [imatinib], Sprycel [dasatinib], Bosulif [bosutinib])
         b. You are 18 years of age or older AND you are resistant or intolerant to prior treatment that included Gleevec (imatinib)
      2. You had a mutational analysis (a type of lab test) prior to start of treatment AND the requested medication is appropriate per the National Comprehensive Cancer Network (NCCN) guideline table for treatment recommendations based on BCR-ABL1 mutation (breakpoint cluster region-Abelson murine leukemia 1: a type of abnormal gene) profile

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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NILOTINIB - TASIGNA (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tasigna.

REFERENCES

Tasigna [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; February 2024.

For Part D use only:

NILOTINIB - TASIGNA (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	PREVIOUSLY TREATED PHILADELPHIA CHROMOSOME-POSITIVE CHRONIC MYELOID LEUKEMIA (Ph+ CML): MUTATIONAL ANALYSIS PRIOR TO INITIATION AND MEDICATION IS APPROPRIATE PER NCCN GUIDELINE TABLE FOR TREATMENT RECOMMENDATIONS BASED ON BCR-ABL1 MUTATION PROFILE.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NIMODIPINE SOLUTION (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NIMODIPINE	NYMALIZE	00184		GPI-10 (3400002200)	BRAND = NYMALIZE

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a history of subarachnoid hemorrhage (SAH) (ICD-10 I60.7) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's SAH is from a ruptured intracranial berry aneurysm within the past 21 days
   - The patient is unable to swallow nimodipine capsules

   If yes, **approve for 21 days by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NIMODIPINE SOLUTION (Nymalize)** requires the following rules be met for approval:
   A. You have a history of subarachnoid hemorrhage (SAH: bleeding in the space surrounding your brain)
   B. You are 18 years of age or older
   C. Your SAH is from a ruptured intracranial berry aneurysm (an area of an artery wall in your brain ballooned and burst) within the past 21 days
   D. You are unable to swallow nimodipine oral capsules

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NIMODIPINE SOLUTION (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Nymalize.

REFERENCES
Nymalize [Prescribing Information]. Atlanta, GA: Arbor Pharmaceuticals, LLC; December 2020.

For Part D use only:

NIMODIPINE SOLUTION (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	21 DAYS
Other Criteria	SUBARACHNOID HEMORRHAGE (SAH): 1) RUPTURED INTRACRANIAL BERRY ANEURYSM WITHIN THE PAST 21 DAYS, AND 2) INABILITY TO SWALLOW NIMODIPINE CAPSULES.

Core	Advantage	Plus
No	No	Yes

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NINTEDANIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NINTEDANIB ESYLATE	OFEV	41489		GPI-10 (4555405020)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of idiopathic pulmonary fibrosis (IPF) (ICD-10 J84.112) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a pulmonologist
   - The patient has a usual interstitial pneumonia (UIP) pattern as evidenced by high-resolution computed tomography (HRCT) alone or via a combination of surgical lung biopsy and HRCT
   - The patient does NOT have other known causes of interstitial lung disease (for example, connective tissue disease, drug toxicity, asbestos or beryllium exposure, hypersensitivity pneumonitis, systemic sclerosis, rheumatoid arthritis, radiation, sarcoidosis, bronchiolitis obliterans organizing pneumonia, human immunodeficiency virus infection, viral hepatitis, or cancer)
   - The patient had a trial of or contraindication to the preferred agent: Esbriet (pirfenidone)

     If yes, **approve for 12 months by HICL or GPI-10.**
     APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

     If no, continue to #2.

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NINTEDANIB (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) (ICD-10 M34.81) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a pulmonologist or rheumatologist
   - The patient has at least 10% fibrosis on a chest high resolution computed tomography (HRCT) (e.g., defined as reticular abnormality with traction bronchiectasis with or without honeycombing)
   - The patient has a baseline forced vital capacity (FVC) of at least 40% of predicted value
   - The patient does NOT have other etiologies of interstitial lung disease (ILD) [e.g., heart failure/fluid overload, drug-induced lung toxicity (cyclophosphamide, methotrexate, ACE-inhibitors), recurrent aspiration (such as from GERD), pulmonary vascular disease, pulmonary edema, pneumonia, chronic pulmonary thromboembolism, alveolar hemorrhage or ILD caused by another rheumatic disease, such as mixed connective tissue disease (MCTD)]

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Does the patient have a diagnosis of chronic fibrosing interstitial lung disease (ILD) with a progressive phenotype (PF-ILD) (ICD-10 J84.170) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a pulmonologist or rheumatologist
   - The patient's lung function and respiratory symptoms OR chest imaging have worsened/progressed despite treatment with medications used in clinical practice for ILD (not attributable to comorbidities e.g., infection, heart failure)
   - The patient has at least 10% fibrosis on a chest high resolution computed tomography (HRCT) (e.g., defined as reticular abnormality with traction bronchiectasis with or without honeycombing)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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NINTEDANIB (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **NINTEDANIB (Ofev)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Idiopathic pulmonary fibrosis (IPF: scarring of the lungs with an unknown cause)
   2. Systemic sclerosis-associated interstitial lung disease (SSc-ILD: disorder that causes hardening of lung tissue)
   3. Chronic fibrosing interstitial lung disease (ILD) with a progressive phenotype (PF-ILD: scarring of the lungs caused by different underlying diseases or conditions that worsen over time)

B. You are 18 years of age or older

C. If you have idiopathic pulmonary fibrosis, approval also requires:
   1. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor)
   2. You have a usual interstitial pneumonia pattern (a specific type of lung scarring) as evidenced by high-resolution computed tomography (HRCT: type of imaging test) alone or via a combination of surgical lung biopsy (small lung sample) and HRCT
   3. You do NOT have other known causes of interstitial lung disease, such as connective tissue disease, drug toxicity, asbestos or beryllium exposure, hypersensitivity pneumonitis (lung inflammation from inhaled substances), systemic sclerosis (an immune system disorder), rheumatoid arthritis (joint pain and inflammation), radiation, sarcoidosis (growth of inflammatory cells in the body), bronchiolitis obliterans organizing pneumonia (type of lung infection), human immunodeficiency virus infection, viral hepatitis (type of liver inflammation), or cancer
   4. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Esbriet (pirfenidone)

(Initial denial text continued on next page)

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NINTEDANIB (PART D)

INITIAL CRITERIA (CONTINUED)

D. If you have systemic sclerosis-associated interstitial lung disease, approval also requires:

1. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or rheumatologist (type of immune system doctor)
2. You have at least 10% fibrosis (tissue scarring) on a chest high resolution computed tomography (HRCT: type of imaging testing)
3. You have a baseline forced vital capacity (FVC: amount of air that can be forcefully exhaled) of at least 40% of predicted value
4. Other causes of interstitial lung disease have been ruled out. Other causes may include heart failure/fluid overload, drug-induced lung toxicity [cyclophosphamide, methotrexate, ACE-inhibitors (class of blood pressure medications)], recurrent aspiration (inhaling) such as from GERD (acid reflux), pulmonary vascular disease (affecting blood vessels in lungs), pulmonary edema (excess fluid in the lungs), pneumonia (type of lung infection), chronic pulmonary thromboembolism (blood clot in lungs), alveolar hemorrhage (bleeding of a part of the lungs) or interstitial lung disease caused by another rheumatic (inflammatory) disease, such as mixed connective tissue disease (MCTD)

E. If you have chronic fibrosing interstitial lung disease with progressive phenotype, approval also requires:

1. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or rheumatologist (type of immune system doctor)
2. Your lung function and respiratory (breathing) symptoms OR chest imaging have worsened/progressed despite treatment with medications used in clinical practice for interstitial lung disease (ILD) (not caused by comorbidities such as infection, heart failure)
3. You have at least 10% fibrosis (tissue scarring) on a chest high resolution computed tomography (HRCT: type of imaging testing)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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NINTEDANIB (PART D)

RENEWAL CRITERIA

1. Does the patient have **ONE** of the following diagnoses?
   - Idiopathic pulmonary fibrosis (IPF) (ICD-10 J84.112)
   - Systemic sclerosis-associated interstitial lung disease (SSc-ILD) (ICD-10 M34.81)
   - Chronic fibrosing interstitial lung disease (ILD) with a progressive phenotype (PF-ILD) (ICD-10 J84.170)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Has the patient experienced a clinically meaningful improvement or maintenance in annual rate of decline?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NINTEDANIB (Ofev)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Idiopathic pulmonary fibrosis (IPF: scarring of the lungs with an unknown cause)
      2. Systemic sclerosis-associated interstitial lung disease (SSc-ILD: disorder that causes hardening of lung tissue)
      3. Chronic fibrosing interstitial lung disease (ILD) with a progressive phenotype (PF-ILD: scarring of the lungs caused by different underlying diseases or conditions that worsens over time)
   B. You have experienced a clinically meaningful improvement or maintenance in annual rate of decline

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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NINTEDANIB (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ofev.

REFERENCES

Ofev [Prescribing Information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; October 2024.

For Part D use only:

NINTEDANIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	INITIAL: IDIOPATHIC PULMONARY FIBROSIS (IPF): A USUAL INTERSTITIAL PNEUMONIA (UIP) PATTERN AS EVIDENCED BY HIGH-RESOLUTION COMPUTED TOMOGRAPHY (HRCT) ALONE OR VIA A COMBINATION OF SURGICAL LUNG BIOPSY AND HRCT. SYSTEMIC SCLEROSIS-ASSOCIATED INTERSTITIAL LUNG DISEASE (SSC-ILD): 1) AT LEAST 10% FIBROSIS ON A CHEST HRCT, AND 2) BASELINE FVC AT LEAST 40% OF PREDICTED VALUE. CHRONIC FIBROSING INTERSTITIAL LUNG DISEASE WITH A PROGRESSIVE PHENOTYPE (PF-ILD): AT LEAST 10% FIBROSIS ON A CHEST HRCT.
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: IPF: PRESCRIBED BY OR IN CONSULTATION WITH A PULMONOLOGIST. SSC-ILD, PF-ILD: PRESCRIBED BY OR IN CONSULTATION WITH A PULMONOLOGIST OR RHEUMATOLOGIST.
Coverage Duration	INITIAL: SSC-ILD: 6 MOS. IPF, PF-ILD: 12 MOS. RENEWAL (ALL INDICATIONS): 12 MOS.
Other Criteria	INITIAL: IPF: 1) DOES NOT HAVE OTHER KNOWN CAUSES OF INTERSTITIAL LUNG DISEASE (E.G., CONNECTIVE TISSUE DISEASE, DRUG TOXICITY, ASBESTOS OR BERYLLIUM EXPOSURE, HYPERSENSITIVITY PNEUMONITIS), AND 2) TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT: ESBRIET (PIRFENIDONE). SSC-ILD: DOES NOT HAVE OTHER KNOWN CAUSES OF INTERSTITIAL LUNG DISEASE (E.G., HEART FAILURE/FLUID OVERLOAD, DRUG-INDUCED LUNG TOXICITY, RECURRENT ASPIRATION). PF-ILD: LUNG FUNCTION AND RESPIRATORY SYMPTOMS OR CHEST IMAGING HAVE WORSENED/PROGRESSED DESPITE TREATMENT WITH MEDICATIONS USED IN CLINICAL PRACTICE FOR ILD (NOT ATTRIBUTABLE TO COMORBIDITIES SUCH AS INFECTION, HEART FAILURE). RENEWAL: IPF, SSC-ILD, PF-ILD: CLINICAL MEANINGFUL

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	IMPROVEMENT OR MAINTENANCE IN ANNUAL RATE OF DECLINE.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NIRAPARIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NIRAPARIB TOSYLATE	ZEJULA	44177		GPI-10 (2153555020)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of epithelial ovarian, fallopian tube, or primary peritoneal cancer (ICD-10 Groups C56, C57.0, C48, C79.6) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the cancer advanced, and does the patient meet **ALL** of the following criteria?
   - The patient is in complete or partial response to first-line platinum-based chemotherapy (e.g., cisplatin, carboplatin)
   - The patient's cancer is associated with homologous recombination deficiency (HRD)-positive status as defined by either a deleterious or suspected deleterious BRCA mutation, and/or genomic instability

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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NIRAPARIB (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Is the cancer recurrent, and does the patient meet **ALL** of the following criteria?
   - The patient is in complete or partial response to platinum-based chemotherapy (e.g., cisplatin, carboplatin)
   - The patient's cancer has deleterious or suspected deleterious germline *BRCA*-mutation (*gBRCAmut*), based on an FDA-approved companion diagnostic for Zejula
   - Zejula will be used as monotherapy
   - Zejula will be started no later than 8 weeks after the patient's most recent platinum-containing regimen

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NIRAPARIB (Zejula)** requires the following rule(s) be met for approval:
   A. You have advanced (has spread to other parts of the body) or recurrent (has returned) epithelial ovarian, fallopian tube, or primary peritoneal cancer (types of reproductive system or abdomen cancer)
   B. If you have advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:
      1. You are 18 years of age or older
      2. You are in complete or partial response (cancer is not detectable or has partly responded to treatment but still did not go away) to first-line platinum-based chemotherapy (such as cisplatin, carboplatin)
      3. Your cancer is associated with homologous recombination deficiency (HRD: a type of gene mutation)-positive status as defined by either a deleterious or suspected deleterious BRCA mutation (a type of gene mutation), and/or genomic instability (high rate of gene mutation)

   (Denial text continued on next page)

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NIRAPARIB (PART D)

GUIDELINES FOR USE (CONTINUED)

C. If you have recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:

1. You are 18 years of age or older
2. You are in complete or partial response (signs or symptoms of cancer have disappeared or cancer partly responded to treatment, but still did not go away) to platinum-based chemotherapy (such as cisplatin, carboplatin)
3. Your cancer has deleterious or suspected deleterious germline *BRCA*-mutation (*gBRCAmut*: a type of gene mutation [abnormal change]) based on a Food and Drug Administration (FDA)-approved companion diagnostic for Zejula
4. Zejula will be used as monotherapy (used by itself for treatment)
5. Zejula will be started no later than 8 weeks after your most recent platinum-containing regimen (such as cisplatin, carboplatin)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zejula.

REFERENCES

Zejula [Prescribing Information]. Research Triangle Park, NC: GlaxoSmithKline; June 2025.

For Part D use only:

NIRAPARIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	RECURRENT EPITHELIAL OVARIAN, FALLOPIAN TUBE, OR PRIMARY PERITONEAL CANCER: 1) ZEJULA WILL BE USED AS MONOTHERAPY, AND 2) ZEJULA IS STARTED NO LATER THAN 8 WEEKS AFTER THE MOST RECENT PLATINUM-CONTAINING REGIMEN.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NIRAPARIB-ABIRATERONE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NIRAPARIB-ABIRATERONE	AKEEGA	49143		GPI-10 (2140990212)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic castration-resistant prostate cancer (mCRPC) (ICD-10 Z19.2, C61) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer has a deleterious or suspected deleterious BRCA mutation (BRCAm) based on an FDA-approved test for Akeega
   - Akeega will be used in combination with oral prednisone

   If yes, continue to #3.
   If no, continue to #2.

2. Does the patient have a diagnosis of metastatic castration-sensitive prostate cancer (mCSPC) (ICD-10 Z19.1, C61) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer has a deleterious or suspected deleterious BRCA2 mutation (BRCA2m) based on an FDA-approved test for Akeega
   - Akeega will be used in combination with oral prednisone

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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NIRAPARIB-ABIRATERONE (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient meet **ONE** of the following criteria?
   - The patient had a bilateral orchiectomy
   - The patient has a castrate level of testosterone (i.e., less than 50 ng/dL)
   - Akeega will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog (e.g., Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NIRAPARIB-ABIRATERONE (Akeega)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Metastatic castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and no longer responds to testosterone lowering treatment)
      2. Metastatic castration-sensitive prostate cancer (mCSPC: prostate cancer that has spread to other parts of the body and responds to hormone therapy)

   B. If you have metastatic castration-resistant prostate cancer, approval also requires:
      1. You are 18 years of age or older
      2. Your cancer has a deleterious (harmful) or suspected deleterious BRCA mutation (BRCAm: abnormal change in gene) based on a Food and Drug Administration (FDA)-approved test for Akeega
      3. Akeega will be used in combination with oral prednisone
      4. You meet ONE of the following:
         a. You had a bilateral orchiectomy (both testicles have been surgically removed)
         b. You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
         c. Akeega will be used together with a gonadotropin-releasing hormone (GnRH) analog (such as Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

   (Denial text continued on next page)

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NIRAPARIB-ABIRATERONE (PART D)

GUIDELINES FOR USE (CONTINUED)

C. If you have metastatic castration-sensitive prostate cancer, approval also requires:

1. You are 18 years of age or older
2. Your cancer has a deleterious (harmful) or suspected deleterious BRCA2 mutation (BRCA2m: abnormal change in gene) based on a Food and Drug Administration (FDA)-approved test for Akeega
3. Akeega will be used in combination with oral prednisone
4. You meet ONE of the following:
   a. You had a bilateral orchiectomy (both testicles have been surgically removed)
   b. You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
   c. Akeega will be used together with a gonadotropin-releasing hormone (GnRH) analog (such as Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Akeega.

REFERENCES

Akeega [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; December 2025.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NIRAPARIB-ABIRATERONE (PART D)

For Part D use only:

NIRAPARIB-ABIRATERONE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	METASTATIC CASTRATION-RESISTANT PROSTATE CANCER (MCRPC), METASTATIC CASTRATION-SENSITIVE PROSTATE CANCER (MCSPC): 1) RECEIVED A BILATERAL ORCHIECTOMY, 2) CASTRATE LEVEL OF TESTOSTERONE (I.E., LESS THAN 50 NG/DL), OR 3) CONCURRENT USE WITH A GONADOTROPIN RELEASING HORMONE (GNRH) ANALOG.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NIROGACESTAT (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NIROGACESTAT HYDROBROMIDE	OGSIVEO	49323		GPI-10 (2153235020)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of progressing desmoid tumors (ICD-10 Group D48.11) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient requires systemic treatment

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NIROGACESTAT (Ogsiveo)** requires the following rule(s) be met for approval:
   A. You have progressing desmoid tumors (noncancerous growths in the connective tissue)
   B. You are 18 years of age or older
   C. You require systemic treatment (treatment that targets the entire body)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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NIROGACESTAT (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ogsiveo.

REFERENCES

Ogsiveo [Prescribing Information]. Stamford, CT: SpringWorks Therapeutics, Inc.; November 2023.

For Part D use only:

NIROGACESTAT (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NIRSEVIMAB-ALIP (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NIRSEVIMAB-ALIP	BEYFORTUS	49077		GPI-10 (1950205205)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the request for the prevention of respiratory syncytial virus (RSV) lower respiratory tract disease (ICD-10 Z29.11) and the patient meets **ONE** of the following criteria?
   - The patient is less than 12 months of age (neonate or infant) and born during or entering their first RSV season
   - The patient is 12 to 24 months of age and remains vulnerable to severe RSV disease

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
   - The patient has not completed a course of Synagis (palivizumab) OR has not received a dose of Synagis in the past 30 days, and will not receive further doses of Synagis within the same RSV season
   - The patient has not received 2 doses of Beyfortus in their lifetime, unless has undergone or is undergoing a cardiac surgery with cardiopulmonary bypass

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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NIRSEVIMAB-ALIP (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Has the patient undergone or will undergo cardiac surgery with cardiopulmonary bypass?

If yes, **approve for 6 months by HICL or GPI-10 for 2 fills.**
If no, **approve for 6 months by HICL or GPI-10 for 1 fill.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **NIRSEVIMAB-ALIP (Beyfortus)** requires the following rule(s) be met for approval:

A. Beyfortus will be used for the prevention of respiratory syncytial virus (RSV: type of lung and respiratory tract infection)
B. You meet ONE of the following:
   1. You are less than 12 months of age (neonate or infant) and were born during or are entering your first RSV season (period of increased rate of infection)
   2. You are 12 to 24 months of age and are vulnerable to (at risk of) severe RSV disease
C. You have not completed a course of Synagis (palivizumab) within this RSV season OR you have not received a dose of Synagis in the past 30 days, and you will not receive further doses of Synagis within this RSV season
D. You have not received more than 2 doses of Beyfortus in your lifetime, unless you have undergone or will undergo a cardiac surgery with cardiopulmonary bypass (type of heart and lung surgery)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Beyfortus.

REFERENCES

Beyfortus [Prescribing Information]. AstraZeneca AB: Södertälje, Sweden; July 2023.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

For Part D use only:

NIRSEVIMAB-ALIP (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 MONTHS
Other Criteria	RESPIRATORY SYNCYTIAL VIRUS (RSV) PREVENTION: 1) HAS NOT COMPLETED A COURSE OF SYNAGIS OR HAS NOT RECEIVED A DOSE OF SYNAGIS IN THE PAST 30 DAYS, AND WILL NOT RECEIVE FURTHER DOSES OF SYNAGIS WITHIN THE SAME RSV SEASON, AND 2) HAS NOT RECEIVED MORE THAN 2 DOSES OF BEYFORTUS PER LIFETIME, UNLESS HAS UNDERGONE OR WILL UNDERGO A CARDIAC SURGERY WITH CARDIOPULMONARY BYPASS

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ADVANTAGE AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NITISINONE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NITISINONE	ORFADIN, NITYR, NITISINONE	23253		GPI-10 (3090404500)	BRAND ≠ HARLIKU

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hereditary tyrosinemia type 1 (HT-1) (ICD-10 E70.21) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a prescriber specializing in inherited metabolic diseases
   - The patient's diagnosis is confirmed by elevated urinary or plasma succinylacetone (SA) levels OR a mutation in the fumarylacetoacetate hydrolase (FAH) gene

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the request for Orfadin (nitisinone) capsules?

   If yes, **approve all strengths for 6 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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NITISINONE (PART D)

INITIAL CRITERIA (CONTINUED)

3. Is the request for Nityr tablets?

   If yes, **approve all strengths for 6 months by NDC or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

4. Is the request for Orfadin suspension **AND** the patient meets the following criterion?
   - The patient had a trial of or contraindication to the preferred agent: nitisinone tablets or capsules

   If yes, **approve for 6 months by GPID or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NITISINONE (Orfadin, Nityr)** requires the following rule(s) be met for approval:
   A. You have hereditary tyrosinemia type 1 (HT-1: a type of genetic disorder)
   B. Therapy is prescribed by or in consultation with a prescriber specializing ininherited metabolic diseases
   C. Your diagnosis is confirmed by elevated urinary or plasma succinylacetone levels (a chemical that is present in hereditary tyrosinemia) OR a mutation (abnormal change) in the fumarylacetoacetate hydrolase gene
   D. If you are requesting Orfadin oral suspension, approval also requires:
      1. You have tried or have a contraindication to (harmful for you to use) the preferred medication: nitisinone tablets or capsules

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ADVANTAGE AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NITISINONE (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary tyrosinemia type 1 (HT-1) (ICD-10 E70.21) **AND** meet the following criterion?
- The patient's urinary or plasma succinylacetone (SA) levels have decreased from baseline while on treatment with nitisinone

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the renewal request for Orfadin (nitisinone) capsules or Orfadin suspension?

If yes, **approve the requested formulation for 12 months by GPID for all strengths or by GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #3.

3. Is the renewal request for Nityr tablets?

If yes, **approve for 12 months by NDC for all strengths or by GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **NITISINONE (Orfadin, Nityr)** requires the following rule(s) be met for renewal:
A. You have hereditary tyrosinemia type 1 (HT-1: a type of genetic disorder)
B. Your urinary or plasma succinylacetone levels (a chemical that is present in hereditary tyrosinemia) have decreased from baseline while on treatment with nitisinone

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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NITISINONE (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Orfadin or Nityr .

REFERENCES

Orfadin [Prescribing Information]. Waltham, MA: Sobi, Inc.; November 2021.
Nityr [Prescribing Information]. Cambridge, UK: Cycle Pharmaceuticals Ltd.; May 2024.

For Part D use only:

NITISINONE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	HEREDITARY TYROSINEMIA TYPE 1 (HT-1): INITIAL: DIAGNOSIS CONFIRMED BY ELEVATED URINARY OR PLASMA SUCCINYLACETONE LEVELS OR A MUTATION IN THE FUMARYLACETOACETATE HYDROLASE GENE. RENEWAL: URINARY OR PLASMA SUCCINYLACETONE LEVELS HAVE DECREASED FROM BASELINE WHILE ON TREATMENT WITH NITISINONE.
Age Restrictions	N/A
Prescriber Restrictions	HT-1: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A PRESCRIBER SPECIALIZING IN INHERITED METABOLIC DISEASES.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	HT-1: INITIAL: ORFADIN SUSPENSION: TRIAL OF OR CONTRAINDICATION TO PREFERRED NITISINONE TABLETS OR CAPSULES.

Created: 11/17
Effective: 01/01/26 Client Approval: 01/26 P&T Approval: 10/18

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NITISINONE-HARLIKU (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NITISINONE	HARLIKU	23253		GPI-10 (3090225500)	BRAND = HARLIKU

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of alkaptonuria (AKU) (ICD-10 E70.29) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Harliku will be used to reduce the level of urine homogentisic acid (HGA)

   If yes, **approve for 12 months by NDC or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NITISINONE-HARLIKU** requires the following rule(s) be met for approval:
   A. You have alkaptonuria (AKU: a type of rare genetic disorder)
   B. You are 18 years of age or older
   C. Harliku will be used to reduce the level of urine homogentisic acid (HGA) (a type of lab test)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NITISINONE-HARLIKU (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Harliku.

REFERENCES

Harliku [Prescribing Information]. Cambridge, United Kingdom: Cycle Pharmaceuticals Ltd;June 2025.

For Part D use only:

NITISINONE-HARLIKU (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 07/25
Effective: 08/04/25 Client Approval: 07/25 P&T Approval: 10/25

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NIVOLUMAB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NIVOLUMAB	OPDIVO	41654		GPI-10 (2135794100)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic melanoma (ICD-10 Group C43) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Opdivo will be used as a single agent OR in combination with Yervoy (ipilimumab)
   - Opdivo will NOT be used concurrently with targeted therapy (i.e., BRAF inhibitors [Braftovi (encorafenib), Tafinlar (dabrafenib)], MEK inhibitors [Mekinist (trametinib)], and NTRK inhibitors [Vitrakvi (larotrectinib), Rozlytrek (entrectinib)])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of stage IIB, IIC, III, or IV melanoma (ICD-10 Group C43) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient has undergone complete resection
   - Opdivo will be used as an adjuvant treatment

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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NIVOLUMAB (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of resectable (node positive or tumor is 4 cm or greater) non-small cell lung cancer (NSCLC) (ICD-10 Group C34) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #4.
   If no, continue to #6.

4. Will Opdivo be used in combination with platinum-doublet chemotherapy (e.g., carboplatin/paclitaxel, cisplatin/pemetrexed, cisplatin/gemcitabine) as neoadjuvant treatment only?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Does the patient meet **ALL** of the following criteria?
   - The patient's cancer has no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements
   - Opdivo will be used in combination with platinum-doublet chemotherapy (e.g., carboplatin/paclitaxel, cisplatin/pemetrexed, carboplatin/pemetrexed, cisplatin/docetaxel) as neoadjuvant treatment, OR as a single agent as adjuvant treatment after surgery and prior use with platinum-doublet chemotherapy as neoadjuvant treatment

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

6. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #7.
   If no, continue to #10.

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NIVOLUMAB (PART D)

GUIDELINES FOR USE (CONTINUED)

7. Does the patient's tumors express PD-L1 (at least 1 percent), as determined by an FDA-approved test, and meet **ALL** of the following criteria?
   - The tumor does NOT have EGFR or ALK genomic tumor aberrations
   - Opdivo will be used in combination with Yervoy (ipilimumab)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #8.

8. Will Opdivo be used in combination with Yervoy (ipilimumab) and 2 cycles of platinum-doublet chemotherapy (e.g., carboplatin/pemetrexed, cisplatin/pemetrexed, carboplatin/paclitaxel) **AND** the patient meets the following criterion?
   - The tumor does NOT have EGFR or ALK genomic tumor aberrations

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #9.

9. Has the patient's disease progressed while on or after platinum-based chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin) and the patient meets **ONE** of the following criteria?
   - The tumor does NOT have EGFR or ALK genomic tumor aberrations
   - The tumor has an ALK mutation, and the patient had disease progression following an FDA-approved ALK-directed therapy (e.g., Xalkori [crizotinib], Zykadia [ceritinib])
   - The tumor has an EGFR mutation, and the patient had disease progression following an FDA-approved EGFR-directed therapy (e.g., Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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NIVOLUMAB (PART D)

GUIDELINES FOR USE (CONTINUED)

10. Does the patient have a diagnosis of recurrent non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - The tumor does NOT have EGFR or ALK genomic tumor aberrations
    - Opdivo will be used in combination with Yervoy (ipilimumab) AND 2 cycles of platinum-doublet chemotherapy (e.g., carboplatin/pemetrexed, cisplatin/pemetrexed, carboplatin/paclitaxel)

    If yes, **approve for 12 months by HICL or GPI-10.**
    APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

    If no, continue to #11.

11. Does the patient have a diagnosis of unresectable malignant pleural mesothelioma (ICD-10 C45.0) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Opdivo will be used in combination with Yervoy (ipilimumab)

    If yes, **approve for 12 months by HICL or GPI-10.**
    APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

    If no, continue to #12.

12. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC) (ICD-10 Groups C64, C65) **AND** meet the following criterion?
    - The patient is 18 years of age or older

    If yes, continue to #13.
    If no, continue to #14.

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NIVOLUMAB (PART D)

GUIDELINES FOR USE (CONTINUED)

13. Does the patient meet **ONE** of the following criteria?
    - The patient has intermediate or poor risk disease AND Opdivo will used in combination with Yervoy (ipilimumab)
    - Opdivo will be used in combination with Cabometyx (cabozantinib)
    - The patient has received prior anti-angiogenic therapy (e.g., Sutent [sunitinib], Votrient [pazopanib], Cabometyx [cabozantinib])

    If yes, **approve for 12 months by HICL or GPI-10.**
    APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

14. Does the patient have a diagnosis of classical Hodgkin lymphoma (cHL) (ICD-10 Group C81)?

    If yes, continue to #15.
    If no, continue to #19.

15. Has the patient's disease been previously treated?

    If yes, continue to #16.
    If no, continue to #18.

16. Has the patient's disease relapsed or progressed after **ONE** of the following?
    - Autologous hematopoietic stem cell transplantation (HSCT) and Adcetris (brentuximab vedotin)
    - 3 or more lines of systemic therapy that includes autologous HSCT

    If yes, continue to #17.
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

17. Is the patient 18 years of age or older?

    If yes, **approve for 12 months by HICL or GPI-10.**
    APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

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NIVOLUMAB (PART D)

GUIDELINES FOR USE (CONTINUED)

18. Is the patient's disease Stage III or IV and the patient meets **ALL** of the following criteria?
    - The patient is 12 years of age or older
    - Opdivo will be used in combination with doxorubicin, vinblastine, and dacarbazine (AVD)

    If yes, **approve for 12 months by HICL or GPI-10.**
    APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

19. Does the patient have a diagnosis of recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN) (ICD-10 Groups C44.42, C76.0, C00, C06, C09, C10, C32) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - The patient has disease progression while on or after treatment with a platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

    If yes, **approve for 12 months by HICL or GPI-10.**
    APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

    If no, continue to #20.

20. Does the patient have a diagnosis of urothelial carcinoma (UC) (ICD-10 Groups C65, C66, C67, C68) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Opdivo will be used as an adjuvant treatment
    - The patient is at high risk of recurrence after undergoing radical resection of UC

    If yes, **approve for 12 months by HICL or GPI-10.**
    APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

    If no, continue to #21.

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NIVOLUMAB (PART D)

GUIDELINES FOR USE (CONTINUED)

21. Does the patient have a diagnosis of unresectable or metastatic urothelial carcinoma (UC) (ICD-10 Groups C65, C66, C67, C68) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Opdivo will be used in combination with cisplatin and gemcitabine

    If yes, **approve for 12 months by HICL or GPI-10.**
    APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

    If no, continue to #22.

22. Does the patient have a diagnosis of locally advanced or metastatic urothelial carcinoma (UC) (ICD-10 Groups C65, C66, C67, C68) **AND** meet the following criterion?
    - The patient is 18 years of age or older

    If yes, continue to #23.
    If no, continue to #24.

23. Does the patient meet **ONE** of the following criteria?
    - The patient has disease progression during or following platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
    - The patient has disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

    If yes, **approve for 12 months by HICL or GPI-10.**
    APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

24. Does the patient have a diagnosis of colorectal cancer (CRC) (ICD-10 C19) and meet **ALL** of the following criteria?
    - The patient is 12 years of age or older
    - The patient's cancer is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)

    If yes, continue to #25.
    If no, continue to #27.

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NIVOLUMAB (PART D)

GUIDELINES FOR USE (CONTINUED)

25. Is the patient's cancer unresectable **AND** the patient meets the following criterion?
    - Opdivo will be used in combination with Yervoy (ipilimumab)

    If yes, **approve for 12 months by HICL or GPI-10.**
    APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

    If no, continue to #26.

26. Is the patient's cancer metastatic and the patient meets **ONE** of the following criteria?
    - Opdivo will be used in combination with Yervoy (ipilimumab)
    - Opdivo will be used as a single agent, AND the patient has disease progression following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan

    If yes, **approve for 12 months by HICL or GPI-10.**
    APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

27. Does the patient have a diagnosis of unresectable or metastatic hepatocellular carcinoma (HCC) (ICD-10 C22.0) **AND** meet the following criterion?
    - The patient is 18 years of age or older

    If yes, continue to #28.
    If no, continue to #29.

28. Does the patient meet **ONE** of the following criteria?
    - Opdivo will be used in combination with Yervoy (ipilimumab) as first-line treatment
    - Opdivo will be used in combination with Yervoy (ipilimumab), AND the patient has been previously treated with Nexavar (sorafenib)

    If yes, **approve for 12 months by HICL or GPI-10.**
    APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

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NIVOLUMAB (PART D)

GUIDELINES FOR USE (CONTINUED)

29. Does the patient have a diagnosis of completely resected esophageal or gastroesophagealjunction cancer (ICD-10 C16.0; Group C15) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Opdivo will be used as an adjuvant treatment
    - The patient has a residual pathologic disease and has received neoadjuvant chemoradiotherapy (CRT)

    If yes, **approve for 12 months by HICL or GPI-10.**
    APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

    If no, continue to #30.

30. Does the patient have a diagnosis of unresectable advanced, recurrent or metastatic esophageal squamous cell carcinoma (ESCC) (ICD-10 Group C15) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - The patient has received prior fluoropyrimidine- and platinum-based chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

    If yes, **approve for 12 months by HICL or GPI-10.**
    APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

    If no, continue to #31.

31. Does the patient have a diagnosis of unresectable advanced or metastatic esophageal squamous cell carcinoma (ESCC) (ICD-10 Group C15) **AND** meet the following criterion?
    - The patient is 18 years of age or older

    If yes, continue to #32.
    If no, continue to #33.

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NIVOLUMAB (PART D)

GUIDELINES FOR USE (CONTINUED)

32. Does the patient meet **ONE** of the following criteria?
    - Opdivo will be used in combination with fluoropyrimidine- and platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
    - Opdivo will be used in combination with Yervoy (ipilimumab)

    If yes, **approve for 12 months by HICL or GPI-10.**
    APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

33. Does the patient have a diagnosis of advanced or metastatic gastric cancer, gastroesophageal junction cancer, or esophageal adenocarcinoma (ICD-10 Groups C15, C16) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Opdivo will be used in combination with fluoropyrimidine- and platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

    If yes, **approve for 12 months by HICL or GPI-10.**
    APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

    If no, do not approve.

    DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

    Our guideline named **NIVOLUMAB (Opdivo)** requires the following rule(s) be met for approval:
    A. You have ONE of the following:
        1. Unresectable or metastatic melanoma (type of skin cancer that cannot be removed by surgery or has spread to other parts of the body)
        2. Stage IIB, IIC, III, or IV melanoma (a type of skin cancer)
        3. Resectable (node positive or tumor is 4 cm or greater) non-small cell lung cancer (NSCLC) (a type of lung cancer that can be removed by surgery)
        4. Metastatic non-small cell lung cancer (NSCLC) (a type of lung cancer that has spread to other parts of the body)
        5. Recurrent non-small cell lung cancer (NSCLC) (a type of lung cancer that has returned)
        6. Unresectable malignant pleural mesothelioma (a tumor of the tissue lining the lungs and chest wall that cannot be removed by surgery)

    (Denial text continued on next page)

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NIVOLUMAB (PART D)

GUIDELINES FOR USE (CONTINUED)

7. Advanced renal cell carcinoma (RCC: type of kidney cancer)
8. Classical Hodgkin lymphoma (cHL: type of blood cancer)
9. Recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN: type of head/neck cancer that has returned or spread to other parts of the body)
10. Urothelial carcinoma (UC: urinary system cancer)
11. Unresectable or metastatic urothelial carcinoma (urinary system cancer that cannot be removed by surgery or has spread to other parts of the body)
12. Locally advanced or metastatic urothelial carcinoma (urinary system cancer that has spread to nearby tissue or lymph nodes or that has spread to other parts of the body)
13. Colorectal cancer (a type of digestive cancer)
14. Unresectable or metastatic hepatocellular carcinoma (HCC: a type of liver cancer that cannot be removed by surgery or has spread to other parts of the body)
15. Completely resected esophageal or gastroesophageal junction cancer (types of digestive system cancer that has been removed by surgery)
16. Unresectable advanced, recurrent or metastatic esophageal squamous cell carcinoma (ESCC: type of digestive system cancer that cannot be removed by surgery, and has returned or has spread to other parts of the body)
17. Unresectable advanced or metastatic esophageal squamous cell carcinoma (ESCC: type of digestive system cancer that cannot be removed by surgery and has spread to other parts of the body)
18. Advanced or metastatic gastric cancer, gastroesophageal junction cancer, or esophageal adenocarcinoma (types of digestive system cancer that has spread to other parts of the body)

B. If you have unresectable or metastatic melanoma, approval also requires:

1. You are 12 years of age or older
2. Opdivo will be used alone OR in combination with Yervoy (ipilimumab)
3. Opdivo will NOT be used concurrently (at the same time) with a targeted therapy (BRAF inhibitors [such as Braftovi (encorafenib), Tafinlar (dabrafenib)], MEK inhibitors [such as Mekinist (trametinib)], and NTRK inhibitors [such as Vitrakvi (larotrectinib), Rozlytrek (entrectinib)])

C. If you have stage IIB, IIC, III, or IV melanoma, approval also requires:

1. You are 12 years of age or older
2. You have undergone complete resection (completely removed by surgery)
3. Opdivo will be used as an adjuvant (add-on) treatment

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NIVOLUMAB (PART D)

GUIDELINES FOR USE (CONTINUED)

D. If you have resectable (node positive or tumor is 4 cm or greater) non-small cell lung cancer, approval also requires:
1. You are 18 years of age or older
2. You meet ONE of the following:
   a. Opdivo will be used in combination with platinum-doublet chemotherapy (a type of cancer treatment, such as carboplatin/paclitaxel, cisplatin/pemetrexed, cisplatin/gemcitabine) as neoadjuvant treatment (given before main treatment) only
   b. Your cancer has NO known epidermal growth factor receptor (EGFR: a type of protein) mutations (abnormal change in a type of gene) or anaplastic lymphoma kinase (ALK: a type of enzyme) rearrangements (type of gene mutation); AND Opdivo will be used in combination with platinum-doublet chemotherapy (such as carboplatin/paclitaxel, cisplatin/pemetrexed, carboplatin/pemetrexed, cisplatin/docetaxel) as neoadjuvant treatment (given before main treatment), OR as a single medication as adjuvant (add-on) treatment after surgery and prior use with platinum-doublet chemotherapy as neoadjuvant treatment

E. If you have metastatic non-small cell lung cancer, approval also requires:
1. You are 18 years of age or older
2. You meet ONE of the following:
   a. Your tumors have programmed death-ligand 1 (PD-L1: a type of protein [of at least 1 percent]) as determined by a Food and Drug Administration (FDA)-approved test; your tumor does NOT have epidermal growth factor receptor (EGFR: a type of protein) or anaplastic lymphoma kinase (ALK: a type of enzyme) genomic tumor aberrations (types of abnormal gene); AND Opdivo will be used in combination with Yervoy (ipilimumab)
   b. Your tumor does NOT have epidermal growth factor receptor (EGFR: a type of protein) or anaplastic lymphoma kinase (ALK: a type of enzyme) genomic tumor aberrations (types of abnormal gene); AND Opdivo will be used in combination with Yervoy (ipilimumab) and 2 cycles of platinum-doublet chemotherapy (a type of cancer treatment, such as carboplatin/pemetrexed, cisplatin/pemetrexed, carboplatin/paclitaxel)

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GUIDELINES FOR USE (CONTINUED)

c. Your disease has worsened while on or after platinum-based chemotherapy (a type of cancer treatment, such as cisplatin, carboplatin, oxaliplatin), and you meet ONE of the following:
   i. Your tumor does NOT have epidermal growth factor receptor (EGFR: type of protein) or anaplastic lymphoma kinase (ALK: type of enzyme) genomic tumor aberrations (types of abnormal gene)
   ii. Your tumor has an ALK mutation, and your disease has worsened after treatment with an FDA-approved ALK-directed therapy (such as Xalkori [crizotinib], Zykadia [ceritinib])
   iii. Your tumor has an EGFR mutation, and your disease has worsened after treatment with an FDA-approved EGFR-directed therapy (such as Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib])

F. If you have recurrent non-small cell lung cancer, approval also requires:
1. You are 18 years of age or older
2. Your tumor does NOT have epidermal growth factor receptor (EGFR: a type of protein) or anaplastic lymphoma kinase (ALK: a type of enzyme) genomic tumor aberrations (types of abnormal gene)
3. Opdivo will be used in combination with Yervoy (ipilimumab) AND 2 cycles of platinum-doublet chemotherapy (a type of cancer treatment, such as carboplatin/pemetrexed, cisplatin/pemetrexed, carboplatin/paclitaxel)

G. If you have unresectable malignant pleural mesothelioma, approval also requires:
1. You are 18 years of age or older
2. Opdivo will be used in combination with Yervoy (ipilimumab)

H. If you have advanced renal cell carcinoma, approval also requires:
1. You are 18 years of age or older
2. You meet ONE of the following:
   a. You have intermediate or poor risk disease AND Opdivo will used in combination with Yervoy (ipilimumab)
   b. Opdivo will be used in combination with Cabometyx (cabozantinib)
   c. You have received prior anti-angiogenic therapy (medication that stop tumors from growing their own blood vessels such as Sutent [sunitinib], Votrient [pazopanib], Cabometyx [cabozantinib])

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NIVOLUMAB (PART D)

GUIDELINES FOR USE (CONTINUED)

I. If you have classical Hodgkin lymphoma, approval also requires ONE of the following:
1. If your disease has been previously treated, you meet ALL of the following:
   a. You are 18 years of age or older
   b. Your disease has relapsed (returned) or worsened after receiving ONE of the following:
      i. Autologous hematopoietic stem cell transplantation (HSCT: a type of procedure to replace damaged bone marrow with your own healthy blood-forming cells) and Adcetris (brentuximab vedotin)
      ii. Three or more lines of systemic therapy (treatment that targets the entire body) that includes autologous hematopoietic stem cell transplantation (HSCT: a type of procedure to replace damaged bone marrow with your own healthy blood-forming cells)
2. If your disease has NOT been previously treated, you meet ALL of the following:
   a. You are 12 years of age or older
   b. Your disease is Stage III or IV
   c. Opdivo will be used in combination with doxorubicin, vinblastine, and dacarbazine (AVD)

J. If you have recurrent or metastatic squamous cell carcinoma of the head and neck, approval also requires:
1. You are 18 years of age or older
2. Your disease has worsened on or after treatment with a platinum-containing chemotherapy (a type of cancer treatment, such as cisplatin, carboplatin, oxaliplatin)

K. If you have urothelial carcinoma, approval also requires:
1. You are 18 years of age or older
2. Opdivo will be used as an adjuvant (add-on) treatment
3. You are at high risk of recurrence (disease returning) after undergoing radical resection (tumor removal) of urothelial carcinoma

L. If you have unresectable or metastatic urothelial carcinoma, approval also requires:
1. You are 18 years of age or older
2. You will be using Opdivo in combination with cisplatin and gemcitabine

M. If you have locally advanced or metastatic urothelial carcinoma, approval also requires:
1. You are 18 years of age or older
2. You meet ONE of the following:
   a. Your disease has worsened during or after platinum-containing chemotherapy (a type of cancer treatment, such as cisplatin, carboplatin, oxaliplatin)
   b. Your disease has worsened within 12 months of neoadjuvant (given before main treatment) or adjuvant (add-on) treatment with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)

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NIVOLUMAB (PART D)

GUIDELINES FOR USE (CONTINUED)

N. If you have colorectal cancer, approval also requires:
1. You are 12 years of age or older
2. Your cancer is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) (types of genetic abnormalities)
3. You meet ONE of the following:
   a. Your cancer is unresectable (cannot be removed by surgery); AND Opdivo will be used in combination with Yervoy (ipilimumab)
   b. Your cancer is metastatic (has spread to other parts of the body), and you meet ONE of the following:
      i. Opdivo will be used in combination with Yervoy (ipilimumab)
      ii. Opdivo will be used as a single medication; AND your disease has worsened after treatment with a fluoropyrimidine, oxaliplatin, and irinotecan

O. If you have unresectable or metastatic hepatocellular carcinoma, approval also requires:
1. You are 18 years of age or older
2. You meet ONE of the following:
   a. You will be using Opdivo in combination with Yervoy (ipilimumab) as first-line treatment
   b. You will be using Opdivo in combination with Yervoy (ipilimumab), AND you have been previously treated with Nexavar (sorafenib)

P. If you have completely resected esophageal or gastroesophageal junction cancer, approval also requires:
1. You are 18 years of age or older
2. Opdivo will be used as an adjuvant (add-on) treatment
3. You have a residual pathologic disease (disease is still present) and have received neoadjuvant chemoradiotherapy (CRT) (a type of cancer treatment given before surgery)

Q. If you have unresectable advanced, recurrent, or metastatic esophageal squamous cell carcinoma, approval also requires:
1. You are 18 years of age or older
2. You have previously received treatment with fluoropyrimidine and platinum-based chemotherapy (a type of cancer treatment, such as cisplatin, carboplatin, oxaliplatin)

R. If you have unresectable advanced or metastatic esophageal squamous cell carcinoma, approval also requires:
1. You are 18 years of age or older
2. You meet ONE of the following:
   a. You will be using Opdivo in combination with fluoropyrimidine and platinum-containing chemotherapy (a type of cancer treatment, such as cisplatin, carboplatin, oxaliplatin)
   b. You will be using Opdivo in combination with Yervoy (ipilimumab)

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NIVOLUMAB (PART D)

GUIDELINES FOR USE (CONTINUED)

S. If you have advanced or metastatic gastric cancer, gastroesophageal junction cancer, or esophageal adenocarcinoma, approval also requires:
1. You are 18 years of age or older
2. You will be using Opdivo in combination with fluoropyrimidine and platinum-containing chemotherapy (a type of cancer treatment, such as cisplatin, carboplatin, oxaliplatin)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Opdivo.

REFERENCES
Opdivo [Prescribing Information]. Princeton, NJ: Bristol-Myers Squibb Company; March 2026.

For Part D use only:

NIVOLUMAB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	UNRESECTABLE OR METASTATIC MELANOMA: NO CONCURRENT USE WITH TARGETED THERAPY (I.E., BRAF INHIBITORS, MEK INHIBITORS, AND NTRK INHIBITORS).

Created: 02/15
Effective: 05/09/26 Client Approval: 05/26 P&T Approval: 04/26

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NIVOLUMAB-HYALURONIDASE-NVHY BVD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NIVOLUMAB-HYALURONIDASE-NVHY	OPDIVO QVANTIG	50124		GPI-10 (2199000250)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	Yes	No	Yes	Yes	No	Yes	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #5.

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NIVOLUMAB-HYALURONIDASE-NVHY BVD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

If yes, **refer to plan. (The health plan makes the final payment determination decision)**

- **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enterany override).**
- **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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NIVOLUMAB-HYALURONIDASE-NVHY BVD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC) (ICD-10 Groups C64, C65) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has intermediate or poor risk disease, and Opdivo Qvantig will be used following treatment with intravenous Opdivo (nivolumab) and Yervoy (ipilimumab) combination therapy
   - Opdivo Qvantig will be used in combination with Cabometyx (cabozantinib)
   - The patient has received prior anti-angiogenic therapy (e.g., Sutent [sunitinib], Votrient [pazopanib])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient have a diagnosis of melanoma (ICD-10 Group C43) **AND** meet the following criterion?
   - The patient is 12 years of age or older

   If yes, continue to #4.
   If no, continue to #6.

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NIVOLUMAB-HYALURONIDASE-NVHY BVD (PART D)

GUIDELINES FOR USE (CONTINUED)

4. Is the patient's cancer unresectable or metastatic?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Is the patient's cancer stage IIB, IIC, III, or IV and the patient meets **ALL** of the following criteria?
   - The patient has undergone complete resection
   - Opdivo Qvantig will be used as an adjuvant treatment

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

6. Does the patient have a diagnosis of non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer is resectable (node positive or tumor is at least 4 cm)

   If yes, continue to #7.
   If no, continue to #9.

7. Will Opdivo Qvantig be used in combination with platinum-doublet chemotherapy (e.g., carboplatin/paclitaxel, cisplatin/pemetrexed, cisplatin/gemcitabine) as neoadjuvant treatment?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #8.

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NIVOLUMAB-HYALURONIDASE-NVHY BVD (PART D)

GUIDELINES FOR USE (CONTINUED)

8. Does the patient's cancer have no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements, and the patient meets **ONE** of the following criteria?
   - Opdivo Qvantig will be used in combination with platinum-doublet chemotherapy (e.g., carboplatin/paclitaxel, cisplatin/pemetrexed, carboplatin/pemetrexed, cisplatin/docetaxel) as neoadjuvant treatment
   - Opdivo Qvantig will be used as monotherapy as adjuvant treatment after surgical resection and prior use with platinum-doublet chemotherapy (e.g., carboplatin/paclitaxel, cisplatin/pemetrexed, carboplatin/pemetrexed, cisplatin/docetaxel) as neoadjuvant treatment

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

9. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has disease progression while on or after platinum-based chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

   If yes, continue to #10.
   If no, continue to #11.

10. Does the patient meet **ONE** of the following criteria?
    - The tumor does NOT have EGFR or ALK genomic aberrations
    - The tumor has an EGFR mutation, and the patient had disease progression following an FDA-approved EGFR-directed therapy (e.g., Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib])
    - The tumor has an ALK mutation, and the patient had disease progression following an FDA-approved ALK-directed therapy (e.g., Xalkori [crizotinib], Zykadia [ceritinib])

    If yes, **approve for 12 months by HICL or GPI-10.**
    APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

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NIVOLUMAB-HYALURONIDASE-NVHY BVD (PART D)

GUIDELINES FOR USE (CONTINUED)

11. Does the patient have a diagnosis of recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN) (ICD-10 Groups C44.42, C76.0, C00, C06, C09, C10, C32) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - The patient has disease progression while on or after treatment with a platinum-based chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

    If yes, **approve for 12 months by HICL or GPI-10.**
    APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

    If no, continue to #12.

12. Does the patient have a diagnosis of urothelial carcinoma (UC) (ICD-10 Groups C65, C66, C67, C68) **AND** meet the following criterion?
    - The patient is 18 years of age or older

    If yes, continue to #13.
    If no, continue to #16.

13. Is the patient at high risk of recurrence after undergoing radical resection of urothelial carcinoma **AND** meets the following criterion?
    - Opdivo Qvantig will be used as an adjuvant treatment

    If yes, **approve for 12 months by HICL or GPI-10.**
    APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

    If no, continue to #14.

14. Is the patient's cancer unresectable or metastatic **AND** the patient meets the following criterion?
    - Opdivo Qvantig will be used in combination with cisplatin and gemcitabine

    If yes, **approve for 12 months by HICL or GPI-10.**
    APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

    If no, continue to #15.

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NIVOLUMAB-HYALURONIDASE-NVHY BVD (PART D)

GUIDELINES FOR USE (CONTINUED)

15. Is the patient's cancer locally advanced or metastatic and the patient meets **ONE** of the following criteria?
    - The patient has disease progression during or following platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
    - The patient has disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

    If yes, **approve for 12 months by HICL or GPI-10.**
    APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

16. Does the patient have a diagnosis of colorectal cancer (CRC) (ICD-10 C19) and meet **ALL** of the following criteria?
    - The patient is 12 years of age or older
    - The patient's cancer is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)

    If yes, continue to #17.
    If no, continue to #19.

17. Is the patient's cancer metastatic and the patient meets **ONE** of the following criteria?
    - Opdivo Qvantig will be used following treatment with intravenous Opdivo (nivolumab) and Yervoy (ipilimumab) combination therapy
    - The patient has disease progression following treatment with a fluoropyrimidine (e.g., fluorouracil, capecitabine), oxaliplatin, and irinotecan

    If yes, **approve for 12 months by HICL or GPI-10.**
    APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

    If no, continue to #18.

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NIVOLUMAB-HYALURONIDASE-NVHY BVD (PART D)

GUIDELINES FOR USE (CONTINUED)

18. Is the patient's cancer unresectable **AND** the patient meets the following criterion?
    - Opdivo Qvantig will be used following treatment with intravenous Opdivo (nivolumab) and Yervoy (ipilimumab) combination therapy

    If yes, **approve for 12 months by HICL or GPI-10.**
    APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

19. Does the patient have a diagnosis of unresectable or metastatic hepatocellular carcinoma (HCC) (ICD-10 C22.0) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Opdivo Qvantig will be used following treatment with intravenous Opdivo (nivolumab) and Yervoy (ipilimumab) combination therapy

    If yes, **approve for 12 months by HICL or GPI-10.**
    APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

    If no, continue to #20.

20. Does the patient have a diagnosis of esophageal or gastroesophageal junction cancer (ICD-10 C16.0; Group C15) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - The patient has undergone complete resection
    - Opdivo Qvantig will be used as an adjuvant treatment
    - The patient has a residual pathologic disease
    - The patient has received neoadjuvant chemoradiotherapy (CRT)

    If yes, **approve for 12 months by HICL or GPI-10.**
    APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

    If no, continue to #21.

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NIVOLUMAB-HYALURONIDASE-NVHY BVD (PART D)

GUIDELINES FOR USE (CONTINUED)

21. Does the patient have a diagnosis of esophageal squamous cell carcinoma (ESCC) (ICD-10 Group C15) **AND** meet the following criterion?
    - The patient is 18 years of age or older

    If yes, continue to #22.
    If no, continue to #24.

22. Is the patient's cancer unresectable advanced or metastatic and the patient meets **ALL** of the following criteria?
    - Opdivo Qvantig will be used in combination with fluoropyrimidine- (e.g., fluorouracil, capecitabine) and platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
    - The patient's tumors express PD-L1 (at least 1%)

    If yes, **approve for 12 months by HICL or GPI-10.**
    APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

    If no, continue to #23.

23. Is the patient's cancer unresectable advanced, recurrent or metastatic **AND** the patient meets the following criterion?
    - The patient has received prior fluoropyrimidine- (e.g., fluorouracil, capecitabine) and platinum-based chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

    If yes, **approve for 12 months by HICL or GPI-10.**
    APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

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NIVOLUMAB-HYALURONIDASE-NVHY BVD (PART D)

GUIDELINES FOR USE (CONTINUED)

24. Does the patient have a diagnosis of advanced or metastatic gastric cancer, gastroesophageal junction cancer, or esophageal adenocarcinoma (ICD-10 Groups C15, C16) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Opdivo Qvantig will be used in combination with fluoropyrimidine- (e.g., fluorouracil, capecitabine) and platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
    - The patient's tumors express PD-L1 (at least 1%)

    If yes, **approve for 12 months by HICL or GPI-10.**
    APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

    If no, do not approve.

    DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

    Our guideline named **NIVOLUMAB-HYALURONIDASE-NVHY (Opdivo Qvantig)** requires the following rule(s) be met for approval:

    A. You have ONE of the following:
        1. Advanced renal cell carcinoma (RCC) (a type of kidney cancer)
        2. Melanoma (a type of skin cancer)
        3. Non-small cell lung cancer (NSCLC) (a type of lung cancer)
        4. Metastatic non-small cell lung cancer (NSCLC) (a type of lung cancer that has spread to other parts of the body)
        5. Recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN) (a type of head/neck cancer that has returned or has spread to other parts of the body)
        6. Urothelial carcinoma (UC: urinary system cancer)
        7. Colorectal cancer (CRC) (a type of digestive cancer)
        8. Unresectable or metastatic hepatocellular carcinoma (HCC: a type of liver cancer that cannot be completely removed with surgery or has spread to other parts of the body)
        9. Esophageal or gastroesophageal junction cancer (types of digestive system cancer)
        10. Esophageal squamous cell carcinoma (ESCC) (a type of digestive system cancer)
        11. Advanced or metastatic gastric cancer, gastroesophageal junction cancer, or esophageal adenocarcinoma (types of digestive system cancer that has spread to other parts of the body)

    (Denial text continued on the next page)

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NIVOLUMAB-HYALURONIDASE-NVHY BVD (PART D)

GUIDELINES FOR USE (CONTINUED)

B. If you have advanced renal cell carcinoma, approval also requires:
1. You are 18 years of age or older
2. You meet ONE of the following:
   a. You have intermediate or poor risk disease, and Opdivo Qvantig will be used following treatment with intravenous (injection into the vein) Opdivo (nivolumab) and Yervoy (ipilimumab) combination therapy
   b. Opdivo Qvantig will be used in combination with Cabometyx (cabozantinib)
   c. You have received prior anti-angiogenic therapy (a type of medication that stops tumors from growing new blood vessels, such as Sutent [sunitinib], Votrient [pazopanib])

C. If you have melanoma, approval also requires:
1. You are 12 years of age or older
2. You meet ONE of the following:
   a. Your cancer is unresectable (cannot be removed by surgery) or metastatic (has spread to other parts of the body)
   b. Your cancer is stage IIB, IIC, III, or IV; you have undergone complete resection (removal by surgery); and Opdivo Qvantig will be used as an adjuvant (add-on) treatment

D. If you have non-small cell lung cancer, approval also requires:
1. You are 18 years of age or older
2. Your cancer is resectable (node positive or tumor is at least 4 cm) (can be removed by surgery)
3. You meet ONE of the following:
   a. Opdivo Qvantig will be used in combination with platinum-doublet chemotherapy (a type of cancer treatment, such as carboplatin/paclitaxel, cisplatin/pemetrexed, cisplatin/gemcitabine) as neoadjuvant treatment (given before main treatment)
   b. Your cancer has no known epidermal growth factor receptor (EGFR: a type of protein) mutations (abnormal change in a type of gene) or anaplastic lymphoma kinase (ALK: a type of enzyme) rearrangements (type of gene mutation), and you meet ONE of the following:
      i. Opdivo Qvantig will be used in combination with platinum-doublet chemotherapy (such as carboplatin/paclitaxel, cisplatin/pemetrexed, carboplatin/pemetrexed, cisplatin/docetaxel) as neoadjuvant treatment (given before main treatment)
      ii. Opdivo Qvantig will be used alone as adjuvant (add-on) treatment after surgical resection (removal by surgery) and prior use with platinum-doublet chemotherapy (such as carboplatin/paclitaxel, cisplatin/pemetrexed, carboplatin/pemetrexed, cisplatin/docetaxel) as neoadjuvant treatment (given before main treatment)

(Denial text continued on the next page)

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GUIDELINES FOR USE (CONTINUED)

E. If you have metastatic non-small cell lung cancer, approval also requires:
1. You are 18 years of age or older
2. Your disease has worsened while on or after platinum-based chemotherapy (a type of cancer treatment, such as cisplatin, carboplatin, oxaliplatin), and you meet ONE of the following:
   a. Your tumor does NOT have epidermal growth factor receptor (EGFR: type of protein) or anaplastic lymphoma kinase (ALK: type of enzyme) genomic aberrations (types of abnormal gene)
   b. Your tumor has an epidermal growth factor receptor (EGFR: type of protein) mutation (abnormal change in a type of gene), and your disease has worsened after treatment with a Food and Drug Administration (FDA)-approved EGFR-directed therapy (such as Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib])
   c. Your tumor has an anaplastic lymphoma kinase (ALK: type of enzyme) mutation (abnormal change in a type of gene), and your disease has worsened after treatment with a Food and Drug Administration (FDA)-approved ALK-directed therapy (such as Xalkori [crizotinib], Zykadia [ceritinib])

F. If you have recurrent or metastatic squamous cell carcinoma of the head and neck, approval also requires:
1. You are 18 years of age or older
2. Your disease has worsened while on or after treatment with a platinum-based chemotherapy (a type of cancer treatment, such as cisplatin, carboplatin, oxaliplatin)

G. If you have urothelial carcinoma, approval also requires:
1. You are 18 years of age or older
2. You meet ONE of the following:
   a. You are at high risk of recurrence (disease returning) after undergoing radical resection (tumor removal) of urothelial carcinoma (UC: urinary system cancer), and Opdivo Qvantig will be used as an adjuvant (add-on) treatment
   b. Your cancer is unresectable (cannot be removed by surgery) or metastatic (has spread to other parts of the body), and Opdivo Qvantig will be used in combination with cisplatin and gemcitabine
   c. Your cancer is locally advanced (has spread to nearby tissue or lymph nodes) or metastatic (has spread to other parts of the body), and you meet ONE of the following:
      i. Your disease has worsened during or following platinum-containing chemotherapy (a type of cancer treatment, such as cisplatin, carboplatin, oxaliplatin)
      ii. Your disease has worsened within 12 months of neoadjuvant (given before main treatment) or adjuvant (add-on) treatment with platinum-containing chemotherapy (a type of cancer treatment, such as cisplatin, carboplatin, oxaliplatin)

(Denial text continued on the next page)

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NIVOLUMAB-HYALURONIDASE-NVHY BVD (PART D)

GUIDELINES FOR USE (CONTINUED)

H. If you have colorectal cancer, approval also requires:
1. You are 12 years of age or older
2. Your cancer is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) (types of genetic abnormalities)
3. You meet ONE of the following:
   a. You have metastatic cancer (cancer that has spread to other parts of the body) and meet ONE of the following:
      i. Opdivo Qvantig will be used following treatment with intravenous (injection into the vein) Opdivo (nivolumab) and Yervoy (ipilimumab) combination therapy
      ii. Your disease has worsened after treatment with a fluoropyrimidine (a type of cancer treatment, such as fluorouracil, capecitabine), oxaliplatin, and irinotecan
   b. You have unresectable (cannot be removed by surgery) cancer and Opdivo Qvantig will be used following treatment with intravenous (injection into the vein) Opdivo (nivolumab) and Yervoy (ipilimumab) combination therapy

I. If you have unresectable or metastatic hepatocellular carcinoma, approval also requires:
1. You are 18 years of age or older
2. Opdivo Qvantig will be used following treatment with intravenous (injection into the vein) Opdivo (nivolumab) and Yervoy (ipilimumab) combination therapy

J. If you have esophageal or gastroesophageal junction cancer, approval also requires:
1. You are 18 years of age or older
2. You have undergone complete resection (removal by surgery)
3. Opdivo Qvantig will be used as an adjuvant (add-on) treatment
4. You have a residual pathologic disease (disease is still present)
5. You have received neoadjuvant chemoradiotherapy (CRT) (a type of cancer treatment given before surgery)

(Denial text continued on the next page)

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NIVOLUMAB-HYALURONIDASE-NVHY BVD (PART D)

GUIDELINES FOR USE (CONTINUED)

K. If you have esophageal squamous cell carcinoma, approval also requires:
1. You are 18 years of age or older
2. You meet ONE of the following:
   a. Your cancer is unresectable (cannot be removed by surgery) advanced or metastatic (has spread to other parts of the body); Opdivo Qvantig will be used in combination with fluoropyrimidine- (a type of cancer treatment, such as fluorouracil, capecitabine) and platinum-containing chemotherapy (a type of cancer treatment, such as cisplatin, carboplatin, oxaliplatin); AND your tumor expresses programmed death-ligand 1 (PD-L1: type of protein) (at least 1%)
   b. Your cancer is unresectable (cannot be removed by surgery) advanced, recurrent (has returned) or metastatic (has spread to other parts of the body), and you have previously received treatment with fluoropyrimidine- (a type of cancer treatment, such as fluorouracil, capecitabine) and platinum-based chemotherapy (a type of cancer treatment, such as cisplatin, carboplatin, oxaliplatin)

L. If you have advanced or metastatic gastric cancer, gastroesophageal junction cancer, or esophageal adenocarcinoma, approval also requires:
1. You are 18 years of age or older
2. Opdivo Qvantig will be used in combination with fluoropyrimidine- (a type of cancer treatment, such as fluorouracil, capecitabine) and platinum-containing chemotherapy (a type of cancer treatment, such as cisplatin, carboplatin, oxaliplatin)
3. Your tumor expresses programmed death-ligand 1 (PD-L1: type of protein) (at least 1%)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Opdivo Qvantig.
The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Opdivo Qvantig [Prescribing Information]. Princeton, NJ: Bristol-Myers Squibb; November 2025.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed January 7, 2025].

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NIVOLUMAB-HYALURONIDASE-NVHY BVD (PART D)

For Part D use only:

NIVOLUMAB-HYALURONIDASE-NVHY (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 01/25
Effective: 01/01/26 Client Approval: 12/25 P&T Approval: 01/25

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NIVOLUMAB-RELATLIMAB-RMBW (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NIVOLUMAB-RELATLIMAB-RMBW	OPDUALAG	47910		GPI-10 (2199350250)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic melanoma (ICD-10 Group C43) **AND** meet the following criterion?
   - The patient is 12 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NIVOLUMAB-RELATLIMAB-RMBW (Opdualag)** requires the following rule(s) be met for approval:
   A. You have unresectable or metastatic melanoma (a type of skin cancer that is unable to be removed by surgery or has spread to other parts of the body)
   B. You are 12 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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NIVOLUMAB-RELATLIMAB-RMBW (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Opdualag.

REFERENCES

Opdualag [Prescribing Information]. Princeton, NJ: Bristol-Myers Squibb Company; March 2022.

For Part D use only:

NIVOLUMAB-RELATLIMAB-RMBW (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A
Quantity Limit (from Formulary ASCII file)	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Created: 03/22
Effective: 01/01/25 Client Approval: 08/24 P&T Approval: 04/22

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CORE, ADVANTAGE, PLUS OPEN, AND PLUS CLOSED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NOGAPENDEKIN ALFA (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NOGAPENDEKIN ALFA INBAKICEPT-PMLN	ANKTIVA	49543		GPI-10 (2170305565)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (ICD-10 D09.0 and Group C67) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer is unresponsive to Bacillus Calmette-Guérin (BCG)
   - Anktiva will be used in combination with Bacillus Calmette-Guérin (BCG)

   If yes, **approve for 40 months total by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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NOGAPENDEKIN ALFA (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **NOGAPENDEKIN ALFA (Anktiva)** requires the following rule(s) be met for approval:

A. You have non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (a type of early stage bladder cancer)
B. You are 18 years of age or older
C. Your cancer did not respond to treatment with Bacillus Calmette-Guérin (BCG: a type of bladder cancer treatment)
D. Anktiva will be used together with Bacillus Calmette-Guérin (BCG: a type of bladder cancer treatment)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Anktiva.

REFERENCES

Anktiva [Prescribing Information]. Culver City, CA: ImmunityBio, Inc.; April 2024.

For Part D use only:

NOGAPENDEKIN ALFA (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	40 MONTHS
Other Criteria	N/A

Part D Effective: 05/17/24
Commercial Effective: N/A
Created: 05/24
Client Approval: 05/24
P&T Approval: 07/24

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OBETICHOLIC ACID (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OBETICHOLIC ACID	OCALIVA	43438		GPI-10 (5275006000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of primary biliary cholangitis (PBC) (ICD-10 K74.3) as confirmed by at least **TWO** of the following criteria?
   - An elevated alkaline phosphatase (ALP)
   - The presence of antimitochondrial antibodies (AMA) OR other PBC-specific autoantibodies, including sp100 or gp210 if AMA is negative
   - Histologic evidence (obtained by liver biopsy) of non-suppurative destructive cholangitis and destruction of interlobular bile ducts

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist or hepatologist
   - The patient does NOT have complete biliary obstruction
   - Ocaliva will NOT be used concurrently with any other second-line PBC treatment (e.g., Iqirvo [elafibranor], Livdelzi [seladelpar])

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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OBETICHOLIC ACID (PART D)

INITIAL CRITERIA (CONTINUED)

3. Does the patient meet **ONE** of the following criteria?
   - Ocaliva will be used as monotherapy in a patient who is unable to tolerate ursodiol (ursodeoxycholic acid)
   - Ocaliva will be used in combination with ursodiol (ursodeoxycholic acid) in a patient who had an inadequate response to at least 1 year of treatment with ursodiol monotherapy

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient meet **ONE** of the following criteria?
   - The patient does not have cirrhosis
   - The patient has compensated cirrhosis with no evidence of portal hypertension

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OBETICHOLIC ACID (Ocaliva)** requires the following rule(s) be met for approval:
   A. You have primary biliary cholangitis (PBC: a type of immune system disorder that destroys the bile duct), as confirmed by TWO of the following criteria:
      1. You have an elevated alkaline phosphatase (ALP) level (a type of lab test)
      2. You have the presence of antimitochondrial antibodies (AMA: indicator of body attacking its own cells) or PBC-specific autoantibodies, including sp100 or gp210 if AMA is negative
      3. Histologic evidence (lab data obtained by liver biopsy [removal of cells or tissue from the liver for examination]) of non-suppurative destructive cholangitis (inflammation of the bile duct) and destruction of interlobular bile ducts
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions) or hepatologist (a type of liver doctor)

   (Initial denial text continued on next page)

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OBETICHOLIC ACID (PART D)

INITIAL CRITERIA (CONTINUED)

D. You do not have complete biliary obstruction (blockage of bile ducts)
E. You will NOT use Ocaliva concurrently (at the same time) with any other second-line therapy for PBC (such as Iqirvo [elafibranor], Livdelzi [seladelpar])
F. You meet ONE of the following:
    1. Ocaliva will be used as monotherapy (one-drug therapy) if you are unable to tolerate ursodiol (ursodeoxycholic acid)
    2. Ocaliva will be used in combination with ursodiol (ursodeoxycholic acid) if you had an inadequate response (drug did not work) to at least 1 year of treatment with ursodiol monotherapy (one-drug treatment)
G. You meet ONE of the following:
    1. You do not have cirrhosis (liver damage)
    2. You have compensated cirrhosis (a type of liver condition) with no evidence of portal hypertension (high blood pressure in the major vein that leads to the liver)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OBETICHOLIC ACID (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of primary biliary cholangitis (PBC) (ICD-10 K74.3) and meet **ALL** of the following criteria?
   - The patient has not developed complete biliary obstruction
   - The patient continues to benefit from the medication
   - Ocaliva will NOT be used concurrently with any other second-line PBC treatment (e.g., Iqirvo [elafibranor], Livdelzi [seladelpar])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OBETICHOLIC ACID (Ocaliva)** requires the following rule(s) be met for renewal:
   A. You have primary biliary cholangitis (PBC: a type of immune system disorder that destroys the bile duct)
   B. You have not developed complete biliary obstruction (blockage of bile ducts)
   C. You continue to benefit from the medication
   D. You will NOT use Ocaliva concurrently (at the same time) with any other second-line therapy for PBC (such as Iqirvo [elafibranor], Livdelzi [seladelpar])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ocaliva.

REFERENCES

Ocaliva [Prescribing Information]. New York, NY: Intercept Pharmaceuticals, Inc.; May 2022.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OBETICHOLIC ACID (PART D)

For Part D use only:

OBETICHOLIC ACID (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	PRIMARY BILIARY CHOLANGITIS (PBC): INITIAL: DIAGNOSIS CONFIRMED BY TWO OF THE FOLLOWING: 1) ELEVATED ALKALINE PHOSPHATASE, 2) PRESENCE OF ANTIMITOCHONDRIAL ANTIBODIES (AMA) OR PBC-SPECIFIC AUTOANTIBODIES, INCLUDING SP100 OR GP210 IF AMA IS NEGATIVE, OR 3) HISTOLOGIC EVIDENCE OF NON-SUPPURATIVE DESTRUCTIVE CHOLANGITIS AND DESTRUCTION OF INTERLOBULAR BILE DUCTS (BY LIVER BIOPSY).
Age Restrictions	N/A
Prescriber Restrictions	PBC: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST OR HEPATOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS
Other Criteria	PBC: INITIAL: 1) DOES NOT HAVE COMPLETE BILIARY OBSTRUCTION, 2) NO CONCURRENT USE WITHANY OTHER SECOND-LINE PBC TREATMENT (E.G., IQIRVO, LIVDELZI), AND 3) ONE OF THE FOLLOWING: (A) USED AS MONOTHERAPY IF UNABLE TO TOLERATE URSODIOL, OR (B) USED IN COMBINATION WITH URSODIOL IF INADEQUATE RESPONSE TO AT LEAST 1 YEAR OF TREATMENT WITH URSODIOL MONOTHERAPY. RENEWAL: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, 2) DOES NOT HAVE COMPLETE BILIARY OBSTRUCTION, AND 3) NO CONCURRENT USE WITH ANY OTHER SECOND-LINE PBC TREATMENT (E.G., IQIRVO, LIVDELZI).

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OBINUTUZUMAB BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OBINUTUZUMAB	GAZYVA	40703		GPI-10 (2135184300)	

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #5.

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OBINUTUZUMAB BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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OBINUTUZUMAB BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic lymphocytic leukemia (CLL) (ICD-10 Group C91.1) and meet **ALL** of the following criteria?
   - The patient has not received previous treatment for CLL
   - Gazyva will be used in combination with Leukeran (chlorambucil)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of follicular lymphoma (FL) (ICD-10 Group C82)?

   If yes, continue to #3.
   If no, continue to #5.

3. Does the patient meet **ALL** of the following criteria?
   - The patient has relapsed after, or is refractory to, a regimen containing rituximab
   - Gazyva will be used in combination with bendamustine for the initial six cycles OR as monotherapy thereafter

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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OBINUTUZUMAB BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

4. Is the patient's cancer stage II bulky, III or IV and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has NOT received previous treatment for stage II bulky, III or IV follicular lymphoma
   - Gazyva will be used in combination with chemotherapy for the initial six or eight cycles [e.g., bendamustine; CHOP (cyclophosphamide, daunorubicin, vincristine, prednisone or prednisolone); CVP (cyclophosphamide, vincristine, prednisone or prednisolone)] OR as monotherapy thereafter

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Will Gazyva be used as a pretreatment prior to initiating Columvi (glofitamab-gxbm)?

   If yes, **approve by HICL or GPI-10 for 1 fill.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #6.

6. Does the patient have a diagnosis of lupus nephritis (LN) (ICD-10 M32.14) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is receiving standard therapy (e.g., mycophenolate mofetil and corticosteroids)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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OBINUTUZUMAB BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OBINUTUZUMAB (Gazyva)** requires the following rule(s) to be met for approval:

A. The request is for ONE of the following:
   1. Chronic lymphocytic leukemia (CLL: a type of blood cancer)
   2. Follicular lymphoma (FL: a type of blood cancer)
   3. Use as a pretreatment prior to initiating Columvi (glofitamab-gxbm)
   4. Lupus nephritis (a type of immune condition that affects the kidneys)

B. If you have chronic lymphocytic leukemia, approval also requires:
   1. You have NOT received previous treatment for chronic lymphocytic leukemia
   2. Gazyva will be used in combination with Leukeran (chlorambucil)

C. If you have follicular lymphoma, approval also requires ONE of the following:
   1. You have relapsed (symptoms returned) after, or are refractory (not responding) to, a regimen containing rituximab; AND Gazyva will be used in combination with bendamustine for the initial six cycles or as monotherapy (one drug treatment) thereafter
   2. Your cancer is stage II bulky, III, or IV; you are 18 years of age or older; you have NOT received previous treatment for stage II bulky, III or IV follicular lymphoma; AND Gazyva will be used in combination with chemotherapy (such as bendamustine; CHOP [cyclophosphamide, daunorubicin, vincristine, prednisone or prednisolone]; CVP [cyclophosphamide, vincristine, prednisone or prednisolone]) for the initial six or eight cycles, or as monotherapy (the only drug used in treatment) thereafter

D. If you have lupus nephritis, approval also requires:
   1. You are 18 years of age or older
   2. You are receiving standard therapy (such as mycophenolate mofetil and corticosteroids)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OBINUTUZUMAB BvD (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Gazyva. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Gazyva [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; October 2025.
Columvi [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; June 2025.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed June 27, 2024].

For Part D use only:

OBINUTUZUMAB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	CLL, FL: 6 MONTHS. LUPUS NEPHRITIS: 12 MONTHS.
Other Criteria	GAZYVA WILL BE APPROVED ONE TIME WHEN USED AS A PRETREATMENT PRIOR TO INITIATING COLUMVI.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OCRELIZUMAB BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OCRELIZUMAB	OCREVUS	44178		GPI-10 (6240506000)	

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, continue to #6.
   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, continue to #6.
   If no, continue to #5.

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

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OCRELIZUMAB BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

6. Is the drug administered via an implantable pump?

   If yes, **approve for a total of 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, continue to #7.

7. Is the drug administered using an external infusion pump?

   If yes, continue to #8.
   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

8. Is the drug specifically infused through an external infusion pump covered by Medicare?

   If yes, **approve for a total of 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OCRELIZUMAB BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of primary progressive multiple sclerosis (PPMS) (ICD-10 G35) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), to include clinically isolated syndrome, or active secondary progressive disease, and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of TWO agents indicated for the treatment of relapsing forms of MS (e.g., Tecfidera [dimethyl fumarate], Vumerity [diroximel fumarate])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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OCRELIZUMAB BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of relapsing-remitting multiple sclerosis (MS) (ICD-10 G35.A) and meet **ALL** of the following criteria?
   - The patient is 10 years of age or older
   - The patient had a trial of TWO agents indicated for the treatment of relapsing forms of MS (e.g., Gilenya (fingolimod), Tascenso ODT (fingolimod lauryl sulfate), Tecfidera [dimethyl fumarate], Vumerity [diroximel fumarate])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OCRELIZUMAB (Ocrevus)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Primary progressive multiple sclerosis (PPMS: a type of nerve disorder)
      2. A relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), or active secondary progressive disease (advanced disease)
      3. Relapsing-remitting multiple sclerosis (MS) (a type of nerve disorder that returns and goes away)

   B. If you have primary progressive multiple sclerosis, approval also requires:
      1. You are 18 years of age or older

   C. If you have a relapsing form of multiple sclerosis, approval also requires:
      1. You are 18 years of age or older
      2. You have tried TWO medications indicated for the treatment of relapsing forms of MS (such as Tecfidera [dimethyl fumarate], Vumerity [diroximel fumarate])

   D. **If you have relapsing-remitting multiple sclerosis, approval also requires**:
      1. You are 10 years of age or older
      2. You have tried TWO medications indicated for the treatment of relapsing forms of MS (such as Gilenya (fingolimod), Tascenso ODT (fingolimod lauryl sulfate), Tecfidera [dimethyl fumarate], Vumerity [diroximel fumarate])

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OCRELIZUMAB BvD (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ocrevus.

The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B. Drugs administered by an implantable pump are covered under Part B. Drugs administered via an external pump are covered under Part B if they are included under the local coverage policy of the applicable Medicare coverage policies (National and/or Local Coverage Policies). Drugs administered via an external pump that are not included under the applicable Medicare coverage policies are covered under Part D. A CMS website to assist with National and Local Coverage Determination for B versus D review is http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx.

REFERENCES

Ocrevus [Prescribing Information]. San Francisco, CA: Genentech, Inc.; May 2026.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed May 29, 2026].

For Part D use only:

OCRELIZUMAB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	RELAPSING FORM OF MULTIPLE SCLEROSIS (MS): TRIAL OF TWO AGENTS INDICATED FOR THE TREATMENT OF RELAPSING FORMS OF MS.

Created: 01/17
Effective: 06/10/26 Client Approval: 06/26 DMC Approval: 05/27/26

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OCRELIZUMAB-HYALURONIDASE-OCSQ BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OCRELIZUMAB-HYALURONIDASE-OCSQ	OCREVUS ZUNOVO	49868		GPI-10 (6240990260)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	Yes	No	Yes	Yes	No	Yes	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #5.

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OCRELIZUMAB-HYALURONIDASE-OCSQ BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override)**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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OCRELIZUMAB-HYALURONIDASE-OCSQ BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), to include clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease, and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of TWO agents indicated for the treatment of relapsing forms of MS (e.g., Tecfidera [dimethyl fumarate], Vumerity [diroximel fumarate])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of primary progressive multiple sclerosis (PPMS) (ICD-10 G35) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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OCRELIZUMAB-HYALURONIDASE-OCSQ BVD (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OCRELIZUMAB-HYALURONIDASE-OCSQ (Ocrevus Zunovo)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. A relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease returns and goes away), or active secondary progressive disease (advanced disease)
   2. Primary progressive multiple sclerosis (PPMS: a type of nerve disorder)

B. If you have a relapsing form of multiple sclerosis, approval also requires:
   1. You are 18 years of age or older
   2. You have tried TWO medications indicated for the treatment of relapsing forms of MS (such as Tecfidera [dimethyl fumarate], Vumerity [diroximel fumarate])

C. If you have primary progressive multiple sclerosis, approval also requires:
   1. You are 18 years of age or older

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ocrevus Zunovo.

The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Ocrevus Zunovo [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; September 2024.

Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed April 8, 2025].

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OCRELIZUMAB-HYALURONIDASE-OCSQ BVD (PART D)

For Part D use only:

OCRELIZUMAB-HYALURONIDASE-OCSQ (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	RELAPSING FORM OF MULTIPLE SCLEROSIS (MS): TRIAL OF TWO AGENTS INDICATED FOR THE TREATMENT OF RELAPSING FORMS OF MS.

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Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 10/24

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OCTREOTIDE - IM (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OCTREOTIDE ACETATE, MI-SPHERES	SANDOSTATIN LAR DEPOT, OCTREOTIDE ACETATE, MI-SPHERES	19000		GPI-14 (30170070106410, 30170070106420, 30170070106430)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of acromegaly (ICD-10 E22.0) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient had an inadequate response to surgery or radiotherapy, OR surgery or radiotherapy is not an option
   - The patient had a prior response to and tolerated subcutaneous octreotide injection for at least 2 weeks

   If yes, **approve for 12 months by HICL or GPI-14 for all strengths.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

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OCTREOTIDE - IM (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of severe diarrhea and flushing episodes (ICD-10 R19.7, R23.2) associated with metastatic carcinoid tumors (ICD-10 Groups C7B.0, C7A.0, D3A.0) **AND** meet the following criterion?
   - The patient had a prior response to and tolerated subcutaneous octreotide injection for at least 2 weeks

   If yes, **approve for 2 months by HICL or GPI-14 for all strengths.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Does the patient have a diagnosis of profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors (VIPomas) (ICD-10 C25.4) **AND** meet the following criterion?
   - The patient had a prior response to and tolerated subcutaneous octreotide injection for at least 2 weeks

   If yes, **approve for 2 months by HICL or GPI-14 for all strengths.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OCTREOTIDE - IM (Sandostatin LAR Depot)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Acromegaly (a type of hormone disorder)
      2. Severe diarrhea and flushing episodes associated with metastatic carcinoid tumors (a type of slow growing cancer that has spread to other parts of the body)
      3. Profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors (a type of cancer that starts from hormone producing cells)

   (Initial denial text continued on next page)

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OCTREOTIDE - IM (PART D)

INITIAL CRITERIA (CONTINUED)

B. If you have acromegaly, approval also requires:
1. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
2. You had an inadequate response (did not work) to surgery or radiotherapy (another type of cancer treatment), OR surgery or radiotherapy is not an option for you
3. You had a prior response to and tolerated subcutaneous (under the skin) octreotide injection for at least 2 weeks

C. If you have severe diarrhea and flushing episodes associated with metastatic carcinoid tumors, approval also requires:
1. You had a prior response to and tolerated subcutaneous (under the skin) octreotide injection for at least 2 weeks

D. If you have profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors, approval also requires:
1. You had a prior response to and tolerated subcutaneous (under the skin) octreotide injection for at least 2 weeks

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OCTREOTIDE - IM (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of acromegaly (ICD-10 E22.0) and meet **ALL** of the following criteria?
   - The patient has had a reduction, normalization, or maintenance of IGF-1 levels based on age and gender
   - The patient has shown improvement or sustained remission of clinical symptoms of acromegaly

   If yes, **approve for 12 months by HICL or GPI-14 for all strengths.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of severe diarrhea and flushing episodes (ICD-10 R19.7, R23.2) associated with metastatic carcinoid tumors (ICD-10 Groups C7B.0, C7A.0, D3A.0), OR profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors (VIPomas) (ICD-10 C25.4) **AND** meet the following criterion?
   - The patient has shown improvement or sustained remission of clinical symptoms

   If yes, **approve for 12 months by HICL or GPI-14 for all strengths.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OCTREOTIDE - IM (Sandostatin LAR Depot)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Acromegaly (a type of hormone disorder)
      2. Severe diarrhea and flushing episodes associated with metastatic carcinoid tumors (a type of slow growing cancer that has spread to other parts of the body)
      3. Profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors (a type of cancer that starts from hormone producing cells)

   (Renewal denial text continued on next page)

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OCTREOTIDE - IM (PART D)

RENEWAL CRITERIA (CONTINUED)

B. If you have acromegaly, renewal also requires:
1. You have had a reduction, normalization, or maintenance of insulin-like growth factor 1 (IGF-1: a type of hormone) levels based on your age and gender
2. You have shown improvement or sustained remission (symptoms have gone away) of clinical symptoms of acromegaly

C. If you have severe diarrhea and flushing episodes associated with metastatic carcinoid tumors OR profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors, renewal also requires:
1. You have shown improvement or sustained remission (symptoms have gone away) of clinical symptoms

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sandostatin LAR Depot.

REFERENCES

Sandostatin LAR Depot [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2024.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OCTREOTIDE - IM (PART D)

For Part D use only:

OCTREOTIDE - IM (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: ACROMEGALY: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST.
Coverage Duration	INITIAL: ACROMEGALY: 12 MOS, CARCINOID TUMORS, VIPOMAS: 2 MOS. RENEWAL (ALL): 12 MOS.
Other Criteria	INITIAL: ACROMEGALY, METASTATIC CARCINOID TUMORS, VASOACTIVE INTESTINAL PEPTIDE SECRETING TUMORS (VIPOMAS): PRIOR RESPONSE TO AND TOLERATED SQ OCTREOTIDE INJECTION FOR AT LEAST TWO WEEKS. RENEWAL: ACROMEGALY: 1) REDUCTION, NORMALIZATION, OR MAINTENANCE OF IGF-1 LEVELS BASED ON AGE AND GENDER, AND 2) IMPROVEMENT OR SUSTAINED REMISSION OF CLINICAL SYMPTOMS. METASTATIC CARCINOID TUMORS, VIPOMAS: IMPROVEMENT OR SUSTAINED REMISSION OF CLINICAL SYMPTOMS.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OCTREOTIDE - ORAL (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OCTREOTIDE ACETATE	MYCAPSSA	02826		GPI-14 (30170070106520)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of acromegaly (ICD-10 E22.0) and meet **ALL** of the following criteria?
   - The patient has responded to and tolerated treatment with octreotide or lanreotide
   - Therapy is prescribed by or in consultation with an endocrinologist

   If yes, **approve for 12 months by HICL or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text continued on next page.

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OCTREOTIDE - ORAL (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OCTREOTIDE - ORAL (Mycapssa)** requires the following rule(s) be met for approval:

A. You have acromegaly (a type of hormone disorder)
B. You have responded to and tolerated treatment with octreotide or lanreotide
C. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OCTREOTIDE - ORAL (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of acromegaly (ICD-10 E22.0) and meet **ALL** of the following criteria?
   - The patient had reduction, normalization, or maintenance of IGF-1 levels based on age and gender
   - The patient has shown improvement or sustained remission of clinical symptoms of acromegaly

   If yes, **approve for 12 months by HICL or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OCTREOTIDE - ORAL (Mycapssa)** requires the following rule(s) be met for renewal:
   A. You have acromegaly (a type of hormone disorder)
   B. You have had reduction, normalization, or maintenance of insulin-like growth factor 1 (IGF-1: a type of hormone) levels based on your age and gender
   C. You have shown improvement or sustained remission (symptoms have gone away) of clinical symptoms of acromegaly

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Mycapssa.

REFERENCES
Mycapssa [Prescribing Information]. Scotland, UK: MW Encap Ltd.; May 2022.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OCTREOTIDE - ORAL (PART D)

For Part D use only:

OCTREOTIDE - ORAL (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	ACROMEGALY: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	ACROMEGALY: RENEWAL: 1) REDUCTION, NORMALIZATION, OR MAINTENANCE OF IGF-1 LEVELS BASED ON AGE AND GENDER, AND 2) IMPROVEMENT OR SUSTAINED REMISSION OF CLINICAL SYMPTOMS.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ODEVIXIBAT (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ODEVIXIBAT	BYLVAY	47501		GPI-10 (5235006000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pruritus associated with progressive familial intrahepatic cholestasis (PFIC) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hepatologist, gastroenterologist, or physician who specializes in PFIC cholestasis
   - Bylvay will NOT be used concurrently with another IBAT inhibitor (e.g., Livmarli [maralixibat])

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient is 3 months to 11 months of age
   - The patient is 12 months of age or older AND had a trial of or contraindication to the preferred agent: Livmarli (maralixibat)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ODEVIXIBAT (PART D)

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of cholestatic pruritus associated with Alagille syndrome (ALGS) (ICD-10 Q44.71) and meet **ALL** of the following criteria?
   - The patient is 12 months of age or older
   - Therapy is prescribed by or in consultation with a hepatologist, gastroenterologist, or physician who specializes in ALGS cholestasis
   - Bylvay will NOT be used concurrently with another IBAT inhibitor (e.g., Livmarli [maralixibat])
   - The patient had a trial of or contraindication to the preferred agent: Livmarli (maralixibat)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ODEVIXIBAT (Bylvay)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Pruritus (itching) associated with progressive familial intrahepatic cholestasis (PFIC: a type of genetic disorder)
      2. Cholestatic pruritus (itching caused by liver disease) associated with Alagille syndrome (ALGS: a type of genetic disorder)

   B. If you have pruritus associated with progressive familial intrahepatic cholestasis, approval also requires:
      1. Therapy is prescribed by or in consultation with a hepatologist (a type of liver doctor), gastroenterologist (doctor who treats digestive conditions), or physician (doctor) who specializes in PFIC cholestasis
      2. You will NOT use Bylvay concurrently (at the same time) with another ileal bile acid transporter (IBAT) inhibitor (such as Livmarli [maralixibat])
      3. You meet ONE of the following:
         a. You are 3 months to 11 months of age
         b. You are 12 months of age or older AND have tried or have a contraindication to (harmful for you to use) the preferred medication: Livmarli (maralixibat)

   (Initial denial text continued on next page)

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ODEVIXIBAT (PART D)

INITIAL CRITERIA (CONTINUED)

C. If you have cholestatic pruritus associated with Alagille syndrome, approval also requires:

1. You are 12 months of age or older
2. Therapy is prescribed by or in consultation with a hepatologist (a type of liver doctor), gastroenterologist (doctor who treats digestive conditions), or physician (doctor) who specializes in PFIC cholestasis
3. You will NOT use Bylvay concurrently (at the same time) with another ileal bile acid transporter (IBAT) inhibitor (such as Livmarli [maralixibat])
4. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Livmarli (maralixibat)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ODEVIXIBAT (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pruritus associated with progressive familial intrahepatic cholestasis (PFIC) and meet **ALL** of the following criteria?
   - The patient has shown a clinical response to therapy, defined as improvement in pruritis symptoms AND a reduction of serum bile acid from baseline
   - The patient does NOT have PFIC type 2 with specific ABCB11 variants that would result in nonfunctional, or the complete absence of, bile salt export pump (BSEP) protein
   - Bylvay will NOT be used concurrently with another IBAT inhibitor (e.g., Livmarli [maralixibat])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of cholestatic pruritus associated with Alagille syndrome (ALGS) (ICD-10 Q44.71) and meet **ALL** of the following criteria?
   - The patient has shown a clinical response to therapy, defined as improvement in pruritis symptoms AND a reduction of serum bile acid from baseline
   - Bylvay will NOT be used concurrently with another IBAT inhibitor (e.g., Livmarli [maralixibat])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ODEVIXIBAT (Bylvay)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Pruritus (itching) associated with progressive familial intrahepatic cholestasis (PFIC: a type of genetic disorder)
      2. Cholestatic pruritus (itching caused by liver disease) associated with Alagille syndrome (ALGS: a type of genetic disorder)

   (Renewal denial text continued on next page)

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ODEVIXIBAT (PART D)

RENEWAL CRITERIA (CONTINUED)

B. If you have pruritus associated with progressive familial intrahepatic cholestasis, renewal also requires:
1. You have shown a clinical response to therapy defined as improvement in pruritis (itching) symptoms AND a reduction of serum (blood) bile acid from baseline
2. You do NOT have PFIC type 2 with specific ABCB11 variants (a type of abnormal gene) that would result in nonfunctional (does not work), or the complete absence of, bile salt export pump (BSEP: a type of protein)
3. You will NOT use Bylvay concurrently (at the same time) with another ileal bile acid transporter (IBAT) inhibitor (such as Livmarli [maralixibat])

C. If you have cholestatic pruritus associated with Alagille syndrome, renewal also requires:
1. You have shown a clinical response to therapy defined as improvement in pruritis (itching) symptoms AND a reduction of serum (blood) bile acid from baseline
2. You will NOT use Bylvay concurrently (at the same time) with another ileal bile acid transporter (IBAT) inhibitor (such as Livmarli [maralixibat])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Bylvay.

REFERENCES
Bylvay [Prescribing Information]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.; February 2024.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ODEVIXIBAT (PART D)

For Part D use only:

ODEVIXIBAT (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: PROGRESSIVE FAMILIAL INTRAHEPATIC CHOLESTASIS (PFIC): PRESCRIBED BY OR IN CONSULTATION WITH A HEPATOLOGIST, GASTROENTEROLOGIST, OR PHYSICIAN WHO SPECIALIZES IN PFIC CHOLESTASIS. ALAGILLE SYNDROME (ALGS): PRESCRIBED BY OR IN CONSULTATION WITH A HEPATOLOGIST, GASTROENTEROLOGIST, OR PHYSICIAN WHO SPECIALIZES IN ALGS CHOLESTASIS.
Coverage Duration	INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS
Other Criteria	INITIAL: PFIC: 1) NO CONCURRENT USE WITH ANOTHER ILEAL BILE ACID TRANSPORTER (IBAT) INHIBITOR, AND 2) TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT, WHERE AGES ALIGN: LIVMARLI. ALGS: 1) NO CONCURRENT USE WITH ANOTHER IBAT INHIBITOR, AND 2) TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT: LIVMARLI. RENEWAL: PFIC: 1) CLINICAL RESPONSE TO THERAPY DEFINED AS IMPROVEMENT IN PRURITIS SYMPTOMS AND A REDUCTION OF SERUM BILE ACID FROM BASELINE, 2) DOES NOT HAVE PFIC TYPE 2 WITH SPECIFIC ABCB11 VARIANTS THAT WOULD RESULT IN NONFUNCTIONAL, OR THE COMPLETE ABSENCE OF, BILE SALT EXPORT PUMP (BSEP) PROTEIN, AND 3) NO CONCURRENT USE WITH ANOTHER IBAT INHIBITOR. ALGS: 1) CLINICAL RESPONSE TO THERAPY DEFINED AS IMPROVEMENT IN PRURITIS SYMPTOMS AND A REDUCTION OF SERUM BILE ACID FROM BASELINE, AND 2) NO CONCURRENT USE WITH ANOTHER IBAT INHIBITOR.

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 08/21
Client Approval: 06/24
P&T Approval: 04/24

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OFATUMUMAB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OFATUMUMAB	ARZERRA		27827	GPI-10 (2135184500)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic lymphocytic leukemia (CLL) (ICD-10 Group C91.1)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the patient previously untreated for chronic lymphocytic leukemia (CLL) (ICD-10 Group C91.1), and meets **ALL** of the following criteria?
   - Fludara (fludarabine)-based therapy is considered inappropriate for this patient
   - Arzerra will be used in combination with Leukeran (chlorambucil)

   If yes, **approve for 12 months by GPID or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Is the request for the treatment of relapsed chronic lymphocytic leukemia (CLL) (ICD-10 Group C91.1), **AND** the patient meets the following criterion?
   - Arzerra will be used in combination with Fludara (fludarabine) and cyclophosphamide

   If yes, **approve for 6 months by GPID or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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OFATUMUMAB (PART D)

GUIDELINES FOR USE (CONTINUED)

4. Is the request for extended treatment of recurrent or progressive chronic lymphocytic leukemia (CLL) (ICD-10 Group C91.1) **AND** the patient meets the following criterion?
   - The patient is in complete or partial response after receiving at least two lines of therapy for chronic lymphocytic leukemia

   If yes, **approve for 12 months by GPID or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Is the request for the treatment of refractory chronic lymphocytic leukemia (CLL) (ICD-10 Group C91.1) **AND** the patient meets the following criterion?
   - The patient is refractory to Fludara (fludarabine) and Campath (alemtuzumab)

   If yes, **approve for 6 months by GPID or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OFATUMUMAB (Arzerra)** requires the following rule(s) be met for approval:
   A. You have chronic lymphocytic leukemia (CLL: type of blood cancer)
   B. If you have previously untreated chronic lymphocytic leukemia, approval also requires:
      1. You have not received previous treatment for chronic lymphocytic leukemia
      2. Fludara (fludarabine)-based therapy is considered inappropriate for you

      Arzerra will be used in combination with Leukeran (chlorambucil)
   C. If you have relapsed (disease has returned) chronic lymphocytic leukemia, approval also requires:
      1. Arzerra will be used in combination with Fludara (fludarabine) and cyclophosphamide
   D. If you are requesting extended treatment of recurrent or progressive chronic lymphocytic leukemia, approval also requires:
      1. You are in complete or partial response after receiving at least two lines of therapy for chronic lymphocytic leukemia

   (Denial text continued on next page)

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OFATUMUMAB (PART D)

GUIDELINES FOR USE (CONTINUED)

E. If you have refractory chronic lymphocytic leukemia, approval also requires:

1. You are refractory (non-responsive) to Fludara (fludarabine) and Campath (alemtuzumab)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Arzerra.

REFERENCES

Arzerra [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation. September 2019.

For Part D use only:

OFATUMUMAB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	PREVIOUSLY UNTREATED CLL, EXTENDED CLL TREATMENT: 12 MO. RELAPSED OR REFRACTORY CLL: 6 MO.
Other Criteria	N/A

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 11/09
Client Approval: 06/24
P&T Approval: 11/16

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ADVANTAGE AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OFATUMUMAB SQ (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OFATUMUMAB	KESIMPTA PEN		48513	GPI-10 (6240506500)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), including clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease, **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by GPID or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OFATUMUMAB SQ (Kesimpta)** requires the following rules be met for approval:
   A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease returns and goes away), or active secondary progressive disease (advanced disease)
   B. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OFATUMUMAB SQ (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kesimpta.

REFERENCES

Kesimpta [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2024.

For Part D use only:

OFATUMUMAB SQ (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 09/20
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 04/20

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OLAPARIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OLAPARIB	LYNPARZA	41642		GPI-10 (2153556000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of epithelial ovarian, fallopian tube or primary peritoneal cancer (ICD-10 Groups C56, C57.0, C48, C79.6) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, continue to #5.

2. Is the patient's cancer advanced and the patient meets **ALL** of the following criteria?
   - The patient is in complete or partial response to first-line platinum-based chemotherapy (e.g., paclitaxel, docetaxel, cisplatin, carboplatin)
   - The patient's diagnosis is confirmed by an FDA-approved companion diagnostic for Lynparza

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet **ONE** of the following criteria?
   - The patient's cancer has a deleterious or suspected deleterious germline or somatic BRCA mutation
   - The patient's cancer is associated with homologous recombination deficiency (HRD)-positive status as defined by either a deleterious or suspected deleterious BRCA mutation, and/or genomic instability, AND Lynparza will be used in combination with bevacizumab

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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OLAPARIB (PART D)

GUIDELINES FOR USE (CONTINUED)

4. Is the patient's cancer recurrent and the patient meets **ALL** of the following criteria?
   - The patient's cancer has a deleterious or suspected deleterious germline or somatic BRCA mutation, as confirmed by an FDA-approved companion diagnostic for Lynparza
   - The patient is in complete or partial response to platinum-based chemotherapy (e.g., paclitaxel, docetaxel, cisplatin, carboplatin)
   - Lynparza will be used as monotherapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Does the patient have a diagnosis breast cancer (ICD-10 Group C50) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer is HER2-negative
   - The patient's cancer has a deleterious or suspected deleterious germline BRCA mutation (gBRCAm), as confirmed by an FDA-approved companion diagnostic for Lynparza

   If yes, continue to #6.
   If no, continue to #9.

6. Is the patient's cancer high risk early breast cancer and the patient meets **ALL** of the following criteria?
   - Lynparza will be used as adjuvant treatment
   - The patient has been treated with neoadjuvant or adjuvant chemotherapy (e.g., doxorubicin, paclitaxel)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #7.

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OLAPARIB (PART D)

GUIDELINES FOR USE (CONTINUED)

7. Is the patient's cancer metastatic **AND** the patient meets the following criterion?
   - The patient has been treated with chemotherapy (e.g., doxorubicin, docetaxel) in the neoadjuvant, adjuvant, or metastatic setting

   If yes, continue to #8.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

8. Does the patient meet **ONE** of the following criteria?
   - The patient does not have hormone receptor (HR)-positive breast cancer
   - The patient has a hormone receptor (HR)-positive breast cancer and has been treated with a prior endocrine therapy or is considered inappropriate for endocrine therapy (e.g., tamoxifen, Arimidex [anastrozole])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

9. Does the patient have a diagnosis of metastatic pancreatic adenocarcinoma (ICD-10 Group C25) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer has a deleterious or suspected deleterious germline BRCA mutation (gBRCAm), as confirmed by an FDA-approved companion diagnostic for Lynparza
   - The patient's disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen (e.g., paclitaxel, docetaxel, cisplatin, carboplatin)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #10.

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OLAPARIB (PART D)

GUIDELINES FOR USE (CONTINUED)

10. Does the patient have a diagnosis of metastatic castration-resistant prostate cancer (mCRPC) (ICD-10 Z19.2, C61) **AND** meet the following criterion?
    - The patient is 18 years of age or older

    If yes, continue to #11.
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

11. Does the patient meet **BOTH** of the following criteria?
    - The patient's cancer has a deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutation, as confirmed by an FDA-approved companion diagnostic for Lynparza
    - The patient's disease has progressed following prior treatment with enzalutamide (Xtandi) or abiraterone (Yonsa, Zytiga)

    If yes, continue to #13.
    If no, continue to #12.

12. Does the patient meet **BOTH** of the following criteria?
    - Lynparza will be used in in combination with abiraterone (Yonsa, Zytiga) AND prednisone or prednisolone
    - The patient's cancer has a deleterious or suspected deleterious BRCA mutation (BRCAm), as confirmed by an FDA-approved companion diagnostic for Lynparza

    If yes, continue to #13.
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

13. Does the patient meet **ONE** of the following criteria?
    - The patient has received a bilateral orchiectomy
    - The patient has a castrate testosterone level (i.e., less than 50 ng/dL)
    - Lynparza will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog (e.g., Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

    If yes, **approve for 12 months by HICL or GPI-10.**
    APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

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OLAPARIB (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OLAPARIB (Lynparza)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer (types of reproductive system cancers)
   2. Breast cancer
   3. Metastatic pancreatic adenocarcinoma (a type of pancreas cancer that has spread to other parts of the body)
   4. Metastatic castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and does not respond to hormone therapy)

B. If you have epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:
   1. You are 18 years of age or older
   2. If your cancer is advanced, you must meet ALL of the following:
      a. You are in complete or partial response to first-line platinum-based chemotherapy (such as paclitaxel, docetaxel, cisplatin, carboplatin)
      b. Your diagnosis is confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
      c. Your cancer has a deleterious or suspected deleterious germline or somatic BRCA mutation (a type of gene mutation) or Your cancer is associated with a homologous recombination deficiency (HRD: type of gene mutation)-positive status as defined by either a deleterious or suspected deleterious BRCA mutation (type of gene mutation), and/or genomic instability (high rate of gene mutation), AND Lynparza will be used in combination with bevacizumab
   3. If your cancer is recurrent (returning), you must meet ALL of the following:
      a. Your cancer has a deleterious or suspected deleterious germline or somatic BRCA mutation (a type of gene mutation), as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
      b. You are in complete or partial response to your most recent platinum-based chemotherapy (such as paclitaxel, docetaxel, cisplatin, carboplatin)
      c. Lynparza will be used as monotherapy (used alone)

(Denial text continued on next page)

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OLAPARIB (PART D)

GUIDELINES FOR USE (CONTINUED)

C. If you have breast cancer, approval also requires:
1. You are 18 years of age or older
2. Your breast cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-negative
3. Your cancer has a deleterious or suspected deleterious germline BRCA mutation (gBRCAm: a type of gene mutation), as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
4. If you have high risk early breast cancer, you must meet ALL of the following:
   a. You have been treated with neoadjuvant or adjuvant chemotherapy (cancer treatment given before main treatment or as add-on therapy such as doxorubicin, paclitaxel)
   b. Lynparza will be used as adjuvant (add-on) treatment
5. If you have metastatic breast cancer (cancer that has spread to other parts of the body), you must meet ALL of the following:
   a. You have been treated with chemotherapy (such as doxorubicin, docetaxel) in the neoadjuvant (given before main treatment), adjuvant (add-on to main treatment), or metastatic setting (to treat disease that has spread to other parts of the body)
   b. You do not have hormone receptor (HR)-positive breast cancer OR you have hormone receptor (HR)-positive breast cancer and you have been treated with prior endocrine (hormone) therapy (such as tamoxifen, Arimidex [anastrozole]) or endocrine therapy is considered inappropriate for you

D. If you have metastatic pancreatic adenocarcinoma, approval also requires:
1. You are 18 years of age or older
2. Your cancer has a deleterious or suspected deleterious germline BRCA mutation (gBRCAm: a type of gene mutation), as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
3. Your disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen (such as paclitaxel, docetaxel, cisplatin, carboplatin)

(Denial text continued on next page)

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OLAPARIB (PART D)

GUIDELINES FOR USE (CONTINUED)

E. If you have metastatic castration-resistant prostate cancer, approval also requires:

1. You are 18 years of age or older
2. You meet ONE of the following:
   a. Your cancer has progressed following prior treatment with enzalutamide (Xtandi) or abiraterone (Yonsa or Zytiga) AND has a deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutation (type of mutation), as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
   b. Lynparza will be used in in combination with abiraterone (Yonsa or Zytiga) and with prednisone or prednisolone AND your cancer has a deleterious or suspected deleterious BRCA mutation (BRCAm: a type of gene mutation), as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
3. You meet ONE of the following:
   a. You have received a bilateral orchiectomy (surgical removal of both testicles)
   b. You have a castrate testosterone level (blood testosterone levels are less than 50 ng/dL)
   c. Lynparza will be used concurrently (at the same time) with a gonadotropin-releasing hormone (GnRH) analog (such as Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lynparza.

REFERENCES

Lynparza Tablets [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals; November 2023.

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OLAPARIB (PART D)

For Part D use only:

OLAPARIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	RECURRENT EPITHELIAL OVARIAN, FALLOPIAN TUBE OR PRIMARY PERITONEAL CANCER: MEDICATION WILL BE USED AS MONOTHERAPY. METASTATIC CASTRATION-RESISTANT PROSTATE CANCER: 1) RECEIVED A BILATERAL ORCHIECTOMY, 2) CASTRATE LEVEL OF TESTOSTERONE (I.E., LESS THAN 50 NG/DL), OR 3) CONCURRENT USE WITH A GONADOTROPIN RELEASING HORMONE (GNRH) ANALOG. ALL OTHER FDA APPROVED INDICATIONS ARE COVERED WITHOUT ADDITIONAL CRITERIA, EXCEPT THOSE CRITERIA IN THE FDA APPROVED LABEL.

Created: 12/14
Effective: 07/01/25 Client Approval: 05/25 P&T Approval: 10/23

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OLEZARSEN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OLEZARSEN SODIUM	TRYNGOLZA	50111		GPI-10 (3090626530)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of familial chylomicronemia syndrome (FCS) (ICD-10 E78.3) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Tryngolza will be used as an adjunct therapy to diet

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of severe hypertriglyceridemia (sHTG) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Tryngolza will be used as an adjunct therapy to diet
   - The patient has a baseline fasting triglyceride level of at least 500 mg/dL
   - The patient had a trial of or contraindication to TWO clinical standard of care triglyceride lowering therapies (e.g., Vascepa [icosapent ethyl], Lovaza [omega-3 acid ethyl esters], Lopid [gemfibrozil], fenofibrate, statin [e.g., atorvastatin, simvastatin, rosuvastatin])

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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OLEZARSEN (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: Our guideline named **OLEZARSEN (Tryngolza)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Familial chylomicronemia syndrome (FCS: a type of rare genetic condition)
   2. Severe hypertriglyceridemia (sHTG: high levels of fat in the blood)

B. If you have familial chylomicronemia syndrome, approval also requires:
   1. You are 18 years of age or older
   2. Tryngolza will be used as an adjunct (add-on) therapy to diet

C. If you have severe hypertriglyceridemia, approval also requires:
   1. You are 18 years of age or older
   2. Tryngolza will be used as an adjunct (add-on) therapy to diet
   3. You have a baseline (before treatment) fasting triglyceride (a type of lab test) level of at least 500 mg/dL
   4. You have tried or have a contraindication to (harmful for you to use) TWO clinical standard of care triglyceride (a type of fat) lowering therapies (such as Vascepa [icosapent ethyl], Lovaza [omega-3 acid ethyl esters], Lopid [gemfibrozil], fenofibrate, statin [such as atorvastatin, simvastatin, rosuvastatin])

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OLEZARSEN (PART D)

RENEWAL CRITERIA

NOTE: For the diagnosis of familial chylomicronemia syndrome (FCS), please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of severe hypertriglyceridemia (sHTG) **AND** meet the following criterion?
   - The patient has experienced a clinical benefit as demonstrated by a reduction in triglyceride levels or acute pancreatitis events

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: Our guideline named **OLEZARSEN (Tryngolza)** requires the following rule(s) be met for renewal:
   A. You have severe hypertriglyceridemia (sHTG): high levels of fat in the blood)
   B. You have experienced a clinical benefit as shown by a reduction (decrease) in triglyceride (a type of fat) levels or acute pancreatitis (short-term inflammation of the pancreas) events

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tryngolza.

REFERENCES

Tryngolza [Prescribing Information]. Carlsbad, CA: Ionis Pharmaceuticals Inc.; June 2026.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OLEZARSEN (PART D)

For Part D use only:

OLEZARSEN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	SEVERE HYPERTRIGLYCERIDEMIA (SHTG): INITIAL: BASELINE FASTING TRIGLYCERIDE LEVEL OF AT LEAST 500 MG/DL.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	FAMILIAL CHYLOMICRONEMIA SYNDROME (FCS): INITIAL: 12 MOS, SHTG: INITIAL/RENEWAL: 6 MOS/12 MOS.
Other Criteria	SHTG: INITIAL: TRIAL OF OR CONTRAINDICATION TO TWO CLINICAL STANDARD OF CARE TRIGLYCERIDE LOWERING THERAPIES, RENEWAL: CLINICAL BENEFIT AS DEMONSTRATED BY A REDUCTION IN TRIGLYCERIDE LEVELS OR ACUTE PANCREATITIS EVENTS.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OLIPUDASE ALFA-RPCP (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OLIPUDASE ALFA-RPCP	XENPOZYME	48267		GPI-10 (3090156030)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of acid sphingomyelinase deficiency (ASMD) (ICD-10 Group E75.24) and meet **ALL** of the following criteria?
   - The patient has non-central nervous system manifestations of ASMD
   - The patient has baseline alanine aminotransferase (ALT) and aspartate aminotransferase (AST) levels within 1 month of Xenpozyme initiation date

   If yes, **approve for lifetime by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OLIPUDASE ALFA-RPCP (Xenpozyme)** requires the following rule(s) be met for approval:
   A. You have acid sphingomyelinase deficiency (ASMD: a type of rare genetic disorder that affects the body's ability to break down fat)
   B. You have non-central nervous system manifestations (affected organs are not in the brain or spinal cord) of ASMD
   C. You have baseline alanine aminotransferase (ALT: a type of liver enzyme test) and aspartate aminotransferase (AST: a type of liver enzyme test) levels within 1 month of Xenpozyme start date

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OLIPUDASE ALFA-RPCP (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xenpozyme.

REFERENCES

Xenpozyme [Prescribing Information]. Cambridge, MA: Genzyme, Corp., August 2022.

For Part D use only:

OLIPUDASE ALFA-RPCP (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	ACID SPHINGOMYELINASE DEFICIENCY (ASMD): BASELINE ALANINE AMINOTRANSFERASE (ALT) AND ASPARTATE AMINOTRANSFERASE (AST) LEVELS WITHIN 1 MONTH OF XENPOZYME INITIATION DATE.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	LIFETIME
Other Criteria	N/A
Quantity Limit (from Formulary ASCII file)	N/A

Core	Advantage	Plus
No	No	Yes

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OLUTASIDENIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OLUTASIDENIB	REZLIDHIA	48490		GPI-10 (2153496000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory acute myeloid leukemia (AML) (ICD-10 C92.02, C92.00) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a susceptible isocitrate dehydrogenase-1 (IDH1) mutation, as detected by an FDA-approved test

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OLUTASIDENIB (Rezlidhia)** requires the following rule(s) be met for approval:
   A. You have relapsed or refractory acute myeloid leukemia (AML: a type of blood cancer that has returned or did not respond to treatment)
   B. You are 18 years of age or older
   C. You have a susceptible (can be treated with the drug) isocitrate dehydrogenase-1 (IDH1: a type of enzyme) mutation, as detected by a Food and Drug Administration (FDA)-approved test

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OLUTASIDENIB (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rezlidhia.

REFERENCES

Rezlidhia [Prescribing Information]. Greenville, NC: Forma Therapeutics, Inc., December 2022.

For Part D use only:

OLUTASIDENIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OMACETAXINE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OMACETAXINE MEPESUCCINATE	SYNRIBO	24243		GPI-10 (2170004010)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic or accelerated phase chronic myeloid leukemia (CML) (ICD-10 Group C92.2) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a resistance or intolerance to TWO or more tyrosine kinase inhibitors (e.g., Gleevec [imatinib], Sprycel [dasatinib], Tasigna [nilotinib], Bosulif [bosutinib], Iclusig [ponatinib])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OMACETAXINE (Synribo)** requires the following rule(s) be met for approval:
   A. You have chronic or accelerated phase chronic myeloid leukemia (type of blood cell cancer)
   B. You are 18 years of age or older
   C. You had a resistance or intolerance (side effect) to TWO or more tyrosine kinase inhibitors (such as Gleevec [imatinib], Sprycel [dasatinib], Tasigna [nilotinib], Bosulif [bosutinib], or Iclusig [ponatinib])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OMACETAXINE (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Synribo.

REFERENCES

Synribo [Prescribing Information]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; November 2020.

For Part D use only:

OMACETAXINE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OMADACYCLINE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OMADACYCLINE TOSYLATE	NUZYRA		45478	GPI-14 (04200050200320)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of community-acquired bacterial pneumonia (CABP) (ICD-10 J15.9) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's CABP infection is caused by any of the following susceptible microorganisms: *Streptococcus pneumoniae, Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae, Haemophilus parainfluenzae, Klebsiella pneumoniae, Legionella pneumophila, Mycoplasma pneumoniae,* or *Chlamydophila pneumoniae*

   If yes, continue to #2.
   If no, continue to #6.

2. Is the request for continuation of care from an inpatient setting?

   If yes, **approve for 1 month by HICL or GPI-10 for one fill.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Is therapy prescribed by or in consultation with an infectious disease (ID) specialist?

   If yes, **approve for 1 month by HICL or GPI-10 for one fill.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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OMADACYCLINE (PART D)

GUIDELINES FOR USE (CONTINUED)

4. Has an antimicrobial susceptibility test been performed that meets **ALL** of the following criteria?
   - The results from the infection site culture indicate pathogenic organism(s) with resistance to TWO standard of care agents for CABP (e.g., azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone)
   - The results from the infection site culture indicate pathogenic organism(s) with susceptibility to Nuzyra

   If yes, **approve for 1 month by HICL or GPI-10 for one fill.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Does the patient meet **ALL** of the following criteria?
   - Antimicrobial susceptibility results are unavailable
   - The patient had a trial of or contraindication to TWO standard of care agents for CABP (e.g., azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone)

   If yes, **approve for 1 month by HICL or GPI-10 for one fill.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

6. Does the patient have a diagnosis of an acute bacterial skin or skin structure infection (ABSSSI) (ICD-10 L02.9) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's ABSSSI infection is caused by any of the following susceptible microorganisms: *Staphylococcus aureus* (methicillin-susceptible and -resistant isolates), *Staphylococcus lugdunensis, Streptococcus pyogenes, Streptococcus anginosus grp.* (includes *S. anginosus, S. intermedius,* and *S. constellatus), Enterococcus faecalis, Enterobacter cloacae,* or *Klebsiella pneumoniae*

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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OMADACYCLINE (PART D)

GUIDELINES FOR USE (CONTINUED)

7. Is therapy prescribed by or in consultation with an infectious disease (ID) specialist?

   If yes, **approve for 1 month by HICL or GPI-10 for one fill.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #8.

8. Has an antimicrobial susceptibility test been performed and meets **ALL** of the following criteria?
   - The results from the infection site culture indicate pathogenic organism(s) with resistance to TWO standard of care agents for ABSSSI (e.g., linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin, amoxicillin, nafcillin, ceftriaxone, cephalexin, cefazolin)
   - The results from the infection site culture indicate pathogenic organism(s) with susceptibility to Nuzyra

   If yes, **approve for 1 month by HICL or GPI-10 for one fill.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #9.

9. Does the patient meet **ALL** of the following criteria?
   - Antimicrobial susceptibility results are unavailable
   - The patient had a trial of or contraindication to TWO standard of care agents for ABSSSI (e.g., linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin, amoxicillin, nafcillin, ceftriaxone, cephalexin, cefazolin)

   If yes, **approve for 1 month by HICL or GPI-10 for one fill.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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OMADACYCLINE (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OMADACYCLINE (Nuzyra)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Community-acquired bacterial pneumonia (type of lung infection)
   2. Acute bacterial skin or skin structure infection (ABSSSI: a type of skin condition)

B. If you have community-acquired bacterial pneumonia, approval also requires:
   1. You are 18 years of age or older
   2. Your infection is caused by any of the following microorganisms (bacteria that the medication can work on): *Streptococcus pneumoniae, Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae, Haemophilus parainfluenzae, Klebsiella pneumoniae, Legionella pneumophila, Mycoplasma pneumoniae,* or *Chlamydophila pneumoniae*
   3. You meet ONE of the following criteria:
      a. Your request is for continuation of care from an inpatient setting (a healthcare facility where medical treatment is given overnight or longer)
      b. Therapy is prescribed by or in consultation with an Infectious Disease specialist (a doctor who specializes in the treatment of infections)
      c. Your antimicrobial susceptibility test (lab test that shows what medications work on which bacteria) shows ALL of the following:
         i. The bacteria at the infection site culture is resistant (medication will not work for that bacteria) to TWO standard of care agents for community-acquired bacterial pneumonia (CABP: a type of lung infection) (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone)
         ii. Nuzyra will work against the bacteria
      d. If antimicrobial susceptibility test (lab test that shows what medications work on which bacteria) is not available, we require you have tried or have a contraindication to (harmful for you to use) TWO standard of care agents for community-acquired bacterial pneumonia (CABP: a type of lung infection) (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone)

(Denial text continued on next page)

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OMADACYCLINE (PART D)

GUIDELINES FOR USE (CONTINUED)

C. If you have acute bacterial skin or skin structure infection (ABSSSI), approval also requires:

1. You are 18 years of age or older
2. Your infection is caused by any of the following microorganisms (bacteria that the medication can work on): Staphylococcus aureus (methicillin-susceptible and -resistant isolates), Staphylococcus lugdunensis, Streptococcus pyogenes, Streptococcus anginosus grp. (includes S. anginosus, S. intermedius, and S. constellatus), Enterococcus faecalis, Enterobacter cloacae, or Klebsiella pneumoniae
3. You meet ONE of the following criteria:
   a. Therapy is prescribed by or in consultation with an Infectious Disease specialist (a doctor who specializes in the treatment of infections)
   b. Your antimicrobial susceptibility test (lab test showing what medications work on which bacteria) shows ALL of the following:
      i. The bacteria at the infection site culture is resistant (medication will not work for that bacteria) to TWO standard of care agents for acute bacterial skin or skin structure infection (such as linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin, amoxicillin, nafcillin, ceftriaxone, cephalexin, cefazolin)
      ii. Nuzyra will work against the bacteria
   c. If antimicrobial susceptibility test (lab test that shows what medications work on which bacteria) is not available, approval requires you have tried or have a contraindication to (harmful for you to use) TWO standard of care medications for acute bacterial skin or skin structure infection (such as linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin, amoxicillin, nafcillin, ceftriaxone, cephalexin, cefazolin)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nuzyra.

REFERENCES

Nuzyra [Prescribing Information]. Boston, MA: Paratek Pharmaceuticals, Inc.; March 2025.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OMADACYCLINE (PART D)

For Part D use only:

OMADACYCLINE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	ONE MONTH
Other Criteria	COMMUNITY-ACQUIRED BACTERIAL PNEUMONIA (CABP): 1) CONTINUATION OF CARE FROM INPATIENT SETTING, 2) PRESCRIBED BY OR IN CONSULTATION WITH AN INFECTIOUS DISEASE SPECIALIST, 3) ANTIMICROBIAL SUSCEPTIBILITY TESTING SHOWS SUSCEPTIBILITY TO NUZYRA AND RESISTANCE TO AT LEAST TWO STANDARD OF CARE AGENTS FOR CABP, OR 4) IF SENSITIVITY RESULTS ARE UNAVAILABLE: TRIAL OF OR CONTRAINDICATION TO TWO STANDARD OF CARE AGENTS FOR CABP. ACUTE BACTERIAL SKIN OR SKIN STRUCTURE INFECTION (ABSSSI): 1) PRESCRIBED BY OR IN CONSULTATION WITH AN INFECTIOUS DISEASE SPECIALIST, 2) ANTIMICROBIAL SUSCEPTIBILITY TESTING SHOWS SUSCEPTIBILITY TO NUZYRA AND RESISTANCE TO AT LEAST TWO STANDARD OF CARE AGENTS FOR ABSSSI, OR 3) IF SENSITIVITY RESULTS ARE UNAVAILABLE: TRIAL OF OR CONTRAINDICATION TO TWO STANDARD OF CARE AGENTS FOR ABSSSI.

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Effective: 09/01/25 Client Approval: 08/25 P&T Approval: 07/25

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OMALIZUMAB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OMALIZUMAB	XOLAIR	25399		GPI-10 (4460306000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate persistent asthma (ICD-10 Group J45.4) to severe persistent asthma (ICD-10 Group J45.5) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a physician specializing in allergy or pulmonary medicine
   - The patient has a positive skin prick or blood test (e.g., ELISA, FEIA) to a perennial aeroallergen
   - The patient has a baseline IgE serum level of at least 30 IU/mL
   - Xolair will be used in combination with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (ICS) (e.g., beclomethasone, mometasone, budesonide) AND at least one other maintenance medication (e.g., long-acting inhaled beta2-agonist [e.g., salmeterol, formoterol], long-acting muscarinic antagonist [e.g., Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], leukotriene receptor antagonist [e.g., montelukast, zafirlukast, zileuton], theophylline, an oral corticosteroid [e.g., prednisone])
   - Xolair will NOT be used concurrently with another systemic biologic (e.g., Tezspire [tezepelumab-ekko]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) forthe treatment of asthma

     If yes, continue to #2.
     If no, continue to #3.

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OMALIZUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient meet **ONE** of the following criteria?
   - The patient has experienced at least ONE asthma exacerbation requiring systemic corticosteroid (e.g., prednisone) burst lasting at least 3 days within the past 12 months
   - The patient has experienced at least ONE serious exacerbation requiring hospitalization or ER visit within the past 12 months
   - The patient has poor symptom control despite current therapy as evidenced by at least THREE of the following within the past 4 weeks: Daytime asthma symptoms more than twice per week, any night waking due to asthma, use of a short-acting inhaled beta2-agonist reliever (e.g., albuterol) for symptoms more than twice per week, any activity limitation due to asthma

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text the end of the guideline.

3. Does the patient have a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) (ICD-10 Groups J32 and J33) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Xolair will be used as add-on maintenance treatment
   - Therapy is prescribed by or in consultation with an otolaryngologist, allergist, or immunologist
   - There is evidence of nasal polyps by direct examination, endoscopy, or sinus CT scan
   - The patient has inadequately controlled disease
   - The patient had a 56-day trial of ONE topical nasal corticosteroid (e.g., mometasone, fluticasone)
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Nucala (mepolizumab), Dupixent (dupilumab)
   - Xolair will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CRSwNP

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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OMALIZUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of chronic spontaneous urticaria (CSU; also called chronic idiopathic urticaria [CIU]) (ICD-10 Groups L50.1, L50, L50.9) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Therapy is prescribed by or in consultation with an allergist, dermatologist, or immunologist
   - The patient still experiences hives or angioedema on most days of the week for at least 6 weeks
   - The patient had a trial of and is maintained on, OR has a contraindication to a second generation H1 anti-histamine (e.g., Clarinex [desloratadine], Xyzal [levocetirizine])
   - Xolair will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of chronic spontaneous urticaria (chronic idiopathic urticaria)
   - The patient had a trial of or contraindication to the following preferred agent: Dupixent (dupilumab)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Does the patient have a diagnosis of an IgE-mediated food allergy (ICD-10 Group Z91.01) and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - The patient will continue to avoid food allergens while on Xolair
   - The patient has an IgE serum level of at least 30 IU/mL
   - The patient has a positive skin prick test to at least one food, OR a positive medically monitored food challenge to at least one food
   - Therapy is prescribed by or in consultation with an allergist or immunologist
   - The patient has an active prescription for epinephrine auto-injector/injection while on Xolair
   - Xolair will NOT be used concurrently with another systemic biologic (e.g., Palforzia) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of IgE-mediated food allergy

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text the end of the guideline.

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OMALIZUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OMALIZUMAB (Xolair)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe persistent asthma (a type of lung condition)
   2. Chronic rhinosinusitis with nasal polyps (CRSwNP: inflammation of nasal and sinus ways with small growths in the nose)
   3. Chronic spontaneous urticaria [also called chronic idiopathic urticaria] (severe itching with unknown cause)
   4. IgE-mediated food allergy (body's reaction to a food allergy)

B. If you have moderate to severe persistent asthma, approval also requires:
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a physician specializing in allergy or pulmonary (lungs/breathing) medicine
   3. You have a positive skin prick or blood test such as ELISA or FEIA (types of blood tests to identify allergies) to a perennial aeroallergen (airborne particles that cause allergies year-round)
   4. You have a baseline IgE (type of antibody produced by the immune system if there is an allergy) serum (blood) level of at least 30 IU/mL
   5. Xolair will be used in combination with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least one other maintenance medication (taken on a regular basis) such as a long-acting inhaled beta2-agonist (such as salmeterol, formoterol), long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast, zileuton), theophylline, or an oral corticosteroid (such as prednisone)
   6. You meet ONE of the following:
      a. You experienced at least ONE asthma exacerbation (worsening of symptoms) requiring systemic corticosteroid (such as prednisone) burst lasting at least 3 days within the past 12 months
      b. You have experienced at least ONE serious exacerbation requiring hospitalization or emergency room visit within the past 12 months
      c. You have poor symptom control despite current therapy as evidenced by at least THREE of the following within the past 4 weeks: Daytime asthma symptoms more than twice per week, any night waking due to asthma, use of a short-acting beta-2-agonist (such as albuterol) reliever for symptoms more than twice per week, any activity limitation due to asthma

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OMALIZUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

7. You will NOT use Xolair concurrently (at the same time) with another systemic biologic (such as Tezspire [tezepelumab-ekko]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of asthma

C. If you have chronic rhinosinusitis with nasal polyps, approval also requires:

1. You are 18 years of age or older
2. Xolair will be used as add-on maintenance treatment
3. Therapy is prescribed by or in consultation with an otolaryngologist (ear, nose, and throat doctor), allergist (type of allergy doctor), or immunologist (type of immune system doctor)
4. There is evidence of nasal polyps (non-cancerous growths) by direct examination, endoscopy (using a small camera), or sinus computed tomography (CT) scan (a type of imaging test)
5. You have inadequately controlled disease
6. You had a 56-day trial of ONE topical nasal corticosteroid (such as mometasone, fluticasone)
7. You had a trial of or contraindication to (harmful for) ONE of the following preferred medications: Nucala (mepolizumab), Dupixent (dupilumab)
8. You will NOT use Xolair concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic rhinosinusitis with nasal polyps

D. If you have chronic spontaneous urticaria, approval also requires:

1. You are 12 years of age or older
2. Therapy is prescribed by or in consultation with an allergist (type of allergy doctor), dermatologist (type of skin doctor), or immunologist (type of immune system doctor)
3. You still experience hives or angioedema (a type of swelling) on most days of the week for at least 6 weeks
4. You have tried and are maintained on, OR you have a contraindication to (harmful for you to use) a second generation H1 antihistamine (type of allergy medication such as Clarinex [desloratadine] or Xyzal [levocetirizine])
5. You will NOT use Xolair concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic spontaneous urticaria (chronic idiopathic urticaria)
6. You have tried or have a contraindication to the preferred medication: Dupixent (dupilumab)

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OMALIZUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

E. If you have an IgE-mediated food allergy, approval also requires:

1. You are 1 year of age or older
2. You will continue to avoid food allergens (not eating or coming into contact with food that causes an allergic reaction) while on Xolair
3. You have an IgE (type of antibody that is produced by the immune system) serum (blood) level of at least 30 IU/mL
4. You have a positive skin prick test (a type of allergy test) to at least one food, OR a positive medically monitored food challenge to at least one food
5. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor) or immunologist (a type of immune system doctor)
6. You have an active prescription for epinephrine auto-injector/injection while on Xolair
7. You will NOT use Xolair concurrently (at the same time) with another systemic biologic (such as Palforzia) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of IgE-mediated food allergy

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OMALIZUMAB (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate persistent asthma (ICD-10 Group J45.4) to severe persistent asthma (ICD-10 Group J45.5) and meet **ALL** of the following criteria?
   - The patient continues to use an inhaled corticosteroid (ICS) (e.g., beclomethasone, mometasone, budesonide) AND at least one other maintenance medication (e.g., a long-acting inhaled beta2-agonist [e.g., formoterol, salmeterol], a long-acting muscarinic antagonist [e.g., aclidinium, tiotropium, umeclidinium], a leukotriene receptor antagonist [e.g., montelukast, zafirlukast, zileuton], theophylline, an oral corticosteroid [e.g., prednisone])
   - Xolair will NOT be used concurrently with another systemic biologic (e.g., Tezspire [tezepelumab-ekko]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of asthma

   If yes, continue to #2.
   If no, continue to #3.

2. Has the patient shown a clinical response as evidenced by **ONE** of the following criteria?
   - Reduction in asthma exacerbations from baseline
   - Decreased utilization of rescue medications (e.g., albuterol)
   - Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing)
   - Increase in percent predicted FEV1 from pretreatment baseline

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

3. Does the patient have a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) (ICD-10 Groups J32 and J33) and meet **ALL** of the following criteria?
   - The patient has shown a clinical benefit compared to baseline (e.g., improvements in nasal congestion, sense of smell, size of polyps)
   - Xolair will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CRSwNP

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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OMALIZUMAB (PART D)

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of chronic spontaneous urticaria (CSU; also called chronic idiopathic urticaria [CIU]) (ICD-10 Groups L50.1, L50, L50.9) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an allergist, dermatologist, or immunologist
   - The patient is maintained on, OR has a contraindication to a second generation H1 anti-histamine (e.g., Clarinex [desloratadine], Xyzal [levocetirizine])
   - Xolair will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of chronic spontaneous urticaria (chronic idiopathic urticaria)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Does the patient have a diagnosis of an IgE-mediated food allergy (ICD-10 Group Z91.01) and meet **ALL** of the following criteria?
   - The patient has persistent IgE-mediated food allergy
   - The patient has an active prescription for epinephrine auto-injector/injection while on Xolair
   - Xolair will NOT be used concurrently with another systemic biologic (e.g., Palforzia) ortargeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of IgE-mediated food allergy

   If yes, **approve for 24 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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OMALIZUMAB (PART D)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OMALIZUMAB (Xolair)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe persistent asthma (a type of lung condition)
   2. Chronic rhinosinusitis with nasal polyps (CRSwNP: inflammation of nasal and sinus ways with small growths in the nose)
   3. Chronic spontaneous urticaria [also called chronic idiopathic urticaria] (severe itching with unknown cause)
   4. IgE-mediated food allergy (body's reaction to a food allergy)

B. If you have moderate to severe persistent asthma, renewal also requires:
   1. You will continue to use an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least one other maintenance medication (taken on a regular basis) such as a long-acting inhaled beta2-agonist (such as salmeterol or formoterol), long-acting muscarinic antagonist (such as aclidinium, tiotropium, umeclidinium), a leukotriene receptor antagonist (such as montelukast, zafirlukast, zileuton), theophylline, or an oral corticosteroid (such as prednisone)
   2. You will NOT use Xolair concurrently (at the same time) with another systemic biologic (such as Tezspire [tezepelumab-ekko]), or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of asthma
   3. You have had a clinical response as evidenced by ONE the following:
      a. You have experienced a reduction in asthma exacerbations (less sudden and severe worsening of symptoms) from baseline
      b. You have decreased use of rescue medications (such as albuterol)
      c. You have decreased the severity or frequency of asthma-related symptoms (such as wheezing, shortness of breath, coughing)
      d. You have an increase in the percent predicted FEV1 (amount of air you can forcefully exhale) from pretreatment baseline (before starting Xolair)

(Renewal denial text continued on next page)

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OMALIZUMAB (PART D)

RENEWAL CRITERIA (CONTINUED)

C. If you have chronic rhinosinusitis with nasal polyps, renewal also requires:
1. You have shown a clinical benefit compared to baseline (before starting Xolair) (such as improvements in nasal congestion, sense of smell, size of polyps)
2. You will NOT use Xolair concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic rhinosinusitis with nasal polyps

D. If you have chronic spontaneous urticaria, renewal also requires:
1. Therapy is prescribed by or in consultation with an allergist (type of allergy doctor), dermatologist (type of skin doctor), or immunologist (type of immune system doctor)
2. You are maintained on (continue to use on a regular basis), OR you have a contraindication to (harmful for you to use) a second generation H1 antihistamine (type of allergy medication such as Clarinex [desloratadine] or Xyzal [levocetirizine])
3. You will NOT use Xolair concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic spontaneous urticaria (chronic idiopathic urticaria)

E. If you have an IgE-mediated food allergy, renewal also requires:
1. You have persistent IgE-mediated food allergy
2. You have an active prescription for epinephrine auto-injector/injection while on Xolair
3. You will NOT use Xolair concurrently (at the same time) with another systemic biologic (such as Palforzia) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of IgE-mediated food allergy

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Xolair.

REFERENCES
Xolair [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; February 2024.

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OMALIZUMAB (PART D)

For Part D use only:

OMALIZUMAB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	INITIAL: ASTHMA: POSITIVE SKIN PRICK OR BLOOD TEST (E.G., ELISA, FEIA) TO A PERENNIAL AEROALLERGEN AND A BASELINE IGE SERUM LEVEL OF AT LEAST 30 IU/ML. FOOD ALLERGY: 1) IGE SERUM LEVEL OF AT LEAST 30 IU/ML, AND 2) POSITIVE SKIN PRICK TEST TO AT LEAST ONE FOOD, OR POSITIVE MEDICALLY MONITORED FOOD CHALLENGE TO AT LEAST ONE FOOD.
Age Restrictions	N/A
Prescriber Restrictions	INITIAL/RENEWAL: CHRONIC SPONTANEOUS URTICARIA (CSU): PRESCRIBED BY OR IN CONSULTATION WITH AN ALLERGIST, DERMATOLOGIST, OR IMMUNOLOGIST. INITIAL: CHRONIC RHINOSINUSITIS WITH NASAL POLYPS (CRSWNP): PRESCRIBED BY OR IN CONSULTATION WITH AN OTOLARYNGOLOGIST, ALLERGIST OR IMMUNOLOGIST. ASTHMA: PRESCRIBED BY OR IN CONSULTATION WITH A PHYSICIAN SPECIALIZING IN ALLERGY OR PULMONARY MEDICINE. FOOD ALLERGY: PRESCRIBED BY OR IN CONSULTATION WITH ALLERGIST OR IMMUNOLOGIST.
Coverage Duration	INITIAL/RENEWAL: ASTHMA 12 MO/12 MO, CSU 6 MO/12 MO, CRSWNP 6 MO/12 MO, FOOD ALLERGY 12 MO/24 MO
Other Criteria	INITIAL: CSU: 1) TRIAL OF AND MAINTAINED ON, OR CONTRAINDICATION TO A SECOND GENERATION H1 ANTI-HISTAMINE, 2) STILL EXPERIENCES HIVES OR ANGIOEDEMA ON MOST DAYS OF THE WEEK FOR AT LEAST 6 WEEKS, AND 3) TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT: DUPIXENT. CRSWNP: 1) A 56 DAY TRIAL OF ONE TOPICAL NASAL CORTICOSTEROID, 2) TRIAL OF OR CONTRAINDICATION TO ONE OF THE FOLLOWING PREFERRED AGENTS: NUCALA, DUPIXENT, 3) EVIDENCE OF NASAL POLYPS BY DIRECT EXAMINATION, ENDOSCOPY, OR SINUS CT SCAN, AND 4) INADEQUATELY CONTROLLED DISEASE. ASTHMA: 1) CONCURRENT THERAPY WITH A MEDIUM, HIGH-DOSE OR MAXIMALLY TOLERATED DOSE OF AN INHALED CORTICOSTEROID (ICS) AND AT LEAST ONE OTHER MAINTENANCE MEDICATION, AND 2) ONE OF THE FOLLOWING: (A) AT LEAST ONE ASTHMA EXACERBATION REQUIRING SYSTEMIC CORTICOSTEROID BURST LASTING AT LEAST 3 DAYS WITHIN THE PAST 12 MONTHS OR AT LEAST ONE SERIOUS EXACERBATION REQUIRING HOSPITALIZATION OR ER VISIT WITHIN THE PAST 12 MONTHS, OR (B) POOR SYMPTOM CONTROL DESPITE

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	CURRENT THERAPY AS EVIDENCED BY AT LEAST THREE OF THE FOLLOWING WITHIN THE PAST 4 WEEKS: DAYTIME ASTHMA SYMPTOMS MORE THAN TWICE/WEEK, ANY NIGHT WAKING DUE TO ASTHMA, SABA RELIEVER FOR SYMPTOMS MORE THAN TWICE/WEEK, ANY ACTIVITY LIMITATION DUE TO ASTHMA. FOOD ALLERGY: CONCURRENT USE WITH AN ACTIVE PRESCRIPTION FOR EPINEPHRINE AUTO-INJECTOR/INJECTION. INITIAL/RENEWAL: ALL INDICATIONS: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION. RENEWAL: CSU: MAINTAINED ON OR CONTRAINDICATION TO A SECOND GENERATION H1 ANTI-HISTAMINE. CRSWNP: CLINICAL BENEFIT COMPARED TO BASELINE. ASTHMA: 1) CONTINUED USE OF ICS AND AT LEAST ONE OTHER MAINTENANCE MEDICATION, AND 2) CLINICAL RESPONSE AS EVIDENCED BY ONE OF THE FOLLOWING: (A) REDUCTION IN ASTHMA EXACERBATIONS FROM BASELINE, (B) DECREASED UTILIZATION OF RESCUE MEDICATIONS, (C) REDUCTION IN SEVERITY OR FREQUENCY OF ASTHMA-RELATED SYMPTOMS, OR (D) INCREASE IN PERCENT PREDICTED FEV1 FROM PRETREATMENT BASELINE. FOOD ALLERGY: 1) PERSISTENT IGE-MEDIATED FOOD ALLERGY, AND 2) CONCURRENT USE WITH AN ACTIVE PRESCRIPTION FOR EPINEPHRINE AUTO-INJECTOR/INJECTION.

Created: 08/03
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 01/25

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STANDARD PART D
PRIOR AUTHORIZATION GUIDELINES

OMALIZUMAB-IGEC (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OMALIZUMAB-IGEC	OMLYCLO	50329		GPI-10 (4460306002)	

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***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate persistent asthma (ICD-10 Group J45.4) to severe persistent asthma (ICD-10 Group J45.5) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a physician specializing in pulmonary or allergy medicine
   - The patient has a positive skin prick or blood test (e.g., ELISA, FEIA) to a perennial aeroallergen
   - The patient has a baseline IgE serum level of at least 30 IU/mL
   - Omlyclo will be used in combination with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (ICS) (e.g., beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (e.g., a long-acting inhaled beta2-agonist [e.g., formoterol, salmeterol], a long-acting muscarinic antagonist [e.g., Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [e.g., montelukast, zafirlukast, zileuton], theophylline, or an oral corticosteroid [e.g., prednisone])
   - Omlyclo will NOT be used concurrently with another systemic biologic (e.g., Tezspire [tezepelumab-ekko]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of asthma

   If yes, continue to #2.
   If no, continue to #3.

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OMALIZUMAB-IGEC (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient meet **ONE** of the following criteria?
   - The patient has experienced at least ONE asthma exacerbation requiring systemic corticosteroid (e.g., prednisone) burst lasting at least 3 days within the past 12 months
   - The patient has experienced at least ONE serious exacerbation requiring hospitalization or ER visit within the past 12 months
   - The patient has poor symptom control despite current therapy as evidenced by at least THREE of the following within the past 4 weeks: Daytime asthma symptoms more than twice per week, any night waking due to asthma, use of a short-acting inhaled beta2-agonist reliever (e.g., albuterol) for symptoms more than twice per week, any activity limitation due to asthma

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text the end of the guideline.

3. Does the patient have a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) (ICD-10 Groups J32 and J33) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Omlyclo will be used as add-on maintenance treatment
   - Therapy is prescribed by or in consultation with an otolaryngologist, allergist, or immunologist
   - There is evidence of nasal polyps by direct examination, endoscopy, or sinus CT scan
   - The patient has inadequately controlled disease
   - The patient had a 56-day trial of ONE clinical standard of care agent: a topical nasal corticosteroid (e.g., mometasone, fluticasone)
   - Omlyclo will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CRSwNP

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, continue to #4.

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OMALIZUMAB-IGEC (PART D)

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of an IgE-mediated food allergy (ICD-10 Group Z91.01) and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - The patient will continue to avoid food allergens while on Omlyclo
   - The patient has an IgE serum level of at least 30 IU/mL
   - The patient has a positive skin prick test to at least one food, OR a positive medically monitored food challenge to at least one food
   - Therapy is prescribed by or in consultation with an allergist or immunologist
   - The patient has an active prescription for epinephrine auto-injector/injection while on Omlyclo
   - Omlyclo will NOT be used concurrently with another systemic biologic (e.g., Palforzia) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of IgE-mediated food allergy

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #5.

5. Does the patient have a diagnosis of chronic spontaneous urticaria (CSU; also called chronic idiopathic urticaria [CIU]) (ICD-10 L50.1, L50.8, L50.9) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Therapy is prescribed by or in consultation with an allergist, dermatologist, or immunologist
   - The patient still experiences hives or angioedema on most days of the week for at least 6 weeks
   - The patient had a trial of and is maintained on, OR has a contraindication to a second generation H1 antihistamine (e.g., Clarinex [desloratadine], Xyzal [levocetirizine])
   - Omlyclo will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of chronic spontaneous urticaria (chronic idiopathic urticaria)

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, continue to #5.
   DENIAL TEXT: See the initial denial text the end of the guideline.

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OMALIZUMAB-IGEC (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT:

Our guideline named **OMALIZUMAB-IGEC (Omlyclo)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe persistent asthma (a type of lung condition)
   2. Chronic rhinosinusitis with nasal polyps (CRSwNP: inflammation of nasal and sinus ways with small growths in the nose)
   3. IgE-mediated food allergy (body's reaction to a food allergy)
   4. Chronic spontaneous urticaria (also called chronic idiopathic urticaria) [severe itching with unknown cause]

B. If you have moderate to severe persistent asthma, approval also requires:
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a physician specializing in pulmonary (relating to lungs/breathing) medicine or allergy medicine
   3. You have a positive skin prick or blood test, such as ELISA or FEIA (types of blood tests to identify allergies), to a perennial aeroallergen (airborne particles that cause allergies year-round)
   4. You have a baseline IgE (type of antibody that is produced by the immune system if there is an allergy) serum (blood) level of at least 30 IU/mL
   5. Omlyclo will be used in combination with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis) such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast, zileuton), theophylline, or an oral corticosteroid (such as prednisone)
   6. You will NOT use Omlyclo concurrently (at the same time) with another systemic biologic (such as Tezspire [tezepelumab-ekko]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of asthma (a type of lung condition)

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OMALIZUMAB-IGEC (PART D)

INITIAL CRITERIA (CONTINUED)

7. You meet ONE of the following:
   a. You have experienced at least ONE asthma (a type of lung condition) exacerbation (worsening of symptoms) requiring systemic corticosteroid (such as prednisone) burst lasting at least 3 days within the past 12 months
   b. You have experienced at least ONE serious asthma exacerbation requiring a hospitalization or an emergency room visit within the past 12 months
   c. You have poor symptom control despite current therapy as shown by at least THREE of the following within the past 4 weeks: Daytime asthma symptoms more than twice per week, any night waking due to asthma, use of a short-acting beta-2-agonist (such as albuterol) reliever for symptoms more than twice per week, any activity limitation due to asthma

C. If you have chronic rhinosinusitis with nasal polyps, approval also requires:

1. You are 18 years of age or older
2. Omlyclo will be used as add-on maintenance treatment (taken on a regular basis)
3. Therapy is prescribed by or in consultation with an otolaryngologist (ear, nose, and throat doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
4. There is evidence of nasal polyps (non-cancerous growths) by direct examination, endoscopy (using a small camera), or sinus computed tomography (CT) scan (a type of imaging test)
5. You have inadequately controlled disease
6. You had a 56-day trial of ONE clinical standard of care medication: a topical nasal corticosteroid (such as mometasone, fluticasone)
7. You will NOT use Omlyclo concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic rhinosinusitis with nasal polyps (inflammation of nasal and sinus ways with small growths in the nose)

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OMALIZUMAB-IGEC (PART D)

INITIAL CRITERIA (CONTINUED)

D. If you have an IgE-mediated food allergy, approval also requires:
1. You are 1 year of age or older
2. You will continue to avoid food allergens (not eating or coming into contact with food that causes an allergic reaction) while on Omlyclo
3. You have an IgE (type of antibody that is produced by the immune system if there is an allergy) serum (blood) level of at least 30 IU/mL
4. You have a positive skin prick test (a type of allergy test) to at least one food, OR a positive medically monitored food challenge to at least one food
5. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor) or immunologist (a type of immune system doctor)
6. You have an active prescription for epinephrine auto-injector/injection while on Omlyclo
7. You will NOT use Omlyclo concurrently (at the same time) with another systemic biologic (such as Palforzia) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of IgE-mediated food allergy (body's reaction to a food allergy)

E. If you have chronic spontaneous urticaria (chronic idiopathic urticaria), approval also requires:
1. You are 12 years of age or older
2. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
3. You still experience hives or angioedema (a type of swelling) on most days of the week for at least 6 weeks
4. You have tried and are maintained on, OR you have a contraindication to (harmful for you to use) a second generation H1 antihistamine (type of allergy medication such as Clarinex [desloratadine] or Xyzal [levocetirizine])
5. You will NOT use Omlyclo concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic spontaneous urticaria (chronic idiopathic urticaria) (severe itching with unknown cause)

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OMALIZUMAB-IGEC (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate persistent asthma (ICD-10 Group J45.4) to severe persistent asthma (ICD-10 Group J45.5) and meet **ALL** of the following criteria?
   - The patient continues to use an inhaled corticosteroid (ICS) (e.g., beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (e.g., a long-acting inhaled beta2-agonist [e.g., formoterol, salmeterol], a long-acting muscarinic antagonist [e.g., aclidinium, tiotropium, umeclidinium], a leukotriene receptor antagonist [e.g., montelukast, zafirlukast, zileuton], theophylline, or an oral corticosteroid [e.g., prednisone])
   - Omlyclo will NOT be used concurrently with another systemic biologic (e.g., Tezspire [tezepelumab-ekko]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of asthma

   If yes, continue to #2.
   If no, continue to #3.

2. Has the patient shown a clinical response as evidenced by **ONE** of the following criteria?
   - Reduction in asthma exacerbations from baseline
   - Decreased utilization of rescue medications (e.g., albuterol)
   - Increase in percent predicted FEV1 from pretreatment baseline
   - Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

3. Does the patient have a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) (ICD-10 Groups J32 and J33) and meet **ALL** of the following criteria?
   - The patient has shown a clinical benefit compared to baseline (e.g., improvements in nasal congestion, sense of smell, size of polyps)
   - Omlyclo will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CRSwNP

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #4.

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OMALIZUMAB-IGEC (PART D)

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of an IgE-mediated food allergy (ICD-10 Group Z91.01) and meet **ALL** of the following criteria?
   - The patient has persistent IgE-mediated food allergy
   - The patient has an active prescription for epinephrine auto-injector/injection while on Omlyclo
   - Omlyclo will NOT be used concurrently with another systemic biologic (e.g., Palforzia) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of IgE-mediated food allergy

   If yes, **approve for 24 months by HICL or GPI-10.**
   If no, continue to #5.

5. Does the patient have a diagnosis of chronic spontaneous urticaria (CSU; also called chronic idiopathic urticaria [CIU]) (ICD-10 L50.1, L50.8, L50.9) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an allergist, dermatologist, or immunologist
   - The patient is maintained on, OR has a contraindication to, a second generation H1 anti-histamine (e.g., Clarinex [desloratadine], Xyzal [levocetirizine])
   - Omlyclo will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of chronic spontaneous urticaria (chronic idiopathic urticaria)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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OMALIZUMAB-IGEC (PART D)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT:

Our guideline named **OMALIZUMAB-IGEC (Omlyclo)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe persistent asthma (a type of lung condition)
   2. Chronic rhinosinusitis with nasal polyps (CRSwNP: inflammation of nasal and sinus ways with small growths in the nose)
   3. IgE-mediated food allergy (body's reaction to a food allergy)
   4. Chronic spontaneous urticaria (also called chronic idiopathic urticaria) [severe itching with unknown cause]

B. If you have moderate to severe persistent asthma, renewal also requires:
   1. You continue to use an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis) such as a long-acting inhaled beta2-agonist (such as salmeterol, formoterol), a long-acting muscarinic antagonist (such as aclidinium, tiotropium, umeclidinium), a leukotriene receptor antagonist (such as montelukast, zafirlukast, zileuton), theophylline, or an oral corticosteroid (such as prednisone)
   2. You will NOT use Omlyclo concurrently (at the same time) with another systemic biologic (such as Tezspire [tezepelumab-ekko]), or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of asthma (a type of lung condition)
   3. You have shown a clinical response as evidenced by ONE of the following:
      a. You have experienced a decrease in asthma (a type of lung condition) exacerbations (worsening of symptoms) from baseline (before starting Omlyclo)
      b. You have decreased your use of rescue medications (such as albuterol)
      c. You have an increase in percent predicted FEV1 (type of lung test) from pre-treatment baseline (before starting Omlyclo)
      d. You have a decrease in the severity or frequency of asthma-related symptoms (such as wheezing, shortness of breath, coughing)

C. If you have chronic rhinosinusitis with nasal polyps, renewal also requires:
   1. You have shown a clinical benefit compared to baseline (before starting Omlyclo) (such as improvements in nasal congestion, sense of smell, size of polyps)
   2. You will NOT use Omlyclo concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic rhinosinusitis with nasal polyps (inflammation of nasal and sinus ways with small growths in the nose)

(Renewal denial text continued on next page)

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OMALIZUMAB-IGEC (PART D)

RENEWAL CRITERIA (CONTINUED)

D. If you have an IgE-mediated food allergy, renewal also requires:
1. You have persistent IgE-mediated food allergy (body's reaction to a food allergy)
2. You have an active prescription for epinephrine auto-injector/injection while on Omlyclo
3. You will NOT use Omlyclo concurrently (at the same time) with another systemic biologic (such as Palforzia) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of IgE-mediated food allergy (body's reaction to a food allergy)

E. If you have chronic spontaneous urticaria (chronic idiopathic urticaria), renewal also requires:
1. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
2. You are maintained on (continue to use on a regular basis), OR you have a contraindication to (harmful for you to use) a second generation H1 antihistamine (type of allergy medication such as Clarinex [desloratadine] or Xyzal [levocetirizine])
3. You will NOT use Omlyclo concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic spontaneous urticaria (chronic idiopathic urticaria) (severe itching with unknown cause)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Omlyclo.

REFERENCES
Omlyclo [Prescribing Information]. Jersey City, NJ: Celltrion USA, Inc.; December 2025.

Created: 08/26
Effective: 08/22/26 DMC Approval: 8/18/26

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OMAVELOXOLONE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OMAVELOXOLONE	SKYCLARYS	48741		GPI-10 (7413506000)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Friedreich's ataxia (FA) (ICD-10 G11.11) and meet **ALL** of the following criteria?
   - The patient is 16 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient's diagnosis is confirmed by genetic testing (homozygous for GAA repeat expansion in intron-1 of FXN gene)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See initial denial text at the end of the guideline.

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OMAVELOXOLONE (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OMAVELOXOLONE (Skyclarys)** requires the following rule(s) be met for approval:

A. You have Friedreich's ataxia (FA: a type of nervous system and movement disorder)
B. You are 16 years of age or older
C. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
D. Your diagnosis is confirmed by genetic testing (homozygous for guanine-adenine-adenine [GAA] repeat expansion in intron-1 of frataxin [FXN] gene [a type of gene mutation])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OMAVELOXOLONE (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Friedreich's ataxia (FA) (ICD-10 G11.11)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OMAVELOXOLONE (Skyclarys)** requires the following rule(s) be met for renewal:
   A. You have Friedreich's ataxia (FA: a type of nervous system and movement disorder)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Skyclarys.

REFERENCES
Skyclarys [Prescribing Information]. Plano, TX: Reata Pharmaceuticals, Inc.; December 2024.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OMAVELOXOLONE (PART D)

For Part D use only:

OMAVELOXOLONE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	FRIEDREICHS ATAXIA (FA): INITIAL: DIAGNOSIS CONFIRMED BY GENETIC TESTING (HOMOZYGOUS FOR GAA REPEAT EXPANSION IN INTRON-1 OF FXN GENE).
Age Restrictions	N/A
Prescriber Restrictions	FA: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS
Other Criteria	N/A

Created: 04/23
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 07/25

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ONABOTULINUM TOXIN A BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ONABOTULINUMTOXINA	BOTOX	04867		GPI-10 (7440002005)	

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #5.

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ONABOTULINUM TOXIN A BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

If yes, **refer to plan. (The health plan makes the final payment determination decision)**

- **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override)**
- **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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ONABOTULINUM TOXIN A BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for treatment of a cosmetic indication (e.g., wrinkles - glabellar lines, lateral canthal lines, forehead lines) (ICD-10 L98.8; Group L81)?

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of chronic migraine (at least 15 days per month with headache lasting 4 hours a day or longer) (ICD-10 Groups G43.7, G43.E) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Botox will be used for the prophylaxis of headaches
   - The patient had a trial of or contraindication to ONE of the following preventive migraine treatments: propranolol, timolol, topiramate, divalproex sodium

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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ONABOTULINUM TOXIN A BvD (PART D)

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of overactive bladder (OAB) (ICD-10 N32.81) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had an inadequate response to or is intolerant of an anticholinergic medication (e.g., oxybutynin, oxybutynin extended-release [Ditropan XL], tolterodine [Detrol], tolterodine extended-release [Detrol LA], fesoterodine [Toviaz], trospium [Sanctura], trospium extended-release [Sanctura XR])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

4. Does the patient have a diagnosis of urinary incontinence (ICD-10 R32) and meet **ALL** of the following criteria?
   - The patient is 5 years of age or older
   - The patient's incontinence is due to detrusor overactivity associated with a neurologic condition (e.g., spinal cord injury, multiple sclerosis, spina bifida)
   - The patient had an inadequate response to or is intolerant of an anticholinergic medication (e.g., oxybutynin, oxybutynin extended-release [Ditropan XL], tolterodine [Detrol], tolterodine extended-release [Detrol LA], fesoterodine [Toviaz], trospium [Sanctura], trospium extended-release [Sanctura XR])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Does the patient have a diagnosis of spasticity (ICD-10 G04.1, G11.4, G80.0, G80.1, G80.2; Group G81.1) **AND** meet the following criterion?
   - The patient is 2 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #6.

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ONABOTULINUM TOXIN A BvD (PART D)

INITIAL CRITERIA (CONTINUED)

6. Does the patient have a diagnosis of cervical dystonia (ICD-10 G24.3) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Dysport (abobotulinumtoxinA), Myobloc (rimabotulinumtoxinB), Xeomin (incobotulinumtoxinA)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #7.

7. Does the patient have a diagnosis of severe axillary hyperhidrosis (ICD-10 L74.510) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #8.

8. Does the patient have a diagnosis of blepharospasm (ICD-10 G24.5) **AND** meet the following criterion?
   - The patient is 12 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #9.

9. Does the patient have a diagnosis of strabismus (ICD-10 H50.9) **AND** meet the following criterion?
   - The patient is 12 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ONABOTULINUM TOXIN A BvD (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ONABOTULINUM TOXIN A (Botox)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Chronic migraine (at least 15 days per month with headache lasting 4 hours a day or longer)
   2. Overactive bladder (a type of bladder condition)
   3. Urinary incontinence (loss of bladder control)
   4. Spasticity (stiffness or tightness of your muscles)
   5. Cervical dystonia (a type of muscle condition)
   6. Severe axillary hyperhidrosis (excessive underarm sweating)
   7. Blepharospasm (a type of eye disease)
   8. Strabismus (a type of eye condition)

B. If you have chronic migraine, approval also requires:
   1. You are 18 years of age or older
   2. Botox will be used for the prevention of headaches
   3. You have tried or have a contraindication to (harmful for you to use) ONE of the following preventive migraine treatments: propranolol, timolol, topiramate, divalproex sodium

C. If you have overactive bladder, approval also requires:
   1. You are 18 years of age or older
   2. You had an inadequate response (medication did not work) to or you are intolerant (side-effect) of an anticholinergic medication, such as oxybutynin, oxybutynin extended-release (Ditropan XL), tolterodine (Detrol), tolterodine extended-release (Detrol LA), fesoterodine (Toviaz), trospium (Sanctura), or trospium extended-release (Sanctura XR)

D. If you have urinary incontinence, approval also requires:
   1. You are 5 years of age or older
   2. Your incontinence is due to detrusor (bladder muscle) overactivity associated with a neurologic (nervous system) condition, such as spinal cord injury, multiple sclerosis (a type of nerve disorder), or spina bifida (a type of birth defect of the spine)
   3. You had an inadequate response (medication did not work) to or you are intolerant (side-effect) of an anticholinergic medication, such as oxybutynin, oxybutynin extended-release (Ditropan XL), tolterodine (Detrol), tolterodine extended-release (Detrol LA), fesoterodine (Toviaz), trospium (Sanctura), or trospium extended-release (Sanctura XR)

(Initial denial text continued on next page)

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ONABOTULINUM TOXIN A BvD (PART D)

INITIAL CRITERIA (CONTINUED)

E. If you have spasticity, approval also requires:
1. You are 2 years of age or older

F. If you have cervical dystonia, approval also requires:
1. You are 18 years of age or older
2. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Dysport (abobotulinumtoxinA), Myobloc (rimabotulinumtoxinB), Xeomin (incobotulinumtoxinA)

G. If you have severe axillary hyperhidrosis, approval also requires:
1. You are 18 years of age or older

H. If you have blepharospasm, approval also requires:
1. You are 12 years of age or older

I. If you have strabismus, approval also requires:
1. You are 12 years of age or older

NOTE: This medication will not be approved for the treatment of a cosmetic indication (such as wrinkles - glabellar [between the eyebrows] lines, lateral canthal [outer corner of eye] lines, forehead lines).

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ONABOTULINUM TOXIN A BvD (PART D)

RENEWAL CRITERIA

NOTE: For a diagnosis other than chronic migraine, please refer to the Initial Criteria section.

1. Is the request for treatment of a cosmetic indication (e.g., wrinkles - glabellar lines, lateral canthal lines, forehead lines) (ICD-10 L98.8, Group L81)?

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, continue to #2.

2. Is the request for the prophylaxis of headaches in a patient with chronic migraines (at least 15 days per month with headache lasting 4 hours a day or longer) (ICD-10 Groups G43.7, G43.E) and the patient meets **ONE** of the following criteria?
   - The patient has experienced a reduction in migraine or headache frequency with therapy
   - The patient has experienced a reduction in migraine severity with therapy
   - The patient has experienced a reduction in migraine duration with therapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ONABOTULINUM TOXIN A (Botox)** requires the following rule(s) be met for renewal:
   A. The request is for the prevention of headaches for chronic migraines (at least 15 days per month with headache lasting 4 hours a day or longer)
   B. You meet ONE of the following:
      1. You have experienced a reduction in migraine or headache frequency with therapy
      2. You have experienced a reduction in migraine severity with therapy
      3. You have experienced a reduction in migraine duration with therapy

   NOTE: This medication will not be approved for the treatment of a cosmetic indication (such as wrinkles - glabellar [between the eyebrows] lines, lateral canthal [outer corner of eye] lines, forehead lines).
   (Renewal denial text continued on next page)

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ONABOTULINUM TOXIN A BvD (PART D)

RENEWAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Botox. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Botox [Prescribing Information]. North Chicago, IL: AbbVie, Inc.; November 2023.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed April 8, 2025].

For Part D use only:

ONABOTULINUM TOXIN A (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	INITIAL/RENEWAL: COSMETIC DIAGNOSIS.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	CHRONIC MIGRAINE: INITIAL: 6 MOS, RENEWAL: 12 MOS. ALL OTHER INDICATIONS: 12 MOS.
Other Criteria	INITIAL: CHRONIC MIGRAINE: TRIAL OF OR CONTRAINDICATION TO ONE OF THE FOLLOWING PREVENTIVE MIGRAINE TREATMENTS: DIVALPROEX SODIUM, TOPIRAMATE, PROPRANOLOL, TIMOLOL. CERVICAL DYSTONIA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: DYSPORT, MYOBLOC, XEOMIN. RENEWAL: CHRONIC MIGRAINE: REDUCTION IN MIGRAINE OR HEADACHE FREQUENCY, MIGRAINE SEVERITY, OR MIGRAINE DURATION WITH THERAPY.

Created: 10/22
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 10/23

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OPICAPONE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OPICAPONE	ONGENTYS	45536		GPI-10 (7315306000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Parkinson's disease (ICD-10 Group G20) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is experiencing “OFF” episodes
   - The patient will also be treated with carbidopa/levodopa (e.g., Sinemet, Sinemet CR, Parcopa)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OPICAPONE (Ongentys)** requires the following rule(s) be met for approval:
   A. You have Parkinson's disease (PD: a type of movement disorder)
   B. You are 18 years of age or older
   C. You are experiencing 'OFF' episodes (period of symptoms in between doses)
   D. You will also be treated with carbidopa/levodopa (such as Sinemet, Sinemet Controlled Release [CR], Parcopa)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OPICAPONE (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Ongentys.

REFERENCES
Ongentys [Prescribing Information]. San Diego, CA: Neurocrine Biosciences, Inc.; April 2020.

For Part D use only:

OPICAPONE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	PARKINSONS DISEASE: 18 YEARS OF AGE OR OLDER
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 09/20
Client Approval: 08/24
P&T Approval: 04/20

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OPIOID CUMULATIVE DOSING OVERRIDE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/other
N/A	N/A	N/A	N/A	N/A	N/A

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

GUIDELINES FOR USE

1. Is the request for an opioid product equal to or exceeding the soft-stop threshold (90 mg morphine milligram equivalent (MME)) or hard-stop threshold (200 mg MME)?

   NOTE: Claims should stop for DUR_MAX_CUMUL_DOSE 2 edit with Soft_DENY_LIMIT = 90 or HARD_DENY_LIMIT = 200 (i.e., Cumulative morphine milligram equivalent of (patient's current MME) = / exceeds threshold of (90 mg MME or 200 mg MME per day)).

   If yes, continue to #2.
   If no, guideline does not apply.

2. Is the requested medication on the "HOSPICE DRUG LIST"?
   NOTE: Please reference the Formulary Analyzer Tool for drug status.

   If yes, continue to #3.
   If no, continue to #5.

3. Has the patient been identified as being enrolled in hospice (i.e., plan notification, member attribute, physician/member notification on the medication request form)?

   If yes, continue to #4.
   If no, continue to #5.

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OPIOID CUMULATIVE DOSING OVERRIDE (PART D)

GUIDELINES FOR USE (CONTINUED)

4. Has the prescriber provided attestation that the requested opioid medication is being used for an indication that is unrelated to the terminal illness?

   If yes, **approve as follows:**
   - **Approve under Part D for 12 months by HICL or GPI-10.**
   - **To enter approvals:**
     - **In the PA override field, override PA_HOSPICE**
     - **Change PA type to HE (Hospice Exception)**
   - **Please enter a class override to override the MME cumulative dosing for theduration of 12 months.**
   - **Ifthe claim rejects after analyzing, then follow the clinical coverage determination process.**

   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of **[XX]** per **[XX]** days.

   If no, do not approve.
   NOTE: This medication is included in the hospice benefit (Part A) and is not a Part D eligible drug.

   MEMBER NOTIFICATION LANGUAGE/DENIAL TEXT: If you are enrolled in hospice (end of life care), your requested medication will be covered under your Part D benefit if your doctor confirms that the medication is being used for the treatment of a condition that is not related to your terminal illness. If you are enrolled in hospice and are taking the medication for a condition related to your terminal illness, coverage may be available through your hospice benefit (Medicare Part A). Your doctor should contact your hospice provider or health plan for coverage information. This decision was based on Title XVIII of the Social Security Act(Section 1861(t)).

   NOTE: Include the quantity limit based on any applicable restriction(s):
   The requested drug has a plan limit of **[XX tablets/capsules/mL]** per **[XX]** days.

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OPIOID CUMULATIVE DOSING OVERRIDE (PART D)

GUIDELINES FOR USE (CONTINUED)

5. Does the patient meet **ONE** of the following criteria?
   - The patient is receiving palliative care (ICD-10 Z51.5) or end-of-life care
   - The patient is a resident of a long-term care facility
   - The patient has sickle cell disease (ICD-10 Group D57)
   - The patient is being treated for cancer-related pain which includes: those undergoing active cancer treatment, cancer survivors with chronic pain who have completed cancer treatment, those in clinical remission, or under cancer surveillance only

   If yes, **approve as follows:**
   - **Set PA type as OP**
   - **Approve for 12 months by HICL or GPI-10.**
   - **Please enter a class override to override the MME cumulative dosing for theduration of 12 months.**
   - **Ifthe claim rejects after analyzing, then follow the clinical coverage determination process.**

   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of **[XX]** per **[XX]** days.

   If no, continue to #6.

6. Does the prescriber attest that the higher MME is medically necessary?

   If yes, **approve as follows:**
   - **Set PA type as OE**
   - **Approve for 12 months by HICL or GPI-10.**
   - **Please enter a class override to override the MME cumulative dosing for theduration of 12 months.**
   - **Ifthe claim rejects after analyzing, then follow the clinical coverage determination process.**

   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of **[XX]** per **[XX]** days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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OPIOID CUMULATIVE DOSING OVERRIDE (PART D)

GUIDELINES FOR USE (CONTINUED)

OPTIONAL OPERATIONAL DENIAL TEXT FOR APPROVAL OF CLINICAL UM, BUT DENIAL OF THE OPIOID SAFETY EDIT:
While your request for **[enter approved UM]** for **[enter requested drug]** has been granted, the drug has not been approved because of the amount of opiates prescribed and because your opiate amount exceeds or is equal to our limit [90mg morphine milligram equivalent] or [200mg morphine milligram equivalent]. **[Proceed to enter Denial Text below]**

DENIAL TEXT:
***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **OPIOID CUMULATIVE DOSING OVERRIDE** will cause a claim for a pain medication to reject when there are two or more providers prescribing opioid medications and if you are receiving a high quantity of these medications. This guideline will allow you to receive a higher quantity of an opioid medication if ONE of the following rules is met:

- You are receiving palliative care (treatment for comfort from symptoms) or end-of life care
- You are enrolled in hospice (end of life care)
- You are a resident of (living in) a long-term care facility
- You have sickle cell disease (a type of blood disorder)
- Your doctor has stated that the prescribed dose of opioids is medically necessary
- You are being treated for pain related to current or past cancer

Please consult your doctor and/or your pharmacist to discuss your options or if you have any questions about this safety edit on prescription opioid medications and the requirements needed for you to obtain an approval for higher quantities of these medications.

NOTE: Include the quantity limit based on any applicable restriction(s):
The requested drug has a plan limit of **[XX]** per **[XX]** days.

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OPIOID CUMULATIVE DOSING OVERRIDE (PART D)

RATIONALE

To ensure appropriate use of opioids and addressing prescription opioid overuse from a medication safety perspective while preserving patient access to medically necessary drug regimens. In addition, align with the opioid restrictions from the CMS 2019 Call Letter.

Prior authorization will be required for opioid prescriptions in excess of hard opioid edit. Soft opioid edit thresholds may be overridden by a dispensing pharmacist or provider/patient may request a coverage determination. MedImpact's standard soft opioid edit is set at ≥ 90 mg morphine milligram equivalent (MME). MedImpact's standard hard opioid edit threshold is set at ≥ 200 mg MME. This requirement should not apply to patients within hospice, those receiving palliative or end of life care, residents of a long-term facility, patients approved by case management or retrospective DUR Programming, or patients being treated for cancer-related pain. Cancer-related pain includes those undergoing active cancer treatment, as well as cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance only. Following CMS guidance, patients with a diagnosis of sickle cell disease are also exempt from this restriction based on acute attacks and painful complications associated with the disease. Additional payment determination is required for patients identified as hospice. Soft-thresholds may also be overridden by the pharmacy via DUR PPS codes or as part of coverage determination process and by certain PPS codes. Hard-thresholds are overridable as part of the coverage determination process. The cumulative opioid edit minimizes false positives by accounting for known exceptions: 1) patients on hospice, have certain cancer diagnosis 2) overlapping dispensing dates for Rx refills and new Rx orders for continuing fills 3) high-dose opioid usage previously determined to be medically necessary (approved PAs, previous coverage determinations, case management) 4) no consecutive high-MME days' criterion as it would not prevent beneficiaries from reaching high opioid doses.

For patients enrolled in hospice, attestation by the prescriber must indicate that the requested opioid medication is being used for the treatment of a diagnosis unrelated to the terminal illness or related condition for coverage under their Part D benefit.

REFERENCES

Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. Available at: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf [Accessed 4/2/18]

The Social Security Act: Title XVIII: Section 1861(t), Center for Medicare and Medicaid Service. March 23, 2012. Available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSFeeSched/DME_SSAct.html [Accessed 9/28/18].

Frequently Asked Questions (FAQs) about Formulary-Level Opioid Point of Sale (POS) Safety Edits. Available at https://www.cms.gov/files/document/frequently-asked-questions-about-formulary- level-opioid-point-sale-safety-edits-july-5-2024.pdf [Accessed 8/14/24].

Created: 09/16
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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OPIOID LONG-ACTING DUPLICATIVE THERAPY (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/other
N/A	N/A	N/A	N/A	N/A	N/A

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

GUIDELINES FOR USE

1. Is the claim rejecting with the following error code?
   - **REJ-1045: THERAPEUTIC DUPLICATION DENIAL (DRUG_TD)**
     (The incoming claim for a long-acting (LA) opioid will reject when the patient is concurrently taking a different long-acting opioid [different HICL] from a different prescriber.)

     If yes, continue to #2.
     If no, guideline does not apply.

2. Is the requested medication on the "**HOSPICE DRUG LIST**"?
   NOTE: Please reference the Formulary Analyzer Tool for drug status.

     If yes, continue to #3.
     If no, continue to #5.

3. Has the patient been identified as being enrolled in hospice (i.e., plan notification, member attribute, physician/member notification on the medication request form)?

     If yes, continue to #4.
     If no, continue to #5.

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OPIOID LONG-ACTING DUPLICATIVE THERAPY (PART D)

GUIDELINES FOR USE (CONTINUED)

4. Has the prescriber provided attestation that the requested opioid medication is being used for an indication that is unrelated to the terminal illness?

   If yes, **approve as follows:**
   - **Approve under Part D for 12 months by HICL or GPI-10.**
   - **Enter a Proactive PA for 12 months by HICL or GPI-10 for the concurrent product(s), based on claim analysis**
   - **To enter approvals:**
     - **In the PA override field, override PA_HOSPICE**
     - **Set DRUG_TD_OVR to 'Y' for Yes**
     - **Change PA type to HE (Hospice Exception)**

   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of **[XX]** per **[XX]** days. If there are no other future restrictions that may apply, you are approved for the concurrent use of the Opioids [insert medication names].

   If no, do not approve.
   NOTE: This medication is included in the hospice benefit (Part A) and is not a Part D eligible drug.
   MEMBER NOTIFICATION LANGUAGE/DENIAL TEXT: If you are enrolled in hospice (end of life care), your requested medication will be covered under your Part D benefit if your doctor confirms that the medication is being used for the treatment of a condition that is not related to your terminal illness. If you are enrolled in hospice and are taking the medication for a condition related to your terminal illness, coverage may be available through your hospice benefit (Medicare Part A). Your doctor should contact your hospice provider or health plan for coverage information. This decision was based on Title XVIII of the Social Security Act (Section 1861(t)).

   NOTE: Include the quantity limit based on any applicable restriction(s):
   The requested drug has a plan limit of **[XX]** per **[XX]** days.

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OPIOID LONG-ACTING DUPLICATIVE THERAPY (PART D)

GUIDELINES FOR USE (CONTINUED)

5. Does the patient meet **ONE** of the following criteria?
   - The patient is receiving palliative care (ICD-10 Z51.5) or end-of-life care
   - The patient is a resident of a long-term care facility
   - The patient has sickle cell disease (ICD-10 Group D57)
   - The patient is being treated for cancer-related pain which includes: those undergoing active cancer treatment, cancer survivors with chronic pain who have completed cancer treatment, those in clinical remission, or under cancer surveillance only

   If yes, **approve as follows:**
   - **Set PA type as OP**
   - **Approve for 12 months by HICL or GPI-10 and set DRUG_TD_OVR to 'Y' for Yes**
   - **Enter a Proactive PA for 12 months by HICL or GPI-10 for the concurrent product(s) [drug XX], based on claim analysis, and set DRUG_TD_OVR to 'Y' for Yes**

   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of **[XX]** per **[XX]** days. If there are no other future restrictions that may apply, you are approved for the concurrent (at the same time) use of the Opioids **[insert medication names]**.

   If no, continue to #6.

6. Has the prescriber provided attestation that they are aware the patient is concurrently receiving more than one long-acting opioid medication?

   If yes, **approve as follows:**
   - **Set PA type as OE**
   - **Approve for 12 months by HICL or GPI-10 and set DRUG_TD_OVR to 'Y' for Yes**
   - **Enter a Proactive PA for 12 months by HICL or GPI-10 for the concurrent product(s) [drug XX], based on claim analysis, and set DRUG_TD_OVR to 'Y' for Yes**

   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of **[XX]** per **[XX]** days. If there are no other future restrictions that may apply, you are approved for the concurrent (at the same time) use of the Opioids **[insert medication names]**.

   If no, do not approve.
   DENIAL TEXT: See the denial text on the next page.

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OPIOID LONG-ACTING DUPLICATIVE THERAPY (PART D)

GUIDELINES FOR USE (CONTINUED)

OPTIONAL OPERATIONAL DENIAL TEXT FOR APPROVAL OF CLINICAL UM, BUT DENIAL OF THE OPIOID SAFETY EDIT: While your request for **[enter approved UM]** for **[enter requested drug]** has been granted, the drug has not been approved because of the use of two long-acting opioid drugs together that are from different prescribers. **[Proceed to enter Denial Text below]**

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OPIOID LONG-ACTING DUPLICATIVE THERAPY** allows approval of the requested drug when taken together with other long-acting opioid drug(s) from different prescribers. An approval will be provided if you meet ONE of the following conditions:

- You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
- You are enrolled in hospice (end of life care)
- You are a resident of (living in) a long-term care facility
- You have sickle cell disease (a type of blood disorder)
- Your doctor has stated that they are aware that you are concurrently (at the same time) receiving more than one long-acting opioid medication
- You are being treated for cancer-related pain which includes: you are undergoing active cancer treatment, you are a cancer survivor with chronic (long-term) pain and have completed cancer treatment, you are in clinical remission (reduction or disappearance of the signs and symptoms of a disease), or you are under cancer surveillance (monitoring) only

Please consult your doctor and/or your pharmacist to discuss your options or if you have any questions about this prescription medication and the requirements needed for you to obtain an approval for this medication.

NOTE: Include the quantity limit based on any applicable restriction(s):
The requested drug has a plan limit of **[XX]** per **[XX]** days.

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OPIOID LONG-ACTING DUPLICATIVE THERAPY (PART D)

RATIONALE

To ensure appropriate use of opioids and addressing prescription opioid overuse from a medication safety perspective while preserving patient access to medically necessary drug regimens. In addition, align with the opioid restrictions from the CMS 2019 Call Letter: "…we expect all Part D plan sponsors to implement a soft POS safety edit (which can be overridden by the pharmacist) for duplicative LA opioid therapy beginning in 2019, with or without a multiple prescriber criterion." *CMS 2019 Call Letter, page 252.*

Prior authorization will be required for Long Acting (LA) opioid prescriptions when an incoming claim for a long-acting opioid overlaps with another a long acting opioid (different HICL) claim(s) from a different prescriber(s). The edit can be overridden by professional pharmacy professional service (PPS) code at POS or by a PA. This requirement does not apply to patients receiving palliative care or end-of-life care, those enrolled in hospice or resident of a long-term care facility, or patients being treated for cancer-related pain. Cancer-related pain includes those undergoing active cancer treatment, as well as cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance only. Following CMS guidance, patients with a diagnosis of sickle cell disease are also exempt from this restriction based on acute attacks and painful complications associated with the disease. This guideline also allows an override when there is physician attestation that the prescriber is aware that the patient is concurrently receiving long acting duplicative therapy and would like to proceed with treatment for a clinically appropriate indication.
For patients enrolled in hospice, attestation by the prescriber must indicate that the requested opioid medication is being used for the treatment of a diagnosis unrelated to the terminal illness or related condition for coverage under their Part D benefit.
For patients enrolled in hospice who are taking opioid medications for a diagnosis related to the terminal illness/condition, coverage may be eligible through their hospice benefit (Medicare Part A). Your physician should contact your hospice provider or health plan for coverage information. This decision is based on Title XVIII of the Social Security Act (Section 1861(t)).

REFERENCES

Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. Available at: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf [Accessed 4/2/18].

The Social Security Act: Title XVIII: Section 1861(t), Center for Medicare and Medicaid Service. March 23, 2012. Available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSFeeSched/DME_SSAct.html [Accessed 9/28/18].

Frequently Asked Questions (FAQs) about Formulary-Level Opioid Point of Sale (POS) Safety Edits. Available at https://www.cms.gov/files/document/frequently-asked-questions-about-formulary- level-opioid-point-sale-safety-edits-july-5-2024.pdf. [Accessed 8/14/24].

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 12/18
Client Approval: 08/24
P&T Approval: 10/24

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OPIOID-BENZODIAZEPINE CONCURRENT USE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
N/A	N/A	N/A	N/A	N/A	N/A

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

GUIDELINES FOR USE

1. Is the claim rejecting with the following error code?
   - **REJ-433-1201: CLAIM CONFLICTS IN THERAPY WITH MEMBER HISTORY. (H: DUR_CONCURRENT_USE)**

   If yes, continue to #2.
   If no, guideline does not apply.

2. Is the requested medication on the "**HOSPICE DRUG LIST**"?
   NOTE: Please reference the Formulary Analyzer Tool for drug status.

   If yes, continue to #3.
   If no, continue to #5.

3. Has the patient been identified as being enrolled in hospice (i.e., plan notification, member attribute, physician/member notification on the medication request form)?

   If yes, continue to #4.
   If no, continue to #5.

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OPIOID-BENZODIAZEPINE CONCURRENT USE (PART D)

GUIDELINES FOR USE (CONTINUED)

4. Has the prescriber provided attestation that the requested medication is being used for an indication that is unrelated to the terminal illness?

   If yes, **approve as follows:**
   - **Approve under Part D for 12 months by HICL or GPI-10.**
   - **Enter a Proactive PA for 12 months by HICL or GPI-10 for the concurrent product(s), based on claim analysis.**
   - **To enter approvals:**
     - **In the PA override field, override PA_HOSPICE**
     - **Set to DUR_CONCURRENT_OVR to 'Y' for Yes**
     - **Change PA type to HE (Hospice Exception)**

   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of **[XX]** per **[XX]** days. If there are no other future restrictions that may apply, you are approved for the concurrent (at the same time) use of the Opioid [insert medication name] and the Benzodiazepine **[insert medication name]**.

   If no, do not approve.
   NOTE: This medication is included in the hospice benefit (Part A) and is not a Part D eligible drug.
   MEMBER NOTIFICATION LANGUAGE/DENIAL TEXT: If you are enrolled in hospice (end of life care), your requested medication will be covered under your Part D benefit if your doctor confirms that the medication is being used for the treatment of a condition that is not related to your terminal illness. If you are enrolled in hospice and are taking the medication for a condition related to your terminal illness, coverage may be available through your hospice benefit (Medicare Part A). Your doctor should contact your hospice provider or health plan for coverage information. This decision was based on Title XVIII of the Social Security Act (Section 1861(t)).

   NOTE: Include the quantity limit based on any applicable restriction(s):
   The requested drug has a plan limit of **[XX]** per **[XX]** days.

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OPIOID-BENZODIAZEPINE CONCURRENT USE (PART D)

GUIDELINES FOR USE (CONTINUED)

5. Does the patient meet **ONE** of the following criteria?
   - The patient is receiving palliative care (ICD-10 Z51.5) or end-of-life care
   - The patient is a resident of a long-term care facility
   - The patient has sickle cell disease (ICD-10 Group D57)
   - The patient is being treated for cancer-related pain which includes: those undergoing active cancer treatment, cancer survivors with chronic pain who have completed cancer treatment, those in clinical remission, or under cancer surveillance only

   If yes, **approve as follows:**
   - **Set PA type as OP**
   - **Approve for 12 months by HICL or GPI-10 and set DUR_CONCURRENT_OVR to 'OP_BZD'**
   - **Enter a Proactive PA for 12 months by HICL or GPI-10 for the concurrent product(s) [drug XX], based on claim analysis, and set DUR_CONCURRENT_OVR to 'OP_BZD'**

   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of **[XX]** per **[XX]** days. If there are no other future restrictions that may apply, you are approved for the concurrent (at the same time) use of the Opioid [insert medication name] and the Benzodiazepine **[insert medication name]**.

   If no, continue to #6.

6. Has the prescriber provided attestation to proceed with the concurrent use of an opioid and a benzodiazepine for a clinically appropriate indication?

   If yes, **approve as follows:**
   - **Set PA type as OE**
   - **Approve for 12 months by HICL or GPI-10 and set DUR_CONCURRENT_OVR to 'OP_BZD'**
   - **Enter a Proactive PA for 12 months by HICL or GPI-10 for the concurrent product(s) [drug XX], based on claim analysis, and set DUR_CONCURRENT_OVR to 'OP_BZD'**

   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of **[XX]** per **[XX]** days. If there are no other future restrictions that may apply, you are approved for the concurrent (at the same time) use of the Opioid [insert medication name] and the Benzodiazepine **[insert medication name]**.

   If no, do not approve.
   DENIAL TEXT: See the denial text on the next page.

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OPIOID-BENZODIAZEPINE CONCURRENT USE (PART D)

GUIDELINES FOR USE (CONTINUED)

OPTIONAL OPERATIONAL DENIAL TEXT FOR APPROVAL OF CLINICAL UM, BUT DENIAL OF THE OPIOID SAFETY EDIT: While your request for **[enter approved UM]** for **[enter requested drug]** has been granted, the drug has not been approved because of the use of an opioid drug and a benzodiazepine drug together. **[Proceed to enter Denial Text below]**

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OPIOID-BENZODIAZEPINE CONCURRENT USE** allows for an approval if you are receiving an opioid with a benzodiazepine. An approval for concurrent (at the same time) use will be provided when ONE of the following criteria is met:

- You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
- You are enrolled in hospice (end of life care)
- You are a resident of (living in) a long-term care facility
- You have sickle cell disease (a type of blood disorder)
- Your doctor agrees to proceed with the concurrent use (at the same time) of an opioid and a benzodiazepine for a clinically appropriate indication (reason)
- You are being treated for cancer-related pain which includes: you are undergoing active cancer treatment, you are a cancer survivor with chronic (long-term) pain and have completed cancer treatment, you are in clinical remission (reduction or disappearance of the signs and symptoms of a disease), or you are under cancer surveillance (monitoring) only

Please consult your doctor and/or your pharmacist to discuss your options or if you have any questions about this prescription pain medication and the requirements needed for you to obtain an approval for this medication.

NOTE: Include the quantity limit based on any applicable restriction(s):
The requested drug has a plan limit of **[XX]** per **[XX]** days.

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OPIOID-BENZODIAZEPINE CONCURRENT USE (PART D)

RATIONALE

To ensure appropriate use of opioids and addressing prescription opioid overuse from a medication safety perspective while preserving patient access to medically necessary drug regimens. In addition, align with the opioid restrictions from the CMS 2019 Call Letter:
"We expect that Part D sponsors implement a concurrent opioid and benzodiazepine soft POS safety edit (which can be overridden by the pharmacist) to prompt additional safety review at the time of dispensing beginning in 2019."*CMS 2019 Call Letter, page 251*

The claim will deny when there is concurrent use of benzodiazepines and opioids with any overlap in day supply. This can be overridden at POS or by a Prior Authorization. If the pharmacy does not submit the specified PPS codes, the claim should reject unless a prior approval is in place.
This guideline allows an approval for patients with one of the following conditions:
Receiving palliative care or end-of-life care
Enrolled in hospice
Resident of a long-term care facility
Diagnosis of sickle cell disease
Prescriber attestation to proceed with the concurrent use of an opioid and a benzodiazepine for a clinically appropriate indication
Being treated for cancer-related pain which includes: those undergoing active cancer treatment, cancer survivors with chronic pain who have completed cancer treatment, those in clinical remission, or under cancer surveillance only

For patients enrolled in hospice, attestation by the prescriber must indicate that the requested opioid medication is being used for the treatment of a diagnosis unrelated to the terminal illness or related condition for coverage under their Part D benefit.
For patients enrolled in hospice who are taking opioid medications for a diagnosis related to the terminal illness/condition, coverage may be eligible through their hospice benefit (Medicare Part A).
This decision is based on Title XVIII of the Social Security Act (Section 1861(t)).

REFERENCES

Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. Available at: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf [Accessed 8/12/24]
The Social Security Act: Title XVIII: Section 1861(t), Center for Medicare and Medicaid Service. March 23, 2012. Available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSFeeSched/DME_SSAct.html [Accessed 9/28/18].
Frequently Asked Questions (FAQs) about Formulary-Level Opioid Point of Sale (POS) Safety Edits. Available at https://www.cms.gov/files/document/frequently-asked-questions-about-formulary- level-opioid-point-sale-safety-edits-july-5-2024.pdf [Accessed 8/12/24].

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25 Created: 12/18
Commercial Effective: N/A Client Approval: 08/24 P&T Approval: 10/24

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OPIOID-BUPRENORPHINE CONCURRENT USE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
N/A	N/A	N/A	N/A	N/A	N/A

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

GUIDELINES FOR USE

1. Is the claim rejecting with the following error code?
   - **REJ-433-1200: CLAIM CONFLICTS IN THERAPY WITH MEMBER HISTORY. (H: DUR_CONCURRENT_USE)**

   If yes, continue to #2.
   If no, guideline does not apply.

2. Is the requested medication on the "**HOSPICE DRUG LIST**"?
   NOTE: Please reference the Formulary Analyzer Tool for drug status.

   If yes, continue to #3.
   If no, continue to #5.

3. Has the patient been identified as being enrolled in hospice (i.e., plan notification, member attribute, physician/member notification on the medication request form)?

   If yes, continue to #4.
   If no, continue to #5.

4. Has the prescriber provided attestation that the requested opioid medication is being used for an indication that is unrelated to the terminal illness?

   If yes, **approve as follows:**
   - **Approve under Part D for 12 months by HICL or GPI-10**
   - **To enter approvals:**
     - **In the PA override field, override PA_HOSPICE**
     - **Set DUR_CONCURRENT_OVR to 'Y' for Yes**
     - **Change PA type to HE (Hospice Exception)**

   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of **[XX]** per **[XX]** days.

   If no, do not approve.
   DENIAL TEXT: See the denial text on the next page.

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OPIOID-BUPRENORPHINE CONCURRENT USE (PART D)

GUIDELINES FOR USE (CONTINUED)

NOTE: This medication is included in the hospice benefit (Part A) and is not a Part D eligible drug. **MEMBER NOTIFICATION LANGUAGE/DENIAL TEXT:** If you are enrolled in hospice (end of life care), your requested medication will be covered under your Part D benefit if your doctor confirms that the medication is being used for the treatment of a condition that is not related to your terminal illness. If you are enrolled in hospice and are taking the medication for a condition related to your terminal illness, coverage may be available through your hospice benefit (Medicare Part A). Your doctor should contact your hospice provider or health plan for coverage information. This decision was based on Title XVIII of the Social Security Act (Section 1861(t)).

NOTE: Include the quantity limit based on any applicable restriction(s):
The requested drug has a plan limit of **[XX]** per **[XX]** days.

5. Does the patient meet **ONE** of the following criteria?
   - The patient is receiving palliative care (ICD-10 Z51.5) or end-of-life care
   - The patient is a resident of a long-term care facility
   - The patient has sickle cell disease (ICD-10 Group D57)
   - The patient is being treated for cancer-related pain which includes: those undergoing active cancer treatment, cancer survivors with chronic pain who have completed cancer treatment, those in clinical remission, or under cancer surveillance only

   If yes, **approve as follows:**
   - **Set PA type as OP**
   - **Approve for 12 months by HICL or GPI-10 and set DUR_CONCURRENT_OVR to 'OP_BUP'**

   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of **[XX]** per **[XX]** days**.**

   If no, continue to #6.

6. Has the prescriber provided attestation that the patient has discontinued or will be discontinuing opioid dependency treatment with buprenorphine or buprenorphine-containing agents and needs to resume chronic opioid treatment? (**NOTE**: Consultation with an addiction medicine specialist is recommended)

   If yes, **approve as follows:**
   - **Set PA type as OP**
   - **Approve for 12 months by HICL or GPI-10 and set DUR_CONCURRENT_OVR to 'OP_BUP'**

   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of **[XX]** per **[XX]** days.

   If no, continue to #7.

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OPIOID-BUPRENORPHINE CONCURRENT USE (PART D)

GUIDELINES FOR USE (CONTINUED)

7. Is the prescriber aware that the patient is currently receiving buprenorphine or buprenorphine-containing agents for treatment of opioid dependency and has provided attestation to proceed with opioid treatment for an acute, clinically appropriate indication? (**NOTE**: Consultation with an addiction medicine specialist is recommended)

   If yes, **approve as follows:**
   - **Set PA type as OE**
   - **Approve for 12 months by HICL or GPI-10 and set DUR_CONCURRENT_OVR to 'OP_BUP'**

   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of **[XX]** per **[XX]** days.

   If no, do not approve.
   OPTIONAL OPERATIONAL DENIAL TEXT FOR APPROVAL OF CLINICAL UM, BUT DENIAL OF THE OPIOID SAFETY EDIT: While your request for **[enter approved UM]** for **[enter requested drug]** has been granted, the drug has not been approved because of the use of an opioid drug and a buprenorphine-containing drug together. **[Proceed to enter Denial Text below]**

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OPIOID-BUPRENORPHINE CONCURRENT USE** is for patients who are receiving an opioid with buprenorphine or a buprenorphine-containing agent. This guideline allows an approval for concurrent (at the same time) use of these medications when ONE of the following criteria is met:
   - You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
   - You are enrolled in hospice (end of life care)
   - You are a resident of (living in) a long-term care facility
   - You have sickle cell disease (a type of blood disorder)
   - Your doctor is aware that you are currently receiving buprenorphine or a buprenorphine-containing agent for treatment of opioid dependency and has advised to proceed with opioid treatment for an acute (short-term), clinically appropriate indication. Consultation with an addiction medicine specialist is recommended
   - Your doctor has stated that you have discontinued or will be discontinuing opioid dependency treatment with buprenorphine or buprenorphine-containing agents and to proceed with opioid treatment. Consultation with an addiction medicine specialist is recommended

   (Denial text continued on next page)

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OPIOID-BUPRENORPHINE CONCURRENT USE (PART D)

GUIDELINES FOR USE (CONTINUED)

- You are being treated for cancer-related pain which includes: you are undergoing active cancer treatment, you are a cancer survivor with chronic (long-term) pain and have completed cancer treatment, you are in clinical remission (reduction or disappearance of the signs and symptoms of a disease), or you are under cancer surveillance (monitoring) only

Please consult your doctor and/or your pharmacist to discuss your options or if you have any questions about this prescription pain medication and the requirements needed for you to obtain an approval for this medication.

NOTE: Include the quantity limit based on any applicable restriction(s):
The requested drug has a plan limit of **[XX]** per **[XX]** days.

RATIONALE

To ensure appropriate use of opioids and addressing prescription opioid overuse from a medication safety perspective while preserving patient access to medically necessary drug regimens. In addition, align with the opioid restrictions from the CMS 2019 Call Letter.

Prior authorization will be required for opioid prescriptions when in concurrent use with buprenorphine. This edit will be utilized to stop opioid claims, which overlap with buprenorphine use. The edit will stop the claim for pharmacy submission of PPS codes. If the pharmacy does not submit the specified PPS codes, the claim should reject unless a prior approval is in place.

The guideline requires that the prescriber is aware that the patient is currently receiving buprenorphine or buprenorphine-containing agents for treatment of opioid dependency and has provided attestation to proceed with opioid treatment for an acute, clinically appropriate indication, or the prescriber has provided attestation that the patient has discontinued or will be discontinuing opioid dependency treatment with buprenorphine or buprenorphine-containing agents and to proceed with opioid treatment. Consultation with an addiction medicine specialist is recommended.
In addition, the guideline allows an override for patients with one of the following conditions:
Receiving palliative care or end-of-life care
Enrolled in hospice
Resident of a long-term care facility
Diagnosis of sickle cell disease
Being treated for cancer-related pain which includes: those undergoing active cancer treatment, cancer survivors with chronic pain who have completed cancer treatment, those in clinical remission, or under cancer surveillance only

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OPIOID-BUPRENORPHINE CONCURRENT USE (PART D)

RATIONALE (CONTINUED)

For patients enrolled in hospice, attestation by the prescriber must indicate that the requested opioid medication is being used for the treatment of a diagnosis unrelated to the terminal illness or related condition for coverage under their Part D benefit.
For patients enrolled in hospice who are taking opioid medications for a diagnosis related to the terminal illness/condition, coverage may be eligible through their hospice benefit (Medicare Part A). This decision is based on Title XVIII of the Social Security Act (Section 1861(t)).

REFERENCES

Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. Available at: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf [Accessed 4/2/18]

The Social Security Act: Title XVIII: Section 1861(t), Center for Medicare and Medicaid Service. March 23, 2012. Available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSFeeSched/DME_SSAct.html [Accessed 9/28/18].

Frequently Asked Questions (FAQs) about Formulary-Level Opioid Point of Sale (POS) Safety Edits. Available at https://www.cms.gov/files/document/frequently-asked-questions-about-formulary- level-opioid-point-sale-safety-edits-july-5-2024.pdf Accessed 8/14/24].

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 12/18
Client Approval: 09/24
P&T Approval: 10/24

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OPIOID-NAIVE DAY SUPPLY LIMITATION (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/other
N/A	N/A	N/A	N/A	N/A	N/A

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

GUIDELINES FOR USE

1. Is the claim rejecting with the following error code?
   - **REJ-1044: INITIAL FILL DAYS SUPPLY EXCEEDS LIMITS (DS-NAIVE)**
     (**NOTE:** The claim will reject when there is an opioid therapy for more than a 7-day supply **AND** the patient is opioid-naive meaning they have not used an opioid analgesic drug(s) in the past 60 days)

     If yes, continue to #2.
     If no, guideline does not apply.

2. Is the requested medication on the "**HOSPICE DRUG LIST**"?
   NOTE: Please reference the Formulary Analyzer Tool for drug status.

   If yes, continue to #3.
   If no, continue to #5.

3. Has the patient been identified as being enrolled in hospice (i.e., plan notification, member attribute, physician/member notification on the medication request form)?

   If yes, continue to #4.
   If no, continue to #5.

4. Has the prescriber provided attestation that the requested opioid medication is being used for an indication that is unrelated to the terminal illness?

   If yes, **approve as follows:**
   - **Approve under Part D for 12 months by HICL or GPI-10.**
   - **To enter approvals:**
     - **In the PA override field, override PA_HOSPICE**
     - **Set DS_NAIVE_OVR to 'Y' for Yes**
     - **Change PA type to HE (Hospice Exception)**

   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of **[XX]** per **[XX]** days.

   If no, do not approve.
   DENIAL TEXT: See the denial text on the next page.

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OPIOID-NAIVE DAY SUPPLY LIMITATION (PART D)

GUIDELINES FOR USE (CONTINUED)

NOTE: This medication is included in the hospice benefit (Part A) and is not a Part D eligible drug. **MEMBER NOTIFICATION LANGUAGE/DENIAL TEXT:** If you are enrolled in hospice (end of life care), your requested medication will be covered under your Part D benefit if your doctor confirms that the medication is being used for the treatment of a condition that is not related to your terminal illness. If you are enrolled in hospice and are taking the medication for a condition related to your terminal illness, coverage may be available through your hospice benefit (Medicare Part A). Your doctor should contact your hospice provider or health plan for coverage information. This decision was based on Title XVIII of the Social Security Act (Section 1861(t)).

NOTE: Include the quantity limit based on any applicable restriction(s):
The requested drug has a plan limit of **[XX]** per **[XX]** days.

5. Does the patient meet **ONE** of the following criteria?
   - The patient is receiving palliative care (ICD-10 Z51.5) or end-of-life care
   - The patient is a resident of a long-term care facility
   - The patient has sickle cell disease (ICD-10 Group D57)
   - The patient is being treated for cancer-related pain which includes: those undergoing active cancer treatment, cancer survivors with chronic pain who have completed cancer treatment, those in clinical remission, or under cancer surveillance only

   If yes, **approve as follows:**
   - **Set PA type as OP**
   - **Approve for 12 months by HICL or GPI-10 and set DS_NAIVE_OVR to 'Y' for Yes**

   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of **[XX]** per **[XX]** days.

   If no, continue to #6.

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OPIOID-NAIVE DAY SUPPLY LIMITATION (PART D)

GUIDELINES FOR USE (CONTINUED)

6. Is the patient **NOT** opioid naive based on the medication request form (not based on claim history)? [*NOTE: Patient is NOT opioid naive when the medication request form from the prescriber refers to the patient being on an opioid analgesic drug(s) within 60 days (e.g., stability, need to continue use or use of opioids within 60 days*)]

   If yes, **approve as follows:**
   - **Set PA type as OP**
   - **Approve for 1 month by HICL or GPI-10 and set DS_NAIVE_OVR to 'Y' for Yes**

   APPROVAL TEXT: The requested drug has a plan limit of **[XX]** per **[XX]** days. Please note, there is an additional condition to your approval. You can continue to receive opioid medications as long as you have an approved claim within 60 days of the last opioid claim you have filled. If there is a gap between opioid claims of more than 60 days, an additional prior authorization will be necessary.

   If no, continue to #7.

7. Has the prescriber provided attestation that the opioid medication with the requested day supply is the intended and medically necessary amount for the beneficiary?

   If yes, **approve as follows:**
   - **Set PA type as OE**
   - **Approve for 1 month by HICL or GPI-10 and set DS_NAIVE_OVR to 'Y' for Yes**

   APPROVAL TEXT: The requested drug has a plan limit of **[XX]** per **[XX]** days. Please note, there is an additional condition to your approval. You can continue to receive opioid medications as long as you have an approved claim within 60 days of the last opioid claim you have filled. If there is a gap between opioid claims of more than 60 days, an additional prior authorization will be necessary.

   If no, continue to #8.

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OPIOID-NAIVE DAY SUPPLY LIMITATION (PART D)

GUIDELINES FOR USE (CONTINUED)

8. Does the member have at least one approved claim for an opioid analgesic within 60 days of the date of review?
   (**NOTE:** Only approved opioid analgesic are considered as valid medication history. Cough and cold products or opioid tinctures are not considered for this edit.)

   If yes, **PA Not Required.**
   LETTER LANGUAGE: The requested drug has a plan limit of **[XX]** per **[XX]** days. Currently, our records show that you have an approved claim for an opioid analgesic (pain medication). This means that you are not considered opioid naive (you have been receiving opioid pain medication on a consistent basis). You can continue to fill your opioid medications for more than a 7-day supply if it is within 60 days of the last opioid approved claim. After this opioid prescription is picked up, you can receive additional opioid medications for more than a 7-day supply. If you stop receiving opioid claims for more than 60 days, you will be considered opioid naive and will be limited to a 7-day supply.

   If no, please use the specific denial text for **PA Request** or **DMR Request**:
   DENIAL TEXT: See the denial text on the next page.

   FOR PA REQUEST:

   OPTIONAL OPERATIONAL DENIAL TEXT FOR APPROVAL OF CLINICAL UM, BUT DENIAL OF THE OPIOID SAFETY EDIT: While your request for **[enter approved UM]** for **[enter requested drug]** has been granted, the drug has not been approved because of the more than 7-day supply you are requesting for this opioid medication. **[Proceed to enter Denial Text below]**

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OPIOID-NAIVE DAY SUPPLY LIMITATION (PART D)

GUIDELINES FOR USE (CONTINUED)

PA DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OPIOID-NAIVE DAY SUPPLY LIMITATION** allows approval of the requested drug for longer than a 7-day supply for opioid-naive patients if you meet ONE of the following conditions:

- You are enrolled in hospice (end of life care)
- You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
- You are a resident of (living in) a long-term care facility
- You have sickle cell disease (a type of blood disorder)
- You are NOT opioid naive (defined as, you have received at least one fill of an opioid medication within the last 60 days or evidence that you are already opioid tolerant [body is used to taking the pain medication])
- Your doctor has stated that prescribed dose of opioids with the requested day supply is intended and medically necessary
- You are being treated for cancer-related pain which includes: you are undergoing active cancer treatment, you are a cancer survivor with chronic (long-term) pain and have completed cancer treatment, you are in clinical remission (reduction or disappearance of the signs and symptoms of a disease), or you are under cancer surveillance (monitoring) only

Although you have been denied for longer than a 7-day supply you may work with your pharmacy to get up to a 7-day supply without a prior authorization, as long as you have a prescription. Please consult your doctor if you have any questions about this prescription pain medication and the requirements needed for you to obtain an approval for this medication.

NOTE: Include the quantity limit based on any applicable restriction(s):
The requested drug has a plan limit of **[XX]** per **[XX]** days.

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OPIOID-NAIVE DAY SUPPLY LIMITATION (PART D)

GUIDELINES FOR USE (CONTINUED)

FOR DMR REQUESTS:

APPROVE REIMBURSEMENT FOR 7 DAYS ONLY and include **DMR DENIAL TEXT.**

DMR DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OPIOID-NAIVE DAY SUPPLY LIMITATION** allows approval of the requested drug for longer than a 7-day supply for patients if you meet ONE of the following conditions:

- You are enrolled in hospice (end of life care)
- You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
- You are a resident of (living in) a long-term care facility
- You have sickle cell disease (a type of blood disorder)
- You are NOT opioid naive (defined as, you have received at least one fill of an opioid medication within the last 60 days or evidence that you are already opioid tolerant [body is used to taking the pain medication])
- Your doctor has stated that the prescribed dose of opioids with the requested day supply is intended and medically necessary
- You are being treated for cancer-related pain which includes: you are undergoing active cancer treatment, you are a cancer survivor with chronic (long-term) pain and have completed cancer treatment, you are in clinical remission (reduction or disappearance of the signs and symptoms of a disease), or you are under cancer surveillance (monitoring) only

Although you have been denied for longer than a 7-day supply, we have approved reimbursement for a 7-day supply.

NOTE: Include the quantity limit based on any applicable restriction(s):
The requested drug has a plan limit of **[XX]** per **[XX]** days.

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OPIOID-NAIVE DAY SUPPLY LIMITATION (PART D)

RATIONALE

The purpose of the guideline is to ensure appropriate use of opioids and address prescription opioid overuse from a medication safety perspective while preserving patient access to medically necessary drug regimens. In addition, the guideline aligns with the opioid restrictions from the CMS 2019 Call Letter.

Prior authorization will be required for opioid prescriptions with a longer day supply for opioid naive patients. This requirement does not apply to patients receiving palliative care or end-of-life care, those enrolled in hospice, residents of a long-term care facility, or patients being treated for cancer-related pain. Cancer-related pain includes those undergoing active cancer treatment, as well as cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance only.

In addition, if the patient is determined to NOT be opioid naive during the coverage determination process, they are exempt from this safety edit. This exemption is based on the following guidance: "If during the coverage determination process, it becomes known that the patient is not opioid naive, he or she should be excluded from the opioid naive edit." *CMS Additional Guidance memo from October 23, 2018, page 8.*

Following CMS guidance, patients with a diagnosis of sickle cell disease are also exempt from this restriction based on acute attacks and painful complications associated with the disease. This guideline also allows an override when there is attestation from the prescriber that the prescribed dose of opioids with the requested day supply is intended and medically necessary.

REFERENCES

Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. Available at: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf [Accessed 4/2/18]

The Social Security Act: Title XVIII: Section 1861(t), Center for Medicare and Medicaid Service. March 23, 2012. Available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSFeeSched/DME_SSAct.html [Accessed 9/28/18].

Additional Guidance on Contract Year 2019 Formulary-Level Opioid Point of Sale Safety Edits. Available at https://mopa.memberclicks.net/assets/docs/Opioid_SafetyEdit_Memo_10232018%20%28002%29. pdf [Accessed 11/20/18].

Medicare Part D Plan Reporting Requirements: Technical Specifications Document Contract Year 2019. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/CY2019-Technical-Specifications_121118.pdf [Accessed 5/20/20]

Frequently Asked Questions (FAQs) about Formulary-Level Opioid Point of Sale (POS) Safety Edits. Available at https://www.cms.gov/files/document/frequently-asked-questions-about-formulary- level-opioid-point-sale-safety-edits-july-5-2024.pdf [Accessed 8/12/24].

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OPIOID-NAIVE DAY SUPPLY LIMITATION (PART D)

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25 Created: 12/18
Commercial Effective: N/A Client Approval: 08/24 P&T Approval: 10/24

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OSILODROSTAT (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OSILODROSTAT PHOSPHATE	ISTURISA	46396		GPI-10 (3002206060)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Cushing's syndrome (ICD-10 Group E24) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Surgery is not an option or has not been curative for the patient
   - Therapy is prescribed by or in consultation with an endocrinologist

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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OSILODROSTAT (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OSILODROSTAT (Isturisa)** requires the following rule(s) be met for approval:

A. You have Cushing's syndrome (a type of hormone disorder)
B. You are 18 years of age or older
C. Surgery is not an option or has not cured your condition
D. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OSILODROSTAT (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Cushing's syndrome (ICD-10 Group E24) and meet **ALL** the following criteria?
   - The patient continues to have improvement of Cushing's disease/Cushing's syndrome (e.g., clinically meaningful reduction in 24-hour urinary free cortisol and/or improvements in signs and symptoms of disease)
   - The patient maintains tolerability to Isturisa

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OSILODROSTAT (Isturisa)** requires the following rule(s) be met for renewal:
   A. You have Cushing's syndrome (a type of hormone disorder)
   B. You continue to have improvement of Cushing's disease/Cushing's syndrome (such as clinically meaningful reduction in 24-hour urinary free cortisol and/or improvements in signs and symptoms of disease)
   C. You continue to tolerate treatment with Isturisa

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Isturisa.

REFERENCES
Isturisa [Prescribing Information]. Lebanon, NJ: Recordati Rare Diseases, Inc.; April 2025.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OSILODROSTAT (PART D)

For Part D use only:

OSILODROSTAT (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	CUSHINGS SYNDROME: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	CUSHINGS SYNDROME: RENEWAL: 1) CONTINUED IMPROVEMENT OF CUSHINGS DISEASE/SYNDROME, AND 2) MAINTAINS TOLERABILITY TO ISTURISA.

Created: 04/20
Effective: 01/01/26 Client Approval: 12/25 P&T Approval: 07/25

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OSIMERTINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OSIMERTINIB MESYLATE	TAGRISSO	42803		GPI-10 (2136006820)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of non-small cell lung cancer (NSCLC) (ICD-10 Group C34) **AND** meet the following criterion?
- The patient is 18 years of age or older

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

2. Will Tagrisso be used as adjuvant therapy after tumor resection **AND** the patient meets the following criterion?
- The patient's tumor has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #3.

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OSIMERTINIB (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Is the cancer locally advanced and unresectable (stage III) and the patient meets **ALL** of the following criteria?
   - The patient's disease has NOT progressed during or following concurrent or sequential platinum-based (e.g., cisplatin, carboplatin) chemoradiation therapy
   - The patient's tumor has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

4. Is the cancer metastatic and the patient meets **ONE** of the following criteria?
   - The patient's tumor has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test
   - The patient's tumor has an epidermal growth factor receptor (EGFR) T790M mutation, as detected by an FDA-approved test, AND the patient's disease has progressed while on or after EGFR tyrosine kinase-inhibitor therapy (e.g., Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Is the cancer locally advanced or metastatic and the patient meets **ALL** of the following criteria?
   - Tagrisso will be used in combination with pemetrexed and platinum-based chemotherapy (e.g., cisplatin, carboplatin)
   - The patient's tumor has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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OSIMERTINIB (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OSIMERTINIB (Tagrisso)** requires the following rule(s) be met for approval:

A. You have non-small cell lung cancer (NSCLC: a type of lung cancer)
B. You are 18 years of age or older
C. You meet ONE of the following:
    1. Tagrisso will be used as adjuvant therapy (add-on treatment) after tumor resection (surgical removal of a tumor), and your tumor has epidermal growth factor receptor (EGFR: type of protein) exon 19 deletions or exon 21 L858R mutations (abnormal changes in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test
    2. Your cancer is locally advanced and unresectable (stage III) (cancer that has spread to nearby tissue or lymph nodes and cannot be surgically removed), and you meet ALL of the following:
        a. Your disease has NOT worsened during or following concurrent (at the same time) or sequential (one after the other) platinum-based (such as cisplatin, carboplatin) chemoradiation therapy (a type of treatment that combines chemotherapy and radiation)
        b. Your tumor has epidermal growth factor receptor (EGFR: type of protein) exon 19 deletions or exon 21 L858R mutations (abnormal changes in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test
    3. Your cancer is metastatic (cancer that has spread to other parts of the body), and you meet ONE of the following:
        a. Your tumor has epidermal growth factor receptor (EGFR: type of protein) exon 19 deletions or exon 21 L858R mutations (abnormal changes in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test
        b. Your tumor has an epidermal growth factor receptor (EGFR) T790M mutation (abnormal change in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test, AND your disease has worsened while on or after EGFR tyrosine kinase-inhibitor therapy (such as Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib])

(Denial text continued on next page)

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OSIMERTINIB (PART D)

GUIDELINES FOR USE (CONTINUED)

4. Your cancer is locally advanced or metastatic (cancer that has spread from where it started to nearby tissue, lymph nodes, or other parts of the body), and you meet ALL of the following:
   a. Tagrisso will be used in combination with pemetrexed and platinum-based chemotherapy (such as cisplatin, carboplatin)
   b. Your tumor has epidermal growth factor receptor (EGFR: type of protein) exon 19 deletions or exon 21 L858R mutations (abnormal changes in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tagrisso.

REFERENCES

Tagrisso [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; September 2024.

For Part D use only:

OSIMERTINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 11/15
Client Approval: 11/24
P&T Approval: 10/24

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OTESECONAZOLE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OTESECONAZOLE	VIVJOA	47976		GPI-10 (1140805000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the request for the reduction in the incidence of recurrent vulvovaginal candidiasis (RVVC) (ICD-10 B37.32) and the patient meets **ALL** of the following criteria?
   - The patient is female
   - The patient is NOT of reproductive potential (defined as a biological female who is postmenopausal or has another reason for permanent infertility [e.g., tubal ligation, hysterectomy, salpingo-oophorectomy])
   - The patient is NOT currently on ibrexafungerp for RVVC

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient previously received Vivjoa?

   If yes, continue to #4.
   If no, continue to #3.

3. Has the patient had 3 or more episodes of VVC in the past 12 months?

   If yes, **approve for 3 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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OTESECONAZOLE (PART D)

GUIDELINES FOR USE (CONTINUED)

4. Does the patient meet **ALL** of the following criteria?
   - The patient has successfully completed a course of Vivjoa for prevention of RVVC
   - The patient is either being treated or has just completed treatment for a new recurrence of VVC

   If yes, **approve for 3 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OTESECONAZOLE (Vivjoa)** requires the following rule(s) be met for approval:
   A. You have recurrent vulvovaginal candidiasis (RVVC: a repeating vaginal fungal infection)
   B. You are female
   C. You are not able to reproduce, which means you are a biological female and are postmenopausal (after menopause) or have another reason for permanent infertility (such as tubal ligation [having tubes tied], hysterectomy [removal of the uterus], salpingo-oophorectomy [removal of an ovary and its fallopian tube])
   D. You are NOT currently on ibrexafungerp for RVVC
   E. If you have not previously received Vivjoa, approval also requires:
      1. You had 3 or more episodes of RVVC in the past 12 months
   F. If you have previously received Vivjoa, approval also requires:
      1. You have successfully completed a course of Vivjoa for prevention of RVVC
      2. You are either being treated or have just completed treatment for a new recurrence of VVC

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OTESECONAZOLE (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Vivjoa.

REFERENCES
Vivjoa [Prescribing Information]. Durham, NC: Mycovia Pharmaceuticals, Inc.; April 2022.

For Part D use only:

OTESECONAZOLE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 MONTHS
Other Criteria	RECURRENT VULVOVAGINAL CANDIDIASIS (RVVC): 1) PATIENT IS NOT OF REPRODUCTIVE POTENTIAL (DEFINED AS A BIOLOGICAL FEMALE WHO IS POSTMENOPAUSAL OR HAS ANOTHER REASON FOR PERMANENT INFERTILITY [E.G., TUBAL LIGATION, HYSTERECTOMY, SALPINGO-OOPHORECTOMY]), 2) NOT CURRENTLY ON IBREXAFUNGERP FOR RVVC, AND 3) ONE OF THE FOLLOWING: (A) IF TREATMENT NAIVE (WITH VIVJOA): HAD 3 OR MORE EPISODES OF VVC IN THE PAST 12 MONTHS, OR (B) IF TREATMENT EXPERIENCED: SUCCESSFULLY COMPLETED A COURSE OF VIVJOA FOR PREVENTION OF RVVC AND IS EITHER BEING TREATED OR HAS JUST COMPLETED TREATMENT FOR A NEW RECURRENCE OF VVC.

Core	Advantage	Plus
No	No	Yes

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OXANDROLONE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OXANDROLONE	OXANDROLONE	01412		GPI-10 (2320004000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of protein catabolism associated with prolonged administration of corticosteroids and meet **ALL** of the following criteria?
   - Oxandrolone will be used as adjunctive therapy
   - The patient will be monitored for peliosis hepatis, liver cell tumors, and blood lipid changes

   If yes, continue to #3.
   If no, continue to #2.

2. Does the patient have a diagnosis of bone pain accompanying osteoporosis **AND** meet the following criterion?
   - The patient will be monitored for peliosis hepatis, liver cell tumors, and blood lipid changes

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient have **ANY** of the following contraindications to therapy?
   - Known or suspected carcinoma of the prostate or breast in male patients
   - Known or suspected carcinoma of the breast in females with hypercalcemia
   - Known or suspected nephrosis (the nephrotic phase of nephritis)
   - Known or suspected hypercalcemia
   - Severe hepatic dysfunction

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

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OXANDROLONE (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OXANDROLONE** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Protein catabolism (breakdown) associated with prolonged administration of corticosteroids (a type of drug)
   2. Bone pain accompanying osteoporosis (a type of bone condition)

B. If you have protein catabolism associated with prolonged administration of corticosteroids, approval also requires:
   1. Oxandrolone will be used as adjunctive (add-on) treatment
   2. You will be monitored for peliosis hepatis (blood-filled spaces in the liver), liver cell tumors, and blood lipid (fats) changes
   3. You do NOT have any of the following reasons why you cannot use oxandrolone treatment:
      a. Known or suspected carcinoma (cancer) of the prostate or breast in male patients
      b. Known or suspected carcinoma of the breast in females with hypercalcemia (high calcium levels)
      c. Known or suspected nephrosis (the nephrotic phase of nephritis) (a type of kidney condition)
      d. Known or suspected hypercalcemia
      e. Severe hepatic (liver) dysfunction

C. If you have bone pain accompanying osteoporosis, approval also requires:
   1. You will be monitored for peliosis hepatis (blood-filled spaces in the liver), liver cell tumors, and blood lipid (fats) changes
   2. You do NOT have any of the following reasons why you cannot use oxandrolone treatment:
      a. Known or suspected carcinoma (cancer) of the prostate or breast in male patients
      b. Known or suspected carcinoma of the breast in females with hypercalcemia (high calcium levels)
      c. Known or suspected nephrosis (the nephrotic phase of nephritis) (a type of kidney condition)
      d. Known or suspected hypercalcemia
      e. Severe hepatic (liver) dysfunction

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OXANDROLONE (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for oxandrolone.

REFERENCES
Oxandrolone [Prescribing Information]. Chestnut Ridge, NY: Par Pharmaceutical; April 2020.

For Part D use only:

OXANDROLONE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 MONTHS
Other Criteria	PROTEIN CATABOLISM, BONE PAIN: 1) MONITORED FOR PELIOSIS HEPATIS, LIVER CELL TUMORS, AND BLOOD LIPID CHANGES, 2) DOES NOT HAVE KNOWN OR SUSPECTED: CARCINOMA OF THE PROSTATE OR BREAST IN MALE PATIENTS, CARCINOMA OF THE BREAST IN FEMALES WITH HYPERCALCEMIA, NEPHROSIS (THE NEPHROTIC PHASE OF NEPHRITIS), OR HYPERCALCEMIA, AND 3) DOES NOT HAVE SEVERE HEPATIC DYSFUNCTION.

Core	Advantage	Plus
Yes	Yes	Yes

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OZANIMOD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OZANIMOD HYDROCHLORIDE	ZEPOSIA	46431		GPI-10 (6240705020)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Zeposia will NOT be used concurrently with another systemic biologic (e.g., Tysabri [natalizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of a relapsing form of MS
   - The patient had a trial of one sphingosine-1-phosphate receptor modulator (e.g., fingolimod, Mayzent [siponimod]) AND one other agent indicated for the treatment of MS (e.g., Tecfidera [dimethyl fumarate], Vumerity [diroximel fumarate])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

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OZANIMOD (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Zeposia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Selarsdi /Yesintek /ustekinumab-aauz
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
     - Rinvoq (upadacitinib) **(NOTE:** Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Skyrizi (risankizumab-rzaa)
     - Tremfya (guselkumab)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OZANIMOD (Zeposia)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. A relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease returns and goes away), and active secondary progressive disease (advanced disease)
      2. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

   (Initial denial text continued on next page)

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OZANIMOD (PART D)

INITIAL CRITERIA (CONTINUED)

B. If you have a relapsing form of multiple sclerosis, approval also requires:
1. You are 18 years of age or older
2. You will NOT use Zeposia concurrently (at the same time) with another systemic biologic (such as Tysabri [natalizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of a relapsing form of multiple sclerosis
3. You have tried one sphingosine-1-phosphate receptor modulator (such as fingolimod, Mayzent [siponimod]) AND one other medication indicated for the treatment of multiple sclerosis (such as Tecfidera [dimethyl fumarate], Vumerity [diroximel fumarate])

C. If you have moderate to severe ulcerative colitis, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
3. You will NOT use Zeposia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis
4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Selarsdi /Yesintek /ustekinumab-aauz
   b. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
   c. Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
   d. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
   e. Skyrizi (risankizumab-rzaa)
   f. Tremfya (guselkumab)

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OZANIMOD (PART D)

RENEWAL CRITERIA

NOTE: For the diagnosis of a relapsing form of multiple sclerosis, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) **AND** meet the following criterion?
   - Zeposia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

     If yes, **approve for 12 months by HICL or GPI-10.**
     APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

     If no, do not approve.

     RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

     Our guideline named **OZANIMOD (Zeposia)** requires the following rule(s) be met for renewal:
     A. You have moderate to severe ulcerative colitis (UC: a type of digestive disorder)
     B. You will NOT use Zeposia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zeposia.

REFERENCES

Zeposia [Prescribing Information]. Summit, NJ: Celgene Corporation; August 2024.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OZANIMOD (PART D)

For Part D use only:

OZANIMOD (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: ULCERATIVE COLITIS (UC): PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST.
Coverage Duration	MULTIPLE SCLEROSIS (MS): 12 MONTHS. UC: INITIAL: 6 MONTHS, RENEWAL:12 MONTHS.
Other Criteria	INITIAL: ALL INDICATIONS: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION. MS: TRIAL OF ONE SPHINGOSINE-1-PHOSPHATE RECEPTOR MODULATOR (E.G. FINGOLIMOD, MAYZENT) AND ONE OTHER AGENT INDICATED FOR THE TREATMENT OF MS. UC: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: SELARSDI/YESINTEK/USTEKINUMAB-AAUZ, XELJANZ, HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, RINVOQ, SKYRIZI, TREMFYA. RENEWAL: UC: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR UC.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PACRITINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PACRITINIB CITRATE	VONJO	47850		GPI-10 (2153755010)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of intermediate- or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocytopenia) myelofibrosis (ICD-10 D47.1, D75.81) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a platelet count below 50,000/uL

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do no approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PACRITINIB (Vonjo)** requires the following rule(s) be met for approval:
   A. You have intermediate- or high-risk primary or secondary (post-polycythemia vera [type of blood cell disorder] or post-essential thrombocythemia [type of blood cell disorder]) myelofibrosis (type of bone marrow cancer)
   B. You are 18 years of age or older
   C. You have a platelet count below 50,000/uL

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PACRITINIB (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of intermediate- or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocytopenia) myelofibrosis (ICD-10 D47.1, D75.81) **AND** meet the following criterion?
   - The patient continues to benefit from the medication

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PACRITINIB (Vonjo)** requires the following rule(s) be met for renewal:
   A. You have intermediate- or high-risk primary or secondary (post-polycythemia vera [type of blood cell disorder] or post-essential thrombocythemia [type of blood cell disorder]) myelofibrosis (type of bone marrow cancer)
   B. You continue to benefit from the medication

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vonjo.

REFERENCES

Vonjo [Prescribing Information]. Seattle, WA: CTI BioPharma Corp.; February 2022.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PACRITINIB (PART D)

For Part D use only:

PACRITINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS
Other Criteria	MYELOFIBROSIS: RENEWAL: CONTINUES TO BENEFIT FROM THE MEDICATION

Core	Advantage	Plus
Yes	Yes	Yes

Created: 03/22
Effective: 01/01/25 Client Approval: 08/24 P&T Approval: 10/21

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PALBOCICLIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PALBOCICLIB	IBRANCE	41725		GPI-10 (2153106000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of breast cancer (ICD-10 Group C50) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the patient's cancer hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative?

   If yes, continue to #3.
   If no, continue to #6.

3. Will Ibrance be used in combination with an aromatase inhibitor (e.g., anastrozole, letrozole, exemestane) as initial endocrine-based therapy **AND** the patient meets the following criterion?
   - The patient's cancer is advanced or metastatic

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #4.

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PALBOCICLIB (PART D)

GUIDELINES FOR USE (CONTINUED)

4. Will Ibrance be used in combination with fulvestrant (Faslodex) and the patient meets **ALL** of the following criteria?
   - The patient's cancer is advanced or metastatic
   - The patient has experienced disease progression following endocrine therapy (e.g., anastrozole, letrozole, tamoxifen)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #5.

5. Will Ibrance be used in combination with Itovebi (inavolisib) and fulvestrant (Faslodex) and the patient meets **ALL** of the following criteria?
   - The patient's cancer is locally advanced or metastatic
   - The patient's tumor has a PIK3CA mutation, as detected by an FDA-approved test
   - The patient has experienced disease recurrence on or after completing an adjuvant endocrine therapy (e.g., anastrozole, letrozole, tamoxifen)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

6. Is the patient's cancer hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-positive and the patient meets **ALL** of the following criteria?
   - The patient's cancer is locally advanced or metastatic
   - Ibrance will be used in combination with trastuzumab (Herceptin or an FDA-approved biosimilar) and endocrine therapy (e.g., letrozole, anastrozole, exemestane, fulvestrant) following induction treatment

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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PALBOCICLIB (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT:

Our guideline named **PALBOCICLIB (Ibrance)** requires the following rule(s) be met for approval:

A. You have breast cancer
B. You are 18 years of age or older
C. If your cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative, approval also requires ONE of the following:
   1. Ibrance will be used in combination with an aromatase inhibitor (such as anastrozole, letrozole, exemestane) as initial endocrine (hormone)-based therapy; and your cancer is advanced or metastatic (cancer that has progressed or has spread to other parts of the body)
   2. Ibrance will be used in combination with fulvestrant (Faslodex); and your cancer is advanced or metastatic (cancer that has progressed or has spread to other parts of the body); and your disease has worsened after endocrine (hormone) therapy (such as anastrozole, letrozole, tamoxifen)
   3. Ibrance will be used in combination with Itovebi (inavolisib) and fulvestrant (Faslodex); your cancer is locally advanced or metastatic (cancer that has spread from where it started to nearby tissue or lymph nodes or to other parts of the body); your tumor has a PIK3CA mutation (abnormal change in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test; and you have experienced disease recurrence (disease has returned) on or after completing adjuvant (add-on) endocrine (hormone) therapy (such as anastrozole, letrozole, tamoxifen)
D. If your cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-positive, approval also requires:
   1. Your cancer is locally advanced or metastatic (cancer that has spread from where it started to nearby tissue or lymph nodes or has spread to other parts of the body)
   2. Ibrance will be used in combination with trastuzumab (Herceptin or a Food and Drug Administration [FDA]-approved biosimilar) and endocrine (hormone) therapy (such as letrozole, anastrozole, exemestane, fulvestrant) following induction (initial) treatment

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PALBOCICLIB (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Ibrance.

REFERENCES
Ibrance [Prescribing Information]. New York, NY: Pfizer Laboratories; June 2026.

For Part D use only:

PALBOCICLIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 04/15
Effective: 07/06/26 Client Approval: 07/26 DMC Approval: 07/26

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PALIVIZUMAB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PALIVIZUMAB	SYNAGIS	18564		GPI-10 (1950206000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Has the patient received Beyfortus (nirsevimab-alip) within this RSV season?

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, continue to #2.

2. Is the patient under 12 months of age?

   If yes, continue to #3.
   If no, continue to #10.

3. Does the patient have chronic lung disease of prematurity (previously called bronchopulmonary dysplasia [BPD]) (ICD-10 P27.1) as defined below?
   - Gestational age less than 32 weeks and
   - Patient required greater than 21% supplemental oxygen for at least the first 28 days after birth

   (**Note:** This does not include respiratory distress in the newborn, wheezing, reactive airway disease (RAD), asthma, or cystic fibrosis. Current data does not support the routine use of palivizumab prophylaxis in patients with cystic fibrosis.)

   If yes, continue to #12.
   If no, continue to #4.

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PALIVIZUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

4. Does the patient meet **ONE** of the following?
   - The patient is profoundly immunocompromised during the RSV season
   - The patient has undergone solid-organ transplantation during the RSV season

   If yes, continue to #12.
   If no, continue to #5.

5. Does the patient have **ONE** of the following congenital heart disease conditions?
   - Acyanotic heart disease requiring medication to control chronic heart failure (for example, furosemide, epinephrine, dopamine, lidocaine, milrinone, atenolol, propranolol, amlodipine, clonidine) AND will require cardiac surgical procedures
   - Moderate or severe pulmonary hypertension (ICD-10 P29.30, I27.0; Group I27.2)
   - Cyanotic heart defect AND Synagis is prescribed by or in consultation with a pediatric cardiologist
     (**Note:** This does not include patients with hemodynamically insignificant heart disease, infants with lesions adequately corrected by surgery, infants with mild cardiomyopathy who are not receiving medical therapy for the condition.)

   If yes, continue to #12.
   If no, continue to #6.

6. Was the patient born prematurely?

   If yes, continue to #8.
   If no, continue to #7.

7. Does the patient have congenital abnormalities of the airways (anatomic pulmonary abnormalities) or neuromuscular disease that compromises the handling of respiratory secretions?

   If yes, continue to #12.
   If no, continue to #8.

8. Was the patient born at less than 29 weeks gestational age?

   If yes, continue to #12.
   If no, continue to #9.

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PALIVIZUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

9. Does the patient meet **ONE** of the following?
   - The patient is an American Navajo infant
   - The patient is an American White Mount Apache infant
   - The patient is an Alaska native infant

   If yes, continue to #12.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

10. Is the patient younger than 24 months of age?

    If yes, continue to #11.
    If no, do not approve.
    DENIAL TEXT: See the initial denial text at the end of the guideline.

11. Does the patient meet **ONE** of the following criteria?
    - The patient is profoundly immunocompromised during the RSV season
    - The patient has chronic lung disease of prematurity (ICD-10 P27.1) AND requires medical support (oxygen, bronchodilator, diuretic, or chronic steroid therapy) within 6 months prior to the start of the second RSV season
    - The patient has undergone solid-organ transplantation during RSV season

    If yes, continue to #12.
    If no, do not approve.
    DENIAL TEXT: See the initial denial text at the end of the guideline.

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PALIVIZUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

12. Approve by GPID or GPI-14 for all strengths for 5 fills as follows:

- **Start Date (Choose ONE):**
  - For requests with a start date of October 1st or further into the RSV season, enter the start date as requested.
    OR
  - For requests with a start date BEFORE October 1st, refer to the CDC website to verify whether RSV cases have started to increase in that region by confirming when the 'detections' (i.e., positive cases) begin to increase. If the detections have increased from baseline as of the date of the request, enter the start date as requested.
- **Approval Duration (Choose ONE):**
  - For requests that extend past April 30th, refer to the CDC website to verify when the RSV season for the specified region ends by confirming when the 'detections' (i.e., positive cases) returned to baseline in the previous years. If the detections returned to baseline after April 30th, enter a duration up to 5 months, but do not extend beyond the time when detections returned to baseline. (For example, if the request is received in February, and the CDC website shows that detection returned to baseline in that region in May of the previous year; then approve for 4 months).
    OR
  - Enter an approval duration up to April 30th.

NOTE: CDC website - https://www.cdc.gov/surveillance/nrevss/rsv/region.html

APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

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PALIVIZUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PALIVIZUMAB (Synagis)** requires the following rule(s) be met for approval:

A. You have not received Beyfortus (nirsevimab-alip) within this respiratory syncytial virus (RSV: type of lung and respiratory tract infection) season
B. You are less than 12 months old or less than 24 months at the start of RSV season (mid-September to mid-May)
C. **If you are less than 12 months old, approval also requires ONE of the following**:
    1. You have chronic lung disease of prematurity (a condition where you were born at less than 32 weeks and required more than 21% of additional oxygen for at least the first 28 days after birth)
    2. You are profoundly immunocompromised (the body cannot fight off infections) during RSV season
    3. You have received a solid-organ transplant during RSV season
    4. You have congenital (starting from birth) heart disease conditions at birth such as: acyanotic heart disease (blood from the left side to the right side of the heart due to a hole in the heart walls) where you need medication to control chronic heart failure and will require heart surgical procedures; moderate to severe pulmonary hypertension (high blood pressure in the lungs); or cyanotic heart defect (low blood oxygen level); AND Synagis is prescribed by or in consultation with a pediatric cardiologist (a heart doctor for children)
    5. You have congenital (starting from birth) abnormalities of the lung airways or a neuromuscular (nerve-muscle) disorder that affects respiratory (lung/breathing) secretions
    6. You were born premature at less than 29 weeks (gestational age)
    7. You are an American Navajo, American White Mountain Apache, or Alaska Native infant born prematurely
D. If you are less than 24 months old, approval also requires ONE of the following:
    1. You are profoundly immunocompromised (a condition where the body cannot fight off infections) during RSV season
    2. You have chronic lung disease of prematurity and need medical support within 6 months before the start of the second RSV season. Medical support includes oxygen, bronchodilator (drug that helps breathing), diuretic (drug that makes you urinate), or chronic steroid therapy
    3. You have received a solid-organ transplant during RSV season

(Initial denial text continued on next page)

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PALIVIZUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PALIVIZUMAB (PART D)

RENEWAL CRITERIA

1. Has the patient received Beyfortus (nirsevimab-alip) within this RSV season?

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, continue to #2.

2. Is the patient younger than 24 months of age?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

3. Did the patient undergo cardiopulmonary bypass surgery during their RSV prophylaxis season?

   If yes, **approve for 1 month by HICL or GPI-10 with a fill count of 2 (do not enter quantity limit on number of vials).**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

4. Is this a request for a second year of coverage (e.g., a previous approval in the previous RSV season)?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

5. Does the patient have chronic lung disease of prematurity (previously called bronchopulmonary dysplasia [BPD]) (ICD-10 P27.1) and requires medical support (oxygen, bronchodilator [e.g., albuterol], diuretic [e.g., furosemide], or chronic steroid therapy [e.g., budesonide]) within 6 months prior to start of the second RSV season?
   (**Note:** This does not include respiratory distress in the newborn period, wheezing, reactive airway disease (RAD), asthma, or cystic fibrosis. Current data does not support the routine use of palivizumab prophylaxis in patients with cystic fibrosis).

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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PALIVIZUMAB (PART D)

RENEWAL CRITERIA (CONTINUED)

6. **Approve by GPID or GPI-14 for all strengths for 5 fills as follows:**
   - **Start Date (Choose ONE):**
     - For requests with a start date of October 1st or further into the RSV season, enter the start date as requested.
       OR
     - For requests with a start date BEFORE October 1st, refer to the CDC website to verify whether RSV cases have started to increase in that region by confirming when the 'detections' (i.e., positive cases) begin to increase. If the detections have increased from baseline as of the date of the request, enter the start date as requested.
   - **Approval Duration (Choose ONE):**
     - For requests that extend past April 30th, refer to the CDC website to verify when the RSV season for the specified region ends by confirming when the 'detections' (i.e., positive cases) returned to baseline in the previous years. If the detections returned to baseline after April 30th, enter a duration up to 5 months, but do not extend beyond the time when detections returned to baseline. (For example, if the request is received in February, and the CDC website shows that detection returned to baseline in that region in May of the previous year; then approve for 4 months).
       OR
     - Enter an approval duration up to April 30th.

   NOTE: CDC website - https://www.cdc.gov/surveillance/nrevss/rsv/region.html

   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

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PALIVIZUMAB (PART D)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PALIVIZUMAB (Synagis)** requires the following rule(s) be met for renewal:

A. You have not received Beyfortus (nirsevimab-alip) within this respiratory syncytial virus (RSV: type of lung and respiratory tract infection) season
B. You are under 24 months of age
C. You meet ONE of the following:
    1. You received cardiopulmonary bypass surgery (type of heart and lung surgery) during RSV prevention season (mid-September to mid-May)
    2. This request is for a second year of coverage, and you have chronic lung disease of prematurity and need medical support during the 6 months before the start of the second RSV season. Medical support includes oxygen, bronchodilator (drug that helps you breathe, such as albuterol), diuretic (drug that makes you urinate such as furosemide), or chronic steroid therapy (such as budesonide)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Synagis.

REFERENCES

Synagis [Prescribing Information]. Waltham, MA: Sobi Inc.; November 2021.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PALIVIZUMAB (PART D)

For Part D use only:

PALIVIZUMAB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	INITIAL: GESTATIONAL AGE
Age Restrictions	INITIAL AND RENEWAL: LESS THAN 24 MONTHS OF AGE.
Prescriber Restrictions	N/A
Coverage Duration	CRITERIA CONSISTENT WITH THE CDC RSV CENSUS REGIONAL TREND. SEE OTHER CRITERIA.
Other Criteria	CRITERIA WILL BE APPLIED CONSISTENT WITH CURRENT RECOMMENDATIONS FROM THE AMERICAN ACADEMY OF PEDIATRICS FOR PALIVIZUMAB PROPHYLAXIS FOR RESPIRATORY SYNCYTIAL VIRUS (RSV) INFECTIONS AND THE CENTERS FOR DISEASE CONTROL AND PREVENTION RSV CENSUS REGIONAL TREND. APPROVAL WILL BE FOR UP TO A MAXIMUM OF 5 MONTHS DEPENDENT UPON REMAINING LENGTH OF RSV SEASON. INITIAL AND RENEWAL: HAS NOT RECEIVED BEYFORTUS WITHIN THE SAME RSV SEASON. RENEWAL: ADDITIONAL 1 MONTH OF TREATMENT FOR CARDIOPULMONARY BYPASS SURGERY DURING RSV PROPHYLAXIS SEASON.

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25 Created: 10/16
Commercial Effective: N/A Client Approval: 06/24 P&T Approval: 10/23

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PALOPEGTERIPARATIDE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PALOPEGTERIPARATIDE	YORVIPATH	49810		GPI-10 (3090516000)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hypoparathyroidism (ICD-10 Group E20) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's hypoparathyroidism is NOT due to impaired responsiveness to parathyroid hormone or a history of disease that affects calcium metabolism or calcium-phosphate homeostasis
   - The patient had a trial of activated vitamin D (e.g., calcitriol)

   If yes, **approve all strengths for 6 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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PALOPEGTERIPARATIDE (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PALOPEGTERIPARATIDE (Yorvipath)** requires the following rule(s) be met for approval:

A. You have hypoparathyroidism (low levels of parathyroid hormone)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
D. Your hypoparathyroidism is NOT due to impaired responsiveness to parathyroid hormone or a history of disease that affects calcium metabolism or calcium-phosphate homeostasis (balance)
E. You have tried activated vitamin D (such as calcitriol)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PALOPEGTERIPARATIDE (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hypoparathyroidism (ICD-10 Group E20) **AND** meet the following criterion?
   - The patient is independent of or managed on a lowered dose of vitamin D and calcium

   If yes, **approve all strengths for 12 months by GPID or GPI-14.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PALOPEGTERIPARATIDE (Yorvipath)** requires the following rule(s) be met for renewal:
   A. You have hypoparathyroidism (low levels of parathyroid hormone)
   B. You are independent of or managed on a lowered dose of vitamin D and calcium

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Yorvipath.

REFERENCES
Yorvipath [Prescribing Information]. Princeton, NJ: Ascendis Pharma; August 2024.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PALOPEGTERIPARATIDE (PART D)

For Part D use only:

PALOPEGTERIPARATIDE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: HYPOPARATHYROIDISM: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	HYPOPARATHYROIDISM: INITIAL: 1) DIAGNOSIS IS NOT DUE TO IMPAIRED RESPONSIVENESS TO PARATHYROID HORMONE OR A HISTORY OF DISEASE THAT AFFECTS CALCIUM METABOLISM OR CALCIUM-PHOSPHATE HOMEOSTASIS, AND 2) TRIAL OF ACTIVATED VITAMIN D (E.G., CALCITRIOL). RENEWAL: THE PATIENT IS INDEPENDENT OF OR MANAGED ON A LOWERED DOSE OF VITAMIN D AND CALCIUM.

Part D Effective: 09/23/24
Commercial Effective: N/A
Created: 09/24
Client Approval: 09/24
P&T Approval: 04/23

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PALOVAROTENE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PALOVAROTENE	SOHONOS	49043		GPI-10 (7588606000)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of fibrodysplasia ossificans progressiva (FOP) (ICD-10 Group M61.1) and meet **ONE** of the following criteria?
   - The patient is female and 8 years of age or older
   - The patient is male and 10 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PALOVAROTENE (Sohonos)** requires the following rule(s) be met for approval:
   A. You have fibrodysplasia ossificans progressiva (FOP: a type of rare genetic tissue disorder)
   B. You meet ONE of the following:
      1. You are female and 8 years of age or older
      2. You are male and 10 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PALOVAROTENE (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sohonos.

REFERENCES

Sohonos [Prescribing Information]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.; August 2023.

For Part D use only:

PALOVAROTENE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 09/23
Effective: 07/01/25 Client Approval: 05/25 P&T Approval: 10/23

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PALTUSOTINE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PALTUSOTINE HCL	PALSONIFY	50910		GPI-10 (3017007310)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of acromegaly (ICD-10 E22.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had an inadequate response to surgery OR surgery is not an option for this patient
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's serum insulin-like growth factor 1 (IGF-1) level (adjusted for the patient's age) is elevated or unequivocal with inadequate suppression of growth hormone after a glucose load
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Mycapssa, Sandostatin LAR Depot (octreotide acetate ER)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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PALTUSOTINE (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PALTUSOTINE (Palsonify)** requires the following rule(s) be met for approval:

A. You have acromegaly (a type of hormone disorder)
B. You are 18 years of age or older
C. You had an inadequate response (did not work) to surgery OR surgery is not an option for you
D. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
E. Your serum insulin-like growth factor 1 (IGF-1: a type of hormone) level (adjusted for your age) is elevated (higher than normal) or unequivocal with inadequate suppression (reduction) of growth hormone after a glucose load (a type of test used to diagnose acromegaly [a type of hormone disorder])
F. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Mycapssa, Sandostatin LAR Depot (octreotide acetate ER)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PALTUSOTINE (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of acromegaly (ICD-10 E22.0) and meet **ALL** of the following criteria?
   - The patient has had a reduction, normalization, or maintenance of IGF-1 levels based on age and gender
   - The patient has shown improvement or has sustained remission of clinical symptoms of acromegaly

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PALTUSOTINE (Palsonify)** requires the following rule(s) be met for renewal:
   A. You have acromegaly (a type of hormone disorder)
   B. You have had a reduction, normalization, or maintenance of insulin-like growth factor 1 (IGF-1: a type of hormone) levels based on your age and gender
   C. You have shown improvement or have sustained remission (reduction or disappearance) of clinical symptoms of acromegaly (a type of hormone disorder)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Palsonify.

REFERENCES

Palsonify [Prescribing Information]. San Diego, CA: Crinetics Pharmaceuticals, Inc.; September 2025.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PALTUSOTINE (PART D)

For Part D use only:

PALTUSOTINE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	ACROMEGALY: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	ACROMEGALY: INITIAL: 1) SERUM INSULIN-LIKE GROWTH FACTOR 1 (IGF-1) LEVEL (ADJUSTED FOR AGE) IS ELEVATED OR UNEQUIVOCAL WITH INADEQUATE SUPPRESSION OF GROWTH HORMONE AFTER A GLUCOSE LOAD, AND 2) TRIAL OF OR CONTRAINDICATION TO ONE OF THE FOLLOWING PREFERRED AGENTS: MYCAPSSA, SANDOSTATIN LAR DEPOT (OCTREOTIDE ACETATE ER). RENEWAL: 1) REDUCTION, NORMALIZATION, OR MAINTENANCE OF IGF-1 LEVELS BASED ON AGE AND GENDER, AND 2) IMPROVEMENT OR SUSTAINED REMISSION OF CLINICAL SYMPTOMS.

Created: 10/25
Effective: 10/20/25 Client Approval: 10/25 P&T Approval: 10/25

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PANITUMUMAB BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PANITUMUMAB	VECTIBIX	34054		GPI-10 (2136007000)	

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is the drug administered via an implantable pump?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B. (Populate the B vs. D field with 'B' in the PA override field. If MI does not process Part B for the client, refer the caller/request back to the Health plan)**

   If no, continue to #2.

2. Is the drug administered via an external pump?

   If yes, continue to #3.

   If no, **approve for 12 months by HICL or GPI-10 under Part D. (Populate the B vs. D field with 'D' in the PA override field)**

3. Is the drug specifically infused through an external infusion pump covered by Medicare?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B. (Populate the B vs. D field with 'B' in the PA override field. If MI does not process Part B for the client, refer the caller/request back to the Health plan)**

   If no, **approve for 12 months by HICL or GPI-10 under Part D. (Populate the B vs. D field with 'D' in the PA override field)**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PANITUMUMAB BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic colorectal cancer (mCRC) (ICD-10 C19) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the patient's cancer wild-type RAS (defined as wild-type in both KRAS and NRAS), as determined by an FDA-approved test?

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet **ONE** of the following criteria?
   - Vectibix will be used in combination with FOLFOX (leucovorin calcium [folinic acid], fluorouracil, oxaliplatin)
   - Vectibix will be used as monotherapy AND the patient has disease progression after treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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PANITUMUMAB BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

4. Does the patient's cancer have a KRAS G12C-mutation, as determined by an FDA-approved test, and meet **ALL** of the following criteria?
   - Vectibix will be used in combination with Lumakras (sotorasib)
   - The patient has received previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PANITUMUMAB (Vectibix)** requires the following rule(s) be met for approval:
   A. You have metastatic colorectal cancer (mCRC: a type of digestive cancer that has spread to other parts of the body)
   B. You are 18 years of age or older.
   C. Your cancer is wild-type RAS (defined as wild-type in both KRAS and NRAS [types of genes without a specific mutation]), OR you have a KRAS G12C-mutation [type of abnormal change in a gene], as determined by a Food and Drug Administration (FDA)-approved test
   D. If your cancer is wild-type RAS, approval also requires ONE of the following:
      1. Vectibix will be used in combination with FOLFOX (treatment regimen containing leucovorin calcium [folinic acid], fluorouracil, oxaliplatin)
      2. Vectibix will be used as monotherapy (one drug treatment), AND you have disease progression (worsening) after treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy (drugs used to treat cancer)
   E. If your cancer has a KRAS G12C-mutation, approval also requires:
      1. Vectibix will be used in combination with Lumakras (sotorasib)
      2. You have received previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PANITUMUMAB BvD (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vectibix. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs administered by an implantable pump are covered under Part B. Drugs administered via an external pump are covered under Part B if they are included under the local coverage policy of the applicable Medicare coverage policies (National and/or Local Coverage Policies). Drugs administered via an external pump that are not included under the applicable Medicare coverage policies are covered under Part D. A CMS website to assist with National and Local Coverage Determination for B versus D review is http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx

REFERENCES

Vectibix [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; January 2025.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: http://www.cms.gov/PrescriptionDrugCovContra/12_PartDManuals.asp. [Accessed March 18, 2024].

For Part D use only:

PANITUMUMAB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 02/13
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 04/25

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PARATHYROID HORMONE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PARATHYROID HORMONE	NATPARA	34000		GPI-10 (3004405510)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of hypocalcemia (ICD-10 E83.51) secondary to hypoparathyroidism (ICD-10 Group E20) and meet **ALL** of the following criteria?
   - Natpara will be used as an adjunct to calcium and vitamin D
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient had a trial of or contraindication to calcitriol
   - The patient's hypoparathyroidism is NOT due to a calcium sensing receptor (CsR) mutation
   - The patient's hypoparathyroidism is NOT considered acute post-surgical hypoparathyroidism

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PARATHYROID HORMONE (Natpara)** requires the following rule(s) be met for approval:
   A. You have hypocalcemia secondary to hypoparathyroidism (low blood calcium due to low levels of a type of hormone)
   B. Natpara will be used as an adjunct (add-on therapy) to calcium and vitamin D
   C. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)

   (Denial text continued on next page)

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PARATHYROID HORMONE (PART D)

GUIDELINES FOR USE (CONTINUED)

D. You have tried or have a contraindication to (harmful for you to use) calcitriol
E. Your hypoparathyroidism is NOT due to a calcium sensing receptor (CsR) mutation (an abnormal change in a type of gene)
F. Your hypoparathyroidism is NOT considered acute post-surgical hypoparathyroidism (not sudden and severe due to surgery)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Natpara.

REFERENCES

Natpara [Prescribing Information]. Lexington, MA: Shire-NPS Pharmaceuticals, Inc.; February 2023.

For Part D use only:

PARATHYROID HORMONE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	HYPOCALCEMIA SECONDARY TO HYPOPARATHYROIDISM: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST.
Coverage Duration	12 MONTHS
Other Criteria	HYPOCALCEMIA SECONDARY TO HYPOPARATHYROIDISM: 1) TRIAL OF OR CONTRAINDICATION TO CALCITRIOL, 2) HYPOPARATHYROIDISM IS NOT DUE TO A CALCIUM SENSING RECEPTOR (CSR) MUTATION, AND 3) HYPOPARATHYROIDISM IS NOT CONSIDERED ACUTE POST-SURGICAL HYPOPARATHYROIDISM.

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 04/15
Client Approval: 06/24
P&T Approval: 11/16

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PASIREOTIDE DIASPARTATE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PASIREOTIDE DIASPARTATE	SIGNIFOR	39866		GPI-10 (3017007520)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Cushing's disease (ICD-10 Group E24) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has undergone non-curative pituitary surgery or pituitary surgery is not an option
   - Therapy is prescribed by or in consultation with an endocrinologist

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PASIREOTIDE DIASPARTATE (Signifor)** requires the following rule(s) be met for approval:
   A. You have Cushing's disease (CD: a type of hormone disorder)
   B. You are 18 years of age or older
   C. You have undergone non-curative pituitary (a major hormone gland) surgery ORpituitary surgery is not an option
   D. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)

   (Initial denial text continued on next page)

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PASIREOTIDE DIASPARTATE (PART D)

INITIAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PASIREOTIDE DIASPARTATE (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Cushing's disease (CD) (ICD-10 Group E24) and meet **ALL** of the following criteria?
   - The patient continues to have improvement of Cushing's disease (e.g., clinically meaningful reduction in 24-hour urinary free cortisol and/or improvements in signs and symptoms of disease)
   - The patient maintains tolerability to Signifor

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PASIREOTIDE DIASPARTATE (Signifor)** requires the following rule(s) be met for renewal:
   A. You have Cushing's disease (CD: a type of hormone disorder)
   B. You continue to have improvement of Cushing's disease (such as clinically meaningful reduction in 24-hour urinary free cortisol and/or improvements in signs and symptoms of your disease)
   C. You continue to tolerate treatment with Signifor

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Signifor.

REFERENCES

Signifor [Prescribing Information]. Lebanon, NJ: Recordati Rare Diseases Inc.; March 2020.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PASIREOTIDE DIASPARTATE (PART D)

For Part D use only:

PASIREOTIDE DIASPARTATE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	CUSHINGS DISEASE (CD): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	CD: RENEWAL: 1) CONTINUED IMPROVEMENT OF CUSHINGS DISEASE, AND 2) MAINTAINED TOLERABILITY TO SIGNIFOR.

Created: 10/19
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 07/20

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PASIREOTIDE PAMOATE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PASIREOTIDE PAMOATE	SIGNIFOR LAR	41635		GPI-10 (3017007540)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of acromegaly (ICD-10 E22.0) and meet **ALL** of the following criteria?
   - The patient had an inadequate response to surgery or surgery is not an option for this patient
   - Therapy is prescribed by or in consultation with an endocrinologist

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

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PASIREOTIDE PAMOATE (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of Cushing's disease (ICD-10 Group E24) and meet **ALL** of the following criteria?
   - The patient has undergone non-curative pituitary surgery or pituitary surgery is not an option for this patient
   - Therapy is prescribed by or in consultation with an endocrinologist

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PASIREOTIDE PAMOATE (Signifor LAR)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Acromegaly (a type of hormone disorder)
      2. Cushing's disease (a type of hormone disorder)

   B. If you have acromegaly, approval also requires:
      1. You had an inadequate response (did not work) to surgery (surgery did not work) or surgery is not an option
      2. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)

   C. If you have Cushing's disease, approval also requires:
      1. You have undergone non-curative pituitary surgery (surgery to remove a hormone gland) or pituitary surgery is not an option
      2. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PASIREOTIDE PAMOATE (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of acromegaly (ICD-10 E22.0) and meet **ALL** of the following criteria?
   - The patient had a reduction, normalization, or maintenance of IGF-1 levels based on age and gender
   - The patient has shown improvement or sustained remission of clinical symptoms of acromegaly

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of Cushing's disease (ICD-10 Group E24) and meet **ALL** of the following criteria?
   - The patient continues to have improvement of Cushing's disease (e.g., clinically meaningful reduction in 24-hour urinary free cortisol or improvements in signs and symptoms of disease)
   - The patient maintains tolerability to Signifor LAR

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PASIREOTIDE PAMOATE (Signifor LAR)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Acromegaly (a type of hormone disorder)
      2. Cushing's disease (a type of hormone disorder)
   B. If you have acromegaly, renewal also requires:
      1. You had a reduction, normalization, or maintenance of insulin-like growth factor 1 (IGF-1: a type of hormone) levels based on your age and gender
      2. You have shown improvement or sustained remission (symptoms have gone away) of clinical symptoms of acromegaly

   (Renewal denial text continued on next page)

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PASIREOTIDE PAMOATE (PART D)

RENEWAL CRITERIA (CONTINUED)

C. If you have Cushing's disease, renewal also requires:

1. You continue to have improvement of Cushing's disease (such as clinically meaningful reduction in 24-hour urinary free cortisol or improvements in signs and symptoms of disease)
2. You continue to tolerate treatment with Signifor LAR

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Signifor LAR.

REFERENCES

Signifor LAR [Prescribing Information]. Bridgewater, NJ: Recordati Rare Diseases Inc.; August 2023.

PASIREOTIDE PAMOATE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: CUSHINGS DISEASE (CD), ACROMEGALY: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST.
Coverage Duration	INITIAL: CD: 6 MOS. ACROMEGALY: 12 MOS. RENEWAL: CD, ACROMEGALY: 12 MOS.
Other Criteria	RENEWAL: ACROMEGALY: 1) REDUCTION, NORMALIZATION, OR MAINTENANCE OF IGF-1 LEVELS BASED ON AGE AND GENDER, AND 2) IMPROVEMENT OR SUSTAINED REMISSION OF CLINICAL SYMPTOMS. CD: 1) CONTINUES TO HAVE IMPROVEMENT, AND 2) MAINTAINS TOLERABILITY TO THERAPY.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PATISIRAN BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PATISIRAN SODIUM,LIPID COMPLEX	ONPATTRO	45155		GPI-10 (6270606010)	

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, continue to #6.
   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, continue to #6.
   If no, continue to #5.

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

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PATISIRAN BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

6. Is the drug administered via an implantable pump?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, continue to #7.

7. Is the drug administered via an external pump?

   If yes, continue to #8.
   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

8. Is the drug specifically infused through an external infusion pump covered by Medicare?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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PATISIRAN BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR) with polyneuropathy (ICD-10 E85.1) and meet **ALL** the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist, cardiologist, physician at an amyloidosis treatment center, or medical geneticist
   - The patient is ambulatory (i.e., familial amyloid polyneuropathy [FAP] stage 1 - 2, OR polyneuropathy disability [PND] stage I - IIIb polyneuropathy)
   - Onpattro will NOT be used concurrently with other hATTR-PN agents (e.g., Wainua [eplontersen], Amvuttra [vutrisiran], Tegsedi [inotersen])

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the hATTR diagnosis confirmed by **ONE** of the following?
   - Biopsy of tissue/organ to confirm amyloid presence AND chemical typing to confirm presence of TTR (transthyretin) protein
   - DNA genetic sequencing to confirm hATTR mutation

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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PATISIRAN BvD (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PATISIRAN (Onpattro)** requires the following rule(s) be met for approval:

A. You have hereditary transthyretin-mediated amyloidosis (hATTR: a rare genetic disorder) with polyneuropathy (widespread nerve pain/damage)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a neurologist (nerve doctor), cardiologist (heart doctor), physician at an amyloidosis treatment center, or medical geneticist (doctor who treats gene disorders)
D. You are ambulatory (able to walk) (you have familial amyloid polyneuropathy [FAP: a tool used to evaluate disease severity] stage 1 to 2, OR polyneuropathy disability [PND: a tool used to evaluate disease severity] stage I to IIIb polyneuropathy)
E. You will NOT use Onpattro concurrently (at the same time) with other hATTR-PN medications (such as Wainua [eplontersen], Amvuttra [vutrisiran], Tegsedi [inotersen])
F. Your diagnosis is confirmed by ONE of the following:
    1. Biopsy (removal of cells from the body for examination) of tissue/organ to confirm amyloid (type of abnormal protein) presence AND chemical typing to confirm presence of TTR (transthyretin) protein
    2. DNA (deoxyribonucleic acid) genetic sequencing (type of lab test) to confirm hATTR mutation (type of abnormal gene)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PATISIRAN BvD (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR) with polyneuropathy (ICD-10 E85.1) and meet **ALL** of the following criteria?
   - The patient has not progressed to familial amyloid polyneuropathy (FAP) stage 3, or polyneuropathy disability (PND) stage 4 polyneuropathy, as evidenced by functional decline (e.g., wheelchair-bound, bedridden)
   - Onpattro will NOT be used concurrently with other hATTR-PN agents (e.g., Wainua [eplontersen], Amvuttra [vutrisiran], Tegsedi [inotersen])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PATISIRAN (Onpattro)** requires the following rule(s) be met for renewal:
   A. You have hereditary transthyretin-mediated amyloidosis (hATTR: a rare genetic disorder) with polyneuropathy (widespread nerve pain/damage)
   B. You have not progressed to familial amyloid polyneuropathy (FAP: a tool used to evaluate disease severity) stage 3 or polyneuropathy disability (PND: a tool used to evaluate disease severity) stage 4 polyneuropathy, as shown by functional decline (such as being wheelchair-bound, being bedridden)
   C. You will NOT use Onpattro concurrently (at the same time) with other hATTR-PN medications (such as Wainua [eplontersen], Amvuttra [vutrisiran], Tegsedi [inotersen])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PATISIRAN BvD (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Onpattro.

The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member are covered under Part B. Drugs administered by an implantable pump are covered under Part B. Drugs administered via an external pump are covered under Part B if they are included under the local coverage policy of the applicable Medicare coverage policies (National and/or Local Coverage Policies). Drugs administered via an external pump that are not included under the applicable Medicare coverage policies are covered under Part D. A CMS website to assist with National and Local Coverage Determination for B versus D review is http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx.

REFERENCES

Onpattro [Prescribing Information]. Cambridge, MA: Alnylam; January 2023.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed July 2, 2024].

For Part D use only:

PATISIRAN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	HEREDITARY TRANSTHYRETIN-MEDIATED AMYLOIDOSIS WITH POLYNEUROPATHY (HATTR-PN): INITIAL: DIAGNOSIS CONFIRMED BY: 1) BIOPSY OF TISSUE/ORGAN TO CONFIRM AMYLOID PRESENCE AND CHEMICAL TYPING TO CONFIRM PRESENCE OF TTR PROTEIN, OR 2) DNA GENETIC SEQUENCING TO CONFIRM HATTR MUTATION.
Age Restrictions	N/A
Prescriber Restrictions	HATTR-PN: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST, CARDIOLOGIST, PHYSICIAN AT AN AMYLOIDOSIS TREATMENT CENTER, OR MEDICAL GENETICIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	HATTR-PN: INITIAL: 1) FAMILIAL AMYLOID POLYNEUROPATHY (FAP) STAGE 1 OR 2, OR UP TO POLYNEUROPATHY DISABILITY (PND) STAGE IIIB POLYNEUROPATHY, AND 2) NO CONCURRENT USE WITH OTHER HATTR-PN AGENTS. RENEWAL: 1) NOT PROGRESSED TO FAP STAGE 3 OR PND STAGE 4 POLYNEUROPATHY AS EVIDENCED BY FUNCTIONAL

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	DECLINE, AND 2) NO CONCURRENT USE WITH OTHER HATTR-PN AGENTS.

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Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 04/24

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PAZOPANIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PAZOPANIB HCL	VOTRIENT, PAZOPANIB HCL	36709		GPI-10 (2153304210)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC) (ICD-10 Groups C64, C65) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of advanced soft tissue sarcoma (STS) (ICD-10 Group C49) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received prior chemotherapy (e.g., doxorubicin, epirubicin)
   - The patient does NOT have adipocytic soft tissue sarcoma (STS) or gastrointestinal stromal tumors (GIST)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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PAZOPANIB (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PAZOPANIB (Votrient)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Advanced renal cell carcinoma (RCC: a type of kidney cancer)
   2. Advanced soft tissue sarcoma (STS: a type of cancer that starts in soft tissues [muscle, tendons, fat, lymph vessels, blood vessels, nerves])

B. If you have advanced renal cell carcinoma, approval also requires:
   1. You are 18 years of age or older

C. If you have advanced soft tissue sarcoma, approval also requires:
   1. You are 18 years of age or older
   2. You have received prior chemotherapy (a type of cancer therapy such as doxorubicin, epirubicin)
   3. You do NOT have adipocytic soft tissue sarcoma (a type of fat cell cancer) or gastrointestinal stromal tumors (GIST: a type of digestive tumor)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Votrient.

REFERENCES

Votrient [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation. January 2024.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PAZOPANIB (PART D)

For Part D use only:

PAZOPANIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	ADVANCED SOFT TISSUE SARCOMA (STS): NOT USED FOR ADIPOCYTIC STS OR GASTROINTESTINAL STROMAL TUMORS (GIST)

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 05/11
Client Approval: 08/24
P&T Approval: 08/16

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEANUT ALLERGEN POWDER-DNFP (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEANUT ALLERGEN POWDER-DNFP	PALFORZIA	46332		GPI-10 (2010004020)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of a peanut allergy (ICD-10 Z91.010) and meet **ALL** of the following criteria?
   - The patient is 1 to 17 years of age
   - Therapy is prescribed by or in consultation with an allergist or immunologist
   - The patient has a clinical history of an allergic reaction to peanuts
   - Palforzia will be used in conjunction with a peanut-avoidance diet
   - Palforzia will NOT be used concurrently with a peanut-specific immunotherapy (e.g., Viaskin Peanut)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Has the patient completed a purposeful food challenge?

   If yes, continue to #3.
   If no, continue to #4.

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PEANUT ALLERGEN POWDER-DNFP (PART D)

INITIAL CRITERIA (CONTINUED)

3. Is the patient's diagnosis confirmed by **ONE** of the following criteria?
   - The patient tested positive on a skin prick test with a wheal diameter of at least 3 mm within the past 24 months
   - The patient has had a peanut-specific immunoglobulin E (IgE) level of at least 0.35 kUA/L within the past 24 months

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Is the patient's diagnosis confirmed by **ONE** of the following criteria?
   - The patient tested positive on a skin prick test with a wheal diameter of at least 8 mm within the past 24 months
   - The patient has had a peanut-specific immunoglobulin E (IgE) level of at least 14 kUA/L within the past 24 months

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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PEANUT ALLERGEN POWDER-DNFP (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PEANUT ALLERGEN POWDER-DNFP (Palforzia)** requires the following rule(s) be met for approval:

A. You have an allergy to peanuts
B. You are 1 to 17 years of age
C. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor) or immunologist (a type of immune system doctor)
D. You have a clinical history of an allergic reaction to peanuts
E. Palforzia will be used together with a peanut-avoidance diet
F. Palforzia will NOT be used concurrently (at the same time) with peanut-specific immunotherapy (such as Viaskin Peanut)
G. Your diagnosis is confirmed by ONE of the following:
    1. If you have completed a purposeful food challenge (a type of test): you had a positive skin prick test (a skin test to check for peanut allergy) with a wheal diameter of at least 3 mm within the past 24 months, OR you have had a peanut-specific immunoglobulin E (IgE) (a blood test that indicates an allergy to peanuts) level of at least 0.35 kUA/L within the past 24 months
    2. If you have NOT completed a purposeful food challenge (a type of test): you had a positive skin prick test (a skin test to check for peanut allergy) with a wheal diameter of at least 8 mm within the past 24 months, OR you have had a peanut-specific immunoglobulin E (IgE) (a blood test that indicates an allergy to peanuts) level of at least 14 kUA/L within the past 24 months

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PEANUT ALLERGEN POWDER-DNFP (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of a peanut allergy (ICD-10 Z91.010) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an allergist or immunologist
   - Palforzia will be used in conjunction with a peanut-avoidance diet
   - Palforzia will NOT be used concurrently with peanut-specific immunotherapy (e.g., Viaskin Peanut)
   - The patient continues to have a persistent peanut allergy

   If yes, **approve for 24 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEANUT ALLERGEN POWDER-DNFP (Palforzia)** requires the following rule(s) be met for renewal:
   A. You have an allergy to peanuts
   B. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor) or immunologist (a type of immune system doctor)
   C. Palforzia will be used together with a peanut-avoidance diet
   D. Palforzia will NOT be used concurrently (at the same time) with peanut-specific immunotherapy (such as Viaskin Peanut)
   E. You continue to have a persistent peanut allergy (peanut allergy has not gone away)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Palforzia.

REFERENCES

Palforzia [Prescribing Information]. Lenoir, NC: Greer Laboratories, Inc.; September 2024.

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PEANUT ALLERGEN POWDER-DNFP (PART D)

For Part D use only:

PEANUT ALLERGEN POWDER-DNFP (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	INITIAL: 1) COMPLETED A PURPOSEFUL FOOD CHALLENGE: (A) POSITIVE SKIN PRICK TEST WITH A WHEAL DIAMETER OF AT LEAST 3 MM WITHIN THE PAST 24 MONTHS, OR (B) PEANUT-SPECIFIC IGE LEVEL OF AT LEAST 0.35 KUA/L WITHIN THE PAST 24 MONTHS, OR 2) DID NOT COMPLETE A PURPOSEFUL FOOD CHALLENGE: (A) POSITIVE SKIN PRICK TEST WITH A WHEAL DIAMETER OF AT LEAST 8 MM WITHIN THE PAST 24 MONTHS, OR (B) PEANUT-SPECIFIC IGE LEVEL OF AT LEAST 14 KUA/L WITHIN THE PAST 24 MONTHS.
Age Restrictions	N/A
Prescriber Restrictions	INITIAL/RENEWAL: PRESCRIBED BY OR IN CONSULTATION WITH AN ALLERGIST OR IMMUNOLOGIST.
Coverage Duration	INITIAL: 12 MONTHS. RENEWAL: 24 MONTHS.
Other Criteria	INITIAL: 1) CLINICAL HISTORY OF ALLERGIC REACTION TO PEANUTS, 2) WILL BE USED IN CONJUNCTION WITH A PEANUT-AVOIDANCE DIET, AND 3) WILL NOT BE USED CONCURRENTLY WITH A PEANUT-SPECIFIC IMMUNOTHERAPY. RENEWAL: 1) CONTINUES TO HAVE PERSISTENT PEANUT ALLERGY, 2) WILL BE USED IN CONJUNCTION WITH A PEANUT-AVOIDANCE DIET, AND 3) WILL NOT BE USED CONCURRENTLY WITH A PEANUT-SPECIFIC IMMUNOTHERAPY.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGASPARGASE BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGASPARGASE	ONCASPAR	08904		GPI-10 (2125006000)	

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit).**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #5.

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PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

If yes, **Refer to plan. (The health plan makes the final payment determination decision)**

- **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
- **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGASPARGASE BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of acute lymphoblastic leukemia (ALL) (ICD-10 Group C91.0) **AND** meet the following criterion?
   - Oncaspar will be used as a component of a multi-agent chemotherapeutic regimen

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - Oncaspar will be used as a first-line therapy
   - The patient has a hypersensitivity to native forms of L-asparaginase

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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PEGASPARGASE BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PEGASPARGASE (Oncaspar)** requires the following rule(s) be met for approval:

A. You have acute lymphoblastic leukemia (ALL: a type of blood cancer)
B. Oncaspar will be used as a part of a chemotherapeutic (cancer treatment) plan that contains multiple medications
C. You meet ONE of the following:
    1. Oncaspar will be used as a first-line therapy (drug used for initial treatment)
    2. You have a hypersensitivity (allergy) to native forms of L-asparaginase (natural forms of a type of enzyme/protein)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Oncaspar. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Oncaspar [Prescribing Information]. Boston, MA: Servier Pharmaceuticals LLC; March 2024.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed June 27, 2024].

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGASPARGASE BvD (PART D)

For Part D use only:

PEGASPARGASE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGCETACOPLAN BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGCETACOPLAN	EMPAVELI	47380		GPI-10 (8580406500)	

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, continue to #6.
   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, continue to #6.
   If no, continue to #5.

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override)**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

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PEGCETACOPLAN BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

6. Is the drug administered via an implantable pump?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**
   If no, continue to #7.

7. Is the drug administered using an external pump?

   If yes, continue to #8.
   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

8. Is the drug specifically infused through an external infusion pump covered by Medicare?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field.).**

   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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PEGCETACOPLAN BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) (ICD-10 D59.5) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a hematologist
   - The patient's diagnosis is confirmed by flow cytometry that shows PNH granulocyte clone size of at least 10% AND at least 2 different GPI-protein deficiencies (e.g., CD55, CD59) on atleast 2 cell lineages (e.g., erythrocytes, granulocytes)
   - Empaveli will NOT be used concurrently with C5 complement inhibitor therapy (e.g., Soliris [eculizumab], Ultomiris [ravulizumab-cwvz], Piasky [crovalimab-akkz]), factor B inhibitor (e.g., Fabhalta [iptacopan]), or factor D inhibitor (e.g., Voydeya [danicopan])
   - The patient has tried and failed (as evidenced by hemoglobin levels less than 10.5 g/dL directly following at least 3 months of stable dosing) OR has a contraindication to Soliris (eculizumab) or Ultomiris (ravulizumab-cwvz)

     If yes, **approve for 4 months by HICL or GPI-10.**
     APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

     If no, continue to #2.

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PEGCETACOPLAN BvD (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of complement 3 glomerulopathy (C3G) (ICD-10 N00.A, N01.A, N02.A, N03.A, N04.A, N05.A, N06.A, N07.A, N00.6, N01.6, N02.6, N03.6, N04.6, N05.6, N06.6, N07.6) or primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Therapy is prescribed by or in consultation with a nephrologist
   - The patient's diagnosis is confirmed by a renal biopsy
   - The patient has a urine-protein creatine ratio (UPCR) of at least 1 g/g
   - The patient has an eGFR of at least 30mL/min/1.73m(2)
   - The patient has tried an ACE inhibitor (e.g., benazepril, lisinopril) or an ARB (e.g., losartan, valsartan) for at least 3 months at a maximum tolerated dose and will continue use, OR has a contraindication to both drug classes
   - Empaveli will NOT be used concurrently with another complement inhibitor (e.g., Fabhalta [iptacopan]) for the same indication

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEGCETACOPLAN (Empaveli)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
      2. Complement 3 glomerulopathy (C3G: a type of kidney disease) or primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN: a type of kidney disease)

   (Initial denial text continued on next page)

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PEGCETACOPLAN BvD (PART D)

INITIAL CRITERIA (CONTINUED)

B. If you have paroxysmal nocturnal hemoglobinuria, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
3. Your PNH diagnosis is confirmed by ALL the following through flow cytometry (test to measure characteristics of cells):
   a. You have at least 2 different GPI-protein deficiencies (missing a certain type of protein, such as CD55, CD59) on at least 2 cell lineages (types of cells such as erythrocytes [red blood cells], granulocytes [a type of white blood cell])
   b. PNH granulocyte clone size is at least 10%
4. You will NOT use Empaveli concurrently (at the same time) with C5 complement inhibitor therapy (such as Soliris [eculizumab], Ultomiris [ravulizumab-cwvz], Piasky [crovalimab-akkz]), factor B inhibitor (such as Fabhalta [iptacopan]), or factor D inhibitor (such as Voydeya [danicopan])
5. You have tried and failed (as shown by hemoglobin [type of protein in red blood cells] levels less than 10.5 g/dL directly following at least 3 months of stable dosing OR have a contraindication to (harmful for you to use) Soliris (eculizumab) or Ultomiris (ravulizumab-cwvz)

C. If you have complement 3 glomerulopathy or primary immune-complex membranoproliferative glomerulonephritis, approval also requires:
1. You are 12 years of age or older
2. Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor)
3. Your diagnosis is confirmed by a renal biopsy (removal of cells or tissue from the kidney for examination)
4. You have a urine-protein creatine ratio (UPCR: a test that measures the amount of protein in urine) of at least 1g/g
5. You have an estimated glomerular filtration rate (eGFR: a tool for evaluating kidney function) of at least 30mL/min/1.73m(2)
6. You have tried an angiotensin converting enzyme inhibitor (ACE-I: a type of medication used to protect kidneys, such as benazepril, lisinopril) or an angiotensin receptor blocker (ARB: a type of medication used to protect kidneys, such as losartan, valsartan) for at least 3 months at a maximum tolerated dose and will continue use, OR you have a contraindication to (harmful for you to use) both of these medication classes
7. You will NOT use Empaveli concurrently (at the same time) with another complement inhibitor (such as Fabhalta [iptacopan]) for the same indication

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PEGCETACOPLAN BvD (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) (ICD-10 D59.5) and meet **ALL** of the following criteria?
   - The patient has had clinical benefit while on Empaveli (e.g., reduction in number of blood transfusions, improvement/stabilization of lactate dehydrogenase [LDH] and hemoglobin levels) compared to baseline (defined as patient's condition post treatment with Soliris [eculizumab] or Ultomiris [ravulizumab-cwvz])
   - Empaveli will NOT be used concurrently with C5 complement inhibitor therapy (e.g., Soliris [eculizumab], Ultomiris [ravulizumab-cwvz], Piasky [crovalimab-akkz]), factor B inhibitor (e.g., Fabhalta [iptacopan]), or factor D inhibitor (e.g., Voydeya [danicopan])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of complement 3 glomerulopathy (C3G) (ICD-10 N00.A, N01.A, N02.A, N03.A, N04.A, N05.A, N06.A, N07.A, N00.6, N01.6, N02.6, N03.6, N04.6, N05.6, N06.6, N07.6) or primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN) and meet **ALL** of the following criteria?
   - The patient has had a reduction in proteinuria OR has improved or stablekidney function compared to baseline
   - Empaveli will NOT be used concurrently with another complement inhibitor (e.g., Fabhalta [iptacopan]) for the same indication

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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PEGCETACOPLAN BvD (PART D)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PEGCETACOPLAN (Empaveli)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
   2. Complement 3 glomerulopathy (C3G: a type of kidney disease) or primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN: a type of kidney disease)

B. If you have paroxysmal nocturnal hemoglobinuria, renewal also requires:
   1. You have had clinical benefit while on Empaveli (such as a reduction in number of blood transfusions [adding blood to the body], improvement/stabilization of lactate dehydrogenase [LDH: type of enzyme] and hemoglobin levels [type of protein in red blood cells]) compared to baseline (defined as your condition after treatment with Soliris [eculizumab] or Ultomiris [ravulizumab-cwvz])
   2. You will NOT use Empaveli concurrently (at the same time) with C5 complement inhibitor therapy (such as Soliris [eculizumab], Ultomiris [ravulizumab-cwvz], Piasky [crovalimab-akkz]), factor B inhibitor (such as Fabhalta [iptacopan]), or factor D inhibitor (such as Voydeya [danicopan])

C. If you have have complement 3 glomerulopathy or primary immune-complex membranoproliferative glomerulonephritis, renewal also requires:
   1. You have had a reduction (decrease) in proteinuria (high levels of protein in the urine) OR you have improved or stable kidney function compared to baseline (before treatment)
   2. You will NOT use Empaveli concurrently (at the same time) with another complement inhibitor (such as Fabhalta [iptacopan]) for the same indication

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PEGCETACOPLAN BvD (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Empaveli.

The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B. Drugs administered by an implantable pump are covered under Part B. Drugs administered via an external pump are covered under Part B if they are included under the local coverage policy of the applicable Medicare coverage policies (National and/or Local Coverage Policies). Drugs administered via an external pump that are not included under the applicable Medicare coverage policies are covered under Part D. A CMS website to assist with National and Local Coverage Determination for BvD review is http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx

REFERENCES

Empaveli [Prescribing Information]. Waltham, MA: Apellis Pharmaceuticals, Inc.: July 2025.

Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed July 30, 2025].

For Part D use only:

PEGCETACOPLAN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	INITIAL: PAROXYSMAL NOCTURNAL HEMOGLOBINURIA (PNH): INITIAL: DIAGNOSIS CONFIRMED VIA FLOW CYTOMETRY: 1) AT LEAST TWO DIFFERENT GPI PROTEIN DEFICIENCIES ON AT LEAST TWO CELL LINEAGES, AND 2) PNH GRANULOCYTE CLONE SIZE OF AT LEAST 10 PERCENT. COMPLEMENT 3 GLOMERULOPATHY (C3G), PRIMARY IMMUNE-COMPLEX MEMBRANOPROLIFERATIVE GLOMERULONEPHRITIS (IC-MPGN): 1) DIAGNOSIS CONFIRMED BY RENAL BIOPSY, 2) URINE-PROTEIN CREATINE RATIO (UPCR) OF AT LEAST 1 G/G, AND 3) EGFR OF AT LEAST 30 ML/MIN/1.73 M2.
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: PNH: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST. C3G, IC-MPGN: PRESCRIBED BY OR IN CONSULTATION WITH A NEPHROLOGIST.
Coverage Duration	INITIAL: PNH: 4 MONTHS, C3G, IC-MPGN: 6 MONTHS. RENEWAL: PNH, C3G, IC-MPGN: 12 MONTHS.
Other Criteria	INITIAL: PNH: 1) NO CONCURRENT USE WITH C5 COMPLEMENT INHIBITOR THERAPY, FACTOR B INHIBITOR, OR FACTOR D INHIBITOR, AND 2) CONTRAINDICATION TO

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	OR TRIAL AND FAILURE OF ULTOMIRIS OR SOLIRIS AS EVIDENCED BY HEMOGLOBIN LEVELS LESS THAN 10.5 G/DL DIRECTLY FOLLOWING AT LEAST 3 MONTHS OF STABLE DOSING. C3G, IC-MPGN: 1) TRIAL AND CONTINUATION OF AN ACE INHIBITOR OR ARB AT MAXIMUM TOLERATED DOSE FOR AT LEAST 3 MONTHS OR CONTRAINDICATION TO BOTH CLASSES, AND 2) NO CONCURRENT USE WITH ANOTHER COMPLEMENT INHIBITOR FOR THE SAME INDICATION. RENEWAL: PNH: 1) CLINICAL BENEFIT WHILE ON EMPAVELI COMPARED TO BASELINE (DEFINED AS CONDITION POST TREATMENT WITH SOLIRIS OR ULTOMIRIS), 2) NO CONCURRENT USE WITH C5 COMPLEMENT INHIBITOR THERAPY, FACTOR B INHIBITOR, OR FACTOR D INHIBITOR. C3G, IC-MPGN: 1) IMPROVED OR STABLE KIDNEY FUNCTION COMPARED TO BASELINE OR REDUCTION IN PROTEINURIA, AND 2) NO CONCURRENT USE WITH ANOTHER COMPLEMENT INHIBITOR FOR THE SAME INDICATION.

Created: 05/21
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 07/25

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGFILGRASTIM - APGF (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGFILGRASTIM-APGF	NYVEPRIA	46612		GPI-10 (8240157002)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the patient receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia and meets **ALL** of the following criteria?
   - The patient has a non-myeloid malignancy
   - Therapy is prescribed by or in consultation with a hematologist or oncologist

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEGFILGRASTIM - APGF (Nyvepria)** requires the following rule(s) be met for approval:
   A. You are receiving myelosuppressive anti-cancer drugs (drugs that decrease bone marrow activity) associated with a clinically significant incidence of febrile neutropenia (a type of blood condition with fever)
   B. You have a non-myeloid malignancy (cancer not affecting bone marrow)
   C. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PEGFILGRASTIM - APGF (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nyvepria.

REFERENCES

Nyvepria [Prescribing Information]. New York, NY: Pfizer; March 2023.

For Part D use only:

PEGFILGRASTIM - APGF (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR ONCOLOGIST.
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 09/22
Client Approval: 06/24
P&T Approval: 01/20

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGFILGRASTIM - BMEZ (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGFILGRASTIM-BMEZ	ZIEXTENZO	46183		GPI-10 (8240157005)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the patient receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia and meets **ALL** of the following criteria?
   - The patient has a non-myeloid malignancy
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred agent: Nyvepria (pegfilgrastim-apgf)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Has the patient been acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of acute radiation syndrome) **AND** the patient meets the following criterion?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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PEGFILGRASTIM - BMEZ (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PEGFILGRASTIM - BMEZ (Ziextenzo)** requires the following rule(s) be met for approval:

A. You meet ONE of the following:
   1. You are receiving myelosuppressive anti-cancer drugs (drugs that decrease bone marrow activity) associated with a clinically significant incidence of febrile neutropenia (a type of blood condition with fever)
   2. You have been acutely exposed to myelosuppressive doses (doses that decrease bone marrow activity) of radiation (hematopoietic subsyndrome of acute radiation syndrome [H-ARS]: an illness that happens after whole body radiation)

B. If you are receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia, approval also requires:
   1. You have a non-myeloid malignancy (cancer not affecting bone marrow)
   2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
   3. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Nyvepria (pegfilgrastim-apgf)

C. If you have been acutely exposed to myelosuppressive doses of radiation, approval also requires:
   1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PEGFILGRASTIM - BMEZ (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ziextenzo.

REFERENCES

Ziextenzo [Prescribing Information]. Princeton, NJ: Sandoz Inc.; February 2024.

For Part D use only:

PEGFILGRASTIM-BMEZ (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR ONCOLOGIST.
Coverage Duration	12 MONTHS
Other Criteria	TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT NYVEPRIA, WHERE INDICATIONS ALIGN.

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25 Created: 09/22
Commercial Effective: N/A Client Approval: 06/24 P&T Approval: 04/23

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ADVANTAGE AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGFILGRASTIM - CBQV (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGFILGRASTIM-CBQV	UDENYCA, UDENYCA ONBODY, UDENYCA AUTOINJECTOR	45445		GPI-10 (8240157010)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the patient receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia and meets **ALL** of the following criteria?
   - The patient has a non-myeloid malignancy
   - Therapy is prescribed by or in consultation with a hematologist or oncologist

   If yes, continue to #2.
   If no, continue to #4.

2. Has the patient had a trial of or contraindication to the preferred agent: Nyvepria (pegfilgrastim-apgf)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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PEGFILGRASTIM - CBQV (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Is the request for Udenyca Onbody **AND** the patient meets the following criterion?
   - The patient has a barrier to access (e.g., travel barriers, patient is unable to return to the clinic for Udenyca injections)

   If yes, **approve for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Has the patient been acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of acute radiation syndrome) **AND** the patient meets the following criterion?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEGFILGRASTIM - CBQV (Udenyca, Udenyca Onbody, Udenyca Autoinjector)** requires the following rule(s) be met for approval:
   A. You meet ONE of the following:
      1. You are receiving myelosuppressive anti-cancer drugs (drugs that decrease bone marrow activity) associated with a clinically significant incidence of febrile neutropenia (a type of blood condition with fever)
      2. You have been acutely exposed to myelosuppressive doses (doses that decrease bone marrow activity) of radiation (hematopoietic subsyndrome of acute radiation syndrome: an illness that happens after whole body radiation)

   (Denial text continued on next page)

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PEGFILGRASTIM - CBQV (PART D)

GUIDELINES FOR USE (CONTINUED)

B. If you are receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia, approval also requires:
1. You have a non-myeloid malignancy (cancer not affecting bone marrow)
2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
3. You meet ONE of the following:
   a. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Nyvepria (pegfilgrastim-apgf)
   b. You are requesting Udenyca Onbody AND you have a barrier to access (such as travel barriers, you are unable to return to the clinic for Udenyca injections)

C. If you have been acutely exposed to myelosuppressive doses of radiation, approval also requires:
1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Udenyca.

REFERENCES
Udenyca [Prescribing Information]. Redwood City, CA: Coherus BioSciences, Inc.; December 2023.

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ADVANTAGE AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGFILGRASTIM - CBQV (PART D)

For Part D use only:

PEGFILGRASTIM - CBQV (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR ONCOLOGIST.
Coverage Duration	12 MONTHS
Other Criteria	NON MYELOID MALIGNANCY: UDENYCA: TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT NYVEPRIA. UDENYCA ONBODY: 1) TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT NYVEPRIA, OR 2) BARRIER TO ACCESS (E.G., TRAVEL BARRIERS, UNABLE TO RETURN TO CLINIC FOR INJECTIONS).

Core	Advantage	Plus
No	Yes	Yes

Part D Effective: 01/01/25 Created: 09/22
Commercial Effective: N/A Client Approval: 06/24 P&T Approval: 04/24

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGFILGRASTIM-FPGK (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGFILGRASTIM-FPGK	STIMUFEND	48269		GPI-10 (8240157015)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the patient receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia and meets **ALL** of the following criteria?
   - The patient has a non-myeloid malignancy
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred agent: Nyvepria (pegfilgrastim-apgf)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Has the patient been acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of acute radiation syndrome [H-ARS]) **AND** the patient meets the following criterion?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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PEGFILGRASTIM-FPGK (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PEGFILGRASTIM-FPGK (Stimufend)** requires the following rule(s) be met for approval:

A. You meet ONE of the following:
   1. You are receiving myelosuppressive anti-cancer drugs (drugs that decrease bone marrow activity) associated with a clinically significant incidence of febrile neutropenia (a type of blood condition with fever)
   2. You have been acutely exposed to myelosuppressive doses (doses that decrease bone marrow activity) of radiation (hematopoietic subsyndrome of acute radiation syndrome [H-ARS]: an illness that happens after whole body radiation)

B. If you are receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia, approval also requires:
   1. You have a non-myeloid malignancy (cancer not affecting bone marrow)
   2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
   3. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Nyvepria (pegfilgrastim-apgf)

C. If you have been acutely exposed to myelosuppressive doses of radiation, approval also requires:
   1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PEGFILGRASTIM-FPGK (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Stimufend.

REFERENCES

Stimufend [Prescribing Information]. Lake Zurich, IL: Fresenius Kabi USA, LLC; September 2023.

For Part D use only:

PEGFILGRASTIM-FPGK (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR ONCOLOGIST.
Coverage Duration	12 MONTHS
Other Criteria	TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT NYVEPRIA, WHERE INDICATIONS ALIGN.

Part D Effective: 01/01/25 Created: 11/23
Commercial Effective: N/A Client Approval: 06/24 P&T Approval: 04/22

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGFILGRASTIM - JMDB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGFILGRASTIM-JMDB	FULPHILA	45010		GPI-10 (8240157020)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the patient receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia and meets **ALL** of the following criteria?
   - The patient has a non-myeloid malignancy
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred agent: Nyvepria (pegfilgrastim-apgf)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEGFILGRASTIM - JMDB (Fulphila)** requires the following rule(s) be met for approval:
   A. You are receiving myelosuppressive anti-cancer drugs (drugs that decrease bone marrow activity) associated with a clinically significant incidence of febrile neutropenia (a type of blood condition with fever)
   B. You have a non-myeloid malignancy (cancer not affecting bone marrow)
   C. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
   D. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Nyvepria (pegfilgrastim-apgf)

   (Denial text continued on next page)

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PEGFILGRASTIM - JMDB (PART D)

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Fulphila.

REFERENCES

Fulphila [Prescribing Information]. Cambridge, MA: Biocon Biologics Inc.; June 2023.

For Part D use only:

PEGFILGRASTIM - JMDB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR ONCOLOGIST.
Coverage Duration	12 MONTHS
Other Criteria	TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT NYVEPRIA, WHERE INDICATIONS ALIGN.

Created: 09/22
Effective: 01/01/26 Client Approval: 01/26 P&T Approval: 01/20

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGFILGRASTIM - NEULASTA (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGFILGRASTIM	NEULASTA	23255		GPI-10 (8240157000)	BRAND = NEULASTA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Has the patient been acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of acute radiation syndrome) **AND** the patient meets the following criterion?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Is the patient receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia and meets **ALL** of the following criteria?
   - The patient has a non-myeloid malignancy
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred agent: Nyvepria (pegfilgrastim-apgf)

   If yes, **approve all strengths for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve
   DENIAL TEXT: See the denial text at the end of the guideline.

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PEGFILGRASTIM - NEULASTA (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PEGFILGRASTIM - NEULASTA** requires the following rule(s) be met for approval:

A. You meet ONE of the following:
   1. You have been acutely exposed to myelosuppressive doses (doses that decrease bone marrow activity) of radiation (hematopoietic subsyndrome of acute radiation syndrome: an illness that happens after whole body radiation)
   2. You are receiving myelosuppressive anti-cancer drugs (drugs that decrease bone marrow activity) associated with a clinically significant incidence of febrile neutropenia (a type of blood condition with fever)

B. If you have been acutely exposed to myelosuppressive doses of radiation, approval also requires:
   1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)

C. If you are receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia, approval also requires:
   1. You have a non-myeloid malignancy (cancer not affecting bone marrow)
   2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
   3. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Nyvepria (pegfilgrastim-apgf)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Neulasta.

REFERENCES

Neulasta [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; August 2025.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGFILGRASTIM - NEULASTA (PART D)

For Part D use only:

PEGFILGRASTIM - NEULASTA (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR ONCOLOGIST.
Coverage Duration	12 MONTHS
Other Criteria	TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT NYVEPRIA, WHERE INDICATIONS ALIGN.

Created: 10/19
Effective: 04/04/26 Client Approval: 04/26 P&T Approval: 01/20

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGFILGRASTIM - NEULASTA ONPRO (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGFILGRASTIM	NEULASTA ONPRO		37706	GPI-14 (8240157000E525)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Has the patient been acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of acute radiation syndrome) **AND** the patient meets the following criterion?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Is the patient receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia and meets **ALL** of the following criteria?
   - The patient has a non-myeloid malignancy
   - Therapy is prescribed by or in consultation with a hematologist or oncologist

   If yes, **approve for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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PEGFILGRASTIM - NEULASTA ONPRO (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PEGFILGRASTIM - NEULASTA ONPRO** requires the following rule(s) be met for approval:

A. You meet ONE of the following:
   1. You have been acutely exposed to myelosuppressive doses (doses that decrease bone marrow activity) of radiation (hematopoietic subsyndrome of acute radiation syndrome: an illness that happens after whole body radiation)
   2. You are receiving myelosuppressive anti-cancer drugs (drugs that decrease bone marrow activity) associated with a clinically significant incidence of febrile neutropenia (a type of blood condition with fever)

B. If you have been acutely exposed to myelosuppressive doses of radiation, approval also requires:
   1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)

C. If you are receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia, approval also requires:
   1. You have a non-myeloid malignancy (cancer not affecting bone marrow)
   2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Neulasta Onpro.

REFERENCES

Neulasta Onpro [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; January 2025.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGFILGRASTIM - NEULASTA ONPRO (PART D)

For Part D use only:

PEGFILGRASTIM-NEULASTA ONPRO (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR ONCOLOGIST.
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 10/19
Effective: 01/01/26 Client Approval: 01/26 P&T Approval: 01/20

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGFILGRASTIM-PBBK (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGFILGRASTIM-PBBK	FYLNETRA	48035		GPI-10 (8240157060)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the patient receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia and meets **ALL** of the following criteria?
   - The patient has a non-myeloid malignancy
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred agent: Nyvepria (pegfilgrastim-apgf)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days

   If no, continue to #2.

2. Has the patient been acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of acute radiation syndrome [H-ARS]) **AND** the patient meets the following criterion?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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PEGFILGRASTIM-PBBK (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PEGFILGRASTIM-PBBK (Fylnetra)** requires the following rule(s) be met for approval:

A. You meet ONE of the following:
   1. You are receiving myelosuppressive anti-cancer medications (medications that decrease bone marrow activity) associated with a clinically significant incidence of febrile neutropenia (a type of blood condition with fever)
   2. You have been acutely exposed to myelosuppressive doses (doses that decrease bone marrow activity) of radiation (hematopoietic subsyndrome of acute radiation syndrome [H-ARS]: an illness that happens after whole body radiation)

B. If you are receiving myelosuppressive anti-cancer medications associated with a clinically significant incidence of febrile neutropenia, approval also requires:
   1. You have a non-myeloid malignancy (cancer not affecting bone marrow)
   2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
   3. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Nyvepria (pegfilgrastim-apgf)

C. If you have been acutely exposed to myelosuppressive doses of radiation, approval also requires:
   1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Fylnetra.

REFERENCES

Fylnetra [Prescribing Information]. Bridgewater, NJ: Amneal Pharmaceuticals LLC, April 2025.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGFILGRASTIM-PBBK (PART D)

For Part D use only:

PEGFILGRASTIM-PBBK (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR ONCOLOGIST.
Coverage Duration	12 MONTHS
Other Criteria	TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT NYVEPRIA, WHERE INDICATIONS ALIGN.

Created: 10/22
Effective: 05/17/25 Client Approval: 05/25 P&T Approval: 07/25

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STANDARD PART D
PRIOR AUTHORIZATION GUIDELINES

PEGFILGRASTIM-UNNE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGFILGRASTIM-UNNE	ARMLUPEG	51183		GPI-10 (8240157074)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the patient receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia and meets **ALL** of the following criteria?
   - The patient has a non-myeloid malignancy
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred agent: Nyvepria (pegfilgrastim-apgf)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Has the patient been acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of acute radiation syndrome [H-ARS]) **AND** meets the following criterion?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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PEGFILGRASTIM-UNNE (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: Our guideline named **PEGFILGRASTIM-UNNE (Armlupeg)** requires the following rule(s) be met for approval:

A. You meet ONE of the following:
   1. You are receiving myelosuppressive anti-cancer medications (medications that decrease bone marrow activity) associated with a clinically significant incidence of febrile neutropenia (a type of blood condition with fever)
   2. You have been acutely exposed to myelosuppressive doses (doses that decrease bone marrow activity) of radiation (hematopoietic subsyndrome of acute radiation syndrome [H-ARS]: an illness that happens after whole body radiation)

B. If you are receiving myelosuppressive anti-cancer medications associated with a clinically significant incidence of febrile neutropenia, approval also requires:
   1. You have a non-myeloid malignancy (cancer not affecting bone marrow)
   2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
   3. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Nyvepria (pegfilgrastim-apgf)

C. If you have been acutely exposed to myelosuppressive doses of radiation, approval also requires:
   1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Armlupeg.

REFERENCES

Armlupeg [Prescribing Information]. Naples, FL: Lupin Pharmaceuticals, Inc.; July 2026.

Created: 09/26
Effective: 09/12/26 Client Approval: 09/26 DMC Approval: 09/09/26

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGINTERFERON ALFA-2A (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGINTERFERON ALFA-2A	PEGASYS	24035		GPI-10 (1235306005)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic hepatitis C virus infection (HCV) (ICD-10 B18.2) **AND** meet the following criterion?
   - The patient has compensated liver disease

   If yes, **approve for 48 weeks by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of chronic hepatitis B (ICD-10 B18.0, B18.1) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with a gastroenterologist, infectious disease specialist, a physician specializing in the treatment of hepatitis (e.g., a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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PEGINTERFERON ALFA-2A (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Is the patient between 3 to 17 years of age and meet **ALL** of the following criteria?
   - The patient does NOT have cirrhosis
   - The patient has serum HBeAg-positive chronic hepatitis B
   - The patient has evidence of viral replication with elevated serum alanine aminotransferase (ALT)

   If yes, **approve for 48 weeks by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

4. Is the patient 18 years of age or older and meet **ALL** of the following criteria?
   - The patient has serum HBeAg-positive or HBe-Ag-negative chronic hepatitis B
   - The patient has compensated liver disease with evidence of viral replication and liver inflammation

   If yes, **approve for 48 weeks by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEGINTERFERON ALFA-2A (Pegasys)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Chronic hepatitis C (a type of liver infection)
      2. Chronic hepatitis B (a type of liver infection)

   B. If you have chronic hepatitis C, approval also requires:
      1. You have compensated liver disease (a type of liver condition)

   (Denial text continued on next page)

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PEGINTERFERON ALFA-2A (PART D)

GUIDELINES FOR USE (CONTINUED)

C. If you have chronic hepatitis B, approval also requires:

1. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive condition), infectious disease specialist (a doctor who specializes in the treatment of infections), a doctor specializing in the treatment of hepatitis such as a hepatologist (liver doctor), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
2. If you are between 3 to 17 years of age, approval also requires:
   a. You do NOT have cirrhosis (liver damage)
   b. Your blood test shows you have HBeAg (marker of active virus multiplying in the body)-positive chronic hepatitis B
   c. You have evidence of viral replication (virus is multiplying in the body) with elevated serum alanine aminotransferase (ALT: a type of liver enzyme test)
3. If you are 18 years of age or older, approval also requires:
   a. Your blood test shows you have HBeAg (marker of active virus multiplying in the body)-positive or HBe-Ag-negative chronic hepatitis B
   b. You have compensated liver disease (a type of liver condition) with evidence of viral replication and liver inflammation

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Pegasys.

REFERENCES

Pegasys [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; March 2021.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGINTERFERON ALFA-2A (PART D)

For Part D use only:

PEGINTERFERON ALFA-2A (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	HEPATITIS B: PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST, INFECTIOUS DISEASE SPECIALIST, OR PHYSICIAN SPECIALIZING IN THE TREATMENT OF HEPATITIS (E.G., HEPATOLOGIST).
Coverage Duration	HEP B/HEP C: 48 WEEKS.
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25 Created: 04/23
Commercial Effective: N/A Client Approval: 11/24 P&T Approval: 01/17

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGUNIGALSIDASE ALFA-IWXJ (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGUNIGALSIDASE ALFA-IWXJ	ELFABRIO	48913		GPI-10 (3090366010)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Fabry disease (ICD-10 E75.21) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a nephrologist, cardiologist, or specialist in genetics or inherited metabolic disorders
   - Elfabrio will NOT be used concurrently with another Fabry disease therapy (e.g., Fabrazyme [agalsidase beta], Galafold [migalastat])

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the request for a female patient who meets the following criterion?
   - The patient has a galactosidase alpha (GLA) gene mutation via genetic testing

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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PEGUNIGALSIDASE ALFA-IWXJ (PART D)

INITIAL CRITERIA (CONTINUED)

3. Is the request for a male patient who meets **ONE** of the following criteria?
   - The patient has an alpha galactosidase A (a-Gal-A) deficiency as indicated by an enzyme assay
   - The patient has a galactosidase alpha (GLA) gene mutation via genetic testing

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEGUNIGALSIDASE ALFA-IWXJ (Elfabrio)** requires the following rule(s) be met for approval:
   A. You have Fabry disease (a rare genetic disease)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with a nephrologist (kidney doctor), cardiologist (heart doctor), or a doctor specializing in genetics or inherited metabolic disorders
   D. You will NOT use Elfabrio concurrently (taking at the same time) with another Fabry disease medication (such as Fabrazyme [agalsidase beta], Galafold [migalastat])
   E. If you are a female, approval also requires:
      1. You have a galactosidase alpha (GLA: a type of gene) gene mutation via genetic testing
   F. If you are a male, approval also requires ONE of the following:
      1. You do not have enough alpha galactosidase A (a-Gal-A: a type of protein) as indicated by an enzyme assay (a type of lab test)
      2. You have a galactosidase alpha (GLA: a type of gene) gene mutation via genetic testing

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PEGUNIGALSIDASE ALFA-IWXJ (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Fabry disease (ICD-10 E75.21) and meet **ALL** of the following criteria?
   - The patient has demonstrated improvement or stabilization
   - Elfabrio will NOT be used concurrently with another Fabry disease therapy (e.g., Fabrazyme [agalsidase beta], Galafold [migalastat])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEGUNIGALSIDASE ALFA-IWXJ (Elfabrio)** requires the following rule(s) be met for renewal:
   A. You have Fabry disease (a rare genetic disease)
   B. You have demonstrated improvement or stabilization
   C. You will NOT use Elfabrio concurrently (taking at the same time) with another Fabry disease medication (such as Fabrazyme [agalsidase beta], Galafold (migalastat])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Elfabrio.

REFERENCES

Elfabrio [Prescribing Information]. Cary, NC: Chiesi USA, Inc.; May 2023.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGUNIGALSIDASE ALFA-IWXJ (PART D)

For Part D use only:

PEGUNIGALSIDASE ALFA-IWXJ (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	FABRY DISEASE: INITIAL: ONE OF THE FOLLOWING: 1) FEMALES: GALACTOSIDASE ALPHA (GLA) GENE MUTATION VIA GENETIC TESTING, OR 2) MALES: ENZYME ASSAY INDICATING ALPHA GALACTOSIDASE A DEFICIENCY OR GLA GENE MUTATION VIA GENETIC TESTING.
Age Restrictions	N/A
Prescriber Restrictions	FABRY DISEASE: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH NEPHROLOGIST, CARDIOLOGIST, OR SPECIALIST IN GENETICS OR INHERITED METABOLIC DISORDERS.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	FABRY DISEASE: INITIAL: NO CONCURRENT USE WITH ANOTHER FABRY DISEASE THERAPY. RENEWAL: 1) DEMONSTRATED IMPROVEMENT OR STABILIZATION, AND 2) NO CONCURRENT USE WITH ANOTHER FABRY DISEASE THERAPY.

Part D Effective: 01/01/25 Created: 08/23
Commercial Effective: N/A Client Approval: 11/24 P&T Approval: 07/23

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGVALIASE-PQPZ (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGVALIASE-PQPZ	PALYNZIQ	44944		GPI-10 (3090855040)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of phenylketonuria (PKU) (ICD-10 E70.0) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient has uncontrolled blood phenylalanine concentrations greater than 600 micromole/L on existing management
   - Palynziq will NOT be used concurrently with Kuvan (sapropterin)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEGVALIASE-PQPZ (Palynziq)** requires the following rules be met for approval:
   A. You have phenylketonuria (PKU: a type of genetic metabolic disorder)
   B. You are 12 years of age or older
   C. You have uncontrolled blood phenylalanine concentrations greater than 600 micromole/L on existing management
   D. You will NOT use Palynziq concurrently (at the same time) with Kuvan (sapropterin)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGVALIASE-PQPZ (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of phenylketonuria (PKU) (ICD-10 E70.0) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Palynziq will NOT be used concurrently with Kuvan (sapropterin)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEGVALIASE-PQPZ (Palynziq)** requires the following rules be met for renewal:
   A. You have phenylketonuria (PKU: a type of genetic metabolic disorder)
   B. You continue to benefit from the medication
   C. You will NOT use Palynziq concurrently (at the same time) with Kuvan (sapropterin)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Palynziq.

REFERENCES
Palynziq [Prescribing Information]. Novato, CA: BioMarin Pharmaceutical, Inc.; February 2026.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGVALIASE-PQPZ (PART D)

For Part D use only:

PEGVALIASE-PQPZ (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	PHENYLKETONURIA (PKU): INITIAL: NO CONCURRENT USE WITH KUVAN. RENEWAL: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH KUVAN.

Created: 06/18
Effective: 03/11/26 Client Approval: 03/26 P&T Approval: 04/26

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGVISOMANT (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGVISOMANT	SOMAVERT	25062		GPI-10 (3018006000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of acromegaly (ICD-10 E22.0) **AND** meet the following criterion?
   - The patient had an inadequate response to surgery or radiation, or these therapies are not appropriate for this patient

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEGVISOMANT (Somavert)** requires the following rule(s) be met for approval:
   A. You have acromegaly (a type of hormone disorder)
   B. You had an inadequate response (did not work) to surgery or radiation, or these therapies are not appropriate for you

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PEGVISOMANT (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Somavert.

REFERENCES

Somavert [Prescribing Information]. New York, NY: Pharmacia and Upjohn Company LLC; August 2021.

PEGVISOMANT (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A
Quantity Limit (from Formulary ASCII file)	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Created: 10/19
Effective: 01/01/25 Client Approval: 08/24 P&T Approval: 05/19

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGZILARGINASE-NBLN BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGZILARGINASE-NBLN	LOARGYS	50171		GPI-10 (3090276000)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	Yes	No	No	Yes	No	No	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #5.

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PEGZILARGINASE-NBLN BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

If yes, **refer to plan. (The health plan makes the final payment determination decision)**

- **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override)**
- **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGZILARGINASE-NBLN BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Arginase 1 Deficiency (ARG1-D) (ICD-10 E72.21) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Loargys will be used in conjunction with dietary protein restriction
   - Therapy is prescribed by or in consultation with a metabolic specialist
   - The patient has a plasma arginine level of at least 250 umol/L

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEGZILARGINASE-NBLN (Loargys)** requires the following rule(s) be met for approval:
   A. You have Arginase 1 Deficiency (ARG1-D: a rare metabolic disorder)
   B. You are 2 years of age or older
   C. Loargys will be used together with dietary protein restriction
   D. Therapy is prescribed by or in consultation with a metabolic specialist
   E. You have a plasma arginine level (a type of lab test) of at least 250 micromole/liter

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGZILARGINASE-NBLN BvD (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Arginase 1 Deficiency (ARG1-D) (ICD-10 E72.21) **AND** meet the following criterion?
   - The patient has shown improvement of symptoms or reduction of arginine levels

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEGZILARGINASE-NBLN (Loargys)** requires the following rule(s) be met for renewal:
   A. You have Arginase 1 Deficiency (ARG1-D: a rare metabolic disorder)
   B. You have shown improvement of symptoms or reduction (decrease) of arginine levels (a type of lab test)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Loargys.

The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Loargys [Prescribing Information]. Chicago, IL: Immedica Pharma US Inc.; February 2026.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed April 28, 2026].

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGZILARGINASE-NBLN BvD (PART D)

For Part D use only:

PEGZILARGINASE-NBLN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	ARGINASE 1 DEFICIENCY (ARG1-D): INITIAL: PLASMA ARGININE LEVEL OF AT LEAST 250 MICROMOLE PER LITER.
Age Restrictions	N/A
Prescriber Restrictions	ARG1-D: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A METABOLIC SPECIALIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	ARG1-D: RENEWAL: IMPROVEMENT OF SYMPTOMS OR REDUCTION OF ARGININE LEVELS.

Created: 06/26
Effective: 07/01/26 Client Approval: 06/26 P&T Approval: 04/26

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEMBROLIZUMAB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEMBROLIZUMAB	KEYTRUDA	41369		GPI-10 (2135795300)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic melanoma (ICD-10 Group C43) **AND** meet the following criterion?
   - Keytruda will NOT be used concurrently with a targeted therapy (i.e., BRAF inhibitors [e.g., Braftovi (encorafenib), Tafinlar (dabrafenib)], MEK inhibitors [e.g., Mekinist (trametinib)], and NTRK inhibitors [e.g., Vitrakvi (larotrectinib), Rozlytrek (entrectinib)])

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of Stage IIB, IIC, or III melanoma (ICD-10 Group C43) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient has undergone complete resection
   - Keytruda will be used as adjuvant treatment

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

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GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of metastatic nonsquamous (e.g., adenocarcinoma, large cell carcinoma) non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - Keytruda will be used in combination with pemetrexed and platinum chemotherapy (e.g., cisplatin, carboplatin)
   - The patient does not have epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #4.

4. Does the patient have a diagnosis of metastatic squamous non-small cell lung cancer (NSCLC) (ICD-10 Group C34) **AND** meet the following criterion?
   - Keytruda will be used in combination with carboplatin and either paclitaxel or paclitaxel protein-bound

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #5.

5. Does the patient have a diagnosis of non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient's tumor expresses programmed death-ligand 1 (PD-L1) [Tumor Proportion Score (TPS) of at least 1%] as determined by an FDA-approved test
   - The patient does not have epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations

   If yes, continue to #6.
   If no, continue to #7.

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GUIDELINES FOR USE (CONTINUED)

6. Does the patient meet **ONE** of the following criteria?
   - The patient has stage III NSCLC AND is not a candidate for surgical resection or definitive chemoradiation
   - The patient has metastatic NSCLC

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

7. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient's tumor expresses programmed death-ligand 1 (PD-L1) [Tumor Proportion Score (TPS) of at least 1%] as determined by an FDA-approved test
   - The patient has disease progression on or after treatment with platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

   If yes, continue to #8.
   If no, continue to #9.

8. Does the patient meet **ONE** of the following criteria?
   - The patient does not have epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations
   - The patient has an anaplastic lymphoma kinase (ALK) genomic tumor aberration AND disease progression on or after ALK-directed therapy (e.g., Xalkori [crizotinib], Zykadia [ceritinib])
   - The patient has an epidermal growth factor receptor (EGFR) genomic tumor aberration AND disease progression on or after EGFR-directed therapy (e.g., Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib])

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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GUIDELINES FOR USE (CONTINUED)

9. Does the patient have resectable (node positive or tumor is at least 4 cm) non-small cell lung cancer (NSCLC) (ICD-10 Group C34) **AND** meet the following criterion?
   - Keytruda will be used in combination with platinum-containing chemotherapy (e.g., cisplatin) as neoadjuvant treatment, OR as a single agent as adjuvant treatment after surgery following prior use in combination with platinum-containing chemotherapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #10.

10. Does the patient have a diagnosis of Stage IB (T2a is at least 4 cm), II, or IIIA non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Keytruda will be used as adjuvant treatment following resection and platinum-based chemotherapy (e.g., cisplatin, carboplatin)

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #11.

11. Does the patient have a diagnosis of unresectable advanced or metastatic malignant pleural mesothelioma (MPM) (ICD-10 C45.0) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Keytruda will be given in combination with pemetrexed and platinum chemotherapy (e.g., cisplatin, carboplatin)

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #12.

12. Does the patient have a diagnosis of head and neck squamous cell carcinoma (HNSCC) (ICD-10 Groups C44.42, C76.0, C00, C06, C09, C10, C32)?

    If yes, continue to #13.
    If no, continue to #17.

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PEMBROLIZUMAB (PART D)

GUIDELINES FOR USE (CONTINUED)

13. Is the cancer resectable and locally advanced, and the patient meets **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - The patient's tumor expresses programmed death-ligand 1 (PD-L1) [Combined Positive Score (CPS) of at least 1] as determined by an FDA-approved test

    If yes, continue to #14.
    If no, continue to #15.

14. Does the patient meet **ONE** of the following criteria?
    - Keytruda will be used as single-agent neoadjuvant treatment and then continued as adjuvant treatment in combination with radiotherapy (RT)
    - Keytruda will be used as a single agent following its prior use both as single-agent neoadjuvant treatment and as adjuvant treatment in combination with RT

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

15. Is the cancer either metastatic or both unresectable and recurrent, and the patient meets **ONE** of the following criteria?
    - Keytruda will be given in combination with platinum and fluorouracil (FU)
    - The patient's tumor expresses programmed death-ligand 1 (PD-L1) [Combined Positive Score (CPS) of at least 1] as determined by an FDA-approved test

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #16.

16. Is the cancer recurrent or metastatic **AND** the patient meets the following criterion?
    - The patient has disease progression on or after treatment with platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

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PEMBROLIZUMAB (PART D)

GUIDELINES FOR USE (CONTINUED)

17. Does the patient have a diagnosis of classical Hodgkin lymphoma (cHL) (ICD-10 Group C81) and meet **ONE** of the following criteria?
    - The patient is 18 years of age or older AND has relapsed or refractory cHL
    - The patient has refractory cHL, or cHL that has relapsed after 2 or more prior lines of therapy

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #18.

18. Does the patient have a diagnosis of primary mediastinal large B-cell lymphoma (PMBCL) (ICD-10 Group C85.2) and meet **ONE** of the following criteria?
    - The patient has refractory PMBCL
    - The patient has relapsed after 2 or more prior lines of therapy

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #19.

19. Does the patient have a diagnosis of locally advanced or metastatic urothelial carcinoma (ICD-10 Groups C66, C67, C68) and meet **ONE** of the following criteria?
    - Keytruda will be used in combination with enfortumab vedotin (Padcev) AND the patient is at least 18 years of age
    - The patient is not eligible for any platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
    - The patient has disease progression on or after treatment with platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
    - The patient has disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #20.

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PEMBROLIZUMAB (PART D)

GUIDELINES FOR USE (CONTINUED)

20. Does the patient have a diagnosis of bladder cancer (ICD-10 Group C67, D09.0)?

    If yes, continue to #21.
    If no, continue to #23.

21. Is the cancer muscle invasive (MIBC) and the patient meets **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Keytruda will be used in combination with enfortumab vedotin (Padcev) as neoadjuvant treatment, and then continued as adjuvant treatment after a cystectomy

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #22.

22. Is the cancer non-muscle invasive (NMIBC) and the patient meets **ALL** of the following criteria?
    - The patient has Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk cancer with carcinoma in situ (CIS)
    - The patient is ineligible for or has elected not to undergo a cystectomy

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

23. Does the patient have a diagnosis of an unresectable or metastatic solid tumor and meet **ALL** of the following criteria?
    - The patient's tumor is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) as determined by an FDA-approved test
    - The patient has disease progression following prior treatment and has no satisfactory alternative treatment options

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #24.

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PEMBROLIZUMAB (PART D)

GUIDELINES FOR USE (CONTINUED)

24. Does the patient have a diagnosis of unresectable or metastatic colorectal cancer (CRC) (ICD-10 C19) **AND** meet the following criterion?
    - The patient's cancer is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) as determined by an FDA-approved test

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #25.

25. Does the patient have a diagnosis of locally advanced unresectable or metastatic gastric or gastroesophageal junction (GEJ) adenocarcinoma (ICD-10 Group C16) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - The patient's tumor expresses programmed death-ligand 1 (PD-L1) (Combined Positive Score [CPS] of at least 1) as determined by an FDA-approved test

    If yes, continue to #26.
    If no, continue to #27.

26. Does the patient meet **ONE** of the following criteria?
    - The cancer is HER2-positive, AND Keytruda will be used in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy
    - The cancer is HER2-negative, AND Keytruda will be used in combination with fluoropyrimidine- and platinum-containing chemotherapy

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

27. Does the patient have a diagnosis of locally advanced or metastatic esophageal or gastroesophageal junction (GEJ) (tumors with epicenter 1 to 5 centimeters above the GEJ) carcinoma (ICD-10 C16.0; Group C15) **AND** meet the following criterion?
    - The tumor is not amenable to surgical resection or definitive chemoradiation

    If yes, continue to #28.
    If no, continue to #29.

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PEMBROLIZUMAB (PART D)

GUIDELINES FOR USE (CONTINUED)

28. Does the patient meet **ONE** of the following criteria?
    - Keytruda will be used in combination with platinum- and fluoropyrimidine-based chemotherapy AND the patient's tumor expresses programmed death-ligand 1 (PD-L1) (Combined Positive Score [CPS] of at least 1)
    - Keytruda will be used after one or more prior lines of systemic therapy AND the patient has a tumor of squamous cell histology that expresses programmed death-ligand 1 (PD-L1) (Combined Positive Score [CPS] of at least 10) as determined by an FDA-approved test

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

29. Does the patient have a diagnosis of cervical cancer (ICD-10 Group C53)?

    If yes, continue to #30.
    If no, continue to #33.

30. Is the cancer locally advanced and the patient meets **ALL** of the following criteria?
    - The cancer is FIGO 2014 Stage III-IVA
    - The cancer involves the lower third of the vagina, hydronephrosis/a non-functioning kidney, or has spread to adjacent pelvic organs
    - Keytruda will be used in combination with chemoradiotherapy (CRT)

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #31.

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PEMBROLIZUMAB (PART D)

GUIDELINES FOR USE (CONTINUED)

31. Is the cancer persistent, recurrent, or metastatic and the patient meets **ALL** of the following criteria?
    - Keytruda will be used in combination with chemotherapy (e.g., paclitaxel, cisplatin, carboplatin)
    - The patient's tumor expresses programmed death-ligand 1 (PD-L1) [Combined Positive Score (CPS) of at least 1] as determined by an FDA-approved test

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #32.

32. Is the cancer recurrent or metastatic and the patient meets **ALL** of the following criteria?
    - The patient has disease progression on or after chemotherapy
    - The patient's tumor expresses programmed death-ligand 1 (PD-L1) [Combined Positive Score (CPS) of at least 1] as determined by an FDA-approved test

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

33. Does the patient have a diagnosis of hepatocellular carcinoma (HCC) (ICD-10 C22.0) and meet **ALL** of the following criteria?
    - The patient's cancer is secondary to hepatitis B
    - The patient has received prior systemic therapy (e.g., Nexavar [sorafenib], oxaliplatin) other than a PD-1/PD-L1-containing regimen (e.g., Opdivo [nivolumab])

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #34.

34. Does the patient have a diagnosis of locally advanced unresectable or metastatic biliary tract cancer (BTC) (ICD-10 Group C24) **AND** meet the following criterion?
    - Keytruda will be used in combination with gemcitabine and cisplatin

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #35.

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PEMBROLIZUMAB (PART D)

GUIDELINES FOR USE (CONTINUED)

35. Does the patient have a diagnosis of recurrent locally advanced or metastatic Merkel cellcarcinoma (MCC) (ICD-10 Group C4A, C7B.1)?

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #36.

36. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC) (ICD-10 Groups C64, C65) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Keytruda will be used in combination with Inlyta (axitinib) OR Lenvima (lenvatinib)

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #37.

37. Does the patient have a diagnosis of renal cell carcinoma (RCC) (ICD-10 Groups C64, C65) and meet **ALL** of the following criteria?
    - Keytruda will be used for adjuvant treatment
    - The patient is at intermediate-high or high risk of recurrence following a nephrectomy, or following a nephrectomy and resection of metastatic lesions

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #38.

38. Does the patient have a diagnosis of renal cell carcinoma (RCC) (ICD-10 Groups C64, C65) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Keytruda will be used for adjuvant treatment
    - Keytruda will be used in combination with Welireg (belzutifan)
    - The patient has renal cell carcinoma with a clear cell component (ccRCC)
    - The patient is at intermediate-high or high risk of recurrence following a nephrectomy, or following a nephrectomy and resection of metastatic lesions

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #39.

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PEMBROLIZUMAB (PART D)

GUIDELINES FOR USE (CONTINUED)

39. Does the patient have a diagnosis of primary advanced or recurrent endometrial carcinoma (ICD-10 C54.1) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Keytruda will be used in combination with carboplatin and paclitaxel, OR as a single agent after prior use in combination with carboplatin and paclitaxel

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #40.

40. Does the patient have a diagnosis of advanced endometrial carcinoma (ICD-10 C54.1) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - The patient has experienced disease progression following prior systemic therapy
    - The patient is not a candidate for curative surgery or radiation

    If yes, continue to #41.
    If no, continue to #43.

41. Does the patient meet **ALL** of the following criteria?
    - Keytruda will be used in combination with lenvatinib (Lenvima)
    - The patient's cancer is mismatch repair proficient (pMMR) as determined by an FDA-approved test, or does NOT have microsatellite instability-high (MSI-H) biomarkers

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #42.

42. Is the patient's cancer microsatellite instability-high (MSI-H) OR mismatch repair deficient (dMMR) as determined by an FDA-approved test?

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

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GUIDELINES FOR USE (CONTINUED)

43. Does the patient have a diagnosis of unresectable or metastatic solid tumor and meet **ALL** of the following criteria?
    - The patient's tumor is tumor mutational burden-high (TMB-H) [at least 10 mutations/megabase (mut/Mb)] as determined by an FDA-approved test
    - The patient has disease progression following prior treatment and has no satisfactory alternative treatment options

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #44.

44. Does the patient have a diagnosis of recurrent or metastatic cutaneous squamous cell carcinoma (cSCC) or locally advanced cSCC (ICD-10 C44.02, C44.42, C44.82, C44.92; Groups C44.12, C44.22, C44.32, C44.52, C44.62, C44.72) **AND** meet the following criterion?
    - The disease is not curable by surgery or radiation

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #45.

45. Does the patient have a diagnosis of high-risk early-stage triple-negative breast cancer (TNBC) (ICD-10 Group C50) **AND** meet the following criterion?
    - Keytruda will be used in combination with chemotherapy (e.g., carboplatin, paclitaxel, doxorubicin) as neoadjuvant treatment, OR as a single agent as adjuvant treatment after surgery following prior use in combination with chemotherapy

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #46.

46. Does the patient have a diagnosis of unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) (ICD-10 Group C50) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Keytruda will be used in combination with Trodelvy (sacituzumab govitecan-hziy)
    - The patient's tumor expresses programmed death-ligand 1 (PD-L1) (Combined Positive Score [CPS] of at least 10), as determined by an FDA-authorized test

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #47.

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PEMBROLIZUMAB (PART D)

GUIDELINES FOR USE (CONTINUED)

47. Does the patient have a diagnosis of locally recurrent unresectable or metastatic triple-negative breast cancer (TNBC) (ICD-10 Group C50) and meet **ALL** of the following criteria?
    - Keytruda will be used in combination with chemotherapy (e.g., paclitaxel, gemcitabine, carboplatin)
    - The tumor expresses programmed death-ligand 1 (PD-L1) (Combined Positive Score [CPS] of at least 10) as determined by an FDA-approved test

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #48.

48. Does the patient have a diagnosis of epithelial ovarian, fallopian tube, or primary peritoneal carcinoma (ICD-10 Groups C56, C57.0, C48, C79.6) and meet **ALL** the following criteria?
    - The patient is 18 years of age or older
    - The patient has platinum-resistant cancer
    - Keytruda will be used in combination with paclitaxel
    - The tumor expresses programmed death-ligand 1 (PD-L1) (Combined Positive Score [CPS] of at least 1) as determined by an FDA-approved test
    - The patient has received one or more prior systemic treatment regimens

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, do not approve.

    DENIAL TEXT: Our guideline named **PEMBROLIZUMAB (Keytruda)** requires the following rule(s) be met for approval:
    A. You have ONE of the following:
        1. Unresectable or metastatic melanoma (type of skin cancer that cannot be completely removed with surgery or has spread to other parts of the body)
        2. Stage IIB, IIC, or III melanoma (type of skin cancer)
        3. Non-small cell lung cancer (type of lung cancer)
        4. Unresectable advanced or metastatic malignant pleural mesothelioma (a tumor of the tissue lining the lungs and chest wall that cannot be removed by surgery or has spread to other parts of the body)
        5. Head and neck squamous cell carcinoma (type of neck cancer)
        6. Classical Hodgkin lymphoma (type of immune system cancer)
        7. Primary mediastinal large B-cell lymphoma (type of immune system cancer)
        8. Locally advanced or metastatic urothelial carcinoma (type of urinary system cancer that has spread to other parts of the body)

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GUIDELINES FOR USE (CONTINUED)

9. Bladder cancer
10. Unresectable or metastatic solid tumor (type of cancer that cannot be removed by surgery or has spread to other parts of the body)
11. Unresectable or metastatic colorectal cancer (CRC: type of colon or rectal cancer that cannot be removed by surgery or has spread to other parts of the body)
12. Locally advanced unresectable or metastatic gastric or gastroesophageal junction (GEJ) adenocarcinoma (a type of digestive system cancer that cannot be surgically removed, has spread to nearby tissue or to other parts of the body)
13. Locally advanced or metastatic esophageal or gastroesophageal junction (GEJ) (tumors with an epicenter of 1 to 5 centimeters above the GEJ) carcinoma (a type of digestive system cancer that has spread to nearby tissue or to other parts of the body)
14. Cervical cancer
15. Hepatocellular carcinoma (liver cancer)
16. Locally advanced unresectable or metastatic biliary tract cancer (BTC) (type of bile duct cancer that cannot be removed with surgery or has spread to other parts of the body)
17. Recurrent locally advanced or metastatic Merkel cell carcinoma (MCC: type of skin cancer that has returned or has spread to other parts of the body)
18. Renal cell carcinoma (kidney cancer)
19. Endometrial carcinoma (type of cancer that starts in the uterus)
20. Recurrent or metastatic OR locally advanced cutaneous squamous cell carcinoma (cSCC: a type of skin cancer that has returned, or has spread to other parts of the body or to nearby tissue or lymph nodes)
21. High-risk early-stage triple-negative breast cancer (TNBC) (type of breast cancer that does not have three receptors)
22. Unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) (type of breast cancer that does not have three receptors and cannot be surgically removed and has spread from where it started to nearby tissue or lymph nodes or to other parts of the body)
23. Locally recurrent unresectable or metastatic triple-negative breast cancer (TNBC) (type of breast cancer that does not have three receptors and cannot be removed with surgery or has spread to other parts of the body)
24. Epithelial ovarian, fallopian tube, or primary peritoneal carcinoma (types of reproductive system or abdomen cancers)

B. If you have unresectable or metastatic melanoma, approval also requires:

1. You will NOT use Keytruda concurrently (at the same time) with a targeted therapy (BRAF inhibitors [such as Braftovi (encorafenib), Tafinlar (dabrafenib)], MEK inhibitors [such as Mekinist (trametinib)], and NTRK inhibitors [such as Vitrakvi (larotrectinib), Rozlytrek (entrectinib)])

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GUIDELINES FOR USE (CONTINUED)

C. If you have Stage IIB, IIC, or III melanoma, approval also requires:
1. You are 12 years of age or older
2. You have undergone complete resection (completely removed by surgery)
3. Keytruda will be used as adjuvant (add-on) treatment

D. If you have metastatic nonsquamous non-small cell lung cancer, approval also requires:
1. Keytruda will be used in combination with pemetrexed and platinum chemotherapy (such as cisplatin, carboplatin)
2. You do not have epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations (types of gene mutations)

E. If you have metastatic squamous non-small cell lung cancer, approval also requires:
1. Keytruda will be used in combination with carboplatin and either paclitaxel or paclitaxel protein-bound

F. If you have non-small cell lung cancer, approval also requires:
1. Your tumor has programmed death-ligand 1 (PD-L1: a type of protein) [Tumor Proportion Score (TPS) of at least 1%] as determined by a Food and Drug Administration (FDA)-approved test
2. You do not have epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations (types of gene mutations)
3. You meet ONE of the following:
   a. You have stage III non-small cell lung cancer AND you are not a candidate for surgical resection (removal) or definitive chemoradiation (a type of treatment)
   b. You have metastatic non-small cell lung cancer (cancer that has spread to other parts of the body)

G. If you have metastatic non-small cell lung cancer, approval also requires:
1. Your tumor has programmed death-ligand 1 (PD-L1: a type of protein) [Tumor Proportion Score (TPS) of at least 1%] as determined by a Food and Drug Administration (FDA)-approved test
2. You experienced disease progression (worsening) on or after treatment with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
3. You meet ONE of the following:
   a. You do not have epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations (types of gene mutations)
   b. You have an anaplastic lymphoma kinase (ALK) genomic tumor aberration (type of gene mutation) AND experienced disease progression (worsening) on or after ALK-directed therapy (such as Xalkori [crizotinib], Zykadia [ceritinib])
   c. You have an epidermal growth factor receptor (EGFR) genomic tumor aberration (type of gene mutation) AND experienced disease progression (worsening) on or after EGFR-directed therapy (such as Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib])

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PEMBROLIZUMAB (PART D)

GUIDELINES FOR USE (CONTINUED)

H. If you have resectable (node positive or tumor is at least 4 cm) non-small cell lung cancer, approval also requires:
1. Keytruda will be used in combination with platinum-containing chemotherapy (such as cisplatin) as neoadjuvant treatment (given before main treatment), OR as a single agent (not given in combination with chemotherapy) as adjuvant (add-on) treatment after surgery following prior use in combination with platinum-containing chemotherapy

I. If you have Stage IB (T2a is at least 4 cm), II, or IIIA non-small cell lung cancer, approval also requires:
1. You are 18 years of age or older
2. Keytruda will be used as adjuvant (add-on) treatment following resection (removed by surgery) and platinum-based chemotherapy (such as cisplatin, carboplatin)

J. If you have unresectable advanced or metastatic malignant pleural mesothelioma, approval also requires:
1. You are 18 years of age or older
2. Keytruda will be given in combination with pemetrexed and platinum chemotherapy (such as cisplatin, carboplatin)

K. If you have head and neck squamous cell carcinoma, approval also requires ONE of the following:
1. Your cancer is resectable (able to be removed by surgery) and locally advanced (cancer that has spread from where it started to nearby tissue or lymph nodes), and you meet ALL of the following:
   a. You are 18 years of age or older
   b. Your tumor expresses programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 1) as determined by a Food and Drug Administration (FDA)-approved test
   c. Keytruda will be used as single-agent neoadjuvant treatment (given before main treatment) and then continued as adjuvant (add-on) treatment in combination with radiotherapy (RT: a type of cancer treatment), OR Keytruda will be used as a single agent following its prior use both as single-agent neoadjuvant treatment and as adjuvant treatment in combination with RT
2. Your cancer is either metastatic (has spread to other parts of the body) or both unresectable (unable to remove by surgery) and recurrent (has returned), and you meet ONE of the following:
   a. Keytruda will be given in combination with platinum and fluorouracil (FU)
   b. Your tumor expresses programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 1) as determined by a Food and Drug Administration (FDA)-approved test
3. Your cancer is recurrent (has returned) or metastatic (has spread to other parts of the body); AND you experienced disease progression (worsening) on or after treatment with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)

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PEMBROLIZUMAB (PART D)

GUIDELINES FOR USE (CONTINUED)

L. If you have classical Hodgkin lymphoma, approval also requires ONE of the following:
1. You are 18 years of age or older AND have relapsed (disease has returned) or refractory (disease is resistant to treatment) classical Hodgkin lymphoma
2. You have refractory (disease is resistant to treatment) classical Hodgkin lymphoma or classical Hodgkin lymphoma that has relapsed (disease has returned) after 2 or more prior lines of therapy

M. If you have primary mediastinal large B-cell lymphoma, approval also requires ONE of the following:
1. You have refractory primary mediastinal large B-cell lymphoma (type of immune system cancer that is resistant to treatment)
2. You have relapsed (disease has returned) after 2 or more prior lines of therapy

N. If you have locally advanced or metastatic urothelial carcinoma, approval also requires ONE of the following:
1. Keytruda will be used in combination with enfortumab vedotin (Padcev), AND you are at least 18 years of age
2. You are not eligible for any platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
3. You have disease progression (worsening) on or after treatment with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
   You have disease progression (worsening) within 12 months of neoadjuvant (given before main treatment) or adjuvant (add-on) treatment with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)

O. If you have bladder cancer, approval also requires ONE of the following:
1. You have muscle invasive bladder cancer (MIBC: bladder cancer that has grown into the muscle wall); AND you are 18 years of age or older; AND Keytruda will be used in combination with enfortumab vedotin (Padcev) as neoadjuvant treatment (given before main treatment), and then continued as adjuvant (add-on) treatment after a cystectomy (surgery to remove part or all of the urinary bladder)
2. You have Bacillus Calmette-Guerin (BCG: a type of anti-cancer treatment)-unresponsive, high-risk, non-muscle invasive bladder cancer with carcinoma in situ (a type of early-stage bladder cancer); AND you are not eligible for or have chosen not to undergo a cystectomy (surgery to remove part or all of the urinary bladder)

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GUIDELINES FOR USE (CONTINUED)

P. If you have an unresectable or metastatic solid tumor, approval also requires:
1. You meet ONE of the following:
   a. Your tumor is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) (types of genetic abnormalities), as determined by a Food and Drug Administration (FDA)-approved test
   b. Your tumor is tumor mutational burden-high (TMB-H: high number of changes found in the genes of the cancer cells) [at least 10 mutations/megabase], as determined by a Food and Drug Administration (FDA)-approved test
2. Your disease has progressed (worsened) following prior treatment, and you have no alternative treatment options

Q. If you have unresectable or metastatic colorectal cancer, approval also requires:
1. Your cancer is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) (types of genetic abnormalities), as determined by a Food and Drug Administration (FDA)-approved test

R. If you have locally advanced unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:
1. You are 18 years of age or older
2. Your tumor expresses programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 1) as determined by a Food and Drug Administration (FDA)-approved test
3. You meet ONE of the following:
   a. Your cancer is human epidermal growth factor receptor 2 (HER2: type of protein that promotes cancer cells)-POSITIVE, and Keytruda will be used in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy
   b. Your cancer is human epidermal growth factor receptor 2 (HER2: type of protein that promotes cancer cells)-NEGATIVE, and Keytruda will be used in combination with fluoropyrimidine- and platinum-containing chemotherapy

S. If you have locally advanced or metastatic esophageal or gastroesophageal junction carcinoma, approval also requires:
1. Your tumor is not amenable (responsive) to surgical resection (removal) or definitive chemoradiation (a type of treatment)
2. You meet ONE of the following:
   a. Keytruda will be used in combination with platinum- and fluoropyrimidine-based chemotherapy; AND your tumor expresses programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 1)
   b. Keytruda will be used after one or more prior lines of systemic therapy AND you have a tumor of squamous cell histology (cancer from flat surface-lining cells) that expresses programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 10) as determined by a Food and Drug Administration (FDA)-approved test

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PEMBROLIZUMAB (PART D)

GUIDELINES FOR USE (CONTINUED)

T. If you have cervical cancer, approval also requires ONE of the following:
1. You have locally advanced cancer, your cancer is FIGO 2014 Stage III-IVA (a way to classify the size and spread of the cancer) and involves the lower third of the vagina, hydronephrosis (swelling of kidney)/a non-functioning kidney, or has spread to adjacent (nearby) pelvic organs; AND Keytruda will be used in combination with chemoradiotherapy (CRT: a type of therapy to treat cancer)
2. You have persistent, recurrent, or metastatic cancer (cancer that does not go away, has returned, or has spread to other parts of the body); AND Keytruda will be used in combination with chemotherapy (such as paclitaxel, cisplatin, carboplatin); AND your tumor expresses programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 1) as determined by a Food and Drug Administration (FDA)-approved test
3. You have recurrent or metastatic cancer; AND you have experienced disease progression (worsening) on or after chemotherapy; AND your tumor has programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 1) as determined by a Food and Drug Administration (FDA)-approved test

U. If you have hepatocellular carcinoma, approval also requires:
1. Your cancer is caused by hepatitis B (a type of liver infection)
2. You have received prior systemic therapy (such as Nexavar [sorafenib], oxaliplatin) other than a PD-1/PD-L1-containing regimen (such as Opdivo [nivolumab])

V. If you have locally advanced unresectable or metastatic biliary tract cancer, approval also requires:
Keytruda will be used in combination with gemcitabine and cisplatin

W. If you have renal cell carcinoma, approval also requires ONE of the following:
1. You have advanced renal cell carcinoma; you are 18 years of age or older; AND Keytruda will be used in combination with Inlyta (axitinib) OR Lenvima (lenvatinib)
2. Keytruda will be used as adjuvant (add-on) treatment; AND your cancer is at intermediate-high or high risk of recurrence (returning) following a nephrectomy (surgical removal of the kidney), or following a nephrectomy and resection (surgical removal) of metastatic lesions (abnormal area of tissue)
3. You are 18 years of age or older; AND Keytruda will be used in combination with Welireg (belzutifan), Keytruda will be used as adjuvant (add-on) treatment; AND you have renal cell carcinoma with a clear cell component (ccRCC: a type of kidney cancer), AND your cancer is at intermediate-high or high risk of recurrence (returning) following a nephrectomy (surgical removal of the kidney), or following a nephrectomy and resection (surgical removal) of metastatic lesions (abnormal area of tissue)

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PEMBROLIZUMAB (PART D)

GUIDELINES FOR USE (CONTINUED)

X. If you have primary advanced or recurrent endometrial carcinoma, approval also requires:
1. You are 18 years of age or older
2. Keytruda will be used in combination with carboplatin and paclitaxel, OR as a single agent after previous use in combination with carboplatin and paclitaxel

Y. If you have advanced endometrial carcinoma, approval also requires:
1. You are 18 years of age or older
2. You have experienced disease progression (worsening) following prior systemic therapy (treatment that affects the entire body)
3. You are not a candidate for curative surgery or radiation
4. You meet ONE of the following:
   a. You will use Keytruda in combination with lenvatinib (Lenvima), AND your cancer is mismatch repair proficient (pMMR) as determined by a Food and Drug Administration (FDA)-approved test or you do NOT have microsatellite instability-high (MSI-H) biomarkers (characteristics that help determine the type of cancer and what treatment options there are for it)
   b. Your cancer is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) (types of genetic abnormalities), as determined by a Food and Drug Administration (FDA)-approved test

Z. If you have recurrent or metastatic OR locally advanced cutaneous squamous cell carcinoma, approval also requires:
1. Your disease is not curable by surgery or radiation

AA. **If you have high-risk early-stage triple-negative breast cancer, approval also requires:**
1. Keytruda will be used in combination with chemotherapy (such as carboplatin, paclitaxel, doxorubicin) as neoadjuvant treatment (given before main treatment), OR as a single agent as adjuvant (add-on) treatment after surgery following prior use in combination with chemotherapy

BB. **If you have unresectable locally advanced or metastatic triple-negative breast cancer, approval also requires:**
1. You are 18 years of age or older
2. Keytruda will be used in combination with Trodelvy (sacituzumab govitecan-hziy)
3. The tumor has programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 10) as determined by a Food and Drug Administration (FDA)-authorized test

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PEMBROLIZUMAB (PART D)

GUIDELINES FOR USE (CONTINUED)

CC. **If you have locally recurrent unresectable or metastatic triple-negative breast cancer, approval also requires:**
1. Keytruda will be used in combination with chemotherapy (such as paclitaxel, gemcitabine, carboplatin)
2. The tumor has programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 10) as determined by a Food and Drug Administration (FDA)-approved test

DD. **If you have epithelial ovarian, fallopian tube, or primary peritoneal carcinoma, approval also requires:**
1. You are 18 years of age or older
2. You have platinum-resistant cancer (cancer that no longer responds to a type of treatment)
3. Keytruda will be used in combination with paclitaxel
4. The tumor has programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 1) as determined by a Food and Drug Administration (FDA)-approved test
5. You have received one or more prior systemic treatment regimens (treatment that affects the entire body)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Keytruda.

REFERENCES
Keytruda [Prescribing Information]. Rahway, NJ: Merck Sharp & Dohme LLC; July 2026.

For Part D use only:

PEMBROLIZUMAB (PART D)	
Covered uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	UNRESECTABLE OR METASTATIC MELANOMA: NO CONCURRENT USE WITH TARGETED THERAPY (I.E., BRAF INHIBITORS, MEK INHIBITORS, AND NTRK INHIBITORS).

Created: 09/14
Effective: 07/29/26 Client Approval: 07/26 DMC Approval: 07/26

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STANDARD PART D
PRIOR AUTHORIZATION GUIDELINES

PEMBROLIZUMAB-BERAHYALURONIDASE ALFA-PMPH BVD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEMBROLIZUM-BERAHYALURON-PMPH	KEYTRUDA QLEX	50902		GPI-10 (2199000253)	

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit).**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #5.

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PEMBROLIZUMAB-BERAHYALURONIDASE ALFA-PMPH BVD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

If yes, **Refer to plan. (The health plan makes the final payment determination decision)**

- **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enterany override).**
- **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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PEMBROLIZUMAB-BERAHYALURONIDASE ALFA-PMPH BVD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic melanoma (ICD-10 Group C43) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of Stage IIB, IIC, or III melanoma (ICD-10 Group C43) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient has undergone complete resection
   - Keytruda Qlex will be used as adjuvant treatment

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

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PEMBROLIZUMAB-BERAHYALURONIDASE ALFA-PMPH BVD (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of metastatic nonsquamous non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Keytruda Qlex will be used in combination with pemetrexed and platinum chemotherapy (e.g., cisplatin, carboplatin)
   - The patient does NOT have epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #4.

4. Does the patient have a diagnosis of metastatic squamous non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Keytruda Qlex will be used in combination with carboplatin and either paclitaxel or paclitaxel protein-bound

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #5.

5. Does the patient have a diagnosis of non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's tumor expresses programmed death-ligand 1 (PD-L1) [Tumor Proportion Score (TPS) of at least 1%] as determined by an FDA-approved test
   - The patient does NOT have epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations

   If yes, continue to #6.
   If no, continue to #7.

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PEMBROLIZUMAB-BERAHYALURONIDASE ALFA-PMPH BVD (PART D)

GUIDELINES FOR USE (CONTINUED)

6. Does the patient meet **ONE** of the following criteria?
   - The patient has stage III NSCLC AND is not a candidate for surgical resection or definitive chemoradiation
   - The patient has metastatic NSCLC

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

7. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's tumor expresses programmed death-ligand 1 (PD-L1) [Tumor Proportion Score (TPS) of at least 1%] as determined by an FDA-approved test
   - The patient has disease progression on or after treatment with platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

   If yes, continue to #8.
   If no, continue to #9.

8. Does the patient meet **ONE** of the following criteria?
   - The patient does NOT have epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations
   - The patient has an anaplastic lymphoma kinase (ALK) genomic tumor aberration AND disease progression on or after ALK-directed therapy (e.g., Xalkori [crizotinib], Zykadia [ceritinib])
   - The patient has an epidermal growth factor receptor (EGFR) genomic tumor aberration AND disease progression on or after EGFR-directed therapy (e.g., Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib])

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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PEMBROLIZUMAB-BERAHYALURONIDASE ALFA-PMPH BVD (PART D)

GUIDELINES FOR USE (CONTINUED)

9. Does the patient have resectable (node positive or tumor is at least 4 cm) non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Keytruda Qlex will be used in combination with platinum-containing chemotherapy (e.g., cisplatin) as neoadjuvant treatment, OR as a single agent as adjuvant treatment after surgery following prior use in combination with platinum-containing chemotherapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #10.

10. Does the patient have a diagnosis of Stage IB (T2a is at least 4 cm), II, or IIIA non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Keytruda Qlex will be used as adjuvant treatment following resection and platinum-based chemotherapy (e.g., cisplatin, carboplatin)

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #11.

11. Does the patient have a diagnosis of unresectable advanced or metastaticmalignant pleural mesothelioma (MPM) (ICD-10 C45.0) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Keytruda Qlex will be used in combination with pemetrexed and platinum chemotherapy (e.g., cisplatin, carboplatin)

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #12.

12. Does the patient have a diagnosis of head and neck squamous cell carcinoma (HNSCC) (ICD-10 Groups C44.42, C76.0, C00, C06, C09, C10, C32) **AND** meet the following criterion?
    - The patient is 18 years of age or older

    If yes, continue to #13.
    If no, continue to #17.

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PEMBROLIZUMAB-BERAHYALURONIDASE ALFA-PMPH BVD (PART D)

GUIDELINES FOR USE (CONTINUED)

13. Is the cancer resectable and locally advanced **AND** the patient meets the following criterion?
    - The patient's tumor expresses programmed death-ligand 1 (PD-L1) [Combined Positive Score (CPS) of at least 1] as determined by an FDA-approved test

    If yes, continue to #14.
    If no, continue to #15.

14. Does the patient meet **ONE** of the following criteria?
    - Keytruda Qlex will be used as single-agent neoadjuvant treatment, and then continued as adjuvant treatment in combination with radiotherapy (RT)
    - Keytruda Qlex will be used as a single agent following its prior use both as single-agent neoadjuvant treatment and as adjuvant treatment in combination with RT

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

15. Is the cancer either metastatic or both unresectable and recurrent, and the patient meets **ONE** of the following criteria?
    - Keytruda Qlex will be used in combination with platinum and fluorouracil (FU)
    - The patient's tumor expresses programmed death-ligand 1 (PD-L1) [Combined Positive Score (CPS) of at least 1] as determined by an FDA-approved test

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #16.

16. Is the cancer recurrent or metastatic **AND** the patient meets the following criterion?
    - The patient has disease progression on or after treatment with platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

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PEMBROLIZUMAB-BERAHYALURONIDASE ALFA-PMPH BVD (PART D)

GUIDELINES FOR USE (CONTINUED)

17. Does the patient have a diagnosis of locally advanced or metastatic urothelial carcinoma (ICD-10 Groups C66, C67, C68) **AND** meet the following criterion?
    - The patient is 18 years of age or older

    If yes, continue to #18.
    If no, continue to #19.

18. Does the patient meet **ONE** of the following criteria?
    - Keytruda Qlex will be used in combination with enfortumab vedotin (Padcev)
    - The patient is not eligible for any platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
    - The patient has disease progression on or after treatment with a platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
    - The patient has disease progression within 12 months of neoadjuvant or adjuvant treatment with a platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

19. Does the patient have a diagnosis of bladder cancer (ICD-10 Group C67, D09.0) **AND** meet the following criterion?
    - The patient is 18 years of age or older

    If yes, continue to #20.
    If no, continue to #22.

20. Is the cancer muscle invasive (MIBC) **AND** the patient meets the following criterion?
    - Keytruda Qlex will be used in combination with enfortumab vedotin (Padcev) as neoadjuvant treatment, and then continued as adjuvant treatment after a cystectomy

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #21.

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PEMBROLIZUMAB-BERAHYALURONIDASE ALFA-PMPH BVD (PART D)

GUIDELINES FOR USE (CONTINUED)

21. Is the cancer non-muscle invasive (NMIBC) and the patient meets **ALL** of the following criteria?
    - The patient has Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk cancer with carcinoma in situ (CIS)
    - The patient is ineligible for or has elected not to undergo a cystectomy

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

22. Does the patient have a diagnosis of an unresectable or metastatic solid tumor and meet **ALL** of the following criteria?
    - The patient is 12 years of age or older
    - The patient's tumor is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) as determined by an FDA-approved test
    - The patient has disease progression following prior treatment and has no satisfactory alternative treatment options

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #23.

23. Does the patient have a diagnosis of unresectable or metastatic colorectal cancer (CRC) (ICD-10 C19) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - The patient's cancer is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) as determined by an FDA-approved test

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #24.

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PEMBROLIZUMAB-BERAHYALURONIDASE ALFA-PMPH BVD (PART D)

GUIDELINES FOR USE (CONTINUED)

24. Does the patient have a diagnosis of locally advanced unresectable or metastatic gastric or gastroesophageal junction (GEJ) adenocarcinoma (ICD-10 Group C16) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - The patient's tumor expresses programmed death-ligand 1 (PD-L1) (Combined Positive Score [CPS] of at least 1) as determined by an FDA-approved test

    If yes, continue to #25.
    If no, continue to #26.

25. Does the patient meet **ONE** of the following criteria?
    - The cancer is HER2-positive, AND Keytruda Qlex will be used in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy
    - The cancer is HER2-negative, AND Keytruda Qlex will be used in combination with fluoropyrimidine- and platinum-containing chemotherapy

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

26. Does the patient have a diagnosis of locally advanced or metastatic esophageal or gastroesophageal junction (GEJ) (tumors with epicenter 1 to 5 centimeters above the GEJ) carcinoma (ICD-10 C16.0; Group C15) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - The tumor is not amenable to surgical resection or definitive chemoradiation

    If yes, continue to #27.
    If no, continue to #28.

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PEMBROLIZUMAB-BERAHYALURONIDASE ALFA-PMPH BVD (PART D)

GUIDELINES FOR USE (CONTINUED)

27. Does the patient meet **ONE** of the following criteria?
    - Keytruda Qlex will be used in combination with platinum- and fluoropyrimidine-based chemotherapy AND the patient's tumor expresses programmed death-ligand 1 (PD-L1) (Combined Positive Score [CPS] of at least 1) as determined by an FDA-authorized test
    - Keytruda Qlex will be used after one or more prior lines of systemic therapy AND the patient has a tumor of squamous cell histology that expresses programmed death-ligand 1 (PD-L1) (Combined Positive Score [CPS] of at least 10) as determined by an FDA-authorized test

    If yes, **approve for 12 months by HICL or GPI-10.**

    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

28. Does the patient have a diagnosis of cervical cancer (ICD-10 Group C53) **AND** meet the following criterion?
    - The patient is 18 years of age or older

    If yes, continue to #29.
    If no, continue to #32.

29. Is the cancer locally advanced and the patient meets **ALL** of the following criteria?
    - Keytruda Qlex will be used in combination with chemoradiotherapy (CRT)
    - The cancer involves the lower third of the vagina, hydronephrosis/a non-functioning kidney, or has spread to adjacent pelvic organs (FIGO 2014 Stage III-IVA)

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #30.

30. Is the cancer persistent, recurrent, or metastatic and the patient meets **ALL** of the following criteria?
    - Keytruda Qlex will be used in combination with chemotherapy (e.g., paclitaxel, cisplatin, carboplatin)
    - The patient's tumor expresses programmed death-ligand 1 (PD-L1) [Combined Positive Score (CPS) of at least 1] as determined by an FDA-approved test

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #31.

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PEMBROLIZUMAB-BERAHYALURONIDASE ALFA-PMPH BVD (PART D)

GUIDELINES FOR USE (CONTINUED)

31. Is the cancer recurrent or metastatic and the patient meets **ALL** of the following criteria?
    - The patient has disease progression on or after chemotherapy
    - The patient's tumor expresses programmed death-ligand 1 (PD-L1) [Combined Positive Score (CPS) of at least 1] as determined by an FDA-approved test

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

32. Does the patient have a diagnosis of hepatocellular carcinoma (HCC) (ICD-10 C22.0) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - The patient's cancer is secondary to hepatitis B
    - The patient has received prior systemic therapy (e.g., Nexavar [sorafenib], oxaliplatin) other than a PD-1/PD-L1-containing regimen (e.g., Opdivo [nivolumab])

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #33.

33. Does the patient have a diagnosis of locally advanced unresectable or metastatic biliary tract cancer (BTC) (ICD-10 Group C24) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Keytruda Qlex will be used in combination with gemcitabine and cisplatin

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #34.

34. Does the patient have a diagnosis of recurrent locally advanced or metastatic Merkel cell carcinoma (MCC) (ICD-10 Group C4A, C7B.1) **AND** meet the following criterion?
    - The patient is 12 years of age or older

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #35.

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PEMBROLIZUMAB-BERAHYALURONIDASE ALFA-PMPH BVD (PART D)

GUIDELINES FOR USE (CONTINUED)

35. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC) (ICD-10 Groups C64, C65) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Keytruda Qlex will be used in combination with Inlyta (axitinib) OR Lenvima (lenvatinib)

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #36.

36. Does the patient have a diagnosis of renal cell carcinoma (RCC) (ICD-10 Groups C64, C65) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Keytruda Qlex will be used for adjuvant treatment
    - The patient is at intermediate-high or high risk of recurrence following a nephrectomy, or following a nephrectomy and resection of metastatic lesions

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #37.

37. Does the patient have a diagnosis of renal cell carcinoma (RCC) (ICD-10 Groups C64, C65) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Keytruda Qlex will be used for adjuvant treatment
    - Keytruda Qlex will be used in combination with Welireg (belzutifan)
    - The patient has renal cell carcinoma with a clear cell component (ccRCC)
    - The patient is at intermediate-high or high risk of recurrence following a nephrectomy, or following a nephrectomy and resection of metastatic lesions

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #38.

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PEMBROLIZUMAB-BERAHYALURONIDASE ALFA-PMPH BVD (PART D)

GUIDELINES FOR USE (CONTINUED)

38. Does the patient have a diagnosis of primary advanced or recurrent endometrial carcinoma (ICD-10 C54.1) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Keytruda Qlex will be used in combination with carboplatin and paclitaxel, OR as a single agent after prior use in combination with carboplatin and paclitaxel

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #39.

39. Does the patient have a diagnosis of advanced endometrial carcinoma (ICD-10 C54.1) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - The patient has experienced disease progression following prior systemic therapy
    - The patient is not a candidate for curative surgery or radiation

    If yes, continue to #40.
    If no, continue to #42.

40. Does the patient meet **ALL** of the following criteria?
    - Keytruda Qlex will be used in combination with lenvatinib (Lenvima)
    - The patient's cancer is mismatch repair proficient (pMMR) OR not microsatellite instability-high (MSI-H) as determined by an FDA-approved test

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #41.

41. Is the patient's cancer microsatellite instability-high (MSI-H) OR mismatch repair deficient (dMMR) as determined by an FDA-approved test?

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

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PEMBROLIZUMAB-BERAHYALURONIDASE ALFA-PMPH BVD (PART D)

GUIDELINES FOR USE (CONTINUED)

42. Does the patient have a diagnosis of unresectable or metastatic solid tumor and meet **ALL** of the following criteria?
    - The patient is 12 years of age or older
    - The patient's tumor is tumor mutational burden-high (TMB-H) [at least 10 mutations/megabase (mut/Mb)] as determined by an FDA-approved test
    - The patient has disease progression following prior treatment and has no satisfactory alternative treatment options

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #43.

43. Does the patient have a diagnosis of recurrent or metastatic cutaneous squamous cell carcinoma (cSCC) or locally advanced cSCC (ICD-10 C44.02, C44.42, C44.82, C44.92; Groups C44.12, C44.22, C44.32, C44.52, C44.62, C44.72) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - The disease is not curable by surgery or radiation

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #44.

44. Does the patient have a diagnosis of high-risk early-stage triple-negative breast cancer (TNBC) (ICD-10 Group C50) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Keytruda Qlex will be used in combination with chemotherapy (e.g., carboplatin, paclitaxel, doxorubicin) as neoadjuvant treatment, OR as a single agent as adjuvant treatment after surgery following prior use in combination with chemotherapy

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #45.

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PEMBROLIZUMAB-BERAHYALURONIDASE ALFA-PMPH BVD (PART D)

GUIDELINES FOR USE (CONTINUED)

45. Does the patient have a diagnosis of unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) (ICD-10 Group C50) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Keytruda Qlex will be used in combination with Trodelvy (sacituzumab govitecan-hziy)
    - The patient's tumor expresses programmed death-ligand 1 (PD-L1) (Combined Positive Score [CPS] of at least 10), as determined by an FDA-authorized test

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #46.

46. Does the patient have a diagnosis of locally recurrent unresectable or metastatic triple-negative breast cancer (TNBC) (ICD-10 Group C50) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Keytruda Qlex will be used in combination with chemotherapy (e.g., paclitaxel, gemcitabine, carboplatin)
    - The tumor expresses programmed death-ligand 1 (PD-L1) (Combined Positive Score [CPS] of at least 10) as determined by an FDA-approved test

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #47.

47. Does the patient have a diagnosis of epithelial ovarian, fallopian tube, or primary peritoneal carcinoma (ICD-10 Groups C56, C57.0, C48, C79.6) and meet **ALL** the following criteria?
    - The patient is 18 years of age or older
    - The patient has platinum-resistant cancer
    - Keytruda Qlex will be used in combination with paclitaxel
    - The tumor expresses programmed death-ligand 1 (PD-L1) (Combined Positive Score [CPS] of at least 1) as determined by an FDA-approved test
    - The patient has received one or more prior systemic treatment regimens

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, do not approve.
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PEMBROLIZUMAB-BERAHYALURONIDASE ALFA-PMPH BVD (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: Our guideline named **PEMBROLIZUMAB-BERAHYALURONIDASE ALFA-PMPH (Keytruda Qlex)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Unresectable or metastatic melanoma (type of skin cancer that cannot be completely removed with surgery or has spread to other parts of the body)
   2. Stage IIB, IIC, or III melanoma (type of skin cancer)
   3. Non-small cell lung cancer (type of lung cancer)
   4. Unresectable advanced or metastatic malignant pleural mesothelioma (a tumor of the tissue lining the lungs and chest wall that cannot be removed by surgery or has spread to other parts of the body)
   5. Head and neck squamous cell carcinoma (type of neck cancer)
   6. Locally advanced or metastatic urothelial carcinoma (type of urinary system cancer that has spread to other parts of the body)
   7. Bladder cancer
   8. Unresectable or metastatic solid tumor (type of cancer that cannot be removed by surgery or has spread to other parts of the body)
   9. Unresectable or metastatic colorectal cancer (CRC: type of colon or rectal cancer that cannot be removed by surgery or has spread to other parts of the body)
   10. Locally advanced unresectable or metastatic gastric or gastroesophageal junction (GEJ) adenocarcinoma (a type of digestive system cancer that cannot be surgically removed, has spread to nearby tissue or has spread to other parts of the body)
   11. Locally advanced or metastatic esophageal or gastroesophageal junction (GEJ) (tumors with an epicenter of 1 to 5 centimeters above the GEJ) carcinoma (a type of digestive system cancer that has spread to nearby tissue or to other parts of the body)
   12. Cervical cancer
   13. Hepatocellular carcinoma (liver cancer)
   14. Locally advanced unresectable or metastatic biliary tract cancer (BTC) (type of bile duct cancer that cannot be removed with surgery or has spread to other parts of the body)
   15. Recurrent locally advanced or metastatic Merkel cell carcinoma (MCC: type of skin cancer that has returned or has spread to other parts of the body)
   16. Renal cell carcinoma (kidney cancer)
   17. Endometrial carcinoma (type of cancer that starts in the uterus)
   18. Recurrent or metastatic OR locally advanced cutaneous squamous cell carcinoma (cSCC: a type of skin cancer that has returned, or has spread to other parts of the body or to nearby tissue or lymph nodes)

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PEMBROLIZUMAB-BERAHYALURONIDASE ALFA-PMPH BVD (PART D)

GUIDELINES FOR USE (CONTINUED)

19. High-risk early-stage triple-negative breast cancer (TNBC) (type of breast cancer that does not have three receptors)
20. Unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) (type of breast cancer that does not have three receptors and cannot be surgically removed and has spread from where it started to nearby tissue or lymph nodes or to other parts of the body)
21. Locally recurrent unresectable or metastatic triple-negative breast cancer (TNBC) (type of breast cancer that does not have three receptors and cannot be removed with surgery or has spread to other parts of the body)
22. Epithelial ovarian, fallopian tube, or primary peritoneal carcinoma (types of reproductive system or abdomen cancers)

B. If you have unresectable or metastatic melanoma, approval also requires:
1. You are 18 years of age or older

C. If you have Stage IIB, IIC, or III melanoma, approval also requires:
1. You are 12 years of age or older
2. You have undergone complete resection (completely removed by surgery)
3. Keytruda Qlex will be used as adjuvant (add-on) treatment

D. If you have metastatic nonsquamous non-small cell lung cancer, approval also requires:
1. You are 18 years of age or older
2. Keytruda Qlex will be used in combination with pemetrexed and platinum chemotherapy (such as cisplatin, carboplatin)
3. You do not have epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations (types of gene mutations)

E. If you have metastatic squamous non-small cell lung cancer, approval also requires:
1. You are 18 years of age or older
2. Keytruda Qlex will be used in combination with carboplatin and either paclitaxel or paclitaxel protein-bound

F. If you have non-small cell lung cancer, approval also requires:
1. You are 18 years of age or older
2. Your tumor has programmed death-ligand 1 (PD-L1: a type of protein) [Tumor Proportion Score (TPS) of at least 1%] as determined by a Food and Drug Administration (FDA)-approved test
3. You do not have epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations (types of gene mutations)
4. You meet ONE of the following:
   a. You have stage III non-small cell lung cancer AND you are not a candidate for surgical resection (removal) or definitive chemoradiation (a type of treatment)
   b. You have metastatic non-small cell lung cancer (cancer that has spread to other parts of the body)

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PEMBROLIZUMAB-BERAHYALURONIDASE ALFA-PMPH BVD (PART D)

GUIDELINES FOR USE (CONTINUED)

G. If you have metastatic non-small cell lung cancer, approval also requires:
1. You are 18 years of age or older
2. Your tumor has programmed death-ligand 1 (PD-L1: a type of protein) [Tumor Proportion Score (TPS) of at least 1%] as determined by a Food and Drug Administration (FDA)-approved test
3. You experienced disease progression (worsening) on or after treatment with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
4. You meet ONE of the following:
   a. You do not have epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations (types of gene mutations)
   b. You have an anaplastic lymphoma kinase (ALK) genomic tumor aberration (type of gene mutation) AND experienced disease progression (worsening) on or after ALK-directed therapy (such as Xalkori [crizotinib], Zykadia [ceritinib])
   c. You have an epidermal growth factor receptor (EGFR) genomic tumor aberration (type of gene mutation) AND experienced disease progression (worsening) on or after EGFR-directed therapy (such as Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib])

H. If you have resectable (node positive or tumor is at least 4 cm) non-small cell lung cancer, approval also requires:
1. You are 18 years of age or older
2. Keytruda Qlex will be used in combination with platinum-containing chemotherapy (such as cisplatin) as neoadjuvant treatment (given before main treatment), OR as a single agent (not given in combination with chemotherapy) as adjuvant (add-on) treatment after surgery following prior use in combination with platinum-containing chemotherapy

I. If you have Stage IB (T2a is at least 4 cm), II, or IIIA non-small cell lung cancer, approval also requires:
1. You are 18 years of age or older
2. Keytruda Qlex will be used as adjuvant (add-on) treatment following resection (removed by surgery) and platinum-based chemotherapy (such as cisplatin, carboplatin)

J. If you have unresectable advanced or metastatic malignant pleural mesothelioma, approval also requires:
1. You are 18 years of age or older
2. Keytruda Qlex will be given in combination with pemetrexed and platinum chemotherapy (such as cisplatin, carboplatin)

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PEMBROLIZUMAB-BERAHYALURONIDASE ALFA-PMPH BVD (PART D)

GUIDELINES FOR USE (CONTINUED)

K. If you have head and neck squamous cell carcinoma, approval also requires:
1. You are 18 years of age or older
2. You meet ONE of the following:
   a. Your cancer is resectable (able to be removed by surgery) and locally advanced (cancer that has spread from where it started to nearby tissue or lymph nodes) and you meet ALL of the following:
      i. Your tumor expresses programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 1) as determined by a Food and Drug Administration (FDA)-approved test
      ii. Keytruda Qlex will be used as single-agent neoadjuvant treatment (given before main treatment) and then continued as adjuvant (add-on) treatment in combination with radiotherapy (RT: a type of cancer treatment), OR Keytruda will be used as a single agent following its prior use both as single-agent neoadjuvant treatment and as adjuvant treatment in combination with RT
   b. Your cancer is either metastatic (has spread to other parts of the body) or both unresectable (unable to remove by surgery) and recurrent (has returned), and you meet ONE of the following:
      i. Keytruda Qlex will be used in combination with platinum and fluorouracil (FU)
      ii. Your tumor expresses programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 1) as determined by a Food and Drug Administration (FDA)-approved test
   c. Your cancer is recurrent (has returned) or metastatic (has spread to other parts of the body); AND you experienced disease progression (worsening) on or after treatment with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)

L. If you have locally advanced or metastatic urothelial carcinoma, approval also requires:
1. You are 18 years of age or older
2. You meet ONE of the following:
   a. Keytruda Qlex will be used in combination with enfortumab vedotin (Padcev)
   b. You are not eligible for any platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
   c. You have disease progression (worsening) on or after treatment with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
   d. You have disease progression (worsening) within 12 months of neoadjuvant (given before main treatment) or adjuvant (add-on) treatment with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)

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PEMBROLIZUMAB-BERAHYALURONIDASE ALFA-PMPH BVD (PART D)

GUIDELINES FOR USE (CONTINUED)

M. If you have bladder cancer, approval also requires:
1. You are 18 years of age or older
2. You meet ONE of the following:
   a. You have muscle invasive bladder cancer (MIBC: bladder cancer that has grown into the muscle wall); AND Keytruda Qlex will be used in combination with enfortumab vedotin (Padcev) as neoadjuvant treatment (given before main treatment), and then continued as adjuvant (add-on) treatment after a cystectomy (surgery to remove part or all of the urinary bladder)
   b. You have Bacillus Calmette-Guerin (BCG: a type of anti-cancer treatment)-unresponsive, high-risk, non-muscle invasive bladder cancer with carcinoma in situ (a type of early-stage bladder cancer); AND you are not eligible for or have chosen not to undergo a cystectomy (surgery to remove part or all of the urinary bladder)

N. If you have an unresectable or metastatic solid tumor, approval also requires:
1. You are 12 years of age or older
2. You meet ONE of the following:
   a. Your tumor is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) (types of genetic abnormalities), as determined by a Food and Drug Administration (FDA)-approved test
   b. Your tumor is tumor mutational burden-high (TMB-H: high number of changes found in the genes of the cancer cells) [at least 10 mutations/megabase], as determined by a Food and Drug Administration (FDA)-approved test
3. Your disease has progressed (worsened) following prior treatment, and you have no alternative treatment options

O. If you have unresectable or metastatic colorectal cancer, approval also requires:
1. You are 18 years of age or older
2. Your cancer is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) (types of genetic abnormalities) as determined by an FDA-approved test

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PEMBROLIZUMAB-BERAHYALURONIDASE ALFA-PMPH BVD (PART D)

GUIDELINES FOR USE (CONTINUED)

P. If you have locally advanced unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:
1. You are 18 years of age or older
2. Your tumor expresses programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 1) as determined by a Food and Drug Administration (FDA)-approved test
3. You meet ONE of the following:
   a. Your cancer is human epidermal growth factor receptor 2 (HER2: type of protein that promotes cancer cells)-POSITIVE, and Keytruda Qlex will be used in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy
   b. Your cancer is human epidermal growth factor receptor 2 (HER2: type of protein that promotes cancer cells)-NEGATIVE, and Keytruda Qlex will be used in combination with fluoropyrimidine- and platinum-containing chemotherapy

Q. If you have locally advanced or metastatic esophageal or gastroesophageal junction carcinoma, approval also requires:
1. You are 18 years of age or older
2. Your tumor is not amenable (responsive) to surgical resection (removal) or definitive chemoradiation (a type of treatment)
3. You meet ONE of the following:
   a. Keytruda Qlex will be used in combination with platinum- and fluoropyrimidine-based chemotherapy; AND your tumor expresses programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 1) as determined by a Food and Drug Administration (FDA)-authorized test
   b. Keytruda Qlex will be used after one or more prior lines of systemic therapy; AND you have a tumor of squamous cell histology (cancer from flat surface-lining cells) that expresses programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 10) as determined by a Food and Drug Administration (FDA)-authorized test

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PEMBROLIZUMAB-BERAHYALURONIDASE ALFA-PMPH BVD (PART D)

GUIDELINES FOR USE (CONTINUED)

R. If you have cervical cancer, approval also requires:
1. You are 18 years of age or older
2. You meet ONE of the following:
   a. You have locally advanced cancer (cancer that has spread from where it started to nearby tissue or lymph nodes); AND Keytruda Qlex will be used in combination with chemoradiotherapy (CRT: a type of therapy to treat cancer); AND your cancer involves the lower third of the vagina, hydronephrosis (swelling of kidney)/a non-functioning kidney, or has spread to adjacent (nearby) pelvic organs (FIGO 2014 Stage III-IVA: a way to classify the size and spread of the cancer)
   b. You have persistent, recurrent, or metastatic cancer (cancer that does not go away, has returned, or has spread to other parts of the body); AND Keytruda Qlex will be used in combination with chemotherapy (such as paclitaxel, cisplatin, carboplatin); AND your tumor expresses programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 1) as determined by a Food and Drug Administration (FDA)-approved test
   c. You have recurrent (has returned) or metastatic (has spread to other parts of the body) cancer; AND you have experienced disease progression (worsening) on or after chemotherapy; AND your tumor has programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 1) as determined by a Food and Drug Administration (FDA)-approved test

S. If you have hepatocellular carcinoma, approval also requires:
1. You are 18 years of age or older
2. Your cancer is caused by hepatitis B (a type of liver infection)
3. You have received prior systemic therapy (such as Nexavar [sorafenib], oxaliplatin) other than a PD-1/PD-L1-containing regimen (such as Opdivo [nivolumab])

T. If you have locally advanced unresectable or metastatic biliary tract cancer, approval also requires:
1. You are 18 years of age or older
2. Keytruda Qlex will be used in combination with gemcitabine and cisplatin

U. If you have recurrent locally advanced or metastatic Merkel cell carcinoma, approval also requires:
1. You are 12 years of age or older

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PEMBROLIZUMAB-BERAHYALURONIDASE ALFA-PMPH BVD (PART D)

GUIDELINES FOR USE (CONTINUED)

V. If you have renal cell carcinoma, approval also requires ONE of the following:
1. You have advanced renal cell carcinoma; you are 18 years of age or older; AND Keytruda Qlex will be used in combination with Inlyta (axitinib) OR Lenvima (lenvatinib)
2. You are 18 years of age or older; Keytruda Qlex will be used as adjuvant (add-on) treatment; AND your cancer is at intermediate-high or high risk of recurrence (returning) following a nephrectomy (surgical removal of the kidney), or following a nephrectomy and resection (surgical removal) of metastatic lesions (abnormal area of tissue).
3. You are 18 years of age or older; AND Keytruda Qlex will be used in combination with Welireg (belzutifan), Keytruda Qlex will be used as adjuvant (add-on) treatment; AND you have renal cell carcinoma with a clear cell component (ccRCC: a type of kidney cancer), AND your cancer is at intermediate-high or high risk of recurrence (returning) following a nephrectomy (surgical removal of the kidney), or following a nephrectomy and resection (surgical removal) of metastatic lesions (abnormal area of tissue)

W. If you have primary advanced or recurrent endometrial carcinoma, approval also requires:
1. You are 18 years of age or older
2. Keytruda Qlex will be used in combination with carboplatin and paclitaxel, OR as a single agent after previous use in combination with carboplatin and paclitaxel

X. If you have advanced endometrial carcinoma, approval also requires:
1. You are 18 years of age or older
2. You have experienced disease progression (worsening) following prior systemic therapy (treatment that affects the entire body)
3. You are not a candidate for curative surgery or radiation
4. You meet ONE of the following:
   a. You will use Keytruda Qlex in combination with lenvatinib (Lenvima), AND your cancer is mismatch repair proficient (pMMR) OR not microsatellite instability-high (MSI-H) (characteristics that help determine the type of cancer and what treatment options there are for it) as determined by a Food and Drug Administration (FDA)-approved test
   b. Your cancer is microsatellite instability-high (MSI-H) OR mismatch repair deficient (dMMR) (types of genetic abnormalities) as determined by an Food and Drug Administration (FDA)-approved test

Y. If you have recurrent or metastatic OR locally advanced cutaneous squamous cell carcinoma, approval also requires:
1. You are 18 years of age or older
2. Your disease is not curable by surgery or radiation

(Denial text continued on next page)

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PEMBROLIZUMAB-BERAHYALURONIDASE ALFA-PMPH BVD (PART D)

GUIDELINES FOR USE (CONTINUED)

Z. If you have high-risk early-stage triple-negative breast cancer, approval also requires:
1. You are 18 years of age or older
2. Keytruda Qlex will be used in combination with chemotherapy (such as carboplatin, paclitaxel, doxorubicin) as neoadjuvant treatment (given before main treatment), OR as a single agent as adjuvant (add-on) treatment after surgery following prior use in combination with chemotherapy

AA. **If you have unresectable locally advanced or metastatic triple-negative breast cancer, approval also requires:**
1. You are 18 years of age or older
2. Keytruda Qlex will be used in combination with Trodelvy (sacituzumab govitecan-hziy)
3. Your tumor has programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 10), as determined by a Food and Drug (FDA)-authorized test

BB. **If you have locally recurrent unresectable or metastatic triple-negative breast cancer, approval also requires:**
1. You are 18 years of age or older
2. Keytruda Qlex will be used in combination with chemotherapy (such as paclitaxel, gemcitabine, carboplatin)
3. The tumor has programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 10) as determined by a Food and Drug Administration (FDA)-approved test

CC. **If you have epithelial ovarian, fallopian tube, or primary peritoneal carcinoma, approval also requires:**
1. You are 18 years of age or older
2. You have platinum-resistant cancer (cancer that no longer responds to a type of treatment)
3. Keytruda Qlex will be used in combination with paclitaxel
4. The tumor has programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 1) as determined by a Food and Drug Administration (FDA)-approved test
5. You have received one or more prior systemic treatment regimens (treatment that affects the entire body)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Keytruda Qlex.

REFERENCES

Keytruda Qlex [Prescribing Information]. Rahway, NJ: Merck & Co., Inc.; July 2026.

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PEMBROLIZUMAB-BERAHYALURONIDASE ALFA-PMPH BVD (PART D)

For Part D use only:

PEMBROLIZUMAB-BERAHYALURONIDASE ALFA-PMPH (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 10/25
Effective: 07/29/26 Client Approval: 07/26 DMC Approval: 07/26

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEMIGATINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEMIGATINIB	PEMAZYRE	46462		GPI-10 (2153226000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable locally advanced or metastatic cholangiocarcinoma (ICD-10 C22.1, C24.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has been previously treated for unresectable locally advanced or metastatic cholangiocarcinoma
   - The patient has a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement, as detected by an FDA-approved test
   - The patient will complete a comprehensive ophthalmological examination, including optical coherence tomography (OCT), prior to initiation of therapy and at the recommended scheduled intervals

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

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PEMIGATINIB (PART D)

GUIDELINES FOR USE (CONTINUED)

2. Does the patient have a diagnosis of relapsed or refractory myeloid/lymphoid neoplasms (MLNs) (ICD-10 C96.9, C96.Z; Groups C94.8, C95.1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a fibroblast growth factor receptor 1 (FGFR1) rearrangement
   - The patient will complete a comprehensive ophthalmological examination, including optical coherence tomography (OCT), prior to initiation of therapy and at the recommended scheduled intervals

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEMIGATINIB (Pemazyre)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Unresectable locally advanced or metastatic cholangiocarcinoma (bile duct cancer that has spread to nearby tissue and lymph nodes and cannot be removed by surgery, or it has spread to other parts of the body)
      2. Relapsed or refractory myeloid/lymphoid neoplasms (a type of blood cancer that has returned or did not respond to treatment)

   B. If you have unresectable locally advanced or metastatic cholangiocarcinoma, approval also requires:
      1. You are 18 years of age or older
      2. You have previously been treated for unresectable locally advanced or metastatic cholangiocarcinoma
      3. You have a fibroblast growth factor receptor 2 (FGFR2: type of protein) fusion or other rearrangement (types of gene mutation), as detected by a Food and Drug Administration (FDA)-approved test
      4. You will complete a comprehensive ophthalmological examination (eye exam), including optical coherence tomography (OCT: a type of eye imaging test), before starting the medication and at the recommended scheduled times

   (Denial text continued on next page)

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PEMIGATINIB (PART D)

GUIDELINES FOR USE (CONTINUED)

C. If you have relapsed or refractory myeloid/lymphoid neoplasms, approval also requires:

1. You are 18 years of age or older
2. You have a fibroblast growth factor receptor 1 (FGFR1: a type of protein) rearrangement
3. You will complete a comprehensive ophthalmological examination (eye exam), including optical coherence tomography (OCT: a type of eye imaging test), before starting the medication and at the recommended scheduled times

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Pemazyre.

REFERENCES

Pemazyre [Prescribing Information]. Wilmington, DE: Incyte Corporation; August 2022.

For Part D use only:

PEMIGATINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	CHOLANGIOCARCINOMA, MYELOID/LYMPHOID NEOPLASMS: COMPREHENSIVE OPHTHALMOLOGICAL EXAMINATION, INCLUDING OPTICAL COHERENCE TOMOGRAPHY (OCT), WILL BE COMPLETED PRIOR TO INITIATION OF THERAPY AND AT THE RECOMMENDED SCHEDULED INTERVALS.

Core	Advantage	Plus
Yes	Yes	Yes

Created: 04/20
Effective: 01/01/25 Client Approval: 08/24 P&T Approval: 10/22

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PENICILLAMINE CAPSULE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PENICILLAMINE	CUPRIMINE, PENICILLAMINE		7091	GPI-14 (99200030000110)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

1. Does the patient have a diagnosis of Wilson's disease (ICD-10 E83.01) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hepatologist or gastroenterologist
   - The patient has a Leipzig score of 4 or greater
   - The patient had a trial of or contraindication to penicillamine tablet (Depen)

   If yes, **approve for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of cystinuria (ICD-10 E72.01) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a nephrologist
   - The patient had a trial of or contraindication to penicillamine tablet (Depen)
   - The patient had a trial of or contraindication to tiopronin (Thiola, Thiola EC, Venxxiva)

   If yes, continue to #3.
   If no, continue to #4.

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PENICILLAMINE CAPSULE (PART D)

INITIAL CRITERIA (CONTINUED)

3. Does the patient have nephrolithiasis and meet **ONE** of the following criteria?
   - The patient's stone analysis shows a presence of cystine
   - The patient's urinalysis shows pathognomonic hexagonal cystine crystals
   - The patient has a family history of cystinuria AND a positive cyanide-nitroprusside screening

   If yes, **approve for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have a diagnosis of severe, active rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient does not have a history or other evidence of renal insufficiency
   - The patient had a trial of or contraindication to 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drug) (e.g., methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, sulfasalazine)
   - The patient had a trial of or contraindication to penicillamine tablet (Depen)

   If yes, **approve for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: **Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PENICILLAMINE CAPSULE (Cuprimine)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Wilson's disease (a type of genetic disorder)
      2. Cystinuria (a type of genetic disorder)
      3. Severe, active rheumatoid arthritis (a type of joint condition)

   (Initial denial text continued on next page)

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PENICILLAMINE CAPSULE (PART D)

INITIAL CRITERIA (CONTINUED)

B. If you have Wilson's disease, approval also requires:
1. Therapy is prescribed by or in consultation with a hepatologist (a type of liver doctor) or gastroenterologist (doctor who treats digestive conditions)
2. You have a Leipzig score of 4 or greater (a type of diagnostic score)
3. You have tried or have a contraindication to (harmful for you to use) penicillamine tablet (Depen)

C. If you have cystinuria, approval also requires:
1. Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor)
2. You have nephrolithiasis (kidney stones) and ONE of the following:
   a. Your kidney stone analysis that shows there is cystine (an amino acid)
   b. Your urine analysis shows there are hexagonal cystine crystals that are pathognomonic (signs relating to the disease)
   c. You have a family history of cystinuria AND tested positive for the cyanide-nitroprusside screening (a test to determine the amount of cystine in the body)
3. You have tried or have a contraindication to (harmful for you to use) penicillamine tablet (Depen)
4. You have tried or have a contraindication to (harmful for you to use) tiopronin (Thiola, Thiola EC, Venxxiva)

D. If you have severe, active rheumatoid arthritis, approval also requires:
1. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
2. You do not have a history or other evidence of renal insufficiency (kidney problems)
3. You have tried or have a contraindication to (harmful for you to use) 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drug, such as methotrexate dose greater than or equal to 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, sulfasalazine)
4. You have tried or have a contraindication to (harmful for you to use) penicillamine tablet (Depen)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PENICILLAMINE CAPSULE (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Wilson's disease (ICD-10 E83.01) or cystinuria (ICD-10 E72.01) **AND** meet the following criterion?
   - The patient continues to benefit from the medication

   If yes, approve for lifetime by GPID or GPI-14.
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of severe, active rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient does not have a history or other evidence of renal insufficiency
   - The patient has experienced or maintained improvement in tender joint count or swollen joint count compared to baseline

   If yes, approve for lifetime by GPID or GPI-14.
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PENICILLAMINE CAPSULE (Cuprimine)** requires the following rule(s) be met for renewal:

   A. You have ONE of the following:
      1. Wilson's disease (a type of genetic disorder)
      2. Cystinuria (a type of genetic disorder)
      3. Severe, active rheumatoid arthritis (a type of joint condition)

   B. If you have Wilson's disease or cystinuria, renewal also requires:
      1. You continue to benefit from the medication

   C. If you have severe, active rheumatoid arthritis, renewal also requires:
      1. You do not have a history or other evidence of renal insufficiency (kidney problems)
      2. You have experienced or maintained improvement in tender joint count or swollen joint count compared to baseline

   (Renewal denial text continued on next page)

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PENICILLAMINE CAPSULE (PART D)

RENEWAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cuprimine.

REFERENCES

Cuprimine [Prescribing Information]. Bridgewater, NJ: Bausch Health US, LLC; October 2024.

For Part D use only:

PENICILLAMINE CAPSULE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	INITIAL: WILSONS DISEASE: LEIPZIG SCORE OF 4 OR GREATER. CYSTINURIA: HAS NEPHROLITHIASIS AND ONE OF THE FOLLOWING: 1) STONE ANALYSIS SHOWING PRESENCE OF CYSTINE, 2) PRESENCE OF PATHOGNOMONIC HEXAGONAL CYSTINE CRYSTALS ON URINALYSIS, OR 3) FAMILY HISTORY OF CYSTINURIA AND POSITIVE CYANIDE-NITROPRUSSIDE SCREENING.
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: WILSONS DISEASE: PRESCRIBED BY OR IN CONSULTATION WITH A HEPATOLOGIST OR GASTROENTEROLOGIST. CYSTINURIA: PRESCRIBED BY OR IN CONSULTATION WITH A NEPHROLOGIST. RHEUMATOID ARTHRITIS (RA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST.
Coverage Duration	INITIAL: 12 MONTHS, RENEWAL: LIFETIME.
Other Criteria	INITIAL: WILSONS DISEASE: TRIAL OF OR CONTRAINDICATION TO PENICILLAMINE TABLET. CYSTINURIA: TRIAL OF OR CONTRAINDICATION TO: 1) PENICILLAMINE TABLET, AND 2) TIOPRONIN. RA: 1) NO HISTORY OR OTHER EVIDENCE OF RENAL INSUFFICIENCY, 2) TRIAL OF OR CONTRAINDICATION TO 3 MONTHS OF TREATMENT WITH ONE DMARD (DISEASE-MODIFYING ANTIRHEUMATIC DRUG) - IF PATIENT TRIED METHOTREXATE, THEN TRIAL AT A DOSE GREATER THAN OR EQUAL TO 20 MG PER WEEK OR MAXIMALLY

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	TOLERATED DOSE IS REQUIRED, AND 3) TRIAL OF OR CONTRAINDICATION TO PENICILLAMINE TABLET. RENEWAL: RA: 1) NO HISTORY OR OTHER EVIDENCE OF RENAL INSUFFICIENCY, AND 2) EXPERIENCED OR MAINTAINED IMPROVEMENT IN TENDER JOINT COUNT OR SWOLLEN JOINT COUNT COMPARED TO BASELINE. WILSONS DISEASE, CYSTINURIA: CONTINUES TO BENEFIT FROM THE MEDICATION.

Created: 11/17
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 05/23

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PENICILLAMINE TABLET (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PENICILLAMINE	DEPEN, PENICILLAMINE		7100	GPI-14 (99200030000305)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

1. Does the patient have a diagnosis of Wilson's disease (ICD-10 E83.01) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hepatologist or gastroenterologist
   - The patient has a Leipzig score of 4 or greater

   If yes, **approve for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of cystinuria (ICD-10 E72.01) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with a nephrologist

   If yes, continue to #3.
   If no, continue to #4.

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PENICILLAMINE TABLET (PART D)

INITIAL CRITERIA (CONTINUED)

3. Does the patient have nephrolithiasis (ICD-10 N20.0) and meet **ONE** of the following criteria?
   - The patient's stone analysis shows a presence of cystine
   - The patient's urinalysis shows pathognomonic hexagonal cystine crystals
   - The patient has a family history of cystinuria AND a positive cyanide-nitroprusside screening

   If yes, **approve for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have a diagnosis of severe, active rheumatoid arthritis (ICD-10 M06.9; Groups M05.7, M05.8, M05.9, M06.0, M06.8) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient does not have a history or other evidence of renal insufficiency
   - The patient had a trial of or contraindication to 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drug) (e.g., methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, sulfasalazine)

   If yes, **approve for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PENICILLAMINE TABLET (Depen)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Wilson's disease (a type of genetic disorder)
      2. Cystinuria (a type of genetic disorder)
      3. Severe, active rheumatoid arthritis (a type of joint condition)

   B. If you have Wilson's disease, approval also requires:
      1. Therapy is prescribed by or in consultation with a hepatologist (a liver doctor) or gastroenterologist (doctor who treats digestive conditions)
      2. You have a Leipzig score of 4 or greater (a type of diagnostic score)

   (Initial denial text continued on next page)

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PENICILLAMINE TABLET (PART D)

INITIAL CRITERIA (CONTINUED)

C. If you have cystinuria, approval also requires:
1. Therapy is prescribed by or in consultation with a nephrologist (kidney doctor)
2. You have nephrolithiasis (kidney stones) and meet ONE of the following:
   a. Your kidney stone analysis shows there is cystine (an amino acid)
   b. Your urine analysis shows there are hexagonal cystine crystals that are pathognomonic (signs relating to the disease)
   c. You have a family history of cystinuria AND tested positive for the cyanide-nitroprusside screening (a test to determine the amount of cystine in your body)

D. If you have severe, active rheumatoid arthritis, approval also requires:
1. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
2. You do not have a history or other evidence of renal insufficiency (kidney problems)
3. You have tried or have a contraindication to (harmful for you to use) 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drug, such as methotrexate at dose greater than or equal to 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, sulfasalazine)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PENICILLAMINE TABLET (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Wilson's disease (ICD-10 E83.01) or cystinuria (ICD-10 E72.01) **AND** meet the following criterion?
   - The patient continues to benefit from the medication

   If yes, approve for lifetime by GPID or GPI-14.
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of severe, active rheumatoid arthritis (ICD-10 M06.9; Groups M05.7, M05.8, M05.9, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient does not have a history or other evidence of renal insufficiency
   - The patient has experienced or maintained improvement in tender joint count or swollen joint count compared to baseline

   If yes, approve for lifetime by GPID or GPI-14.
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PENICILLAMINE TABLET (Depen)** requires the following rule(s) be met for renewal:

   A. You have ONE of the following:
      1. Wilson's disease (a type of genetic disorder)
      2. Cystinuria (a type of genetic disorder)
      3. Severe, active rheumatoid arthritis (a type of joint condition)

   B. If you have Wilson's disease or cystinuria, renewal also requires:
      1. You continue to benefit from the medication

   C. If you have severe, active rheumatoid arthritis, renewal also requires:
      1. You do not have a history or other evidence of renal insufficiency (kidney problems)
      2. You have experienced or maintained improvement in tender joint count or swollen joint count compared to baseline

   (Renewal denial text continued on next page)

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PENICILLAMINE TABLET (PART D)

RENEWAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Depen.

REFERENCES

Depen [Prescribing Information]. Canonsburg, PA: Meda Pharmaceuticals; July 2023.

For Part D use only:

PENICILLAMINE TABLET (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	INITIAL: CYSTINURIA: HAS NEPHROLITHIASIS AND ONE OF THE FOLLOWING: 1) STONE ANALYSIS SHOWING PRESENCE OF CYSTINE, 2) PRESENCE OF PATHOGNOMONIC HEXAGONAL CYSTINE CRYSTALS ON URINALYSIS, OR 3) FAMILY HISTORY OF CYSTINURIA AND POSITIVE CYANIDE-NITROPRUSSIDE SCREENING.
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: WILSONS DISEASE: PRESCRIBED BY OR IN CONSULTATION WITH A HEPATOLOGIST OR GASTROENTEROLOGIST. CYSTINURIA: PRESCRIBED BY OR IN CONSULTATION WITH A NEPHROLOGIST. RHEUMATOID ARTHRITIS (RA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST.
Coverage Duration	INITIAL: 12 MONTHS, RENEWAL: LIFETIME.
Other Criteria	INITIAL: WILSONS DISEASE: 1) LEIPZIG SCORE OF 4 OR GREATER. RA: 1) NO HISTORY OR OTHER EVIDENCE OF RENAL INSUFFICIENCY, AND 2) TRIAL OF OR CONTRAINDICATION TO 3 MONTHS OF TREATMENT WITH ONE DMARD (DISEASE-MODIFYING ANTIRHEUMATIC DRUG) - IF PATIENT TRIED METHOTREXATE, THEN TRIAL AT A DOSE GREATER THAN OR EQUAL TO 20 MG PER WEEK OR MAXIMALLY TOLERATED DOSE IS REQUIRED. RENEWAL: RA: 1) NO HISTORY OR OTHER EVIDENCE OF RENAL INSUFFICIENCY, AND 2) EXPERIENCED OR MAINTAINED IMPROVEMENT IN TENDER JOINT COUNT OR SWOLLEN JOINT COUNT COMPARED TO BASELINE. WILSONS

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	DISEASE, CYSTINURIA: CONTINUES TO BENEFIT FROM THE MEDICATION.

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25 Created: 11/17
Commercial Effective: N/A Client Approval: 06/24 P&T Approval: 05/23

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PERTUZUMAB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PERTUZUMAB	PERJETA	39102		GPI-10 (2117005400)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of breast cancer (ICD-10 Group C50) **AND** meet the following criterion?
   - The patient's breast cancer is HER2-positive

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See denial text at the end of the guideline.

2. Is the patient's cancer metastatic and the patient meets **ALL** of the following criteria?
   - The patient has not received prior therapy with an anti-HER2 agent or chemotherapy for metastatic disease
   - Perjeta will be used in combination with trastuzumab (Herceptin or an FDA approved biosimilar) and docetaxel

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.
   If no, continue to #3.

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PERTUZUMAB (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Is the patient's cancer locally advanced, inflammatory, or early stage (either greater than 2 cm in diameter or node positive) and the patient meets **ALL** of the following criteria?
   - Perjeta will be used in the neoadjuvant setting
   - Perjeta will be used in combination with trastuzumab (Herceptin or an FDA approved biosimilar) and chemotherapy (e.g., paclitaxel, carboplatin, cyclophosphamide) as part of a complete treatment regimen for early breast cancer

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

4. Is the patient's disease early breast cancer (EBC) and the patient meets **ALL** of the following criteria?
   - The patient's breast cancer is at high risk of recurrence
   - Perjeta will be used in the adjuvant setting
   - Perjeta will be used in combination with trastuzumab (Herceptin or an FDA approved biosimilar) and chemotherapy (e.g., paclitaxel, carboplatin, cyclophosphamide)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PERTUZUMAB (Perjeta)** requires the following rule(s) be met for approval:
   A. You have breast cancer
   B. Your breast cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive
   C. If you have metastatic breast cancer (cancer that has spread to other parts of the body), approval also requires:
      1. You have not received prior therapy with an anti-HER2 agent or chemotherapy for metastatic disease (treatment for cancer that has spread to other parts of the body)
      2. Perjeta will be used in combination with trastuzumab and docetaxel

   (Denial text continued on the next page)

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PERTUZUMAB (PART D)

GUIDELINES FOR USE (CONTINUED)

D. If you have locally advanced (cancer that has spread to nearby tissue or lymph nodes), inflammatory, or early stage breast cancer (defined as either tumor is greater than 2 cm in diameter or node positive), approval also requires:
1. Perjeta will be used in the neoadjuvant setting (given before main treatment)
2. Perjeta will be used in combination with trastuzumab and chemotherapy (such as paclitaxel, carboplatin cyclophosphamide) as part of a complete treatment regimen for early breast cancer

E. If you have early breast cancer, approval also requires:
1. Your breast cancer is at high risk of recurrence (returning)
2. Perjeta will be used in the adjuvant setting (given as add-on treatment)
3. Perjeta will be used in combination with trastuzumab and chemotherapy (such as paclitaxel, carboplatin, cyclophosphamide)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Perjeta.

REFERENCES
Perjeta [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; May 2025.

For Part D use only:

PERTUZUMAB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 08/12
Effective: 07/01/25 Client Approval: 05/25 P&T Approval: 01/18

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PERTUZUMAB-TRASTUZUMAB-HY-ZZXF BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PERTUZUMAB-TRASTUZUMAB-HY-ZZXF	PHESGO	46674		GPI-10 (2199000355)	

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #5.

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PERTUZUMAB-TRASTUZUMAB-HY-ZZXF BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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PERTUZUMAB-TRASTUZUMAB-HY-ZZXF BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of breast cancer (ICD-10 Group 50) **AND** meet the following criterion?
   - The patient's breast cancer is HER2-positive

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See denial text at the end of the guideline.

2. Is the patient's cancer locally advanced, inflammatory, or early stage (either greater than 2 cm in diameter or node positive) **AND** the patient meets the following criterion?
   - Phesgo will be used in combination with chemotherapy as part of a complete treatment regimen for early breast cancer in the neoadjuvant setting

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Is the patient's disease early breast cancer (EBC) and the patient meets **ALL** of the following criteria?
   - The patient's breast cancer is at high risk of recurrence
   - Phesgo will be used in combination with chemotherapy in the adjuvant setting

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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PERTUZUMAB-TRASTUZUMAB-HY-ZZXF BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

4. Is the patient's cancer metastatic and the patient meets **ALL** of the following criteria?
   - The patient has not received prior anti-HER2 therapy or chemotherapy for metastatic disease
   - Phesgo will be used in combination with docetaxel

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PERTUZUMAB-TRASTUZUMAB-HY-ZZXF (Phesgo)** requires the following rule(s) be met for approval:
   A. You have breast cancer
   B. Your breast cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive
   C. If you have locally advanced (cancer that has spread to nearby tissue or lymph nodes), inflammatory or early breast cancer (defined as either tumor is greater than 2 cm in diameter or node positive), approval also requires:
      1. Phesgo will be used in combination with chemotherapy as part of a complete treatment regimen for early breast cancer in the neoadjuvant setting (given before surgery)
   D. If you have early breast cancer, approval also requires:
      1. Your breast cancer is at high risk of recurrence (returning)
      2. Phesgo will be used in combination with chemotherapy in the adjuvant setting (given as add-on treatment)
   E. If you have metastatic breast cancer (cancer that has spread to other parts of the body), approval also requires:
      1. You have not received anti-HER2 therapy or chemotherapy for metastatic disease (cancer treatment for disease that has spread to other parts of the body)
      2. Phesgo will be used in combination with docetaxel

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PERTUZUMAB-TRASTUZUMAB-HY-ZZXF BvD (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Phesgo. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Phesgo [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; November 2024.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals . [Accessed June 28, 2024].

For Part D use only:

PERTUZUMAB-TRASTUZUMAB-HY-ZZXF (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 07/20
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 10/20

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEXIDARTINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEXIDARTINIB HYDROCHLORIDE	TURALIO	45912		GPI-10 (2153304501)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of symptomatic tenosynovial giant cell tumor (TGCT) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's TGCT is associated with severe morbidity or functional limitations
   - The patient's TGCT is NOT amenable to improvement with surgery

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEXIDARTINIB (Turalio)** requires the following rule(s) be met for approval:
   A. You have symptomatic tenosynovial giant cell tumor (TGCT: a type of rare tumor)
   B. You are 18 years of age or older
   C. Your TGCT is associated with severe morbidity (illness) or functional limitations
   D. Your TGCT is NOT amenable to improvement with surgery (unable to get better with surgery)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PEXIDARTINIB (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Turalio.

REFERENCES

Turalio [Prescribing Information]. Basking Ridge, NJ: Daiichi Sankyo, Inc., October 2021.

For Part D use only:

PEXIDARTINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Created: 08/19
Effective: 01/01/25 Client Approval: 08/24 P&T Approval: 07/19

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PHENYLEPHRINE-PROMETHAZINE DVE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PHENYLEPHRINE HCL/PROMETH HCL	PROMETHAZINE-PHENYLEPHRINE	00418		GPI-10 (4399300270)	

These are DvE drugs requiring a payment determination for "Part D" or "Non-Part D".

PAYMENT DETERMINATION CRITERIA

1. Is the request for temporary relief of upper respiratory symptoms, including nasal congestion, associated with allergy (ICD-10 Group J30 except J30.0)?

   If yes, **set CMS_DVE_OVR to 'D', and approve for 12 months by HICL or GPI-10. Document in the PA comments: Part D Determination Override.**

   If no, **set CMS_DVE_OVR to 'E', and approve for 12 months by HICL or GPI-10. Document in the PA comments: Payment Determination Override. This is not a Part D indication.**

   NOTE: If the claim rejects after analyzing, then follow the clinical authorization process within HQ notes.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PHENYLEPHRINE-PROMETHAZINE** requires the following rule(s) be met for approval:
   A. The request is for temporary relief of upper respiratory (breathing) symptoms, including nasal congestion (stuffy nose), associated with allergy

RATIONALE

To limit the coverage of phenylephrine-promethazine to the Medicare Part D covered indication of relief of upper respiratory symptoms, including nasal congestion, associated with allergy, and exclude coverage for the symptomatic relief of coughs and colds.

REFERENCES

Promethazine VC [Prescribing Information]. Greenville, SC: Pharmaceutical Associates, Inc.; August 2020.

Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements. Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf. [Accessed March 2026].

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PHENYLEPHRINE-PROMETHAZINE DVE (PART D)

For Part D use only:

PHENYLEPHRINE-PROMETHAZINE DVE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	PART D DOES NOT COVER THIS DRUG WHEN USED FOR SYMPTOMATIC RELIEF OF COUGHS AND COLDS.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 11/19
Effective: 03/09/26 Client Approval: 03/26 P&T Approval: 10/19

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PIMAVANSERIN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PIMAVANSERIN TARTRATE	NUPLAZID	43373		GPI-10 (5940002820)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of psychosis (ICD-10 F02.82, F02.A2, F02.B2, F02.C2) associated with Parkinson's disease (ICD-10 Group G20) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist, geriatrician, or behavioral health specialist (e.g., psychiatrist)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline for the drug named **PIMAVANSERIN (Nuplazid)** requires you to meet the following rule(s) for approval:
   A. You have psychosis associated with Parkinson's disease (a type of mental disorder and is related to a movement disorder)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor), geriatrician (doctor that focuses on health care of elderly people), or behavioral health specialist (such as a psychiatrist [a type of mental health doctor])

   (Initial denial text continued on next page)

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PIMAVANSERIN (PART D)

INITIAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PIMAVANSERIN (PART D)

RENEWAL CRITERIA

1. During the past 12 months of therapy, has the patient experienced an improvement in psychosis symptoms from baseline **AND** demonstrates a continued need for treatment?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PIMAVANSERIN (Nuplazid)** requires the following rule(s) be met for renewal:
   A. You have an improvement in psychosis (a type of mental health disorder) symptoms from baseline during the past 12 months of therapy AND you show a continued need for treatment

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Nuplazid.

REFERENCES
Nuplazid [Prescribing Information]. San Diego, CA: Acadia Pharmaceuticals, Inc.; February 2022.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PIMAVANSERIN (PART D)

For Part D use only:

PIMAVANSERIN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	PSYCHOSIS IN PARKINSONS DISEASE (PD): INITIAL: 18 YEARS OR OLDER
Prescriber Restrictions	PSYCHOSIS IN PD: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST, GERIATRICIAN, OR A BEHAVIORAL HEALTH SPECIALIST (E.G., PSYCHIATRIST).
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	PSYCHOSIS IN PD: RENEWAL: IMPROVEMENT IN PSYCHOSIS SYMPTOMS FROM BASELINE AND DEMONSTRATES A CONTINUED NEED FOR TREATMENT.

Core	Advantage	Plus
Yes	Yes	Yes

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PIRFENIDONE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PIRFENIDONE	ESBRIET, PIRFENIDONE	40237		GPI-10 (4555006000)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
Yes	No	No	Yes	No	No	Yes	No	No	Yes	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of idiopathic pulmonary fibrosis (IPF) (ICD-10 J84.112) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a pulmonologist
   - The patient does NOT have other known causes of interstitial lung disease (ILD) (e.g., connective tissue disease, drug toxicity, asbestos or beryllium exposure, hypersensitivity pneumonitis, systemic sclerosis, rheumatoid arthritis, radiation, sarcoidosis, bronchiolitis obliterans organizing pneumonia, human immunodeficiency virus (HIV) infection, viral hepatitis, or cancer)
   - The patient has a usual interstitial pneumonia (UIP) pattern as evidenced by high-resolution computed tomography (HRCT) alone or via a combination of surgical lung biopsy and HRCT

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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PIRFENIDONE (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PIRFENIDONE (Esbriet)** requires the following rule(s) be met for approval:

A. You have idiopathic pulmonary fibrosis (IPF: a type of lung condition)
B. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor)
C. You do NOT have other known causes of interstitial lung disease. Other known causes include connective tissue disease, drug toxicity, asbestos or beryllium exposure, hypersensitivity pneumonitis (type of lung infection), systemic sclerosis (chronic hardening and tightening of the skin and connective tissues), rheumatoid arthritis (a type of joint condition), radiation, sarcoidosis (a type of inflammatory disorder), bronchiolitis obliterans organizing pneumonia (infection affecting the small airways of the lung), human immunodeficiency virus infection (HIV: a type of immune disorder), viral hepatitis (a type of liver inflammation), or cancer
D. You have a usual interstitial pneumonia (a specific type of lung scarring) pattern as evidenced by high-resolution computed tomography (HRCT: type of imaging test) alone or via a combination of surgical lung biopsy (small lung sample) and HRCT

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PIRFENIDONE (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of idiopathic pulmonary fibrosis (IPF) (ICD-10 J84.112) **AND** meet the following criterion?

- The patient has experienced a clinical meaningful improvement or maintenance in annual rate of decline

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PIRFENIDONE (Esbriet)** requires the following rule(s) be met for renewal:
A. You have idiopathic pulmonary fibrosis (IPF: a type of lung condition)
B. You have experienced a clinical meaningful improvement or maintenance in annual rate of decline

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Esbriet.

REFERENCES
Esbriet [Prescribing Information]. South San Francisco, CA: Genentech USA, Inc.; February 2022.

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PIRFENIDONE (PART D)

For Part D use only:

PIRFENIDONE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	IDIOPATHIC PULMONARY FIBROSIS (IPF): INITIAL: A USUAL INTERSTITIAL PNEUMONIA (UIP) PATTERN AS EVIDENCED BY HIGH-RESOLUTION COMPUTED TOMOGRAPHY (HRCT) ALONE OR VIA A COMBINATION OF SURGICAL LUNG BIOPSY AND HRCT.
Age Restrictions	N/A
Prescriber Restrictions	IPF: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A PULMONOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	IPF: INITIAL: 1) DOES NOT HAVE OTHER KNOWN CAUSES OF INTERSTITIAL LUNG DISEASE (E.G., CONNECTIVE TISSUE DISEASE, DRUG TOXICITY, ASBESTOS OR BERYLLIUM EXPOSURE, HYPERSENSITIVITY PNEUMONITIS, SYSTEMIC SCLEROSIS, RHEUMATOID ARTHRITIS, RADIATION, SARCOIDOSIS, BRONCHIOLITIS OBLITERANS ORGANIZING PNEUMONIA, HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION, VIRAL HEPATITIS, OR CANCER). RENEWAL: CLINICAL MEANINGFUL IMPROVEMENT OR MAINTENANCE IN ANNUAL RATE OF DECLINE.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PIRTOBRUTINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PIRTOBRUTINIB	JAYPIRCA	48657		GPI-10 (2153216500)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory mantle cell lymphoma (MCL) (ICD-10 Group C83.1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received at least TWO lines of systemic therapy including a Bruton's tyrosine kinase (BTK) inhibitor (e.g., Imbruvica [ibrutinib], Calquence [acalabrutinib], Brukinsa [zanubrutinib])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of relapsed or refractory chronic lymphocytic leukemia (CLL) (ICD-10 Group C91.1) or small lymphocytic lymphoma (SLL) (ICD-10 Group C83.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received a covalent Bruton's tyrosine kinase (BTK) inhibitor (e.g., Imbruvica [ibrutinib], Calquence [acalabrutinib], Brukinsa [zanubrutinib])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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PIRTOBRUTINIB (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PIRTOBRUTINIB (Jaypirca)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Relapsed or refractory mantle cell lymphoma (MCL) (a type of blood cancer that has returned or did not respond to treatment)
   2. Relapsed or refractory chronic lymphocytic leukemia (CLL) (a type of blood cancer that has returned or did not respond to treatment)
   3. Relapsed or refractory small lymphocytic lymphoma (SLL) (a type of blood cancer that has returned or did not respond to treatment)

B. If you have relapsed or refractory mantle cell lymphoma, approval also requires:
   1. You are 18 years of age or older
   2. You have previously received at least TWO lines of systemic therapy (treatment that targets the entire body) for mantle cell lymphoma, including a BTK inhibitor (Bruton's tyrosine kinase inhibitor such as Imbruvica [ibrutinib], Calquence [acalabrutinib], Brukinsa [zanubrutinib])

C. If you have relapsed or refractory chronic lymphocytic leukemia or small lymphocytic lymphoma, approval also requires:
   1. You are 18 years of age or older
   2. You have previously received a covalent BTK inhibitor (Bruton's tyrosine kinase inhibitor such as Imbruvica [ibrutinib], Calquence [acalabrutinib], Brukinsa [zanubrutinib])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PIRTOBRUTINIB (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Jaypirca.

REFERENCES

Jaypirca [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; December 2025.

For Part D use only:

PIRTOBRUTINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PITOLISANT (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PITOLISANT HCL	WAKIX	45575		GPI-10 (6145007010)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of excessive daytime sleepiness (EDS) with narcolepsy (ICD-10 G47.419) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with a neurologist, psychiatrist, or specialist insleep medicine

   If yes, continue to #2.
   If no, continue to #4.

2. Is the patient 6 to 17 years of age **AND** meets the following criterion?
   - The patient had a trial of or contraindication to ONE generic typical stimulant indicated forEDS with narcolepsy (e.g., amphetamine sulfate [Evekeo], dextroamphetamine [Dexedrine], methylphenidate [Ritalin])

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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PITOLISANT (PART D)

INITIAL CRITERIA (CONTINUED)

3. Is the patient 18 years of age or older and meets **ALL** of the following criteria?
   - The patient had a trial of or contraindication to ONE generic typical stimulant indicated for EDS with narcolepsy (e.g., amphetamine sulfate [Evekeo], dextroamphetamine [Dexedrine], methylphenidate [Ritalin])
   - The patient had a trial of or contraindication to Sunosi (solriamfetol), Nuvigil (armodafinil), OR Provigil (modafinil)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have a diagnosis of cataplexy with narcolepsy (ICD-10 G47.411) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist, psychiatrist, or specialist in sleep medicine

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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PITOLISANT (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PITOLISANT (Wakix)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Excessive daytime sleepiness (EDS) with narcolepsy (a type of sleep condition with overwhelming daytime drowsiness)
   2. Cataplexy with narcolepsy (a type of sleep condition with extreme drowsiness with sudden and uncontrollable muscle weakness)

B. If you have excessive daytime sleepiness with narcolepsy, approval also requires:
   1. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor), psychiatrist (a type of mental health doctor), or specialist in sleep medicine
   2. You meet ONE of the following:
      a. You are 6 to 17 years old AND have tried or have a contraindication to (harmful for you to use) ONE generic typical stimulant used for excessive daytime sleepiness (EDS) with narcolepsy (such as amphetamine sulfate [Evekeo], dextroamphetamine [Dexedrine], methylphenidate [Ritalin])
      b. You are 18 years or older AND have tried or have a contraindication to (harmful for you to use) ONE generic typical stimulant used for excessive daytime sleepiness (EDS) with narcolepsy (such as amphetamine sulfate [Evekeo], dextroamphetamine [Dexedrine], methylphenidate [Ritalin]) AND Sunosi (solriamfetol), Nuvigil (armodafinil), or Provigil (modafinil)

C. If you have cataplexy with narcolepsy, approval also requires:
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor), psychiatrist (a type of mental health doctor), or specialist in sleep medicine

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PITOLISANT (PART D)

RENEWAL CRITERIA

1. Does the patient have **ONE** of the following diagnoses?
   Excessive daytime sleepiness (EDS) with narcolepsy (ICD-10 G47.419)
   Cataplexy with narcolepsy (ICD-10 G47.411)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Has the patient shown sustained improvement of symptoms compared to baseline?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PITOLISANT (Wakix)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Excessive daytime sleepiness (EDS) with narcolepsy (a type of sleep condition with overwhelming daytime drowsiness)
      2. Cataplexy with narcolepsy (a type of sleep condition with extreme drowsiness with sudden and uncontrollable muscle weakness)
   B. You have shown sustained improvement in symptoms compared to baseline

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Wakix.

REFERENCES

Wakix [Prescribing Information]. Plymouth Meeting, PA: Harmony Biosciences, LLC; February 2026.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PITOLISANT (PART D)

For Part D use only:

PITOLISANT (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: EXCESSIVE DAYTIME SLEEPINESS (EDS) IN NARCOLEPSY, CATAPLEXY IN NARCOLEPSY: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST, PSYCHIATRIST, OR SPECIALIST IN SLEEP MEDICINE.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: EDS IN NARCOLEPSY: 1) AGES 18 YEARS OR OLDER: TRIAL OF OR CONTRAINDICATION TO SUNOSI, ARMODAFINIL, OR MODAFINIL, AND ONE OTHER GENERIC STIMULANT INDICATED FOR EDS IN NARCOLEPSY, 2) AGES 6 TO 17 YEARS: TRIAL OF OR CONTRAINDICATION TO ONE GENERIC STIMULANT INDICATED FOR EDS IN NARCOLEPSY. RENEWAL: EDS IN NARCOLEPSY, CATAPLEXY IN NARCOLEPSY: SUSTAINED IMPROVEMENT OF SYMPTOMS COMPARED TO BASELINE.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PLOZASIRAN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PLOZASIRAN SODIUM	REDEMPLO	51006		GPI-10 (3090627030)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of familial chylomicronemia syndrome (FCS) (ICD-10 E78.3)and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Redemplo will be used as an adjunct therapy to diet
   - The patient's diagnosis of FCS has been confirmed by genetic testing
   - Redemplo will NOT be used concurrently with another agent (e.g., Tryngolza [olezarsen]) forthe treatment of FCS

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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PLOZASIRAN (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PLOZASIRAN (Redemplo)** requires the following rule(s) be met for approval:

A. You have familial chylomicronemia syndrome (FCS: a type of rare genetic condition)
B. You are 18 years of age or older
C. You will use Redemplo as an adjunct (add-on) therapy to diet
D. Your diagnosis of familial chylomicronemia syndrome (FCS: a typeof rare genetic condition) has been confirmed by genetic testing (a type of lab test)
E. You will NOT use Redemplo concurrently (at the same time) with another medication (such as Tryngolza [olezarsen]) for the treatment of familial chylomicronemia syndrome (FCS: a type of rare genetic condition)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PLOZASIRAN (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of familial chylomicronemia syndrome (FCS) (ICD-10 E78.3) and meet **ALL** of the following criteria?
   - The patient has experienced a clinical benefit as demonstrated by a reduction in triglyceride levels
   - Redemplo will NOT be used concurrently with another agent (e.g., Tryngolza [olezarsen]) for the treatment of FCS

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PLOZASIRAN (Redemplo)** requires the following rule(s) be met for renewal:
   A. You have familial chylomicronemia syndrome (FCS: a type of rare genetic condition)
   B. You have experienced a clinical benefit as shown by a reduction (decrease) in triglyceride (a type of fat) levels
   C. You will NOT use Redemplo concurrently (at the same time) with another medication (such as Tryngolza [olezarsen]) for the treatment of familial chylomicronemia syndrome (FCS: a type of rare genetic condition)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Redemplo.

REFERENCES

Redemplo [Prescribing Information]. Pasadena, CA: Arrowhead Pharmaceuticals, Inc.; November 2025.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PLOZASIRAN (PART D)

For Part D use only:

PLOZASIRAN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	FAMILIAL CHYLOMICRONEMIA SYNDROME (FCS): INITIAL: DIAGNOSIS CONFIRMED BY GENETIC TESTING.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	FCS: INITIAL/RENEWAL: NO CONCURRENT USE WITH ANOTHER AGENT (E.G., TRYNGOLZA) FOR THE TREATMENT OF FCS. RENEWAL: CLINICAL BENEFIT AS DEMONSTRATED BY A REDUCTION IN TRIGLYCERIDE LEVELS.

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Effective: 01/26/26 Client Approval: 01/26 P&T Approval: 10/25

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

POLATUZUMAB VEDOTIN-PIIQ (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
POLATUZUMAB VEDOTIN-PIIQ	POLIVY	45781		GPI-10 (2135486030)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified (ICD-10 Group C83.3), and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Polivy will be used in combination with bendamustine and a rituximab product
   - The patient has received at least two prior therapies (e.g., R-CHOP [rituximab, cyclophosphamide, doxorubicin, vincristine and prednisone], tafasitamab with lenalidomide)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [xx] per [xx] days.

   If no, continue to #2.

2. Does that patient have a diagnosis of previously untreated diffuse large B-cell lymphoma (DLBCL), not otherwise specified (ICD-10 Group C83.3), and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Polivy will be used in combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone (R-CHP)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [xx] per [xx] days.

   If no, continue to #3.

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POLATUZUMAB VEDOTIN-PIIQ (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does that patient have a diagnosis of previously untreated high-grade B-cell lymphoma (HGBL), and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has an International Prognostic Index score of 2 or greater
   - Polivy will be used in combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone (R-CHP)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [xx] per [xx] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **POLATUZUMAB VEDOTIN-PIIQ (Polivy)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Relapsed (returned) or refractory (resistant to treatment) diffuse large B-cell lymphoma (DLBCL: a type of blood cancer), not otherwise specified
      2. Previously untreated diffuse large B-cell lymphoma (DLBCL: a type of blood cancer), not otherwise specified
      3. Previously untreated high-grade B-cell lymphoma (HGBL: an aggressive type of blood cancer)

   B. If you have relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified, approval also requires:
      1. You are 18 years of age or older
      2. Polivy will be used in combination with bendamustine and a rituximab product (type of cancer drug)
      3. You have had at least two prior therapies (such as R-CHOP [rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone], tafasitamab with lenalidomide)

   C. If you have previously untreated diffuse large B-cell lymphoma, not otherwise specified, approval also requires:
      1. You are 18 years of age or older
      2. Polivy will be used in combination with a rituximab product (type of cancer drug), cyclophosphamide, doxorubicin, and prednisone (R-CHP)

   (Denial text continued on next page)

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POLATUZUMAB VEDOTIN-PIIQ (PART D)

GUIDELINES FOR USE (CONTINUED)

D. If you have previously untreated high-grade B-cell lymphoma, approval also requires:

1. You are 18 years of age or older
2. You have International Prognostic Index (a tool used to determine the likely cause of a disease) score of 2 or greater
3. Polivy will be used in combination with a rituximab product (type of cancer drug), cyclophosphamide, doxorubicin, and prednisone (R-CHP)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Polivy.

REFERENCES

Polivy [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; April 2023.

For Part D use only:

POLATUZUMAB VEDOTIN-PIIQ (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
No	No	Yes

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

POMALIDOMIDE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
POMALIDOMIDE	POMALYST, POMALIDOMIDE	39996		GPI-10 (2145008000)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of multiple myeloma (MM) (ICD-10 Group C90.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The requested medication will be used in combination with dexamethasone
   - The patient has received at least two prior therapies including Revlimid (lenalidomide) and a proteasome inhibitor (e.g., Velcade [bortezomib], Kyprolis [carfilzomib], Ninlaro [ixazomib])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of Kaposi sarcoma (KS) (ICD-10 Group C46) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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POMALIDOMIDE (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient meet **ONE** of the following criteria?
   - The patient has AIDS-related Kaposi sarcoma after failing highly active antiretroviral therapy (HAART)
   - The patient is HIV-negative

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **POMALIDOMIDE (Pomalyst)** requires the following rules be met for approval:
   A. You have ONE of the following:
      1. Multiple myeloma (MM: a type of blood cancer)
      2. Kaposi sarcoma (KS: a type of cancer in the lining of lymph or blood vessels)
   B. If you have multiple myeloma, approval also requires:
      1. You are 18 years of age or older
      2. The requested medication will be used in combination with dexamethasone
      3. You have tried at least two drugs including Revlimid (lenalidomide) and a proteasome inhibitor (such as Velcade [bortezomib], Kyprolis [carfilzomib], Ninlaro [ixazomib])
   C. If you have Kaposi sarcoma, approval also requires:
      1. You are 18 years of age or older
      2. You meet ONE of the following:
         a. You have acquired immunodeficiency syndrome (AIDS: a type of immune system disorder caused by virus infection)-related Kaposi sarcoma after failing highly active antiretroviral therapy (HAART: medications used to treat human immunodeficiency virus [HIV: a type of immune disorder])
         b. You are human immunodeficiency virus (HIV)-negative

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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POMALIDOMIDE (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Pomalyst.

REFERENCES

Pomalyst [Prescribing Information]. Summit, NJ: Celgene Corporation; March 2023.

For Part D use only:

POMALIDOMIDE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PONATINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PONATINIB HCL	ICLUSIG	39859		GPI-10 (2153187510)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic myeloid leukemia (CML) (ICD-10 Groups C92.1, C92.2) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a mutational analysis prior to initiation AND Iclusig is appropriate per the NCCN guideline table for treatment recommendations based on BCR-ABL1 mutation profile *(Please see header CML-5 of the current NCCN guidelines)*

   If yes, continue to #2.
   If no, continue to #5.

2. Does the patient have T315I-positive CML (chronic phase, accelerated phase, or blast phase)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Does the patient have chronic phase (CP) chronic myeloid leukemia (CML) **AND** meet the following criterion?
   - The patient has a resistance or intolerance to at least TWO prior kinase inhibitors [e.g., Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Gleevec (imatinib)]

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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PONATINIB (PART D)

GUIDELINES FOR USE (CONTINUED)

4. Does the patient have a diagnosis of accelerated phase (AP) or blast phase (BP) chronic myeloid leukemia (CML) **AND** meet the following criterion?
   - There are no other kinase inhibitors [e.g., Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Gleevec (imatinib)] indicated for the patient

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Does the patient have a diagnosis of Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) (ICD-10 Group C91.0) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

6. Does the patient meet **ONE** of the following criteria?
   - The patient's cancer is positive for the T315I mutation
   - There are no other kinase inhibitors [e.g., Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Gleevec (imatinib)] indicated for the patient
   - The patient is newly diagnosed AND Iclusig will be used in combination with chemotherapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **PONATINIB (Iclusig)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Chronic myeloid leukemia (CML: type of blood cell cancer)
      2. Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL: a type of white blood cell cancer)

   (Denial text continued on next page)

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PONATINIB (PART D)

GUIDELINES FOR USE (CONTINUED)

B. If you have chronic myeloid leukemia, approval also requires:
1. You are 18 years of age or older
2. You had a mutational analysis (a type of test) before starting therapy AND Iclusig is appropriate per the National Comprehensive Cancer Network (NCCN) guideline table for treatment recommendations based on BCR-ABL1 mutation (breakpoint cluster region-Abelson murine leukemia 1; a type of abnormal gene) profile
3. You meet ONE of the following:
   a. You have T315I-positive (a genetic mutation) CML (chronic phase, accelerated phase, or blast phase)
   b. You have chronic phase CML AND have a resistance to or are not able to safely use at least two prior kinase inhibitor treatments such as Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Gleevec (imatinib)
   c. You have accelerated phase or blast phase CML AND there are no other kinase inhibitors, such as Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Gleevec (imatinib), that can be used for your disease

C. If you have Philadelphia chromosome positive acute lymphoblastic leukemia, approval also requires:
1. You are 18 years of age or older
2. You meet ONE of the following:
   a. Your cancer is positive for the T315I mutation (a type of abnormal gene)
   b. There are no other kinase inhibitors treatment, such as Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Gleevec (imatinib), that can be used for your disease
   c. You are newly diagnosed AND Iclusig will be used in combination with chemotherapy

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Iclusig.

REFERENCES
Iclusig [Prescribing Information]. Cambridge, MA: ARIAD Pharmaceuticals, Inc.; March 2024.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PONATINIB (PART D)

For Part D use only:

PONATINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	CHRONIC MYELOID LEUKEMIA (CML): MUTATIONAL ANALYSIS PRIOR TO INITIATION AND ICLUSIG IS APPROPRIATE PER NCCN GUIDELINE TABLE FOR TREATMENT RECOMMENDATIONS BASED ON BCR-ABL1 MUTATION PROFILE.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 01/13
Effective: 07/01/25 Client Approval: 05/25 P&T Approval: 04/24

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PONESIMOD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PONESIMOD	PONVORY	47221		GPI-10 (6240706000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), including clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease, and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of one sphingosine-1-phosphate receptor modulator (e.g., fingolimod, Mayzent [siponimod]) AND one other agent indicated for the treatment of MS (e.g., Tecfidera [dimethyl fumarate], Vumerity [diroximel fumarate])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PONESIMOD (Ponvory)** requires the following rule(s) be met for approval:
   A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease returns and goes away), or active secondary progressive disease (advanced disease)
   B. You are 18 years of age or older
   C. You have tried one sphingosine-1-phosphate receptor modulator (such as fingolimod, Mayzent [siponimod]) AND one other medication indicated for the treatment of multiple sclerosis (such as Tecfidera [dimethyl fumarate], Vumerity [diroximel fumarate])

   (Denial text continued on next page)

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PONESIMOD (PART D)

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ponvory.

REFERENCES

Ponvory [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; June 2024.

For Part D use only:

PONESIMOD (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	RELAPSING FORM OF MULTIPLE SCLEROSIS (MS): TRIAL OF ONE SPHINGOSINE-1-PHOSPHATE RECEPTOR MODULATOR (E.G., FINGOLIMOD, MAYZENT) AND ONE OTHER AGENT INDICATED FOR THE TREATMENT OF MULTIPLE SCLEROSIS.

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 03/21
Client Approval: 06/24
P&T Approval: 01/21

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

POSACONAZOLE-POWDERMIX (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
POSACONAZOLE	NOXAFIL		49744	GPI-14 (11407060003020)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the request for continuation of therapy after the patient was started on posaconazole inthe hospital?

   If yes, **approve for 6 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Is the request for the treatment of invasive aspergillosis (ICD-10 B44.0) and the patient meets **ALL** of the following criteria?
   - The patient is 2 to 17 years of age or older
   - The patient has a contraindication or inability to swallow tablets

   If yes, **approve for 12 weeks by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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POSACONAZOLE-POWDERMIX (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Is the request for prophylaxis of invasive Aspergillus or Candida infections and the patient meets **ALL** of the following criteria?
   - The patient is at high risk of developing these infections due to being severely immunocompromised, such as HSCT recipients with GVHD or has a hematologic malignancy with prolonged neutropenia from chemotherapy
   - The patient is 2 to 17 years of age
   - The patient is unable to swallow tablets

   If yes, **approve for 6 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **POSACONAZOLE-POWDERMIX (Noxafil)** requires the following rule(s) be met for approval:

   A. The request is for ONE of the following:
      1. Continuation of therapy after hospital discharge
      2. Treatment of invasive aspergillosis (type of fungal infection)
      3. Prophylaxis (prevention) of invasive aspergillus or candida infections (types of fungal infection)

   B. If the request is for treatment of invasive Aspergillosis, approval also requires:
      1. You are 2 to 17 years of age
      2. You have a contraindication to (harmful for you to use) or are unable to swallow tablets

   C. If the request is for the prophylaxis of invasive Aspergillus or Candida infections, approval also requires:
      1. You are at high risk of developing these infections due to being severely immunocompromised (low immune system), such as a hematopoietic stem cell transplantation (HSCT: bone marrow transplant) recipient with graft versus host disease (GVHD: a type of immune disorder), or you have a hematologic malignancy (cancer affecting the blood) with prolonged neutropenia (a type of blood condition) from chemotherapy (cancer treatment)
      2. You are 2 to 17 years of age
      3. You are unable to swallow tablets

   D. A request for continuation of therapy after hospital discharge does not require extra criteria

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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POSACONAZOLE-POWDERMIX (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Noxafil.

REFERENCES
Noxafil [Prescribing Information]. Rahway, NJ: Merck & Co., Inc.; January 2026.

For Part D use only:

POSACONAZOLE-POWDERMIX (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	CONTINUATION OF THERAPY AFTER HOSPITAL DISCHARGE, PROPHYLAXIS: 6 MONTHS. TREATMENT: 12 WEEKS.
Other Criteria	PROPHYLAXIS OF INVASIVE ASPERGILLUS AND CANDIDA INFECTION: INABILITY TO SWALLOW TABLETS. CONTINUATION OF THERAPY AFTER HOSPITAL DISCHARGE REQUIRES NO EXTRA CRITERIA. TREATMENT OF INVASIVE ASPERGILLOSIS: CONTRAINDICATION TO OR UNABLE TO SWALLOW TABLETS.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

POSACONAZOLE SUSPENSION (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
POSACONAZOLE	NOXAFIL, POSACONAZOLE		26502	GPI-14 (11407060001820)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the request for **ONE** of the following?
   - Prophylaxis of invasive Aspergillus or Candida infections
   - Treatment oropharyngeal candidiasis (ICD-10 B37.0)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the request for continuation of therapy after the patient was started on posaconazole in the hospital?

   If yes, **approve for 6 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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POSACONAZOLE SUSPENSION (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Is the request for prophylaxis of invasive Aspergillus or Candida infections and the patient meets **ALL** of the following criteria?
   - The patient is 13 years of age or older
   - The patient is at high risk of developing these infections due to being severely immunocompromised, such as HSCT recipients with graft-versus-host disease (GVHD) or those with hematologic malignancies with prolonged neutropenia from chemotherapy
   - The patient is unable to swallow tablets

   If yes, **approve for 6 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

4. Does the patient have a diagnosis of oropharyngeal candidiasis (ICD-10 B37.0) and meet **ALL** of the following criteria?
   - The patient is 13 years of age or older
   - The patient had a trial of or contraindication to fluconazole OR itraconazole

   If yes, **approve for 3 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **POSACONAZOLE SUSPENSION (Noxafil)** requires the following rule(s) be met for approval:
   A. The request is for ONE of the following:
      1. Prophylaxis of invasive Aspergillus or Candida infections (prevention of a type of fungal infection)
      2. Oropharyngeal candidiasis (fungal infection of the throat)

   (Denial text continued on next page)

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POSACONAZOLE SUSPENSION (PART D)

GUIDELINES FOR USE (CONTINUED)

B. If the request is for prophylaxis of invasive Aspergillus or Candida infections, approval also requires:
1. You are 13 years of age or older
2. You are at high risk of developing these infections due to being severely immunocompromised (low immune system), such as a hematopoietic stem cell transplantation (HSCT: bone marrow transplant) recipient with graft versus host disease (GVHD: a type of immune disorder) or having a hematologic malignancy (cancer affecting the blood) with prolonged neutropenia (a type of blood condition) from chemotherapy (cancer treatment)
3. You are unable to swallow tablets

C. If the request is for oropharyngeal candidiasis, approval also requires:
1. You are 13 years of age or older
2. You have tried or have a contraindication to (harmful for you to use) fluconazole OR itraconazole

D. Request for continuation of therapy after hospital discharge does not require extra criteria

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Noxafil.

REFERENCES
Noxafil [Prescribing Information]. Whitehouse Station, NJ: Merck & Co., Inc.; September 2022.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

POSACONAZOLE SUSPENSION (PART D)

For Part D use only:

POSACONAZOLE SUSPENSION (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	OPC: 3 MONTHS. CONTINUATION OF THERAPY AFTER HOSPITAL DISCHARGE, PROPHYLAXIS: 6 MONTHS.
Other Criteria	OROPHARYNGEAL CANDIDIASIS (OPC): TRIAL OF OR CONTRAINDICATION TO FLUCONAZOLE OR ITRACONAZOLE. PROPHYLAXIS OF INVASIVE ASPERGILLUS AND CANDIDA INFECTION: UNABLE TO SWALLOW TABLETS. CONTINUATION OF THERAPY AFTER HOSPITAL DISCHARGE REQUIRES NO EXTRA CRITERIA.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

POSACONAZOLE TABLET (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
POSACONAZOLE	NOXAFIL, POSACONAZOLE		35649	GPI-14 (11407060000620)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
Yes	No	No	Yes	No	No	Yes	No	No	Yes	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the request for **ONE** of the following?
   - Treatment of invasive aspergillosis (ICD-10 B44.0)
   - Prophylaxis of invasive Aspergillus or Candida infections

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the request for continuation of therapy after the patient was started on posaconazole in the hospital?

   If yes, **approve for 6 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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POSACONAZOLE TABLET (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Is the request for the treatment of invasive aspergillosis (ICD-10 B44.0) **AND** the patient meets the following criterion?
   - The patient is 2 years of age or older

   If yes, **approve for 12 weeks by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

4. Is the request for prophylaxis of invasive Aspergillus or Candida infections **AND** the patient meets the following criterion?
   - The patient is 2 years of age or older
   - The patient is at high risk of developing these infections due to being severely immunocompromised, such as HSCT recipients with graft-versus-host disease (GVHD) orthose with hematologic malignancies with prolonged neutropenia from chemotherapy

   If yes, **approve for 6 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **POSACONAZOLE TABLET (Noxafil)** requires the following rule(s) be met for approval:
   A. The request is for ONE of the following:
      1. Treatment of invasive aspergillosis (a type of fungal infection)
      2. Prophylaxis of invasive Aspergillus or Candida infections (prevention of types offungal infections)
   B. If the request is for the treatment of invasive aspergillosis, approval also requires:
      1. You are 2 years of age or older

   (Denial text continued on next page)

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POSACONAZOLE TABLET (PART D)

GUIDELINES FOR USE (CONTINUED)

C. If the request is for prophylaxis of invasive Aspergillus or Candida infections, approval also requires:
1. You are 2 years of age or older
2. You are at high risk of developing these infections due to being severely immunocompromised (low immune system), such as a hematopoietic stem cell transplantation (HSCT: bone marrow transplant) recipient with graft versus host disease (GVHD: a type of immune disorder) or having a hematologic malignancy (cancer affecting the blood) with prolonged neutropenia (a type of blood condition) from chemotherapy (cancer treatment)

D. Request for continuation of therapy after hospital discharge does not require extra criteria

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Noxafil.

REFERENCES
Noxafil [Prescribing Information]. Rahway, NJ: Merck & Co., Inc.; January 2026.

For Part D use only:

POSACONAZOLE TABLET (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	CONTINUATION OF THERAPY AFTER HOSPITAL DISCHARGE, PROPHYLAXIS: 6 MONTHS. TREATMENT: 12 WEEKS.
Other Criteria	N/A

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

POZELIMAB-BBFG BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
POZELIMAB-BBFG	VEOPOZ	49162		GPI-10 (8580507015)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	Yes	No	No	Yes	No	No	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #5.

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POZELIMAB-BBFG BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

If yes, **Refer to plan. (The health plan makes the final payment determination decision)**

- **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
- **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

POZELIMAB-BBFG BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of CD55-deficient protein-losing enteropathy (PLE), also known as CHAPLE disease (ICD-10 D84.1), **AND** meet the following criterion?
   - The patient is 1 year of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **POZELIMAB-BBFG (Veopoz)** requires the following rule(s) be met for approval:
   A. You have CD55-deficient protein-losing enteropathy (PLE, also known as CHAPLE disease [a rare genetic disorder])
   B. You are 1 year of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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POZELIMAB-BBFG BvD (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Veopoz. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Veopoz [Prescribing Information]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; August 2023.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed June 28, 2024].

For Part D use only:

POZELIMAB-BBFG (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 08/23
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 10/23

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PRALATREXATE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PRALATREXATE	FOLOTYN, PRALATREXATE	36644		GPI-10 (2130005400)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory peripheral T-cell lymphoma (PTCL) (ICD-10 Group C84.4)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PRALATREXATE (Folotyn)** requires the following rule(s) be met for approval:
   A. You have relapsed or refractory peripheral T-cell lymphoma (PTCL) (a type of blood cancer that has returned or did not respond to treatment)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Folotyn.

REFERENCES
Folotyn [Prescribing Information]. East Windsor, NJ: Acrotech Biopharma Inc; June 2023.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PRALATREXATE (PART D)

For Part D use only:

PRALATREXATE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
No	No	Yes

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PRALSETINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PRALSETINIB	GAVRETO	46818		GPI-10 (2153575000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a *RET* fusion-positive tumor, as detected by an FDA-approved test

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of advanced or metastatic thyroid cancer (ICD-10 C73) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient has a *RET* fusion-positive tumor
   - The patient requires systemic therapy
   - The patient is radioactive iodine-refractory (if radioactive iodine is appropriate)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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PRALSETINIB (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PRALSETINIB (Gavreto)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of the body)
   2. Advanced or metastatic thyroid cancer (thyroid cancer that has spread to other parts of the body)

B. If you have metastatic non-small cell lung cancer, approval also requires:
   1. You are 18 years of age or older
   2. You have a rearranged during transfection (RET) fusion-positive (a type of gene mutation) tumor, as detected by a Food and Drug Administration (FDA)-approved test

C. If you have advanced or metastatic thyroid cancer, approval also requires:
   1. You are 12 years of age or older
   2. You have a rearranged during transfection (RET) fusion-positive (a type of gene mutation) tumor
   3. You need systemic therapy (treatment that targets the entire body)
   4. You have received treatment with radioactive iodine, and it did not work or is no longer working (if radioactive iodine is appropriate)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Gavreto.

REFERENCES

Gavreto [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; August 2023.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PRALSETINIB (PART D)

For Part D use only:

PRALSETINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

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ADVANTAGE AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PRAMLINTIDE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PRAMLINTIDE ACETATE	SYMLINPEN 60, SYMLINPEN 120	32805		GPI-10 (2715005010)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of type 1 or type 2 diabetes (ICD Groups E08, E09, E10, E11, E13) **AND** meet the following criterion?
   - The patient requires insulin, such as an insulin pump or rapid-acting/short-acting insulin (e.g., Humulin R [insulin regular], Novolin R [insulin regular], Humalog [insulin lispro], Novolog [insulin aspart], Apidra [insulin glulisine]) for glycemic control

     If yes, **approve for 12 months by HICL or GPI-10.**
     APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

     If no, do not approve.

     DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

     Our guideline named **PRAMLINTIDE (SymlinPen)** requires the following rule(s) be met for approval:
     A. You have type 1 or type 2 diabetes (a disorder with high blood sugar)
     B. You require insulin, such as an insulin pump or rapid-acting/short-acting insulin (such as Humulin R [insulin regular], Novolin R [insulin regular], Humalog [insulin lispro], Novolog [insulin aspart], Apidra [insulin glulisine]) to control your blood sugar

     Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ADVANTAGE AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PRAMLINTIDE (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Symlin.

REFERENCES

Symlin [Prescribing Information] Wilmington, DE: AstraZeneca Pharmaceuticals LP; December 2019.

For Part D use only:

PRAMLINTIDE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	TYPE I OR TYPE II DIABETES: REQUIRING INSULIN OR CONTINUOUS INSULIN INFUSION (INSULIN PUMP) FOR GLYCEMIC CONTROL

Core	Advantage	Plus
No	Yes	Yes

Part D Effective: 01/01/25 Created: 05/05
Commercial Effective: N/A Client Approval: 06/24 P&T Approval: 11/16

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PROGESTERONE GEL DvE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PROGESTERONE MICRONIZED	CRINONE		96805 63011	GPI-10 (5537006000)	

This is a DvE drug requiring a payment determination for 'Part D' or 'Not Part D'.

PAYMENT DETERMINATION CRITERIA

1. Does the patient have a diagnosis of secondary amenorrhea (ICD-10 N91.1)?

   If yes, **set CMS_DVE_OVR to 'D', and approve for 12 months by GPID or GPI-10. Document in the PA comments: Part D Determination Override.**

   If no, **set CMS_DVE_OVR to 'E', and approve for 12 months by GPID or GPI-10. Document in the PA comments: Payment Determination Override. This is not a Part D indication.**

   NOTE: If the claim rejects after analyzing, then follow the clinical authorization process within the HQ notes.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PROGESTERONE GEL (Crinone)** requires the following rule(s) be met for approval:
   A. You have secondary amenorrhea (absence of a period in a woman who previously had regular periods)

RATIONALE
To limit the coverage of Crinone 4% and 8% to the Medicare Part D covered indication of secondary amenorrhea and exclude coverage for supplementation or replacement as part of an Assisted Reproductive Technology ("ART") treatment for infertile women with progesterone deficiency.

REFERENCES
Crinone [Prescribing Information]. Parsippany, NJ: Watson Pharma, Inc.. November 2017.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements. Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf. [Accessed March 2026].

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PROGESTERONE GEL DvE (PART D)

For Part D use only:

PROGESTERONE GEL DvE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	PART D DOES NOT COVER THIS DRUG WHEN USED FOR SUPPLEMENTATION OR REPLACEMENT AS PART OF AN ASSISTED REPRODUCTIVE TECHNOLOGY (ART) TREATMENT FOR INFERTILE WOMEN WITH PROGESTERONE DEFICIENCY.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 11/15
Effective: 03/09/26 Client Approval: 03/26 P&T Approval: N/A

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PYRIMETHAMINE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PYRIMETHAMINE	DARAPRIM, PYRIMETHAMINE		42930	GPI-10 (1300004000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

1. Does the patient have a diagnosis of toxoplasmosis (ICD-10 Group B58) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an infectious disease specialist
   - The requested medication will be used concurrently with a sulfonamide (e.g., sulfadiazine)

   If yes, **approve for 8 weeks by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PYRIMETHAMINE (Daraprim)** requires the following rules be met for approval:
   A. You have toxoplasmosis (disease from a parasite infection)
   B. Therapy is prescribed by or in consultation with an infectious disease specialist (a doctor that specializes in the treatment of infections)
   C. You will use the requested medication concurrently (at the same time) with a sulfonamide (such as sulfadiazine)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PYRIMETHAMINE (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of toxoplasmosis (ICD-10 Group B58) and meet **ONE** of the following criteria?
   - The patient has persistent clinical disease (headache, neurological symptoms, or fever) AND persistent radiographic disease (one or more mass lesions on brain imaging)
   - The patient's CD4 count is less than 200 cells/mm(3) and the patient is currently taking ART (anti-retroviral therapy), if HIV positive

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PYRIMETHAMINE (Daraprim)** requires the following rules to be met for renewal:
   A. You have toxoplasmosis (disease from a parasite infection)
   B. You meet ONE of the following:
      1. You have persistent clinical disease (headache, neurological symptoms, or fever) AND persistent radiographic disease (one or more mass lesions on brain imaging)
      2. If you are human immunodeficiency virus (HIV: a type of immune disorder) positive, your CD4 (type of white blood cell) count is less than 200 cells/mm(3) AND you are currently taking anti-retroviral therapy (ART: drugs that treat HIV)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Daraprim.

REFERENCES

Daraprim [Prescribing Information]. New York, New York: Vyera Pharmaceuticals, LLC.; November 2021.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PYRIMETHAMINE (PART D)

For Part D use only:

PYRIMETHAMINE (PART D)	
Covered uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	TOXOPLASMOSIS: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH AN INFECTIOUS DISEASE SPECIALIST.
Coverage Duration	TOXOPLASMOSIS: INITIAL: 8 WEEKS, RENEWAL: 6 MOS.
Other Criteria	TOXOPLASMOSIS: RENEWAL: ONE OF THE FOLLOWING: (1) PERSISTENT CLINICAL DISEASE (HEADACHE, NEUROLOGICAL SYMPTOMS, OR FEVER) AND PERSISTENT RADIOGRAPHIC DISEASE (ONE OR MORE MASS LESIONS ON BRAIN IMAGING), OR (2) CD4 COUNT LESS THAN 200 CELLS/MM3 AND CURRENTLY TAKING AN ANTI-RETROVIRAL THERAPY IF HIV POSITIVE.

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 10/16
Client Approval: 06/24
P&T Approval: 01/20

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

QUININE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
QUININE SULFATE	QUALAQUIN, QUININE SULFATE	04142		GPI-10 (1300006010)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of malaria (ICD-10 B50.9, B54)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **QUININE (Qualaquin)** requires the following rule(s) be met for approval:
   A. You have malaria (an infection caused by a parasite)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Qualaquin.

REFERENCES
Qualaquin [Prescribing Information]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; June 2019.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

QUININE (PART D)

For Part D use only:

QUININE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Created: 11/07
Effective: 01/01/25 Client Approval: 08/24 P&T Approval: 11/14

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

QUIZARTINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
QUIZARTINIB DIHYDROCHLORIDE	VANFLYTA	49083		GPI-10 (2153304710)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have newly diagnosed acute myeloid leukemia (AML) (ICD-10 Group C92.0)and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer is FLT3 internal tandem duplication (ITD) positive, as detected by a Food and Drug Administration (FDA)-approved test

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - Vanflyta will be used in combination with standard cytarabine and anthracycline (e.g., daunorubicin, idarubicin) as induction therapy, followed by use with cytarabine as consolidation therapy
   - Vanflyta will be used as maintenance monotherapy following consolidation chemotherapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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QUIZARTINIB (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **QUIZARTINIB (Vanflyta)** requires the following rule(s) be met for approval:

A. You have newly diagnosed acute myeloid leukemia (AML: a type of blood cancer)
B. You are 18 years of age or older
C. Your cancer is FMS-like tyrosine kinase 3 internal tandem duplication (FLT3-ITD: a type of mutation) positive, as detected by a Food and Drug Administration (FDA)- approved test
D. You meet ONE of the following:
    1. Vanflyta will be used in combination with standard cytarabine and anthracycline (such as daunorubicin, idarubicin) as induction therapy (a type of therapy to treat cancer), followed by use with cytarabine as consolidation therapy (type of therapy to treat cancer)
    2. Vanflyta will be used as maintenance monotherapy (one drug treatment) following consolidation chemotherapy (treatment following initial therapy)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vanflyta.

REFERENCES

Vanflyta [Prescribing Information]. Basking Ridge, NJ: Daiichi Sankyo, Inc.; July 2023.

For Part D use only:

QUIZARTINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 08/23
Effective: 01/01/25 Client Approval: 08/24 P&T Approval: 10/23

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RABIES VACCINE BVD DETERMINATION (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RABIES VACCINE (PCEC)/PF	RABAVERT	35580		GPI-10 (1710007020)	
RABIES VACCINE HUMAN DIPLOID/PF	IMOVAX	04199		GPI-10 (1710007000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

NOTE: This PA is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

GUIDELINES FOR USE

1. Is this drug to be administered as prophylaxis to a member as a result of being exposed to rabies (for example, post-exposure prophylaxis)?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B. (Deny under Part D before approving under Part B. Populate the B vs. D field with "B" in the PA override field)**

   If no, **approve for 12 months by HICL or GPI-10 under Part D. (Populate the B vs. D field with "D" in the PA override field)**

RATIONALE

Rabies vaccine requires a Part B vs. Part D determination. The vaccine is Part D for pre-exposure vaccination. The vaccine is Part B if used for post exposure prophylaxis against rabies in all age groups.

REFERENCES

Medicare Prescription Drug Benefit Manual Chapter 6 – Part D Drugs and Formulary Requirements, Appendix C- Summary of Coverage Policy Medicare Part B Versus Part D Coverage Issues. Rev 10, 02-19-10. Available at: http://www.cms.gov/PrescriptionDrugCovContra/12_PartDManuals.asp. [Accessed July 11, 2024].

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RABIES VACCINE BVD DETERMINATION (PART D)

For Part D use only:

RABIES VACCINE BVD DETERMINATION (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	PART D DOES NOT COVER THIS DRUG FOR PROPHYLAXIS FOR PATIENTS EXPOSED TO RABIES
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A
Quantity Limit (from Formulary ASCII file)	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25 Created: 11/07
Commercial Effective: N/A Client Approval: 08/24 P&T Approval: 05/17

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RAMUCIRUMAB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RAMUCIRUMAB	CYRAMZA	41109		GPI-10 (2133507000)	

Do not review Part D guidelines with physicians; if the caller wished to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced or metastatic gastric cancer or gastro-esophageal junction (GEJ) adenocarcinoma (ICD-10 Group C16) and meet **ALL** of the following criteria?
   - Cyramza will be used as a single agent or in combination with paclitaxel
   - The patient has experienced disease progression on or after prior fluoropyrimidine-containing chemotherapy (e.g., fluorouracil [5-FU], capecitabine, floxuridine) OR platinum-containing chemotherapy (e.g., cisplatin, oxaliplatin, carboplatin)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

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RAMUCIRUMAB (PART D)

GUIDELINES FOR USE (CONTINUED)

2. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ONE** of the following criteria?
   - Cyramza will be used in combination with docetaxel AND the patient has experienced disease progression on or after platinum-based chemotherapy (e.g., cisplatin, oxaliplatin, carboplatin)
   - Cyramza will be used in combination with docetaxel AND the patient has an EGFR or ALK genomic tumor aberration and had disease progression on an FDA-approved therapy for these aberrations (e.g., Tarceva [erlotinib], Gilotrif [afatinib], Xalkori [crizotinib], Zykadia [ceritinib]) prior to receiving Cyramza
   - Cyramza will be used in combination with Tarceva [erlotinib] AND the patient's tumor(s) have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Does the patient have a diagnosis of metastatic colorectal cancer (mCRC) (ICD-10 C19) and meet **ALL** of the following criteria?
   - Cyramza will be used in combination with FOLFIRI (irinotecan, folinic acid, and 5-fluorouracil)
   - The patient has experienced disease progression on or after prior therapy with bevacizumab, oxaliplatin, and a fluoropyrimidine (e.g., 5-fluorouracil, capecitabine)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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RAMUCIRUMAB (PART D)

GUIDELINES FOR USE (CONTINUED)

4. Does the patient have a diagnosis of hepatocellular carcinoma (HCC) (ICD-10 C22.0) and meet **ALL** of the following criteria?
   - The patient has an alpha fetoprotein (AFP) greater than or equal to 400 ng/mL
   - The patient has been treated with Nexavar (sorafenib)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RAMUCIRUMAB (Cyramza)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Advanced or metastatic gastric cancer or gastro-esophageal junction (GEJ) adenocarcinoma (a type of digestive system cancer that has spread to other parts of the body)
      2. Metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of your body)
      3. Metastatic colorectal cancer (mCRC: a type of colon or rectum cancer that has spread to other parts of the body)
      4. Hepatocellular carcinoma (HCC: a type of liver cancer)

   B. If you have advanced or metastatic gastric cancer or gastro-esophageal junction adenocarcinoma, approval also requires:
      1. Cyramza will be used as a single agent or in combination with paclitaxel
      2. You have experienced disease progression (worsening) on or after prior fluoropyrimidine-containing chemotherapy (such as fluorouracil [5-FU], capecitabine, floxuridine) OR platinum-containing chemotherapy (such as cisplatin, oxaliplatin, carboplatin)

   (Denial text continued on next page)

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RAMUCIRUMAB (PART D)

GUIDELINES FOR USE (CONTINUED)

C. If you have metastatic non-small cell lung cancer, approval also requires ONE of the following:
1. Cyramza will be used in combination with docetaxel and you meet ONE of the following:
   a. You have experienced disease progression (worsening) on or after platinum-based chemotherapy (such as cisplatin, oxaliplatin, carboplatin)
   b. You have an epidermal growth factor receptor (EGFR: type of protein) or anaplastic lymphoma kinase (ALK: type of enzyme) genomic tumor abnormality AND your disease has gotten worse on a Food and Drug Administration (FDA)-approved therapy (such as Tarceva [erlotinib], Gilotrif [afatinib], Xalkori [crizotinib], Zykadia [ceritinib]) prior to receiving Cyramza
2. Cyramza will be used in combination with Tarceva (erlotinib) AND your tumor(s) have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations

D. If you have metastatic colorectal cancer, approval also requires:
1. Cyramza will be used in combination with FOLFIRI (drug combination of irinotecan, folinic acid, and 5-fluorouracil)
2. You have experienced disease progression (worsening) on or after prior therapy with bevacizumab, oxaliplatin, and a fluoropyrimidine (such as 5-fluorouracil, capecitabine)

E. If you have hepatocellular carcinoma, approval also requires:
1. You have an alpha fetoprotein (AFP) greater than or equal to 400 ng/mL
2. You have been treated with Nexavar (sorafenib)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Cyramza.

REFERENCES
Cyramza [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; March 2022.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RAMUCIRUMAB (PART D)

For Part D use:

RAMUCIRUMAB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 04/14
Effective: 01/01/26 Client Approval: 01/26 P&T Approval: 07/20

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RAVULIZUMAB-CWVZ (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RAVULIZUMAB-CWVZ	ULTOMIRIS	45548		GPI-10 (8580508020)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) (ICD-10 D59.5) and meet **ALL** of the following criteria?
   - The patient is 1 month of age or older
   - Therapy is prescribed by or in consultation with a hematologist
   - The patient's diagnosis is confirmed by flow cytometry that shows PNH granulocyte clone size of at least 10% AND at least 2 different GPI-protein deficiencies (e.g., CD55, CD59) on at least 2 cell lineages (e.g., erythrocytes, granulocytes)
   - Ultomiris will NOT be used concurrently with another C5 complement inhibitor therapy (e.g., Soliris [eculizumab], Piasky [crovalimab-akkz]), C3 complement inhibitor (e.g., Empaveli [pegcetacoplan]), or factor B inhibitor (e.g., Fabhalta [iptacopan])

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of atypical hemolytic uremic syndrome (aHUS) (ICD-10 D59.32, D59.39) **AND** meet the following criterion?
   - The patient is 1 month of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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RAVULIZUMAB-CWVZ (PART D)

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of generalized myasthenia gravis (gMG) (ICD-10 Group G70.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is anti-acetylcholine receptor (AChR) antibody-positive
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient is in Myasthenia Gravis Foundation of America class II, III, or IV
   - The patient had a trial of or contraindication to ONE corticosteroid (e.g., prednisone)
   - The patient had a trial of or contraindication to ONE non-steroidal immunosuppressive therapy (e.g., azathioprine, cyclophosphamide, methotrexate)
   - Ultomiris will NOT be used concurrently with another neonatal Fc receptor blocker (e.g., Rystiggo [rozanolixizumab-noli], Vyvgart [efgartigimod alfa-fcab]) or complement inhibitor (e.g., Soliris [eculizumab], Zilbrysq [zilucoplan]) for the treatment of gMG

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

4. Does the patient have a diagnosis of neuromyelitis optica spectrum disorder (NMOSD) (ICD-10 G36.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a positive serologic test for anti-aquaporin-4 (AQP4) antibodies
   - Therapy is prescribed by or in consultation with a neurologist or ophthalmologist
   - Ultomiris will NOT be used concurrently with other NMOSD agents (e.g., Rituxan [rituximab], Enspryng [satralizumab-mwge], Uplizna [inebilizumab-cdon], Soliris [eculizumab])

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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RAVULIZUMAB-CWVZ (PART D)

INITIAL CRITERIA (CONTINUED)

5. Does the patient have at least **ONE** of the following core clinical characteristics?
   - Optic neuritis
   - Acute myelitis
   - Area postrema syndrome
   - Acute brainstem syndrome
   - Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions
   - Symptomatic cerebral syndrome with NMOSD-typical brain lesions

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RAVULIZUMAB-CWVZ (Ultomiris)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
      2. Atypical hemolytic uremic syndrome (aHUS: a rare blood disorder)
      3. Generalized myasthenia gravis (gMG: a chronic autoimmune disorder)
      4. Neuromyelitis optica spectrum disorder (NMOSD: a type of brain disorder)

   B. If you have paroxysmal nocturnal hemoglobinuria, approval also requires:
      1. You are 1 month of age or older
      2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
      3. You will NOT use Ultomiris concurrently (at the same time) with another C5 complement inhibitor therapy (such as Soliris [eculizumab],Piasky [crovalimab-akkz]), C3 complement inhibitor (such as Empaveli [pegcetacoplan]), or factor B inhibitor (such as Fabhalta [iptacopan])
      4. Your PNH diagnosis is confirmed by ALL of the following through flow cytometry (test to measure characteristics of cells):
         a. You have at least 2 different GPI-protein deficiencies (missing a certain type of protein, such as CD55, CD59) on at least 2 cell lineages (types of cells such as erythrocytes [red blood cells], granulocytes [a type of white blood cell])
         b. PNH granulocyte clone size is at least 10%

   (Initial denial text continued on next page)

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RAVULIZUMAB-CWVZ (PART D)

INITIAL CRITERIA (CONTINUED)

C. If you have atypical hemolytic uremic syndrome, approval also requires:
1. You are 1 month of age or older

D. If you have generalized myasthenia gravis, approval also requires:
1. You are 18 years of age or older
2. You are anti-acetylcholine receptor (AChR) antibody-positive (an indicator of myasthenia gravis)
3. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor)
4. You are in Myasthenia Gravis Foundation of America class II, III, or IV (indicates severity of disease)
5. You have tried or have a contraindication to (harmful for you to use) ONE corticosteroid (such as prednisone)
6. You have tried or have a contraindication to (harmful for you to use) ONE non-steroidal immunosuppressive therapy (treatment that lowers body's immune system activity, such as azathioprine, cyclophosphamide, methotrexate)
7. You will NOT use Ultomiris concurrently (at the same time) with another neonatal Fc receptor blocker (such as Rystiggo [rozanolixizumab-noli], Vyvgart [efgartigimod alfa-fcab]) or complement inhibitor (such as Soliris [eculizumab], Zilbrysq [zilucoplan]) for the treatment of generalized myasthenia gravis

E. If you have neuromyelitis optica spectrum disorder, approval also requires:
1. You are 18 years of age or older
2. You have a positive serologic (blood) test for anti-aquaporin-4 (AQP4: a type of protein) antibodies
3. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor) or ophthalmologist (a type of eye doctor)
4. You have at least ONE of the following core clinical characteristics:
   a. Optic neuritis (type of brain disorder)
   b. Acute myelitis (type of brain disorder)
   c. Area postrema syndrome (type of brain disorder)
   d. Acute brainstem syndrome (type of brain disorder)
   e. Symptomatic narcolepsy (type of sleep condition) or acute diencephalic clinical syndrome (type of brain disorder) with NMOSD-typical diencephalic magnetic resonance imaging (MRI: a type of imaging lab) lesions (affected areas)
   f. Symptomatic cerebral syndrome with NMOSD-typical brain lesions
5. You will NOT use Ultomiris concurrently (at the same time) with other neuromyelitis optica spectrum disorder (NMOSD) medications (such as Rituxan [rituximab], Enspryng [satralizumab-mwge], Uplizna [inebilizumab-cdon], Soliris [eculizumab])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RAVULIZUMAB-CWVZ (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) (ICD-10 D59.5) and meet **ALL** of the following criteria?
   - The patient has had clinical benefit (e.g., reduction in number of blood transfusions, improvement/stabilization of lactate dehydrogenase and hemoglobin levels) compared to baseline
   - Ultomiris will NOT be used concurrently with another C5 complement inhibitor therapy (e.g., Soliris [eculizumab], Piasky [crovalimab-akkz]), C3 complement inhibitor (e.g., Empaveli [pegcetacoplan]), or factor B inhibitor (e.g., Fabhalta [iptacopan])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of atypical hemolytic uremic syndrome (aHUS) (ICD-10 D59.32, D59.39)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Does the patient have a diagnosis of generalized myasthenia gravis (gMG) (ICD-10 Group G70.0) and meet **ALL** of the following criteria?
   - The patient has had clinical benefit compared to baseline (e.g., Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool)
   - Ultomiris will NOT be used concurrently with another neonatal Fc receptor blocker (e.g., Rystiggo [rozanolixizumab-noli], Vyvgart [efgartigimod alfa-fcab]) or complement inhibitor (e.g., Soliris [eculizumab], Zilbrysq [zilucoplan]) for the treatment of gMG

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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RAVULIZUMAB-CWVZ (PART D)

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of neuromyelitis optica spectrum disorder (NMOSD) (ICD-10 G36.0) and meet **ALL** of the following criteria?
   - The patient has shown clinical benefit (e.g., reduction in relapse frequency from baseline, decrease in NMOSD-related hospitalizations) while on therapy with Ultomiris
   - Ultomiris will NOT be used concurrently with other NMOSD agents (e.g., Rituxan [rituximab], Enspryng [satralizumab-mwge], Uplizna [inebilizumab-cdon], Soliris [eculizumab])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RAVULIZUMAB-CWVZ (Ultomiris)** requires the following rule(s) be met for renewal:

   A. You have ONE of the following:
      1. Paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
      2. Atypical hemolytic uremic syndrome (aHUS: a rare blood disorder)
      3. Generalized myasthenia gravis (gMG: a chronic autoimmune disorder)
      4. Neuromyelitis optica spectrum disorder (NMOSD: a type of brain disorder)

   B. If you have paroxysmal nocturnal hemoglobinuria, renewal also requires:
      1. You have had clinical benefit (such as a reduction in number of blood transfusions [adding blood to the body], improvement/stabilization of lactate dehydrogenase [an enzyme] and hemoglobin levels) compared to baseline (before treatment)
      2. You will NOT use Ultomiris concurrently (at the same time) with another C5 complement inhibitor therapy (such as Soliris [eculizumab], Piasky [crovalimab-akkz]), C3 complement inhibitor (such as Empaveli [pegcetacoplan]), or factor B inhibitor (such as Fabhalta [iptacopan])

   C. If you have generalized myasthenia gravis, renewal also requires:
      1. You have had clinical benefit compared to baseline (such as shown by the Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool)
      2. You will NOT use Ultomiris concurrently (at the same time) with another neonatal Fc receptor blocker (such as Rystiggo [rozanolixizumab-noli], Vyvgart [efgartigimod alfa-fcab]) or complement inhibitor (such as Soliris [eculizumab], Zilbrysq [zilucoplan]) for the treatment of generalized myasthenia gravis

   (Renewal denial text continued on next page)

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RAVULIZUMAB-CWVZ (PART D)

RENEWAL CRITERIA (CONTINUED)

D. If you have neuromyelitis optica spectrum disorder, renewal also requires:

1. You have shown clinical benefit (such as a reduction in relapse frequency from baseline, a decrease in NMOSD-related hospitalizations) while on therapy with Ultomiris
2. You will NOT use Ultomiris concurrently (at the same time) with other neuromyelitis optica spectrum disorder (NMOSD) medications (such as Rituxan [rituximab], Enspryng [satralizumab-mwge], Uplizna [inebilizumab-cdon], Soliris [eculizumab])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ultomiris.

REFERENCES

Ultomiris [Prescribing Information]. Boston, MA: Alexion Pharmaceuticals, Inc.; September 2024.

For Part D use only:

RAVULIZUMAB-CWVZ (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	INITIAL: PAROXYSMAL NOCTURNAL HEMOGLOBINURIA (PNH): DIAGNOSIS CONFIRMED VIA FLOW CYTOMETRY: 1) AT LEAST TWO DIFFERENT GPI PROTEIN DEFICIENCIES ON AT LEAST TWO CELL LINEAGES, AND 2) PNH GRANULOCYTE CLONE SIZE OF AT LEAST 10 PERCENT.
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: PNH: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST. GENERALIZED MYASTHENIA GRAVIS (GMG): PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST. NEUROMYELITIS OPTICA SPECTRUM DISORDER (NMOSD): PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST OR OPHTHALMOLOGIST.
Coverage Duration	INITIAL: PNH, GMG: 6 MONTHS, AHUS, NMOSD: 12 MONTHS. RENEWAL (ALL INDICATIONS): 12 MONTHS.
Other Criteria	INITIAL: PNH: NO CONCURRENT USE WITH ANOTHER C5 COMPLEMENT INHIBITOR THERAPY, C3 COMPLEMENT INHIBITOR, OR FACTOR B INHIBITOR. GMG: 1) MYASTHENIA GRAVIS FOUNDATION OF AMERICA CLASS II, III, OR IV, 2)

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	TRIAL OF OR CONTRAINDICATION TO ONE CORTICOSTEROID, 3) TRIAL OF OR CONTRAINDICATION TO ONE NON-STEROIDAL IMMUNOSUPPRESSIVE THERAPY, AND 4) NO CONCURRENT USE WITH ANOTHER NEONATAL FC RECEPTOR BLOCKER OR COMPLEMENT INHIBITOR FOR GMG. NMOSD: 1) HAS ONE CORE CLINICAL CHARACTERISTIC: OPTIC NEURITIS, ACUTE MYELITIS, AREA POSTREMA SYNDROME, ACUTE BRAINSTEM SYNDROME, SYMPTOMATIC NARCOLEPSY OR ACUTE DIENCEPHALIC CLINICAL SYNDROME WITH NMOSD-TYPICAL DIENCEPHALIC MRI LESIONS, OR SYMPTOMATIC CEREBRAL SYNDROME WITH NMOSD-TYPICAL BRAIN LESIONS, AND 2) NO CONCURRENT USE WITH OTHER NMOSD AGENTS. RENEWAL: PNH: 1) CLINICAL BENEFIT COMPARED TO BASELINE, AND 2) NO CONCURRENT USE WITH ANOTHER C5 COMPLEMENT INHIBITOR THERAPY, C3 COMPLEMENT INHIBITOR, OR FACTOR B INHIBITOR. GMG: 1) CLINICAL BENEFIT COMPARED TO BASELINE, AND 2) NO CONCURRENT USE WITH ANOTHER NEONATAL FC RECEPTOR BLOCKER OR COMPLEMENT INHIBITOR FOR GMG. NMOSD: 1) HAS SHOWN CLINICAL BENEFIT, AND 2) NO CONCURRENT USE WITH OTHER NMOSD AGENTS.

Created: 01/19
Effective: 01/01/26 Client Approval: 11/25 P&T Approval: 10/25

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

REGORAFENIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
REGORAFENIB	STIVARGA	39665		GPI-10 (2153305000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic colorectal cancer (CRC) (ICD-10 C19) and meet **ALL** of the following criteria?
   - The patient has received previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy regimen (e.g., FOLFOX, FOLFIRI, FOLFOXIRI, CapeOx, infusional 5-FU/LV, capecitabine)
   - The patient has received previous treatment with an anti-VEGF therapy (e.g., Avastin [bevacizumab], Zaltrap [ziv-aflibercept])

   If yes, continue to #2.
   If no, continue to #4.

2. Is the patient's metastatic colorectal cancer RAS wild-type (mutation negative)?

   If yes, continue to #3**.**
   If no, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

3. Has the patient received previous treatment with an anti-EGFR therapy (e.g., Erbitux [cetuximab], Vectibix [panitumumab])?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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REGORAFENIB (PART D)

GUIDELINES FOR USE (CONTINUED)

4. Does the patient have a diagnosis of locally advanced, unresectable, or metastatic gastrointestinal stromal tumor (GIST) (ICD-10 Group C49.A) **AND** meet the following criterion?
   - The patient has received previous treatment with Gleevec (imatinib) and Sutent (sunitinib)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Does the patient have a diagnosis of hepatocellular carcinoma (HCC) (ICD-10 C22.0) **AND** meet the following criterion?
   - The patient has received previous treatment with Nexavar (sorafenib)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **REGORAFENIB (Stivarga)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Metastatic colorectal cancer (CRC) (a type of digestive cancer that has spread to other parts of the body)
      2. Locally advanced, unresectable, or metastatic gastrointestinal stromal tumor (GIST) (a type of digestive tumor that has spread from where it started to nearby tissue or lymph nodes, is unable to be removed by surgery, or has spread to other parts of the body)
      3. Hepatocellular carcinoma (HCC: a type of liver cancer)
   B. For the diagnosis of metastatic colorectal cancer, approval requires:
      1. You had previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy such as FOLFOX, FOLFIRI, FOLFOXIRI, CapeOx, infusional 5-FU/LV, capecitabine
      2. You had previous treatment with an anti-VEGF therapy such as Avastin (bevacizumab), Zaltrap (ziv-aflibercept)
      3. If you have RAS wild-type (a type of gene that has not mutated) metastatic colorectal cancer**,** approval also requires you had previous treatment with an anti-EGFR therapy such as Erbitux (cetuximab), Vectibix (panitumumab)
   (Denial text continued on next page)

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REGORAFENIB (PART D)

GUIDELINES FOR USE (CONTINUED)

C. For the diagnosis of locally advanced, unresectable, or metastatic gastrointestinal stromal tumor, approval requires:
1. You had previous treatment with Gleevec (imatinib) and Sutent (sunitinib)

D. For the diagnosis of hepatocellular carcinoma, approval requires:
1. You had previous treatment with Nexavar (sorafenib)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Stivarga.

REFERENCES
Stivarga [Prescribing Information]. Wayne, NJ: Bayer HealthCare Pharmaceuticals Inc, December 2020.

For Part D use only:

REGORAFENIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Created: 11/07
Effective: 01/01/25 Client Approval: 08/24 P&T Approval: 07/17

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STANDARD PART D
PRIOR AUTHORIZATION GUIDELINES

RELACORILANT (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RELACORILANT	LIFYORLI	51244		GPI-10 (2140536500)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of epithelial ovarian, fallopian tube, or primary peritoneal cancer (ICD-10 Groups C56, C57.0, C48, C79.6) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer is platinum-resistant
   - Lifyorli will be used in combination with Abraxane (nab-paclitaxel)
   - The patient has received one to three prior systemic treatment regimens, at least one of which included Avastin (bevacizumab)

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.

   INITIAL DENIAL TEXT: Our guideline named **RELACORILANT (Lifyorli)** requires the following rule(s) be met for approval:
   A. You have epithelial ovarian, fallopian tube, or primary peritoneal cancer (type of reproductive system or abdominal tissue cancer)
   B. You are 18 years of age or older
   C. Your cancer is platinum-resistant (resistant to medications such as paclitaxel, docetaxel, cisplatin, carboplatin)
   D. Lifyorli will be used in combination with Abraxane (nab-paclitaxel)
   E. You have received one to three prior systemic treatment regimens (treatment that targets the entire body), at least one of which included Avastin (bevacizumab)

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STANDARD PART D
PRIOR AUTHORIZATION GUIDELINES

RELACORILANT (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of epithelial ovarian, fallopian tube, or primary peritoneal cancer (ICD-10 Groups C56, C57.0, C48, C79.6) and meet **ALL** of the following criteria?
   - The patient has shown clinical benefit (radiographic response, stable disease)
   - The patient will continue Abraxane (nab-paclitaxel) therapy

   If yes, **approve for 12 months by HICL or GPI-10**.
   If no, do not approve.

   RENEWAL DENIAL TEXT: Our guideline named **RELACORILANT (Lifyorli)** requires the following rule(s) be met for renewal:
   A. You have epithelial ovarian, fallopian tube, or primary peritoneal cancer (type of reproductive system or abdominal tissue cancer)
   B. You have shown clinical benefit (radiographic [imaging] response, stable disease)
   C. You will continue Abraxane (nab-paclitaxel) therapy

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Lifyorli.

REFERENCES
Lifyorli [Prescribing Information]. Redwood City, CA: Corcept Therapeutics Inc.; March 2026.

For Part D use only:

RELACORILANT (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	RENEWAL: 1) CLINICAL BENEFIT WHILE ON THERAPY, AND 2) CONTINUATION OF NAB-PACLITAXEL THERAPY.

Created: 07/26
Effective: 08/01/26 DMC Approval: 07/14/26

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RELUGOLIX (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RELUGOLIX	ORGOVYX	47035		GPI-10 (2140557000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced prostate cancer (ICD-10 C61) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RELUGOLIX (Orgovyx)** requires the following rule(s) be met for approval:
   A. You have advanced prostate cancer (prostate cancer has spread to other nearby tissue or organs)
   B. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Orgovyx.

REFERENCES
Orgovyx [Prescribing Information]. Brisbane, CA: Myovant Sciences, Inc.; December 2020.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RELUGOLIX (PART D)

For Part D use only:

RELUGOLIX (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Created: 12/20
Effective: 01/01/25 Client Approval: 08/24 P&T Approval: 01/21

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RELUGOLIX-ESTRADIOL-NORETHINDRONE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RELUGOLIX/ ESTRADIOL/ NORETHINDRONE ACETATE	MYFEMBREE	47392		GPI-10 (2499350380)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

************Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Has the patient received a total of 24 months cumulative treatment with Myfembree?

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, continue to #2.

2. Is the request for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) (ICD-10 D25.9) and the patient meets **ALL** the following criteria?
   - The patient is 18 years of age or older
   - The patient is a premenopausal woman
   - Therapy is prescribed by or in consultation with an obstetrician or gynecologist (OB/GYN)
   - The patient had a trial and failure of or contraindication to TWO agents from the following: oral tranexamic acid, contraceptive preparations (e.g., oral contraceptive, levonorgestrel intra-uterine device [e.g., Mirena, Kyleena, Skyla, Liletta] or other forms of contraceptive)

   If yes, **approve for 6 months by HICL or GPI-10.**

   If no, continue to #3.

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RELUGOLIX-ESTRADIOL-NORETHINDRONE (PART D)

INITIAL CRITERIA (CONTINUED)

3. Is the request for the management of moderate to severe pain associated with endometriosis (ICD-10 R52 and Group N80) and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is a premenopausal woman
   - Therapy is prescribed by or in consultation with an obstetrician or gynecologist (OB/GYN)
   - Myfembree will NOT be used concurrently with another GnRH-modulating agent (e.g., Orilissa [elagolix], Lupron Depot [leuprolide], Synarel [nafarelin])

   If yes, **approve for 6 months by HICL or GPI-10.**

   If no, do not approve.

   INITIAL DENIAL TEXT:

   Our guideline named **RELUGOLIX-ESTRADIOL-NORETHINDRONE (Myfembree)** requires the following rule(s) be met for approval:

   A. The request is for ONE of the following:
      1. Management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids: non-cancerous growths in the uterus)
      2. Management of moderate to severe pain associated with endometriosis (condition affecting the uterus)

   B. If the request is for management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids), approval also requires:
      1. You are 18 years of age or older
      2. You are a premenopausal (before menopause) woman
      3. Therapy is prescribed by or in consultation with an obstetrician or gynecologist (OB/GYN: a type of women's health doctor)
      4. You have tried and failed or have a contraindication to (harmful for you to use) TWO medications from the following: oral tranexamic acid, contraceptive preparations (such as oral contraceptive, levonorgestrel intra-uterine device [such as Mirena, Kyleena, Skyla, Liletta], or other forms of contraceptive)
      5. You have not received a total of 24 months cumulative treatment with Myfembree

   (Initial denial text continued on next page)

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RELUGOLIX-ESTRADIOL-NORETHINDRONE (PART D)

INITIAL CRITERIA (CONTINUED)

C. If the request is for management of moderate to severe pain associated with endometriosis, approval also requires:

1. You are 18 years of age or older
2. You are a premenopausal (before menopause) woman
3. Therapy is prescribed by or in consultation with an obstetrician or gynecologist (OB/GYN: a type of women's health doctor)
4. Myfembree will NOT be used concurrently (at the same time) with another GnRH-modulating agent (such as Orilissa [elagolix], Lupron Depot [leuprolide], Synarel [nafarelin])
5. You have not received a total of 24 months cumulative (total) treatment with Myfembree

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RELUGOLIX-ESTRADIOL-NORETHINDRONE (PART D)

RENEWAL CRITERIA

1. Has the patient received a total of 24 months cumulative treatment with Myfembree?

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.
   If no, continue to #2.

2. Is the request for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) (ICD-10 D25.9) **AND** the patient meets the following criterion?
   - The patient has had improvement of heavy menstrual bleeding

   If yes, **approve for 18 months (or up to 24 months cumulative lifetime treatment duration) by HICL or GPI-10.**

   If no, continue to #3.

3. Is the request for the management of moderate to severe pain associated with endometriosis (ICD-10 R52 and Group N80) and the patient meets **ALL** of the following criteria?
   - The patient has had improvement in pain related to endometriosis
   - Myfembree will NOT be used concurrently with another GnRH-modulating agent (e.g., Orilissa [elagolix], Lupron Depot [leuprolide], Synarel [nafarelin])

   If yes, **approve for 18 months (or up to 24 months cumulative lifetime treatment duration) by HICL or GPI-10.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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RELUGOLIX-ESTRADIOL-NORETHINDRONE (PART D)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT:

Our guideline named **RELUGOLIX-ESTRADIOL-NORETHINDRONE (Myfembree)** requires the following rule(s) be met for renewal:

A. The request is for ONE of the following:
   1. Management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids: non-cancerous growths in the uterus)
   2. Management of moderate to severe pain associated with endometriosis (condition affecting the uterus)

B. If the request is for management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids), renewal also requires:
   1. You had improvement of heavy menstrual bleeding while on therapy
   2. You have not received a total of 24 months cumulative (total) treatment with Myfembree

C. If the request is for management of moderate to severe pain associated with endometriosis, renewal also requires:
   1. You have had improvement in pain related to endometriosis while on therapy
   2. Myfembree will NOT be used concurrently (at the same time) with another GnRH-modulating agent (such as Orilissa [elagolix], Lupron Depot [leuprolide], Synarel [nafarelin])
   3. You have not received a total of 24 months cumulative (total) treatment with Myfembree

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RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Myfembree.

REFERENCES

Myfembree [Prescribing Information]. Brisbane, CA: Myovant Sciences, Inc., August 2025.

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RELUGOLIX-ESTRADIOL-NORETHINDRONE (PART D)

For Part D use only:

RELUGOLIX-ESTRADIOL-NORETHINDRONE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 YEARS OR OLDER
Prescriber Restrictions	INITIAL: HEAVY MENSTRUAL BLEEDING ASSOCIATED WITH UTERINE LEIOMYOMAS, ENDOMETRIOSIS: PRESCRIBED BY OR IN CONSULTATION WITH OBSTETRICIAN/GYNECOLOGIST.
Coverage Duration	INITIAL: 6 MOS. RENEWAL: 18 MOS OR UP TO 24 MOS CUMULATIVE LIFETIME TREATMENT DURATION.
Other Criteria	INITIAL: HEAVY MENSTRUAL BLEEDING ASSOCIATED WITH UTERINE LEIOMYOMAS: 1) HAS NOT RECEIVED A TOTAL OF 24 MONTHS CUMULATIVE TREATMENT WITH MYFEMBREE, AND 2) TRIAL AND FAILURE OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING: ORAL TRANEXAMIC ACID, CONTRACEPTIVE PREPARATIONS. ENDOMETRIOSIS: 1) HAS NOT RECEIVED A TOTAL OF 24 MONTHS CUMULATIVE TREATMENT WITH MYFEMBREE, AND 2) NO CONCURRENT USE WITH ANOTHER GNRH-MODULATING AGENT. RENEWAL: HEAVY MENSTRUAL BLEEDING ASSOCIATED WITH UTERINE LEIOMYOMAS: 1) IMPROVEMENT OF HEAVY MENSTRUAL BLEEDING, AND 2) HAS NOT RECEIVED A TOTAL OF 24 MONTHS CUMULATIVE TREATMENT WITH MYFEMBREE. ENDOMETRIOSIS: 1) IMPROVEMENT IN PAIN RELATED TO ENDOMETRIOSIS, 2) NO CONCURRENT USE WITH ANOTHER GNRH-MODULATING AGENT, AND 3) HAS NOT RECEIVED A TOTAL OF 24 MONTHS CUMULATIVE TREATMENT WITH MYFEMBREE.

Created: 06/21
Effective: 09/01/26 Client Approval: 08/26 DMC Approval: 08/04/26

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

REMIBRUTINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
REMIBRUTINIB	RHAPSIDO	50918		GPI-10 (9939376500)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of chronic spontaneous urticaria (CSU; also called chronic idiopathic urticaria [CIU]) (ICD-10 L50.1, L50.8, L50.9) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an allergist, dermatologist, or immunologist
   - The patient still experiences hives or angioedema on most days of the week for at least 6 weeks
   - The patient had a trial of and is maintained on, OR has a contraindication to, a second generation H1 antihistamine (e.g., Clarinex [desloratadine], Xyzal [levocetirizine])
   - Rhapsido will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of chronic spontaneous urticaria (chronic idiopathic urticaria)
   - The patient had a trial of or contraindication to the preferred agent: Dupixent (dupilumab)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

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REMIBRUTINIB (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **REMIBRUTINIB (Rhapsido)** requires the following rule(s) be met for approval:

1. You have chronic spontaneous urticaria (CSU) (also called chronic idiopathic urticaria [CIU]) [severe itching with unknown cause]
2. You are 18 years of age or older
3. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
4. You still experience hives or angioedema (a type of swelling) on most days of the week for at least 6 weeks
5. You have tried and are maintained on (continue to use on a regular basis), OR you have a contraindication to (harmful for you to use), a second generation H1 antihistamine (type of allergy medication, such as Clarinex [desloratadine], Xyzal [levocetirizine])
6. You will NOT use Rhapsido concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic spontaneous urticaria (chronic idiopathic urticaria)
7. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Dupixent (dupilumab)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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REMIBRUTINIB (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of chronic spontaneous urticaria (CSU; also called chronic idiopathic urticaria [CIU]) (ICD-10 L50.1, L50.8, L50.9) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an allergist, dermatologist, or immunologist
   - The patient is maintained on, OR has a contraindication to, a second generation H1 antihistamine (e.g., Clarinex [desloratadine], Xyzal [levocetirizine])
   - Rhapsido will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of chronic spontaneous urticaria (chronic idiopathic urticaria)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **REMIBRUTINIB (Rhapsido)** requires the following rule(s) be met for renewal:
   A. You have chronic spontaneous urticaria (CSU) (also called chronic idiopathic urticaria [CIU]) [severe itching with unknown cause]
   B. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
   C. You are maintained on (continue to use on a regular basis), OR you have a contraindication to (harmful for you to use), a second generation H1 antihistamine (type of allergy medication, such as Clarinex [desloratadine], Xyzal [levocetirizine])
   D. You will NOT use Rhapsido concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic spontaneous urticaria (chronic idiopathic urticaria)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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REMIBRUTINIB (PART D)

RATIONALE

For further information, refer to the Prescribing Information and/or Drug Monograph for Rhapsido.

REFERENCES

Rhapsido [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2025.

For Part D use only:

REMIBRUTINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	CHRONIC SPONTANEOUS URTICARIA (CSU): INITIAL/RENEWAL: PRESCRIBED BY OR IN CONSULTATION WITH AN ALLERGIST, DERMATOLOGIST, OR IMMUNOLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	CSU: INITIAL: 1) TRIAL OF AND MAINTAINED ON, OR CONTRAINDICATION TO, A SECOND GENERATION H1 ANTIHISTAMINE, 2) STILL EXPERIENCES HIVES OR ANGIOEDEMA ON MOST DAYS OF THE WEEK FOR AT LEAST 6 WEEKS, AND 3) TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT: DUPIXENT. INITIAL/RENEWAL: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION. RENEWAL: MAINTAINED ON OR CONTRAINDICATION TO A SECOND GENERATION H1 ANTIHISTAMINE.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

REPOTRECTINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
REPOTRECTINIB	AUGTYRO	49312		GPI-10 (2153386500)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has *ROS1*-positive tumors

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have solid tumors and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The tumors have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion
   - The tumors are locally advanced or metastatic, OR surgical resection is likely to result in severe morbidity
   - The patient has progressed following treatment OR has no satisfactory alternative therapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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REPOTRECTINIB (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **REPOTRECTINIB (Augtyro)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Locally advanced or metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread from where it started to nearby tissue or lymph nodes or to other parts of the body)
   2. Solid tumors

B. If you have non-small cell lung cancer, approval also requires:
   1. You are 18 years of age or older
   2. You have *ROS1*-positive (abnormal change in a type of gene) tumors

C. If you have solid tumors, approval also requires:
   1. You are 12 years of age or older
   2. Your tumors have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion (abnormal change in a type of gene)
   3. Yours tumors are locally advanced or metastatic (cancer that has spread from where it started to nearby tissue or lymph nodes or to other parts of the body), OR surgical resection (removal by surgery) is likely to result in severe morbidity (illness)
   4. You have progressed following treatment OR have no satisfactory alternative (other) therapy

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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REPOTRECTINIB (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Augtyro.

REFERENCES

Augtyro [Prescribing Information]. Princeton, NJ: Bristol-Myers Squibb Company; June 2024.

For Part D use only:

REPOTRECTINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 11/23
Effective: 01/01/25 Client Approval: 08/24 P&T Approval: 10/24

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RESLIZUMAB BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RESLIZUMAB	CINQAIR	43211		GPI-10 (4460446000)	

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #5.

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RESLIZUMAB BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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RESLIZUMAB BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of severe asthma with an eosinophilic phenotype (ICD-10 J82.83) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a physician specializing in allergy or pulmonary medicine
   - The patient has a blood eosinophil level of at least 150 cells/mcL within the past 12 months
   - Cinqair will be used in combination with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (e.g., beclomethasone, mometasone, budesonide) AND at least one other maintenance medication (e.g., long-acting inhaled beta2-agonist [e.g., salmeterol, formoterol], long-acting muscarinic antagonist [e.g., Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], leukotriene receptor antagonist [e.g., montelukast, zafirlukast, zileuton], theophylline)
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Fasenra (benralizumab), Nucala (mepolizumab), Dupixent (dupilumab)
   - Cinqair will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of eosinophilic phenotype asthma

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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RESLIZUMAB BvD (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient meet **ONE** of the following criteria?
   - The patient experienced at least ONE asthma exacerbation requiring systemic corticosteroid (e.g., prednisone) burst lasting at least 3 days within the past 12 months
   - The patient experienced at least ONE serious exacerbation requiring hospitalization or ER visit within the past 12 months

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Does the patient have poor symptom control despite current therapy as evidenced by at least **THREE** of the following within the past 4 weeks?
   - Daytime asthma symptoms more than twice per week
   - Any night waking due to asthma
   - Use of a short-acting inhaled beta2-agonist (SABA) reliever (e.g., albuterol) for symptoms more than twice per week
   - Any activity limitation due to asthma

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RESLIZUMAB (Cinqair)** requires the following rule(s) be met for approval:
   A. You have severe asthma with an eosinophilic phenotype (a type of lung condition with inflammation)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with a physician specializing in allergy or pulmonary (lungs/breathing) medicine
   D. You have a blood eosinophil (type of white blood cell) level of at least 150 cells/mcL within the past 12 months

   (Initial denial text continued on next page)

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RESLIZUMAB BvD (PART D)

INITIAL CRITERIA (CONTINUED)

E. Cinqair will be used in combination with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least one other maintenance medication (taken on a regular basis) such as a long-acting inhaled beta2-agonist (such as salmeterol, formoterol), long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast, zileuton), or theophylline
F. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Fasenra (benralizumab), Nucala (mepolizumab), Dupixent (dupilumab)
G. You will NOT use Cinqair concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic phenotype asthma
H. You meet ONE of the following:
    1. You have experienced at least ONE asthma exacerbation (worsening of symptoms) requiring systemic corticosteroid (such as prednisone) burst lasting at least 3 days within the past 12 months
    2. You have experienced at least ONE serious asthma exacerbation requiring hospitalization or emergency room visit within the past 12 months
    3. You have poor symptom control despite current therapy as evidenced by at least THREE of the following within the past 4 weeks:
        a. Daytime asthma symptoms more than twice per week
        b. Any night waking due to asthma
        c. Use of a short-acting beta-2-agonist (SABA) reliever (such as albuterol) for symptoms more than twice per week
        d. Any activity limitation due to asthma

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RESLIZUMAB BvD (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of severe asthma with an eosinophilic phenotype (ICD-10 J82.83) and meet **ALL** of the following criteria?
   - The patient will continue to use an inhaled corticosteroid (ICS) (e.g., beclomethasone, mometasone, budesonide) AND at least one other maintenance medication (e.g., a long-acting inhaled beta2-agonist [e.g., formoterol, salmeterol], a long-acting muscarinic antagonist [e.g., Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], leukotriene receptor antagonist [e.g., montelukast, zafirlukast, zileuton], theophylline)
   - Cinqair will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of eosinophilic phenotype asthma

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See renewal denial text at the end of the guideline.

2. Has the patient shown a clinical response as evidenced by **ONE** of the following criteria?
   - Reduction in asthma exacerbations from baseline
   - Decreased utilization of rescue medications (e.g., albuterol)
   - Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing)
   - Increase in percent predicted FEV1 from pretreatment baseline

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See renewal denial text at the end of the guideline.

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RESLIZUMAB BvD (PART D)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RESLIZUMAB (Cinqair)** requires the following rule(s) be met for renewal:

A. You have severe asthma with an eosinophilic phenotype (a type of lung condition with inflammation)
B. You will continue to use an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least one other maintenance medication (taken on a regular basis) such as a long-acting inhaled beta2-agonist (such as formoterol or salmeterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast), or theophylline
C. You will NOT use Cinqair concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic phenotype asthma
D. You have shown a clinical response as evidenced by ONE the following:
    1. You have experienced a reduction in asthma exacerbations (worsening of symptoms) from baseline
    2. You have decreased your use of rescue medications (such as albuterol)
    3. You have experienced a reduction in severity or frequency of asthma-related symptoms (such as wheezing, shortness of breath, coughing)
    4. Your percent predicted FEV1 (amount of air exhaled in one second) has increased from pretreatment baseline (before starting Cinqair)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RESLIZUMAB BvD (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cinqair. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Cinqair [Prescribing Information]. Frazer, PA: Teva Pharmaceutical Industries Ltd.; June 2020.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed July 2, 2024].

For Part D use only:

RESLIZUMAB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	ASTHMA: INITIAL: BLOOD EOSINOPHIL LEVEL OF AT LEAST 150 CELLS/MCL WITHIN THE PAST 12 MONTHS.
Age Restrictions	N/A
Prescriber Restrictions	ASTHMA: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A PHYSICIAN SPECIALIZING IN ALLERGY OR PULMONARY MEDICINE.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	ASTHMA: INITIAL: 1) CONCURRENT THERAPY WITH A MEDIUM, HIGH-DOSE OR MAXIMALLY TOLERATED DOSE OF AN INHALED CORTICOSTEROID (ICS) AND ONE OTHER MAINTENANCE MEDICATION, 2) ONE ASTHMA EXACERBATION REQUIRING SYSTEMIC CORTICOSTEROID BURST LASTING AT LEAST 3 DAYS WITHIN THE PAST 12 MONTHS, OR AT LEAST ONE SERIOUS EXACERBATION REQUIRING HOSPITALIZATION OR ER VISIT WITHIN THE PAST 12 MONTHS, OR POOR SYMPTOM CONTROL DESPITE CURRENT THERAPY AS EVIDENCED BY AT LEAST THREE OF THE FOLLOWING WITHIN THE PAST 4 WEEKS: (A) DAYTIME ASTHMA SYMPTOMS MORE THAN TWICE/WEEK, (B) ANY NIGHT WAKING DUE TO ASTHMA, (C) SABA RELIEVER FOR SYMPTOMS MORE THAN TWICE/WEEK, (D) ANY ACTIVITY LIMITATION DUE TO ASTHMA, AND 3) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: FASENRA, NUCALA, DUPIXENT. INITIAL/RENEWAL: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME

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	INDICATION. RENEWAL: 1) CONTINUED USE OF ICS AND ONE OTHER MAINTENANCE MEDICATION, AND 2) CLINICAL RESPONSE AS EVIDENCED BY: (A) REDUCTION IN ASTHMA EXACERBATIONS FROM BASELINE, (B) DECREASED UTILIZATION OF RESCUE MEDICATIONS, (C) REDUCTION IN SEVERITY OR FREQUENCY OF ASTHMA-RELATED SYMPTOMS, OR (D) INCREASE IN PERCENT PREDICTED FEV1 FROM PRETREATMENT BASELINE.

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CORE, ADVANTAGE, AND PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RESMETIROM (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RESMETIROM	REZDIFFRA	49451		GPI-10 (5260106000)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of non-alcoholic steatohepatitis (NASH) (ICD-10 K75.81) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient does not have cirrhosis
   - Therapy is prescribed by or in consultation with a hepatologist, gastroenterologist, or endocrinologist

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Has the NASH diagnosis been confirmed by biopsy or noninvasive testing (e.g., elastography), obtained within the past 12 months, which demonstrates **ONE** of the following?
   - The patient has liver fibrosis stage 2 or 3
   - The patient has a non-alcoholic fatty liver disease (NAFLD) Activity Score (NAS) of at least 4

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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RESMETIROM (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RESMETIROM (Rezdiffra)** requires the following rule(s) be met for approval:

A. You have non-alcoholic steatohepatitis (NASH: a type of liver disease)
B. You are 18 years of age or older
C. You do not have cirrhosis (liver damage and scarring)
D. Therapy is prescribed by or in consultation with a hepatologist (a type of liver doctor), gastroenterologist (doctor who treats digestive conditions), or endocrinologist (a type of hormone doctor)
E. Your diagnosis has been confirmed by biopsy (removal of cells or tissue from the body for examination) or noninvasive testing (such as elastography [type of imaging test]) within the past 12 months which demonstrates ONE of the following:
    1. You have liver fibrosis stage 2 or 3 (scoring system to measure liver damage)
    2. You have a non-alcoholic fatty liver disease (NAFLD) Activity Score (NAS: a scoring system used to measure disease activity and severity) of at least 4

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RESMETIROM (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of non-alcoholic steatohepatitis (NASH) (ICD-10 K75.81) and meet the following criterion?
   - The patient continues to have noncirrhotic NASH with moderate to advanced liverfibrosis (consistent with stages F2 to F3 fibrosis)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RESMETIROM (Rezdiffra)** requires the following rule(s) be met for renewal:
   A. You have non-alcoholic steatohepatitis (NASH: a type of liver disease)
   B. You continue to have noncirrhotic NASH (a type of liver disease) with moderate toadvanced fibrosis (consistent with stages F2 to F3 fibrosis [scoring system to measure liver damage])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Rezdiffra.

REFERENCES
Rezdiffra [Prescribing Information]. West Conshohocken, PA: Madrigal Pharmaceuticals; March 2024.

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CORE, ADVANTAGE, AND PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RESMETIROM (PART D)

For Part D use only:

RESMETIROM (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	NONALCOHOLIC STEATOHEPATITIS (NASH): INITIAL: DIAGNOSIS CONFIRMED BY BIOPSY OR NONINVASIVE TESTING, OBTAINED IN THE PAST 12 MONTHS, DEMONSTRATING: 1) LIVER FIBROSIS STAGE 2 OR 3, OR 2) NONALCOHOLIC FATTY LIVER DISEASE (NAFLD) ACTIVITY SCORE OF 4 OR MORE.
Age Restrictions	N/A
Prescriber Restrictions	NASH: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A HEPATOLOGIST, GASTROENTEROLOGIST, OR ENDOCRINOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS
Other Criteria	NASH: RENEWAL: CONTINUES TO HAVE NONCIRRHOTIC NASH WITH MODERATE TO ADVANCED LIVER FIBROSIS (CONSISTENT WITH STAGES F2 TO F3 FIBROSIS).

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RETIFANLIMAB-DLWR (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RETIFANLIMAB-DLWR	ZYNYZ	48795		GPI-10 (2135796020)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic or recurrent locally advanced Merkel cell carcinoma (MCC) (ICD-10 C7B.1; Group C4A) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of locally recurrent or metastatic squamous cell carcinoma of the anal canal (SCAC) (ICD-10 C44.520) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #3.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - Zynyz will be used in combination with carboplatin and paclitaxel AND the patient's cancer is inoperable
   - Zynyz will be used as a single agent AND the patient has experienced disease progression on or is intolerant to platinum-based chemotherapy (e.g., paclitaxel, docetaxel, cisplatin, carboplatin)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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RETIFANLIMAB-DLWR (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RETIFANLIMAB-DLWR (Zynyz)** requires the following rule(s) be met for approval:

A. You have ONE of the following
   1. Metastatic or recurrent locally advanced Merkel cell carcinoma (MCC: a type of skin cancer that has spread to other parts of the body or has returned and spread from where it started to nearby tissue or lymph nodes)
   2. Locally recurrent or metastatic squamous cell carcinoma of the anal canal (SCAC: a type of cancer of the anal canal that has returned from where it started or has spread to other parts of the body)

B. If you have metastatic or recurrent locally advanced Merkel cell carcinoma, approval also requires:
   1. You are 18 years of age or older

C. If you have locally recurrent or metastatic squamous cell carcinoma of the anal canal, approval also requires:
   1. You are 18 years of age or older
   2. You meet ONE of the following:
      a. Zynyz will be used in combination with carboplatin and paclitaxel AND your cancer is inoperable (not able to operate on)
      b. Zynyz will be used as a single agent (used alone) AND your disease has progressed (worsened) while on platinum-based chemotherapy (such as paclitaxel, docetaxel, cisplatin, carboplatin) or you are intolerant (side effects) to platinum-based chemotherapy

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RETIFANLIMAB-DLWR (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zynyz.

REFERENCES

Zynyz [Prescribing Information]. Wilmington, DE: Incyte Corporation; May 2025.

For Part D use only:

RETIFANLIMAB-DLWR (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 04/23
Effective: 07/01/25 Client Approval: 05/25 P&T Approval: 07/25

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

REVUMENIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
REVUMENIB CITRATE	REVUFORJ	50008		GPI-10 (2148007020)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory acute leukemia (ICD-10 C91.00, C91.02, C92.00, C92.02, C92.40, C92.42, C92.50, C92.52, C92.60, C92.62, C92.A0, C92.A2, C95.00, C95.02) **AND** meet the following criterion?
   - The patient is 1 year of age or older

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has a lysine methyltransferase 2A gene (KMT2A) translocation, as determined by an FDA-authorized test
   - The patient has a susceptible nucleophosmin 1 (NPM1) mutation AND has no satisfactory alternative treatment options

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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REVUMENIB (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **REVUMENIB (Revuforj)** requires the following rule(s) be met for approval:

A. You have relapsed or refractory acute leukemia (a type of blood cancer that has returned or did not respond to treatment)
B. You are 1 year of age or older
C. You meet ONE of the following:
   1. You have a lysine methyltransferase 2A gene (KMT2A) translocation (a type of gene abnormality), as determined by a Food and Drug Administration (FDA)-authorized test
   2. You have a susceptible nucleophosmin 1 (NPM1) mutation (an abnormal change in gene) AND you have no satisfactory alternative treatment options

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Revuforj.

REFERENCES

Revuforj [Prescribing Information]. Waltham, MA: Syndax Pharmaceuticals, Inc.; October 2025.

For Part D use only:

REVUMENIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

REZAFUNGIN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
REZAFUNGIN ACETATE	REZZAYO	48846		GPI-10 (1150007010)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the request for the treatment of candidemia or invasive candidiasis (ICD-10 Group B37 except B37.81 and Group B37.3) and the patient meets **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient has limited or no alternative treatment options

   If yes, **approve for 4 weeks by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **REZAFUNGIN (Rezzayo)** requires the following rule(s) be met for approval:
   A. The request is for the treatment of candidemia (a type of fungal infection) or invasive candidiasis (a type of fungal infection)
   B. You are 12 years of age or older
   C. You have limited or no alternative treatment options

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

REZAFUNGIN (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rezzayo.

REFERENCES

Rezzayo [Prescribing Information]. Lincolnshire, IL: Melinta Therapeutics LLC.; July 2026.

For Part D use only:

REZAFUNGIN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	4 WEEKS
Other Criteria	N/A

Created: 07/23
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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RIBOCICLIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RIBOCICLIB SUCCINATE	KISQALI	44151		GPI-10 (2153107050)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of breast cancer (ICD-10 Group C50) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the patient in stage II or III early cancer and the patient meets **ALL** of the following criteria?
   - Kisqali will be used in combination with an aromatase inhibitor (e.g., anastrozole, exemestane, letrozole) for adjuvant treatment
   - The patient is at high risk of recurrence

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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RIBOCICLIB (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Is the patient's cancer advanced or metastatic and the patient meets **ONE** of the following criteria?
   - Kisqali will be used in combination with an aromatase inhibitor (e.g., anastrozole, exemestane, letrozole) as initial endocrine-based therapy
   - Kisqali will be used in combination with fulvestrant (Faslodex), as initial endocrine-based therapy or following disease progression on endocrine therapy (e.g., anastrozole, letrozole, tamoxifen)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RIBOCICLIB (Kisqali)** requires the following rule(s) be met for approval:
   A. You have breast cancer
   B. You are 18 years of age or older
   C. Your cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative
   D. You meet ONE of the following:
      1. You have stage II or III early breast cancer (initial stage of cancer); you will use Kisqali in combination with an aromatase inhibitor (such as anastrozole, exemestane, letrozole) for adjuvant (add-on) treatment; AND you are at high risk of recurrence (disease returning)
      2. You have advanced or metastatic breast cancer (cancer that has progressed or has spread to other parts of the body), and you meet ONE of the following:
         a. You will use Kisqali in combination with an aromatase inhibitor (such as anastrozole, exemestane, letrozole) as initial endocrine (hormone)-based therapy
         b. You will use Kisqali in combination with fulvestrant (Faslodex), as initial endocrine (hormone)-based therapy or following disease progression (your condition worsened) on endocrine (hormone) therapy (such as anastrozole, letrozole, tamoxifen)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RIBOCICLIB (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kisqali.

REFERENCES

Kisqali [Prescribing Information]. East Hanover, NJ: Novartis; September 2024.

For Part D use only:

RIBOCICLIB (PART D)	
Covered uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 03/17
Effective: 07/01/25 Client Approval: 05/25 P&T Approval: 10/24

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RIBOCICLIB-LETROZOLE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RIBOCICLIB SUCCINATE/ LETROZOLE	KISQALI FEMARA CO-PACK	44246		GPI-10 (2199000260)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of breast cancer (ICD-10 Group C50) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative

   If yes continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the patient in stage II or III early cancer and the patient meets **ALL** of the following criteria?
   - Kisqali Femara Co-Pack will be used for adjuvant treatment
   - The patient is at high risk of recurrence

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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RIBOCICLIB-LETROZOLE (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Is the patient's cancer advanced or metastatic breast cancer **AND** the patient meets the following criterion?
   - Kisqali Femara Co-Pack will be used as initial endocrine-based therapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RIBOCICLIB-LETROZOLE (Kisqali Femara Co-Pack)** requires the following rule(s) be met for approval:
   A. You have breast cancer
   B. You are 18 years of age or older
   C. Your cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative
   D. You meet ONE of the following:
      1. You have stage II or III early breast cancer (initial stage of cancer); Kisqali Femara Co-Pack will be used for adjuvant (add-on) treatment; AND you are at high risk of recurrence (disease returning)
      2. You have advanced or metastatic breast cancer (cancer that has progressed or has spread to other parts of the body) AND Kisqali Femara Co-Pack will be used as initial endocrine (hormone)-based therapy

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Kisqali Femara Co-Pack.

REFERENCES
Kisqali Femara Co-Pack [Prescribing Information]. East Hanover, NJ. Novartis; September 2024.

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RIBOCICLIB-LETROZOLE (PART D)

For Part D use only:

RIBOCICLIB-LETROZOLE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 03/17
Effective: 07/01/25 Client Approval: 05/25 P&T Approval: 10/24

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RIFAXIMIN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RIFAXIMIN	XIFAXAN	20401		GPI-10 (1600004900)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of hepatic encephalopathy (HE) (ICD-10 K76.82) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to lactulose OR will be on concurrent lactulose therapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of irritable bowel syndrome with diarrhea (IBS-D) (ICD-10 K58.0) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 8 weeks by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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RIFAXIMIN (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of travelers' diarrhea (TD) (ICD-10 A09) **AND** meet the following criterion?
   - The patient is 12 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RIFAXIMIN (Xifaxan)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Hepatic encephalopathy (HE: a type of brain condition caused by liver damage)
      2. Irritable bowel syndrome with diarrhea (IBS: a type of bowel disease)
      3. Travelers' diarrhea (TD)
   B. If you have hepatic encephalopathy, approval also requires:
      1. You are 18 years of age or older
      2. You have tried or have a contraindication to (harmful for you to use) lactulose ORyou will be taking rifaximin and lactulose concurrently (at the same time)
   C. If you have irritable bowel syndrome with diarrhea, approval also requires:
      1. You are 18 years of age or older
   D. If you have travelers' diarrhea, approval also requires:
      1. You are 12 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Xifaxan.

REFERENCES
Xifaxan [Prescribing Information]. Bridgewater, NJ: Salix Pharmaceuticals; October 2023.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RIFAXIMIN (PART D)

For Part D use only:

RIFAXIMIN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	TRAVELERS DIARRHEA, HEPATIC ENCEPHALOPATHY (HE): 12 MOS. IBS-D: 8 WKS.
Other Criteria	HE: TRIAL OF OR CONTRAINDICATION TO LACTULOSE OR CONCURRENT LACTULOSE THERAPY.

Created: 02/05
Effective: 10/04/25 Client Approval: 09/25 P&T Approval: 01/22

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RILONACEPT (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RILONACEPT	ARCALYST	35438		GPI-10 (6645006000)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of cryopyrin-associated periodic syndromes (CAPS), including familial cold autoinflammatory syndrome (FCAS) or Muckle-Wells syndrome (MWS), (ICD-10 M04.2) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient had genetic testing for gain-of-function mutations in the NLRP3 gene OR has inflammatory markers (i.e., elevated CRP, ESR, serum amyloid A protein [SAA] or S100 proteins)
   - The patient has TWO of the following: urticarial-like rash (neutrophilic dermatitis), cold triggered episodes, sensorineural hearing loss, musculoskeletal symptoms, chronic aseptic meningitis, skeletal abnormalities
   - Arcalyst will NOT be used concurrently with another systemic biologic (e.g., Ilaris [canakinumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CAPS

   If yes, **approve for lifetime by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

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RILONACEPT (PART D)

GUIDELINES FOR USE (CONTINUED)

2. Does the patient have a diagnosis of deficiency of interleukin-1 receptor antagonist (DIRA) (ICD-10 M04.8) and meet **ALL** of the following criteria?
   - The patient had genetic testing for gain-of-function mutations in the IL1RN gene OR has inflammatory markers (i.e., elevated CRP, ESR)
   - The patient has ONE of the following: pustular psoriasis-like rashes, osteomyelitis, absence of bacterial osteomyelitis, nail changes (i.e., onychomadesis)
   - Arcalyst will NOT be used concurrently with another systemic biologic (e.g., Kineret [anakinra]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of DIRA
   - The patient has tried the preferred agent: Kineret (anakinra)

   If yes, **approve for lifetime by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Is the request for the treatment or reduction in risk of recurrent pericarditis (RP) (ICD-10 I31.9) and the patient meets **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient had an episode of acute pericarditis
   - The patient has been symptom-free for an interval of 4 to 6 weeks
   - The patient has TWO of the following: chest pain consistent with pericarditis, pericardial friction rub, ECG showing diffuse ST-segment elevation or PR-segment depression, new or worsening pericardial effusion
   - Arcalyst will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of recurrent pericarditis

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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RILONACEPT (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RILONACEPT (Arcalyst)** requires the following rule(s) be met for approval:

A. The request is for ONE of the following:
   1. Cryopyrin-associated periodic syndromes (CAPS), including familial cold autoinflammatory syndrome (FCAS) or Muckle-Wells syndrome (MWS) (types of immune system disorders)
   2. Deficiency of interleukin-1 receptor antagonist (DIRA: a type of immune system disorder)
   3. Treatment or reduction in risk of recurrent pericarditis (RP: a type of heart condition that returns)

B. If you have cryopyrin-associated periodic syndromes, including familial cold autoinflammatory syndrome or Muckle-Wells syndrome, approval also requires:
   1. You are 12 years of age or older
   2. You had genetic testing for gain-of-function mutations (abnormal change in gene) in the NLRP3 gene (a type of gene) OR you have inflammatory markers (elevated C-reactive protein [CRP: sign of inflammation], erythrocyte sedimentation rate [ESR: a type of blood test], serum amyloid A protein [SAA: a type of protein] or S100 proteins [a type of protein])
   3. You have TWO of the following: urticarial-like rash (neutrophilic dermatitis: a type of skin condition), cold triggered episodes, sensorineural hearing loss (a type of hearing loss), musculoskeletal symptoms (symptoms related to the muscles and bones), chronic aseptic meningitis (inflammation of the brain and spinal cord), skeletal (bone) abnormalities
   4. You will NOT use Arcalyst concurrently (at the same time) with another systemic biologic (such as Ilaris [canakinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Cryopyrin-Associated Periodic Syndromes

(Denial text continued on next page)

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RILONACEPT (PART D)

GUIDELINES FOR USE (CONTINUED)

C. If you have deficiency of interleukin-1 receptor antagonist, approval also requires:

1. You had genetic testing for gain-of-function mutations (abnormal change in gene) in the IL1RN gene (a type of gene) OR you have inflammatory markers (elevated C-reactive protein [CRP: sign of inflammation], erythrocyte sedimentation rate [ESR: a type of blood test])
2. You have ONE of the following: pustular psoriasis-like rashes (a type of skin condition), osteomyelitis (bone infection), absence of bacterial osteomyelitis (do not have a type of bone infection), nail changes (onychomadesis: nail shedding)
3. You will NOT use Arcalyst concurrently (at the same time) with another systemic biologic (such as Kineret [anakinra]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Deficiency of Interleukin-1 Receptor Antagonist
4. You have tried the preferred agent: Kineret (anakinra)

D. If the request is for treatment or reduction in risk of recurrent pericarditis, approval also requires:

1. You are 12 years of age or older
2. You had had an episode of acute pericarditis (a type of short-term heart condition)
3. You have been symptom-free for 4 to 6 weeks
4. You have TWO of the following: chest pain consistent with pericarditis, pericardial friction rub (a type of heart condition), electrocardiogram (ECG: a type of lab test) showing diffuse ST-segment elevation or PR-segment depression (an abnormal heart test), new or worsening pericardial effusion (a type of heart condition)
5. You will NOT use Arcalyst concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of recurrent pericarditis

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Arcalyst.

REFERENCES

Arcalyst [Prescribing Information]. London, UK: Kiniksa Pharmaceuticals; May 2021.

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RILONACEPT (PART D)

For Part D use only:

RILONACEPT (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	CRYOPYRIN-ASSOCIATED PERIODIC SYNDROMES (CAPS): 1) ONE OF THE FOLLOWING: (A) GENETIC TEST FOR GAIN-OF-FUNCTION MUTATIONS IN THE NLRP3 GENE, OR (B) HAS INFLAMMATORY MARKERS (I.E., ELEVATED CRP, ESR, SERUM AMYLOID A PROTEIN (SAA) OR S100 PROTEINS), AND 2) TWO OF THE FOLLOWING: URTICARIAL-LIKE RASH (NEUTROPHILIC DERMATITIS), COLD-TRIGGERED EPISODES, SENSORINEURAL HEARING LOSS, MUSCULOSKELETAL SYMPTOMS, CHRONIC ASEPTIC MENINGITIS, SKELETAL ABNORMALITIES. DEFICIENCY OF INTERLEUKIN-1 RECEPTOR ANTAGONIST (DIRA): 1) ONE OF THE FOLLOWING: (A) GENETIC TEST FOR GAIN-OF-FUNCTION MUTATIONS IN THE IL1RN GENE, OR (B) HAS INFLAMMATORY MARKERS (I.E., ELEVATED CRP, ESR), AND 2) ONE OF THE FOLLOWING: PUSTULAR PSORIASIS-LIKE RASHES, OSTEOMYELITIS, ABSENCE OF BACTERIAL OSTEOMYELITIS, ONYCHOMADESIS. RECURRENT PERICARDITIS (RP): TWO OF THE FOLLOWING: CHEST PAIN CONSISTENT WITH PERICARDITIS, PERICARDIAL FRICTION RUB, ECG SHOWING DIFFUSE ST-SEGMENT ELEVATION OR PR-SEGMENT DEPRESSION, NEW OR WORSENING PERICARDIAL EFFUSION.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	CAPS, DIRA: LIFETIME. RP: 12 MONTHS.
Other Criteria	CAPS: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR CAPS. DIRA: 1) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR DIRA, AND 2) TRIAL OF THE PREFERRED AGENT: KINERET. RP: 1) HAD AN EPISODE OF ACUTE PERICARDITIS, 2) SYMPTOM-FREE FOR 4 TO 6 WEEKS, AND 3) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR RP.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RILUZOLE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RILUZOLE	EXSERVAN, TIGLUTIK	10247		GPI-10 (7450307000)	FORM ≠ TABLET

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of amyotrophic lateral sclerosis (ALS) (ICD-10 G12.21) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has had a trial of riluzole tablets
   - The patient is unable to take riluzole tablet formulation

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RILUZOLE (Exservan, Tiglutik)** requires the following rule(s) be met for approval:
   A. You have amyotrophic lateral sclerosis (ALS: nervous system disease that weakens muscles and affects physical function)
   B. You are 18 years of age or older
   C. You have tried riluzole tablets
   D. You are unable to take riluzole tablet formulation

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RILUZOLE (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Exservan or Tiglutik.

REFERENCES
Exservan. [Prescribing Information]. Warren, NJ: Aquestive Therapeutics; April 2020.
Tiglutik. [Prescribing Information]. Berwyn, PA: ITF Pharma, Inc.; March 2020.

For Part D use only:

RILUZOLE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 YEARS OR OLDER
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	AMYOTROPHIC LATERAL SCLEROSIS (ALS): (1) TRIAL OF RILUZOLE TABLETS, AND (2) PATIENT IS UNABLE TO TAKE TABLET FORMULATION.

Core	Advantage	Plus
No	No	Yes

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RILZABRUTINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RILZABRUTINIB	WAYRILZ	50857		GPI-10 (8575205000)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of persistent or chronic immune thrombocytopenia (ITP) (ICD-10 D69.3) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a hematologist or immunologist
   - The patient has a platelet count of less than 30 x 10^9/L, OR has a platelet count of less than 50 x 10^9/L and had a prior bleeding event
   - The patient had a trial of or contraindication to a corticosteroid (e.g., prednisone, dexamethasone, prednisolone) or an IV immunoglobulin (e.g., Gammagard, Gamunex-C, Gammaplex), OR had an insufficient response to a splenectomy
   - The patient had a trial of or contraindication to a thrombopoietin receptor agonist (e.g., Promacta [eltrombopag])

   If yes, **approve for 3 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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RILZABRUTINIB (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RILZABRUTINIB (Wayrilz)** requires the following rule(s) be met for approval:

A. You have persistent or chronic immune thrombocytopenia (ITP: a type of blood disorder)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or immunologist (immune system doctor)
D. You have a platelet (a type of blood cell) count of less than 30 x10^9/L, OR you have a platelet count of less than 50 x 10^9/L and had a prior bleeding event
E. You have tried or have a contraindication to (harmful for you to use) a corticosteroid (such as prednisone, dexamethasone, prednisolone) or an intravenous immunoglobulin (such as Gammagard, Gamunex-C, Gammaplex), OR you had an insufficient response to a splenectomy (surgical removal of spleen did not work)
F. You have tried or have a contraindication to (harmful for you to use) a thrombopoietin receptor agonist (such as Promacta [eltrombopag])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RILZABRUTINIB (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of persistent or chronic immune thrombocytopenia (cITP) (ICD-10 D69.3) **AND** meet the following criterion?
   - The patient has shown improvement in platelet counts from baseline or a reduction in bleeding events

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RILZABRUTINIB (Wayrilz)** requires the following rule(s) be met for renewal:
   A. You have persistent or chronic immune thrombocytopenia (ITP: a type of blood disorder)
   B. You have shown improvement in platelet (a type of blood cell) counts from baseline or a reduction in bleeding events

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Wayrilz.

REFERENCES

Wayrilz [Prescribing Information]. Cambridge, MA: Genzyme Corporation; August 2025.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RILZABRUTINIB (PART D)

For Part D use only:

RILZABRUTINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	PERSISTENT OR CHRONIC IMMUNE THROMBOCYTOPENIA (ITP): INITIAL: 1) PLATELET COUNT OF LESS THAN 30 X 10^9/L, OR 2) PLATELET COUNT OF LESS THAN 50 X 10^9/L AND A PRIOR BLEEDING EVENT.
Age Restrictions	N/A
Prescriber Restrictions	ITP: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR IMMUNOLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	ITP: INITIAL: 1) TRIAL OF OR CONTRAINDICATION TO ONE CORTICOSTEROID OR INTRAVENOUS IMMUNOGLOBULIN, OR HAD AN INSUFFICIENT RESPONSE TO A SPLENECTOMY, AND 2) TRIAL OF OR CONTRAINDICATION TO A THROMBOPOIETIN RECEPTOR AGONIST (E.G., PROMACTA [ELTROMBOPAG]). RENEWAL: IMPROVEMENT IN PLATELET COUNTS FROM BASELINE OR REDUCTION IN BLEEDING EVENTS.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RIMABOTULINUM TOXIN B BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RIMABOTULINUMTOXINB	MYOBLOC	21869		GPI-10 (7440002010)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	NO	Yes	No	NO	Yes	No	NO	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #5.

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RIMABOTULINUM TOXIN B BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override)**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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RIMABOTULINUM TOXIN B BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the request for treatment of a cosmetic indication (e.g., wrinkles - glabellar lines, lateral canthal lines, forehead lines) (ICD-10 L98.8; Group L81)?

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.
   If no, continue to #2.

2. Does the patient have a diagnosis of cervical dystonia (ICD-10 G24.3) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Does the patient have a diagnosis of chronic sialorrhea (ICD-10 K11.7) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See denial text at the end of the guideline.

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RIMABOTULINUM TOXIN B BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RIMABOTULINUM TOXIN B (Myobloc)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Cervical dystonia (a type of muscle condition)
   2. Chronic sialorrhea (long-term drooling)
B. You are 18 years of age or older

NOTE: This medication will not be approved for the treatment of a cosmetic indication (such as wrinkles - glabellar [between the eyebrows] lines, lateral canthal [outer corner of eye] lines, forehead lines).

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Myobloc. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Myobloc [Prescribing Information] Louisville, KY: Solstice Neurosciences, Inc.; March 2021.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals . [Accessed March 26, 2024].

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RIMABOTULINUM TOXIN B BvD (PART D)

For Part D use only:

RIMABOTULINUM TOXIN B (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	COSMETIC DIAGNOSIS.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RIMEGEPANT (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RIMEGEPANT SULFATE	NURTEC ODT	46383		GPI-10 (6770106070)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for the acute treatment of migraines (ICD-10 Group G43 except G43.7 and G43.E) and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Nurtec ODT will NOT be used concurrently with other cGRP inhibitors (e.g., Zavzpret [zavegepant], Ubrelvy [ubrogepant]) for the acute treatment of migraines
   - The patient had a trial of or contraindication to ONE triptan (e.g., Maxalt [rizatriptan], Imitrex [sumatriptan], Axert [almotriptan])

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Is the request for the preventive treatment of episodic migraines and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Nurtec ODT will NOT be used concurrently with other CGRP inhibitors (e.g., Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm]) for migraine prevention

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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RIMEGEPANT (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RIMEGEPANT (Nurtec ODT)** requires the following rule(s) be met for approval:

A. The request is for ONE of the following:
   1. Acute (quick onset) treatment of migraines (a type of headache)
   2. Preventive treatment of episodic migraines (a type of headache)

B. If the request is for acute treatment of migraines, approval also requires:
   1. You are 18 years of age or older
   2. You will NOT use Nurtec ODT concurrently (at the same time) with other calcitonin gene-related peptide (cGRP) inhibitors (such as Zavzpret [zavegepant], Ubrelvy [ubrogepant]) for the acute treatment of migraines
   3. You have tried or have a contraindication to (harmful for you to use) ONE triptan (such as Maxalt [rizatriptan], Imitrex [sumatriptan], Axert [almotriptan])

C. If the request is for preventive treatment of episodic migraines, approval also requires:
   1. You are 18 years of age or older
   2. You will NOT use Nurtec ODT concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm]) for migraine prevention

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RIMEGEPANT (PART D)

RENEWAL CRITERIA

1. Is the request for the acute treatment of migraines (ICD-10 Group G43 except G43.7 and G43.E) **AND** the patient meets the following criterion?
   - Nurtec ODT will NOT be used concurrently with other cGRP inhibitors (e.g., Zavzpret [zavegepant], Ubrelvy [ubrogepant]) for the acute treatment of migraines

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has experienced an improvement from baseline in a validated acute treatment patient-reported outcome questionnaire (e.g., Migraine Assessment of Current Therapy [Migraine-ACT])
   - Therapy works consistently in the majority of migraine attacks

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

3. Is the request for the preventive treatment of episodic migraines **AND** the patient meets the following criterion?
   - Nurtec ODT will NOT be used concurrently with other CGRP inhibitors (e.g., Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm]) for migraine prevention

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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RIMEGEPANT (PART D)

RENEWAL CRITERIA (CONTINUED)

4. Does the patient meet **ONE** of the following criteria?
   - The patient has experienced a reduction in migraine or headache frequency with therapy
   - The patient has experienced a reduction in migraine severity with therapy
   - The patient has experienced a reduction in migraine duration with therapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RIMEGEPANT (Nurtec ODT)** requires the following rule(s) be met for renewal:

   A. The request is for ONE of the following:
      1. Acute (quick onset) treatment of migraines (a type of headache)
      2. Preventive treatment of episodic migraines (a type of headache)

   B. If the request is for acute treatment of migraines, renewal also requires:
      1. You will NOT use Nurtec ODT concurrently (at the same time) with other calcitonin gene-related peptide (cGRP) inhibitors (such as Zavzpret [zavegepant], Ubrelvy [ubrogepant]) for the acute treatment of migraines
      2. You meet ONE of the following:
         a. You have experienced an improvement from baseline in a validated acute treatment patient-reported outcome questionnaire (assessment tool used to help guide treatment such as Migraine Assessment of Current Therapy [MIGRAINE-ACT])
         b. Treatment works consistently in the majority of migraine attacks

   C. If the request is for preventive treatment of episodic migraines, renewal also requires:
      1. You will NOT use Nurtec ODT concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm]) for migraine prevention
      2. You meet ONE of the following:
         a. You have experienced a reduction in migraine or headache frequency with therapy
         b. You experienced a reduction in migraine severity with therapy
         c. You experienced a reduction in migraine duration with therapy

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RIMEGEPANT (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nurtec ODT.

REFERENCES

Nurtec ODT [Prescribing Information]. New York, NY: Pfizer Labs; April 2023.

For Part D use only:

RIMEGEPANT (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	ACUTE MIGRAINE TREATMENT: INITIAL: TRIAL OF OR CONTRAINDICATION TO ONE TRIPTAN (E.G., SUMATRIPTAN, RIZATRIPTAN). INITIAL/RENEWAL: NO CONCURRENT USE WITH OTHER CGRP INHIBITORS FOR ACUTE MIGRAINE TREATMENT. RENEWAL: 1) IMPROVEMENT FROM BASELINE IN A VALIDATED ACUTE TREATMENT PATIENT-REPORTED OUTCOME QUESTIONNAIRE, OR 2) THERAPY WORKS CONSISTENTLY IN MAJORITY OF MIGRAINE ATTACKS. EPISODIC MIGRAINE PREVENTION: INITIAL/RENEWAL NO CONCURRENT USE WITH OTHER CGRP INHIBITORS FOR MIGRAINE PREVENTION. RENEWAL: REDUCTION IN MIGRAINE OR HEADACHE FREQUENCY, MIGRAINE SEVERITY, OR MIGRAINE DURATION WITH THERAPY.

Created: 05/20
Effective: 07/01/25 Client Approval: 06/25 P&T Approval: 10/23

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ADVANTAGE AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RIOCIGUAT (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RIOCIGUAT	ADEMPAS	40644		GPI-10 (4013405000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   - Adempas will NOT be used concurrently with nitrates or nitric oxide donors (e.g., amyl nitrate), phosphodiesterase (PDE) inhibitors (e.g., Viagra [sildenafil], Cialis [tadalafil], Levitra [vardenafil]), or non-specific PDE inhibitors (e.g., dipyridamole, theophylline)

   If yes, continue to #2.
   If no, continue to #3.

2. Is the PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of 15 mmHg or less
   - Pulmonary vascular resistance (PVR) greater than 2 Wood units

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See initial denial text at the end of the guideline.

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RIOCIGUAT (PART D)

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH) WHO Group 4 (ICD-10 I27.24) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   - The patient has persistent/recurrent disease after surgical treatment OR the patient is not a candidate for surgery or has inoperable CTEPH
   - The patient has World Health Organization (WHO) Functional Class II to IV symptoms
   - Adempas will NOT be used concurrently with nitrates or nitric oxide donors (e.g., amyl nitrate), phosphodiesterase (PDE) inhibitors (e.g., Viagra [sildenafil], Cialis [tadalafil], Levitra [vardenafil]), or non-specific PDE inhibitors (e.g., dipyridamole, theophylline)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RIOCIGUAT (Adempas)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1: a way to classify the severity of disease)
      2. Persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH: a type of heart and lung condition) (World Health Organization Group 4: a way to classify the severity of disease)

   (Initial denial text continued on next page)

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RIOCIGUAT (PART D)

INITIAL CRITERIA (CONTINUED)

B. If you have pulmonary arterial hypertension (WHO Group 1), approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
3. You will NOT use Adempas concurrently (at the same time) with nitrates or nitric oxide donors (such as amyl nitrate), phosphodiesterase inhibitors (such as Viagra [sildenafil], Cialis [tadalafil], Levitra [vardenafil]), or non-specific phosphodiesterase inhibitors (such as dipyridamole, theophylline)
4. Your pulmonary arterial hypertension diagnosis is confirmed by right heart catheterization (a test used to measure how well the heart is pumping) with ALL of the following lab values:
   a. Mean pulmonary artery pressure (PAP: a type of measurement for pulmonary artery pressure) greater than 20 mmHg
   b. Pulmonary capillary wedge pressure (PCWP: a type of measurement for pulmonary artery pressure) of 15 mmHg or less
   c. Pulmonary vascular resistance (PVR: a type of measurement for pulmonary artery pressure) greater than 2 Wood units

C. If you have chronic thromboembolic pulmonary hypertension (WHO Group 4), approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
3. You will NOT use Adempas concurrently (at the same time) with nitrates or nitric oxide donors (such as amyl nitrate), phosphodiesterase inhibitors (such as Viagra [sildenafil], Cialis [tadalafil], Levitra [vardenafil]), or non-specific phosphodiesterase inhibitors (such as dipyridamole, theophylline)
4. You have persistent or recurrent disease after surgical treatment (it continues to exist or returns after surgery) OR you are not a candidate for surgery or have inoperable chronic thromboembolic pulmonary hypertension
5. You have World Health Organization (WHO) Functional Class II to IV symptoms (a tool used to rate severity of pulmonary hypertension)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RIOCIGUAT (PART D)

RENEWAL CRITERIA

1. Does the patient have **ONE** of the following diagnoses?
   - Persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH) (WHO Group 4) (ICD-10 I27.24)
   - Pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet the following criterion?
   - Adempas will NOT be used concurrently with nitrates or nitric oxide donors (e.g., amyl nitrate), phosphodiesterase (PDE) inhibitors (e.g., Viagra [sildenafil], Cialis [tadalafil], Levitra [vardenafil]), or non-specific PDE inhibitors (e.g., dipyridamole, theophylline)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RIOCIGUAT (Adempas)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH: a type of heart and lung condition) (World Health Organization Group 4: a way to classify the severity of disease)
      2. Pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization Group 1: a way to classify the severity of disease)
   B. You will NOT use Adempas concurrently (at the same time) with nitrates or nitric oxide donors (such as amyl nitrate), phosphodiesterase inhibitors (such as Viagra [sildenafil], Cialis [tadalafil], Levitra [vardenafil]), or non-specific phosphodiesterase inhibitors (such as dipyridamole, theophylline)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RIOCIGUAT (PART D)

RATIONALE

For further information, please refer to the prescribing information and/or Drug Monograph for Adempas.

REFERENCES

Adempas [Prescribing Information]. Wayne, NJ: Bayer HealthCare Pharmaceuticals Inc.; September 2021.

For Part D use only:

RIOCIGUAT (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	INITIAL: PULMONARY ARTERIAL HYPERTENSION (PAH): DIAGNOSIS CONFIRMED BY RIGHT HEART CATHETERIZATION WITH THE FOLLOWING PARAMETERS: 1) MEAN PULMONARY ARTERY PRESSURE (PAP) GREATER THAN 20 MMHG, 2) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF 15 MMHG OR LESS, AND 3) PULMONARY VASCULAR RESISTANCE (PVR) GREATER THAN 2 WOOD UNITS. PERSISTENT/RECURRENT CHRONIC THROMBOEMBOLIC PULMONARY HYPERTENSION (CTEPH) (WHO GROUP 4): WHO FUNCTIONAL CLASS II-IV SYMPTOMS.
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: PAH, CTEPH: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: PAH: NO CONCURRENT USE WITH NITRATES, NITRIC OXIDE DONORS, PHOSPHODIESTERASE (PDE) INHIBITORS, OR NON-SPECIFIC PDE INHIBITORS. CTEPH: 1) NO CONCURRENT USE WITH NITRATES, NITRIC OXIDE DONORS, PDE INHIBITORS, OR NON-SPECIFIC PDE INHIBITORS, AND 2) NOT A CANDIDATE FOR SURGERY OR HAS INOPERABLE CTEPH OR HAS PERSISTENT OR RECURRENT DISEASE AFTER SURGICAL TREATMENT. RENEWAL: PAH, CTEPH: NO CONCURRENT USE WITH NITRATES, NITRIC OXIDE DONORS, PDE INHIBITORS, OR NON-SPECIFIC PDE INHIBITORS.

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ADVANTAGE AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RIOCIGUAT (PART D)

Core	Advantage	Plus
No	Yes	Yes

Part D Effective: 01/01/25 Created: 11/13
Commercial Effective: N/A Client Approval: 06/24 P&T Approval: 01/24

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RIPRETINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RIPRETINIB	QINLOCK	46544		GPI-10 (2153305300)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced gastrointestinal stromal tumor (GIST) (ICD-10 Group C49.A) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received prior treatment with three or more kinase inhibitors, including Gleevec (imatinib)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RIPRETINIB (Qinlock)** requires the following rule(s) be met for approval:
   A. You have advanced gastrointestinal stromal tumor (GIST: a type of digestive cancer)
   B. You are 18 years of age or older
   C. You have received prior treatment with three or more kinase inhibitors (class of drugs), including Gleevec (imatinib)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RIPRETINIB (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Qinlock.

REFERENCES

Qinlock [Prescribing Information]. Waltham, MA: Deciphera Pharmaceuticals, June 2021.

For Part D use only:

RIPRETINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Created: 05/20
Effective: 01/01/25 Client Approval: 08/24 P&T Approval: 07/20

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RISANKIZUMAB-RZAA (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RISANKIZUMAB-RZAA	SKYRIZI	45699		GPI-10 (9025057070, 5250406070)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist
   - The patient has psoriasis covering 3% or more of body surface area (BSA) OR psoriatic lesions affecting the hands, feet, face, scalp, or genital area
   - Skyrizi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy)
   - The patient has a contraindication or intolerance to both immunosuppressant and PUVA (phototherapy)
   - The patient is switching from a different biologic (e.g., Humira [adalimumab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline

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RISANKIZUMAB-RZAA (PART D)

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
- The patient is 6 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
- Skyrizi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

If yes, **approve for 6 months by HICL or GPI-10.**
If no, continue to #4.

4. Does the patient have a diagnosis of moderate to severe Crohn's disease (ICD-10 Group K50) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a gastroenterologist
- Skyrizi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

If yes, **approve for 6 months by HICL or GPI-10.**
If no, continue to #5.

5. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a gastroenterologist
- Skyrizi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

If yes, **approve for 6 months by HICL or GPI-10.**
If no, do not approve.

INITIAL DENIAL TEXT: Our guideline named **RISANKIZUMAB-RZAA (Skyrizi)** requires the following rule(s) be met for approval:
A. You have ONE of the following:
   1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

(Initial denial text continued on next page)

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RISANKIZUMAB-RZAA (PART D)

INITIAL CRITERIA (CONTINUED)

B. If you have moderate to severe plaque psoriasis, approval also requires:
1. You are 6 years of age or older
2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
3. You have psoriasis covering 3% or more of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, genital area, scalp, or face
4. You will NOT use Skyrizi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis
5. You meet ONE of the following:
   a. You have had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy)
   b. You have a contraindication (harmful for you to use) or intolerance (side effect) to both immunosuppressant (a type of drug that decreases the body's immune response) and PUVA (phototherapy)
   c. You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication

C. If you have psoriatic arthritis, approval also requires:
1. You are 6 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (skin doctor)
3. You will NOT use Skyrizi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

D. If you have moderate to severe Crohn's disease, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who specializes in digestive conditions)
3. You will NOT use Skyrizi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease

E. If you have moderate to severe ulcerative colitis, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who specializes in digestive conditions)
3. You will NOT use Skyrizi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

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RISANKIZUMAB-RZAA (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Skyrizi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Skyrizi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

3. Does the patient have a diagnosis of moderate to severe Crohn's disease (ICD-10 Group K50) **AND** meet the following criterion?
   - Skyrizi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #4.

4. Does the patient have a diagnosis of moderate to severe ulcerative colitis (ICD-10 Group K51) **AND** meet the following criterion?
   - Skyrizi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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RISANKIZUMAB-RZAA (PART D)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: Our guideline named **RISANKIZUMAB-RZAA (Skyrizi)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe plaque psoriasis (a type of skin condition)
   2. Psoriatic arthritis (a type of skin and joint condition)
   3. Moderate to severe Crohn's disease (a type of bowel disorder)
   4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. If you have moderate to severe plaque psoriasis, renewal also requires:
   1. You continue to benefit from the medication
   2. You will NOT use Skyrizi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis

C. If you have psoriatic arthritis, renewal also requires:
   1. You continue to benefit from the medication
   2. You will NOT use Skyrizi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

D. If you have moderate to severe Crohn's disease, renewal also requires:
   1. You will NOT use Skyrizi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease

E. If you have moderate to severe ulcerative colitis, renewal also requires:
   1. You will NOT use Skyrizi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Skyrizi.

REFERENCES

Skyrizi [Prescribing Information]. North Chicago, IL: AbbVie Inc.; June 2026.

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RISANKIZUMAB-RZAA (PART D)

For Part D use only:

RISANKIZUMAB-RZAA (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	INITIAL: PLAQUE PSORIASIS (PSO): PLAQUE PSORIASIS COVERING 3 PERCENT OR MORE OF BODY SURFACE AREA OR PSORIATIC LESIONS AFFECTING THE HANDS, FEET, FACE, SCALP, OR GENITAL AREA.
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: PSO: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST. PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST OR DERMATOLOGIST. CROHNS DISEASE (CD), ULCERATIVE COLITIS (UC): PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS
Other Criteria	INITIAL: PSO: 1) AT LEAST A 3 MONTH TRIAL OF ONE ORAL IMMUNOSUPPRESSANT (CYCLOSPORINE, METHOTREXATE, TACROLIMUS) OR PUVA (PHOTOTHERAPY), 2) CONTRAINDICATION OR INTOLERANCE TO BOTH IMMUNOSUPPRESSANT AND PUVA, OR 3) PATIENT IS SWITCHING FROM A DIFFERENT BIOLOGIC, PDE-4 INHIBITOR, OR JAK INHIBITOR FOR THE SAME INDICATION. INITIAL/RENEWAL: ALL INDICATIONS: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION. RENEWAL: PSO, PSA: CONTINUES TO BENEFIT FROM THE MEDICATION.

Created: 04/19
Effective: 07/15/26 Client Approval: 07/26 DMC Approval: 07/26

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RISDIPLAM (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RISDIPLAM	EVRYSDI	46765		GPI-10 (7470656000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of spinal muscular atrophy (SMA) (ICD-10 G12.9) and meet **ALL** of the following criteria?
- Therapy is prescribed by or in consultation with a neuromuscular specialist or spinal muscular atrophy (SMA) specialist at a SMA Specialty Center
- The diagnosis is confirmed by gene mutation analysis indicating mutations or deletions of both alleles of the survival motor neuron 1 (SMN1) gene (e.g., homozygous deletions of SMN1, homozygous mutations of SMN1, compound heterozygous mutations in SMN1 [i.e., deletion of SMN1 on one allele and point mutation of SMN1 on the other allele])

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient presymptomatic **AND** meets the following criterion?
- The patient has up to (i.e., no more than) three copies of survival motor neuron 2 (SMN2) based on newborn screening

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #3.

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RISDIPLAM (PART D)

INITIAL CRITERIA (CONTINUED)

3. Is the patient symptomatic and meets **ALL** of the following criteria?
   - The patient had a baseline motor function assessment by a neuromuscular specialist or SMA specialist
   - If the patient received prior gene therapy, the patient had less than expected clinical benefit with gene therapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RISDIPLAM (Evrysdi)** requires the following rule(s) be met for approval:
   A. You have spinal muscular atrophy (SMA: a type of nerve and muscle movement disorder)
   B. Therapy is prescribed by or in consultation with a neuromuscular (nerve and muscle) specialist or spinal muscular atrophy (SMA) specialist at a SMA Specialty Center
   C. Your diagnosis is confirmed by gene mutation analysis indicating mutations or deletions of both alleles of the survival motor neuron 1 (SMN1: type of protein in spinal cord) gene (such as homozygous deletions of SMN1, homozygous mutations of SMN1, compound heterozygous mutations in SMN1 [deletion of SMN1 on one allele and point mutation of SMN1 on the other allele])
   D. If you are presymptomatic (symptoms have not yet appeared), approval also requires:
      1. You have no more than three copies of survival motor neuron 2 (SMN2: type of protein in spinal cord) based on newborn screening
   E. If you are symptomatic (symptoms have appeared), approval also requires:
      1. You had a baseline motor function assessment by a neuromuscular (nerve and muscle) specialist or SMA specialist
      2. If you have received prior gene therapy, you had less than expected clinical benefit with gene therapy

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RISDIPLAM (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of spinal muscular atrophy (SMA) (ICD-10 G12.9) and meet **ONE** of the following criteria?

- The patient has improved, maintained, or demonstrated less than expected decline in motor function assessments compared to baseline (e.g., HINE, HFMSE, CHOP-INTEND)
- The patient has improved, maintained, or demonstrated less than expected decline in other muscle function (e.g., pulmonary)

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RISDIPLAM (Evrysdi)** requires the following rule(s) be met for renewal:
A. You have spinal muscular atrophy (SMA: a type of nerve and muscle movement disorder)
B. You meet ONE of the following:
   1. You have improved, maintained, or demonstrated less than expected decline in motor function assessments compared to baseline. Some types of motor assessment tests include Hammersmith Infant Neurological Examination (HINE), Hammersmith Functional Motor Scale - Expanded (HFMSE) and Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)
   2. You have improved, maintained, or demonstrated less than expected decline in other muscle function such as pulmonary (lung/breathing) function

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Evrysdi.

REFERENCES

Evrysdi [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; February 2024.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RISDIPLAM (PART D)

For Part D use only:

RISDIPLAM (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	SPINAL MUSCULAR ATROPHY (SMA): INITIAL: GENE MUTATION ANALYSIS INDICATING MUTATIONS OR DELETIONS OF BOTH ALLELES OF THE SURVIVAL MOTOR NEURON 1 (SMN1) GENE. FOR PRESYMPTOMATIC PATIENTS: UP TO THREE COPIES OF SURVIVAL MOTOR NEURON 2 (SMN2) BASED ON NEWBORN SCREENING.
Age Restrictions	N/A
Prescriber Restrictions	SMA: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROMUSCULAR SPECIALIST OR SMA SPECIALIST AT A SMA SPECIALTY CENTER.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS
Other Criteria	SMA: INITIAL: FOR SYMPTOMATIC PATIENTS: 1) BASELINE MOTOR FUNCTION ASSESSMENT BY A NEUROMUSCULAR SPECIALIST OR SMA SPECIALIST, AND 2) IF PATIENT RECEIVED GENE THERAPY, PATIENT HAD LESS THAN EXPECTED CLINICAL BENEFIT WITH GENE THERAPY. RENEWAL: IMPROVED, MAINTAINED, OR DEMONSTRATED LESS THAN EXPECTED DECLINE IN: 1) MOTOR FUNCTION ASSESSMENTS COMPARED TO BASELINE, OR 2) OTHER MUSCLE FUNCTION.

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Effective: 01/01/26 Client Approval: 01/26 P&T Approval: 10/20

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RITUXIMAB BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RITUXIMAB	RITUXAN	16848		GPI-10 (2135186000)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	Yes	No	No	Yes	No	No	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, continue to #6.
   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, continue to #6.
   If no, continue to #5.

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RITUXIMAB BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in PA override field).**

6. Is the drug administered via an implantable pump?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, continue to #7.

7. Is the drug administered via an external pump?

   If yes, continue to #8.
   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

8. Is the drug specifically infused through an external infusion pump covered by Medicare?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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RITUXIMAB BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of non-Hodgkin's lymphoma (NHL) (ICD-10 Group C85) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an oncologist
   - Rituxan will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of NHL
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Riabni (rituximab-arrx), Ruxience (rituximab-pvvr), Truxima (rituximab-abbs)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

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RITUXIMAB BvD (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient have previously untreated advanced stage, CD20-positive diffuse large B-cell lymphoma (DLBCL) (ICD-10 Group C83.3), Burkitt lymphoma (BL) (ICD-10 Group C83.7), Burkitt-like lymphoma (BLL) (ICD-10 Group C83.7) or mature B-cell acute leukemia (B-AL) (ICD-10 Group C91.A) and meet **ALL** of the following criteria?
   - The patient is 6 months to 17 years of age
   - Therapy is prescribed by or in consultation with an oncologist
   - Rituxan will be used in combination with chemotherapy (e.g., CVP [cyclophosphamide-vincristine-prednisolone])
   - Rituxan will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of DLBCL, BL, BLL, or B-AL

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Does the patient have a diagnosis of chronic lymphocytic leukemia (CLL) (ICD-10 Group C91.1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an oncologist
   - Rituxan will be used in combination with fludarabine and cyclophosphamide (FC)
   - Rituxan will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CLL
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Riabni (rituximab-arrx), Ruxience (rituximab-pvvr), Truxima (rituximab-abbs)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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RITUXIMAB BvD (PART D)

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Rituxan will be used in combination with methotrexate
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Rituxan will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Orencia (abatacept)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Does the patient have a diagnosis of granulomatosis with polyangiitis (GPA) (Wegener's granulomatosis [WG]) (ICD-10 Group M31.3) or microscopic polyangiitis (MPA) (ICD-10 M31.7) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Rituxan will be used concurrently with glucocorticoids (e.g., methylprednisolone, prednisone)
   - Rituxan will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of GPA (Wegener's granulomatosis) or MPA
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Riabni (rituximab-arrx), Ruxience (rituximab-pvvr), Truxima (rituximab-abbs)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #6.

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RITUXIMAB BvD (PART D)

INITIAL CRITERIA (CONTINUED)

6. Does the patient have a diagnosis of moderate to severe pemphigus vulgaris (PV) (ICD-10 L10.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Rituxan will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of PV

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RITUXIMAB (Rituxan)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Non-Hodgkin's lymphoma (NHL: a type of blood cancer)
      2. Previously untreated advanced stage, CD20-positive diffuse large B-cell lymphoma (DLBCL: a type of blood cancer), Burkitt lymphoma (BL: a type of blood cancer), Burkitt-like lymphoma (BLL: a type of blood cancer), or mature B-cell acute leukemia (B-AL: a type of blood cancer)
      3. Chronic lymphocytic leukemia (CLL: a type of blood cancer)
      4. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
      5. Granulomatosis with polyangiitis (GPA) (Wegener's granulomatosis [WG: a condition that affects the blood vessels])
      6. Microscopic polyangiitis (MPA: a condition that affects the blood vessel)
      7. Moderate to severe pemphigus vulgaris (PV: a type of skin condition)
   B. If you have non-Hodgkin's lymphoma, approval also requires:
      1. You are 18 years of age or older
      2. Therapy is prescribed by or in consultation with an oncologist (a type of cancer doctor)
      3. You will NOT use Rituxan concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-Hodgkin's lymphoma
      4. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Riabni (rituximab-arrx), Ruxience (rituximab-pvvr), Truxima (rituximab-abbs)
   (Initial denial text continued on next page)

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RITUXIMAB BvD (PART D)

INITIAL CRITERIA (CONTINUED)

C. If you have previously untreated advanced stage, CD20-positive diffuse large B-cell lymphoma, Burkitt lymphoma, Burkitt-like lymphoma, or mature B-cell acute leukemia, approval also requires:
1. You are 6 months to 17 years of age
2. Therapy is prescribed by or in consultation with an oncologist (a type of cancer doctor)
3. Rituxan will be used in combination with chemotherapy (such as CVP [cyclophosphamide-vincristine-prednisolone])
4. You will NOT use Rituxan concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of diffuse large B-cell lymphoma, Burkitt lymphoma, Burkitt-like lymphoma, or mature B-cell acute leukemia

D. If you have chronic lymphocytic leukemia, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with an oncologist (a type of cancer doctor)
3. Rituxan will be used in combination with fludarabine and cyclophosphamide (FC)
4. You will NOT use Rituxan concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic lymphocytic leukemia
5. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Riabni (rituximab-arrx), Ruxience (rituximab-pvvr), Truxima (rituximab-abbs)

E. If you have moderate to severe rheumatoid arthritis, approval also requires:
1. You are 18 years of age or older
2. Rituxan will be used with methotrexate
3. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
4. You will NOT use Rituxan concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
5. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:

a. Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
b. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
c. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
d. Orencia (abatacept)

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RITUXIMAB BvD (PART D)

INITIAL CRITERIA (CONTINUED)

F. If you have granulomatosis with polyangiitis or microscopic polyangiitis, approval also requires:
1. You are 2 years of age or older
2. Rituxan will be used with glucocorticoids (such as methylprednisolone, prednisone)
3. You will NOT use Rituxan concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of granulomatosis with polyangiitis (Wegener's granulomatosis) or microscopic polyangiitis
4. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Riabni (rituximab-arrx), Ruxience (rituximab-pvvr), Truxima (rituximab-abbs)

G. If you have moderate to severe pemphigus vulgaris, approval also requires:
1. You are 18 years of age or older
2. You will NOT use Rituxan concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of pemphigus vulgaris

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RITUXIMAB BvD (PART D)

RENEWAL CRITERIA

NOTE: For the diagnoses of non-Hodgkin's lymphoma (NHL), diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL), Burkitt-like lymphoma (BLL), or mature B-cell acute leukemia (B-AL), chronic lymphocytic leukemia (CLL), granulomatosis with polyangiitis (GPA) (Wegener's granulomatosis [WG]), microscopic polyangiitis (MPA), or moderate to severe pemphigus vulgaris (PV), please refer to the initial criteria section.

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Rituxan will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RITUXIMAB (Rituxan)** requires the following rule(s) be met for renewal:
   A. You have moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   B. You continue to benefit from the medication
   C. You will NOT use Rituxan concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis

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RITUXIMAB BvD (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rituxan.

The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B. Drugs administered by an implantable pump are covered under Part B. Drugs administered via an external pump are covered under Part B if they are included under the local coverage policy of the applicable Medicare coverage policies (National and/or Local Coverage Policies). Drugs administered via an external pump that are not included under the applicable Medicare coverage policies are covered under Part D. A CMS website to assist with National and Local Coverage Determination for B versus D review is http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx.

REFERENCES

Rituxan [Prescribing Information]. South San Francisco, CA: Genentech; December 2021.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed March 18, 2026].

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RITUXIMAB BvD (PART D)

For Part D use only:

RITUXIMAB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: RHEUMATOID ARTHRITIS (RA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. NON-HODGKINS LYMPHOMA (NHL), DIFFUSE LARGE B-CELL LYMPHOMA (DLBCL), BURKITT LYMPHOMA (BL), BURKITT-LIKE LYMPHOMA (BLL), MATURE B-CELL ACUTE LEUKEMIA (B-AL), CHRONIC LYMPHOCYTIC LEUKEMIA (CLL): PRESCRIBED BY OR IN CONSULTATION WITH AN ONCOLOGIST.
Coverage Duration	RA: INITIAL: 6 MO, RENEWAL: 12 MO. NHL, DLBCL, BL, BLL, B-AL, PV, GPA, MPA: 12 MO. CLL: 6 MO.
Other Criteria	INITIAL: ALL INDICATIONS: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION. RA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, XELJANZ, RINVOQ, ORENCIA. NHL, DLBCL, BL, BLL, B-AL, CLL, GPA, MPA, PV: TRIAL OF OR CONTRAINDICATION TO ONE OF THE FOLLOWING PREFERRED AGENTS: RIABNI, RUXIENCE, TRUXIMA, WHERE INDICATIONS ALIGN. RENEWAL: RA: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR THE SAME INDICATION.

Created: 01/09
Effective: 05/01/26 Client Approval: 04/26 P&T Approval: 10/24

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RITUXIMAB-ABBS BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RITUXIMAB-ABBS	TRUXIMA	45522		GPI-10 (2135186010)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	Yes	No	Yes	Yes	No	Yes	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, continue to #6.
   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, continue to #6.
   If no, continue to #5.

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RITUXIMAB-ABBS BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

6. Is the drug administered via an implantable pump?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, continue to #7.

7. Is the drug administered via an external pump?

   If yes, continue to #8.
   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

8. Is the drug specifically infused through an external infusion pump covered by Medicare?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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RITUXIMAB-ABBS BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of non-Hodgkin's lymphoma (NHL) (ICD-10 Group C85) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an oncologist
   - Truxima will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of NHL

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of chronic lymphocytic leukemia (CLL) (ICD-10 Group C91.1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Truxima will be used in combination with fludarabine and cyclophosphamide (FC)
   - Therapy is prescribed by or in consultation with an oncologist
   - Truxima will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CLL

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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RITUXIMAB-ABBS BvD (PART D)

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Truxima will be used in combination with methotrexate
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Truxima will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima)
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima)
     - Orencia (abatacept)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

4. Does the patient have a diagnosis of granulomatosis with polyangiitis (GPA) (Wegener's granulomatosis [WG]) (ICD-10 Group M31.3) or microscopic polyangiitis (MPA) (ICD-10 M31.7) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Truxima will be used concurrently with glucocorticoids (e.g., methylprednisolone, prednisone)
   - Truxima will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of GPA (Wegener's granulomatosis) or MPA

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

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RITUXIMAB-ABBS BvD (PART D)

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of moderate to severe pemphigus vulgaris (PV) (ICD-10 L10.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Truxima will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of PV

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RITUXIMAB-ABBS (Truxima)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Non-Hodgkin's lymphoma (NHL: a type of blood cancer)
      2. Chronic lymphocytic leukemia (CLL: a type of blood cancer)
      3. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
      4. Granulomatosis with polyangiitis (GPA) (Wegener's granulomatosis [WG: A condition that causes inflammation of the blood vessels])
      5. Microscopic polyangiitis (MPA: a condition that causes inflammation of the blood vessels)
      6. Moderate to severe pemphigus vulgaris (PV: a type of skin condition)

   B. If you have non-Hodgkin's lymphoma, approval also requires:
      1. You are 18 years of age or older
      2. Therapy is prescribed by or in consultation with an oncologist (a type of cancer doctor)
      3. You will NOT use Truxima concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-Hodgkin's lymphoma

   C. If you have chronic lymphocytic leukemia, approval also requires:
      1. You are 18 years of age or older
      2. Truxima will be used in combination with fludarabine and cyclophosphamide (FC)
      3. Therapy is prescribed by or in consultation with an oncologist (a type of cancer doctor)
      4. You will NOT use Truxima concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic lymphocytic leukemia

   (Initial denial text continued on next page)

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RITUXIMAB-ABBS BvD (PART D)

INITIAL CRITERIA (CONTINUED)

D. If you have moderate to severe rheumatoid arthritis, approval also requires:
1. You are 18 years of age or older
2. Truxima will be used with methotrexate
3. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
4. You will NOT use Truxima concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
5. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
   b. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima)
   c. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima)
   d. Orencia (abatacept)

E. If you have granulomatosis with polyangiitis or microscopic polyangiitis, approval also requires:
1. You are 18 years of age or older
2. Truxima will be used with glucocorticoids (such as methylprednisolone, prednisone)
3. You will NOT use Truxima concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of granulomatosis with polyangiitis (Wegener's granulomatosis) or microscopic polyangiitis

F. If you have moderate to severe pemphigus vulgaris, approval also requires:
1. You are 18 years of age or older
2. You will NOT use Truxima concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of pemphigus vulgaris

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RITUXIMAB-ABBS BvD (PART D)

RENEWAL CRITERIA

NOTE: For the diagnoses of non-Hodgkin's lymphoma (NHL), chronic lymphocytic leukemia (CLL), granulomatosis with polyangiitis (GPA) (Wegener's granulomatosis [WG]), microscopic polyangiitis (MPA), or moderate to severe pemphigus vulgaris (PV), please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Truxima will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RITUXIMAB-ABBS (Truxima)** requires the following rule(s) be met for renewal:
   A. You have moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   B. You continue to benefit from the medication
   C. You will NOT use Truxima concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis

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RITUXIMAB-ABBS BvD (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Truxima.

The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B. Drugs administered by an implantable pump are covered under Part B. Drugs administered via an external pump are covered under Part B if they are included under the local coverage policy of the applicable Medicare coverage policies (National and/or Local Coverage Policies). Drugs administered via an external pump that are not included under the applicable Medicare coverage policies are covered under Part D. A CMS website to assist with National and Local Coverage Determination for B versus D review is http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx.

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Truxima [Prescribing Information]. North Wales, PA: Celltrion, Inc; June 2025.

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For Part D use only:

RITUXIMAB-ABBS (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: RHEUMATOID ARTHRITIS (RA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. NON-HODGKINS LYMPHOMA (NHL), CHRONIC LYMPHOCYTIC LEUKEMIA (CLL): PRESCRIBED BY OR IN CONSULTATION WITH AN ONCOLOGIST.
Coverage Duration	RA: INITIAL: 6 MO, RENEWAL: 12 MO. NHL, GPA, MPA, PV: 12 MO. CLL: 6 MO.
Other Criteria	INITIAL: ALL INDICATIONS: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION. RA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, XELJANZ, RINVOQ, ORENCIA. RENEWAL: RA: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR THE SAME INDICATION.

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RITUXIMAB-ABBS BvD (PART D)

Created: 11/19
Effective: 05/01/26 Client Approval: 04/26 P&T Approval: 10/25

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RITUXIMAB-ARRX BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RITUXIMAB-ARRX	RIABNI	47033		GPI-10 (2135186014)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	Yes	No	No	Yes	No	No	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, continue to #6.
   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, continue to #6.
   If no, continue to #5.

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RITUXIMAB-ARRX BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

6. Is the drug administered via an implantable pump?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, continue to #7.

7. Is the drug administered via an external pump?

   If yes, continue to #8.
   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

8. Is the drug specifically infused through an external infusion pump covered by Medicare?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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RITUXIMAB-ARRX BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of non-Hodgkin's lymphoma (NHL) (ICD-10 Group C85) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an oncologist
   - Riabni will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of NHL

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of chronic lymphocytic leukemia (CLL) (ICD-10 Group C91.1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Riabni will be used in combination with fludarabine and cyclophosphamide (FC)
   - Therapy is prescribed by or in consultation with an oncologist
   - Riabni will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CLL

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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RITUXIMAB-ARRX BvD (PART D)

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of granulomatosis with polyangiitis (GPA) (Wegener's granulomatosis [WG]) (ICD-10 Group M31.3) or microscopic polyangiitis (MPA) (ICD-10 M31.7) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Riabni will be used concurrently with glucocorticoids (e.g., methylprednisolone, prednisone)
   - Riabni will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of GPA (Wegener's granulomatosis) or MPA

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

4. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Riabni will be used in combination with methotrexate
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Riabni will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima)
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima)
     - Orencia (abatacept)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

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RITUXIMAB-ARRX BvD (PART D)

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of moderate to severe pemphigus vulgaris (PV) (ICD-10 L10.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Riabni will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of PV

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RITUXIMAB-ARRX (Riabni)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Non-Hodgkin's lymphoma (NHL: a type of blood cancer)
      2. Chronic lymphocytic leukemia (CLL: a type of blood cancer)
      3. Granulomatosis with polyangiitis (GPA) (Wegener's granulomatosis [WG: a condition that causes inflammation of the blood vessels])
      4. Microscopic polyangiitis (MPA: a condition that causes inflammation of the blood vessels)
      5. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
      6. Moderate to severe pemphigus vulgaris (PV: a type of skin condition)

   B. If you have non-Hodgkin's lymphoma, approval also requires:
      1. You are 18 years of age or older
      2. Therapy is prescribed by or in consultation with an oncologist (a type of cancer doctor)
      3. You will NOT use Riabni concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-Hodgkin's lymphoma

   C. If you have chronic lymphocytic leukemia, approval also requires:
      1. You are 18 years of age or older
      2. Riabni will be used in combination with fludarabine and cyclophosphamide (FC)
      3. Therapy is prescribed by or in consultation with an oncologist (a type of cancer doctor)
      4. You will NOT use Riabni concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic lymphocytic leukemia

   (Initial denial text continued on next page)

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RITUXIMAB-ARRX BvD (PART D)

INITIAL CRITERIA (CONTINUED)

D. If you have granulomatosis with polyangiitis or microscopic polyangiitis, approval also requires:
1. You are 18 years of age or older
2. Riabni will be used with glucocorticoids (such as methylprednisolone, prednisone)
3. You will NOT use Riabni concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of granulomatosis with polyangiitis (Wegener's granulomatosis) or microscopic polyangiitis

E. If you have moderate to severe rheumatoid arthritis, approval also requires:
1. You are 18 years of age or older
2. Riabni will be used with methotrexate
3. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
4. You will NOT use Riabni concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
5. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
   b. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima)
   c. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima)
   d. Orencia (abatacept)

F. If you have moderate to severe pemphigus vulgaris, approval also requires:
1. You are 18 years of age or older
2. You will NOT use Riabni concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of pemphigus vulgaris

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RITUXIMAB-ARRX BvD (PART D)

RENEWAL CRITERIA

NOTE: For the diagnoses of non-Hodgkin's lymphoma (NHL), chronic lymphocytic leukemia (CLL), granulomatosis with polyangiitis (GPA) (Wegener's granulomatosis [WG]), microscopic polyangiitis (MPA), or moderate to severe pemphigus vulgaris (PV), please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Riabni will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RITUXIMAB-ARRX (Riabni)** requires the following rule(s) be met for renewal:
   A. You have moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   B. You continue to benefit from the medication
   C. You will NOT use Riabni concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis

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RITUXIMAB-ARRX BvD (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Riabni.

The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B. Drugs administered by an implantable pump are covered under Part B. Drugs administered via an external pump are covered under Part B if they are included under the local coverage policy of the applicable Medicare coverage policies (National and/or Local Coverage Policies). Drugs administered via an external pump that are not included under the applicable Medicare coverage policies are covered under Part D. A CMS website to assist with National and Local Coverage Determination for B versus D review is http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx.

REFERENCES

Riabni [Prescribing Information]. Thousand Oaks, CA: Amgen, Inc.; July 2025.

Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/medicare/coverage/prescription-drug-coverage-contracting/prescription-drug-benefit-manual. [Accessed March 18, 2026].

For Part D use only:

RITUXIMAB-ARRX (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	RHEUMATOID ARTHRITIS (RA): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. NON-HODGKINS LYMPHOMA (NHL), CHRONIC LYMPHOCYTIC LEUKEMIA (CLL): PRESCRIBED BY OR IN CONSULTATION WITH AN ONCOLOGIST.
Coverage Duration	RA: INITIAL: 6 MO, RENEWAL: 12 MO. NHL, GPA, MPA, PV: 12 MO. CLL: 6 MO.
Other Criteria	INITIAL: ALL INDICATIONS: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION. RA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, XELJANZ, RINVOQ, ORENCIA. RENEWAL: RA: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR THE SAME INDICATION.

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RITUXIMAB-ARRX BvD (PART D)

Created: 12/20
Effective: 05/01/26 Client Approval: 04/26 P&T Approval: 07/25

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RITUXIMAB AND HYALURONIDASE HUMAN - SQ BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RITUXIMAB/ HYALURONIDASE, HUMAN	RITUXAN HYCELA	44378		GPI-10 (2199000264)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	Yes	No	Yes	Yes	No	Yes	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #5.

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RITUXIMAB AND HYALURONIDASE HUMAN - SQ BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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RITUXIMAB AND HYALURONIDASE HUMAN - SQ BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of follicular lymphoma (FL) (ICD-10 Group C82) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- The patient has received or will receive at least one full dose of a rituximabproduct by intravenous infusion prior to the initiation of Rituxan Hycela
- Rituxan Hycela will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of FL

If yes, continue to #2.
If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
- The patient has relapsed or refractory FL
- The patient has previously untreated FL AND Rituxan Hycela will be used in combination with chemotherapy (e.g., CHOP [cyclophosphamide, doxorubicin, vincristine, prednisone], CVP [cyclophosphamide, vincristine, prednisone])
- The patient has achieved a complete or partial response to rituximab in combination with chemotherapy (e.g., R-CHOP [rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone])
- The patient has non-progressing (including stable disease) FL AND Rituxan Hycela will be used after cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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RITUXIMAB AND HYALURONIDASE HUMAN - SQ BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of diffuse large B-cell lymphoma (DLBCL) (ICD-10 Group C83.3) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received or will receive at least one full dose of a rituximabproduct by intravenous infusion prior to the initiation of Rituxan Hycela
   - The patient has not been previously treated for DLBCL
   - Rituxan Hycela will be used in combination with cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP), or another anthracycline-based chemotherapy regimen
   - Rituxan Hycela will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of DLBCL

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

4. Does the patient have a diagnosis of chronic lymphocytic leukemia (CLL) (ICD-10 Group C91.1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received or will receive at least one full dose of a rituximabproduct by intravenous infusion prior to the initiation of Rituxan Hycela
   - Rituxan Hycela will be used in combination with fludarabine and cyclophosphamide (FC)
   - Rituxan Hycela will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CLL

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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RITUXIMAB AND HYALURONIDASE HUMAN - SQ BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RITUXIMAB AND HYALURONIDASE HUMAN - SQ (Rituxan Hycela)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Follicular lymphoma (FL: a type of blood cancer)
   2. Diffuse large B-cell lymphoma (DLBCL: a type of blood cancer)
   3. Chronic lymphocytic leukemia (CLL: a type of blood cancer)

B. If you have follicular lymphoma, approval also requires ONE of the following:
   1. You are 18 years of age or older
   2. You have received or will receive at least one full dose of a rituximab product by intravenous infusion (given into the veins) before starting Rituxan Hycela
   3. You will NOT use Rituxan Hycela concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of follicular lymphoma
   4. You meet ONE of the following:
      a. You have relapsed or refractory follicular lymphoma (cancer that has returned or does not fully respond to treatment)
      b. You have previously untreated follicular lymphoma AND Rituxan Hycela will be used in combination with chemotherapy (such as CHOP [cyclophosphamide, doxorubicin, vincristine, prednisone], CVP [cyclophosphamide, vincristine, prednisone])
      c. You have achieved a complete or partial response to rituximab in combination with chemotherapy (such as R-CHOP [rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone])
      d. You have non-progressing (does not get worse, including stable disease) follicular lymphoma AND Rituxan Hycela will be used after cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy

C. If you have diffuse large B-cell lymphoma, approval also requires:
   1. You are 18 years of age or older
   2. You have received or will receive at least one full dose of a rituximab product by intravenous infusion (given into the veins) before starting Rituxan Hycela
   3. You have not been previously treated for diffuse large B-cell lymphoma
   4. Rituxan Hycela will be used in combination with cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP), or another anthracycline-based chemotherapy regimen
   5. You will NOT use Rituxan Hycela concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of diffuse large B-cell lymphoma

(Denial text continued on next page)

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RITUXIMAB AND HYALURONIDASE HUMAN - SQ BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

D. If you have chronic lymphocytic leukemia, approval also requires:

1. You are 18 years of age or older
2. You have received or will receive at least one full dose of a rituximab product by intravenous infusion (given into the veins) before starting Rituxan Hycela
3. Rituxan Hycela will be used in combination with fludarabine and cyclophosphamide (FC)
4. You will NOT use Rituxan Hycela concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic lymphocytic leukemia

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rituxan Hycela.

The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Rituxan Hycela [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; June 2021.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed July 1, 2025].

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RITUXIMAB AND HYALURONIDASE HUMAN - SQ BvD (PART D)

For Part D use only:

RITUXIMAB AND HYALURONIDASE HUMAN - SQ (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	FOLLICULAR LYMPHOMA (FL), DIFFUSE LARGE B-CELL LYMPHOMA (DLBCL), CHRONIC LYMPHOCYTIC LEUKEMIA (CLL): 1) HAS RECEIVED OR WILL RECEIVE AT LEAST ONE FULL DOSE OF A RITUXIMAB PRODUCT BY INTRAVENOUS INFUSION PRIOR TO INITIATION OF RITUXIMAB AND HYALURONIDASE, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION.

Created: 07/17
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 07/17

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RITUXIMAB-PVVR BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RITUXIMAB-PVVR	RUXIENCE	45899		GPI-10 (2135186060)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	Yes	No	No	Yes	No	No	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit).**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, continue to #6.
   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, continue to #6.
   If no, continue to #5.

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RITUXIMAB-PVVR BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

6. Is the drug administered via an implantable pump?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, continue to #7.

7. Is the drug administered via an external pump?

   If yes, continue to #8.
   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

8. Is the drug specifically infused through an external infusion pump covered by Medicare?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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RITUXIMAB-PVVR BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of non-Hodgkin's lymphoma (NHL) (ICD-10 Group C85) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an oncologist
   - Ruxience will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of NHL

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of chronic lymphocytic leukemia (CLL) (ICD-10 Group C91.1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Ruxience will be used in combination with fludarabine and cyclophosphamide (FC)
   - Therapy is prescribed by or in consultation with an oncologist
   - Ruxience will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CLL

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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RITUXIMAB-PVVR BvD (PART D)

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of granulomatosis with polyangiitis (GPA) (Wegener's granulomatosis [WG]) (ICD-10 Group M31.3) or microscopic polyangiitis (MPA) (ICD-10 M31.7) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Ruxience will be used concurrently with glucocorticoids (e.g., methylprednisolone, prednisone)
   - Ruxience will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of GPA (Wegener's granulomatosis) or MPA
   -

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

4. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Ruxience will be used in combination with methotrexate
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Ruxience will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Orencia (abatacept)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

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RITUXIMAB-PVVR BvD (PART D)

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of moderate to severe pemphigus vulgaris (PV) (ICD-10 L10.0) **AND** meet the following criterion?
   - The patient is 18 years of age or older
   - Ruxience will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of PV

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RITUXIMAB-PVVR (Ruxience)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Non-Hodgkin's lymphoma (NHL: a type of blood cancer)
      2. Chronic lymphocytic leukemia (CLL: a type of blood cancer)
      3. Granulomatosis with polyangiitis (GPA) (Wegener's granulomatosis [WG: a condition that causes inflammation of the blood vessels])
      4. Microscopic polyangiitis (MPA: a condition that causes inflammation of the blood vessels)
      5. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
      6. Moderate to severe pemphigus vulgaris (PV: a type of skin condition)

   B. If you have non-Hodgkin's lymphoma, approval also requires:
      1. You are 18 years of age or older
      2. Therapy is prescribed by or in consultation with an oncologist (a type of cancer doctor)
      3. You will NOT use Ruxience concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-Hodgkin's lymphoma

   C. If you have chronic lymphocytic leukemia, approval also requires:
      1. You are 18 years of age or older
      2. Ruxience will be used in combination with fludarabine and cyclophosphamide (FC)
      3. Therapy is prescribed by or in consultation with an oncologist (a type of cancer doctor)
      4. You will NOT use Ruxience concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic lymphocytic leukemia

   (Initial denial text continued on next page)

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RITUXIMAB-PVVR BvD (PART D)

INITIAL CRITERIA (CONTINUED)

D. If you have granulomatosis with polyangiitis or microscopic polyangiitis, approval also requires:
1. You are 18 years of age or older
2. Ruxience will be used with glucocorticoids (such as methylprednisolone, prednisone)
3. You will NOT use Ruxience concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of granulomatosis with polyangiitis (Wegener's granulomatosis) or microscopic polyangiitis

E. If you have moderate to severe rheumatoid arthritis, approval also requires:
1. You are 18 years of age or older
2. Ruxience will be used with methotrexate
3. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
4. You will NOT use Ruxience concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
5. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
   b. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
   c. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
   d. Orencia (abatacept)

F. If you have moderate to severe pemphigus vulgaris, approval also requires:
1. You are 18 years of age or older
2. You will NOT use Ruxience concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of pemphigus vulgaris

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RITUXIMAB-PVVR BvD (PART D)

RENEWAL CRITERIA

NOTE: For the diagnoses of non-Hodgkin's lymphoma (NHL), chronic lymphocytic leukemia (CLL), granulomatosis with polyangiitis (GPA) (Wegener's granulomatosis [WG]), microscopic polyangiitis (MPA), or moderate to severe pemphigus vulgaris (PV), please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Ruxience will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RITUXIMAB-PVVR (Ruxience)** requires the following rule(s) be met for renewal:
   A. You have moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   B. You continue to benefit from the medication
   C. You will NOT use Ruxience concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ruxience.
The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B. Drugs administered by an implantable pump are covered under Part B. Drugs administered via an external pump are covered under Part B if they are included under the local coverage policy of the applicable Medicare coverage policies (National and/or Local Coverage Policies). Drugs administered via an external pump that are not included under the applicable Medicare coverage policies are covered under Part D. A CMS website to assist with National and Local Coverage Determination for B versus D review is http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx.

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RITUXIMAB-PVVR BvD (PART D)

REFERENCES

Ruxience [Prescribing Information]. New York, NY: Pfizer Ireland Pharmaceuticals; June 2023.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed March 18, 2026].

For Part D use only:

RITUXIMAB-PVVR (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	RHEUMATOID ARTHRITIS (RA): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. NON-HODGKINS LYMPHOMA (NHL), CHRONIC LYMPHOCYTIC LEUKEMIA (CLL): PRESCRIBED BY OR IN CONSULTATION WITH AN ONCOLOGIST.
Coverage Duration	RA: INITIAL: 6 MO, RENEWAL: 12 MO. NHL, GPA, MPA, PV: 12 MO. CLL: 6 MO.
Other Criteria	INITIAL: ALL INDICATIONS: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION. RA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, XELJANZ, RINVOQ, ORENCIA. RENEWAL: RA: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR THE SAME INDICATION.

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Effective: 05/01/26 Client Approval: 04/26 P&T Approval: 10/25

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ROFLUMILAST 0.05% CREAM (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ROFLUMILAST	ZORYVE		58432	GPI-14 (90230061003710)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of mild to moderate atopic dermatitis (ICD-10 Group L20) and meet **ALL** of the following criteria?
   - The patient is 2 to 5 years of age
   - The patient had a trial of or contraindication to a topical corticosteroid (e.g., triamcinolone 0.1% cream or ointment, mometasone furoate 0.1% ointment, fluocinonide 0.05% cream, halobetasol propionate 0.05% ointment) OR a topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus)
   - The patient had a trial of or contraindication to Eucrisa (crisaborole)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ROFLUMILAST 0.05% CREAM (PART D)

INITIAL CRITERIA (CONTINUED)

2. Will Zoryve be used concurrently with **ANY** of the following for the treatment of atopic dermatitis?
   - Other non-steroidal topicals (e.g., calcineurin inhibitors [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)], PDE-4 inhibitors [e.g., Eucrisa (crisaborole)], JAK inhibitors [e.g., Opzelura (ruxolitinib), Anzupgo (delgocitinib)], AhR agonists [e.g., Vtama (tapinarof)])
   - Systemic therapeutic biologics (e.g., Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
   - Other JAK inhibitors (e.g., Rinvoq [upadacitinib], Cibinqo [abrocitinib])
   - Potent immunosuppressants (e.g., azathioprine, cyclosporine)

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, **approve for 3 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ROFLUMILAST 0.05% CREAM (Zoryve)** requires the following rule(s) be met for approval:
   A. You have mild to moderate atopic dermatitis (a type of skin condition)
   B. You are 2 to 5 years of age
   C. You have tried or have a contraindication to (harmful for you to use) a topical corticosteroid (such as triamcinolone 0.1% cream or ointment, mometasone furoate 0.1% ointment, fluocinonide 0.05% cream, halobetasol propionate 0.05% ointment) OR a topicalcalcineurin inhibitor (such as pimecrolimus, tacrolimus)
   D. You have tried or have a contraindication to (harmful for you to use) Eucrisa (crisaborole)
   (Initial denial text continued on next page)

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ROFLUMILAST 0.05% CREAM (PART D)

INITIAL CRITERIA (CONTINUED)

E. You will NOT use Zoryve concurrently (at the same time) with ANY of the following for the treatment of atopic dermatitis (a type of skin condition):
   1. Other non-steroidal topicals (such as calcineurin inhibitors [such as Elidel (pimecrolimus), Protopic (tacrolimus)], PDE-4 [phosphodiesterase-4] inhibitors [such as Eucrisa (crisaborole)], JAK [Janus kinase] inhibitors [such as Opzelura (ruxolitinib), Anzupgo (delgocitinib)], AhR [aryl hydrocarbon receptor] agonists [such as Vtama (tapinarof)])
   2. Systemic therapeutic biologics (such as Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
   3. Other JAK (Janus kinase) inhibitors (such as Rinvoq [upadacitinib], Cibinqo [abrocitinib])
   4. Potent immunosuppressants (such as azathioprine, cyclosporine)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ROFLUMILAST 0.05% CREAM (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of mild to moderate atopic dermatitis (ICD-10 Group L20) **AND** meet the following criterion?
- The patient has experienced or maintained improvement in pruritus, relapsing-remitting dermatitis, or facial/interdigital involvement

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Will Zoryve be used concurrently with **ANY** of the following for the treatment of atopic dermatitis?
- Other non-steroidal topicals (e.g., calcineurin inhibitors [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)], PDE-4 inhibitors [e.g., Eucrisa (crisaborole)], JAK inhibitors [e.g., Opzelura (ruxolitinib), Anzupgo (delgocitinib)], AhR agonists [e.g., Vtama (tapinarof)])
- Systemic therapeutic biologics (e.g., Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
- Other JAK inhibitors (e.g., Rinvoq [upadacitinib], Cibinqo [abrocitinib])
- Potent immunosuppressants (e.g., azathioprine, cyclosporine)

If yes, do not approve.
DENIAL TEXT: See the renewal denial text at the end of the guideline.

If no, **approve for 12 months by GPID or GPI-14.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ROFLUMILAST 0.05% CREAM (Zoryve)** requires the following rule(s) be met for renewal:
A. You have mild to moderate atopic dermatitis (a type of skin condition)
B. You have experienced or maintained improvement in pruritus (itchiness), relapsing-remitting (disease returns and goes away) dermatitis, or facial/interdigital (between the fingers or toes) involvement

(Renewal denial text continued on next page)

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ROFLUMILAST 0.05% CREAM (PART D)

RENEWAL CRITERIA (CONTINUED)

C. You will NOT use Zoryve concurrently (at the same time) with ANY of the following for the treatment of atopic dermatitis (a type of skin condition):
   1. Other non-steroidal topicals (such as calcineurin inhibitors [such as Elidel (pimecrolimus), Protopic (tacrolimus)], PDE-4 [phosphodiesterase-4] inhibitors [such as Eucrisa (crisaborole)], JAK [Janus kinase] inhibitors [such as Opzelura (ruxolitinib), Anzupgo (delgocitinib)], AhR [aryl hydrocarbon receptor] agonists [such as Vtama (tapinarof)])
   2. Systemic therapeutic biologics (such as Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
   3. Other JAK (Janus kinase) inhibitors (such as Rinvoq [upadacitinib], Cibinqo [abrocitinib])
   4. Potent immunosuppressants (such as azathioprine, cyclosporine)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Zoryve.

REFERENCES
Zoryve [Prescribing Information]. Westlake Village, CA: Arcutis Biotherapeutics, Inc.; October 2025.

For Part D use only:

ROFLUMILAST 0.05% CREAM (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	INITIAL: 3 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	ATOPIC DERMATITIS: INITIAL: TRIAL OF OR CONTRAINDICATION TO: 1) A TOPICAL CORTICOSTEROID OR A TOPICAL CALCINEURIN INHIBITOR, AND 2) EUCRISA. INITIAL/RENEWAL: NO CONCURRENT USE WITH ANY OF THE FOLLOWING FOR ATOPIC DERMATITIS: 1) NON-STEROIDAL TOPICALS (E.G., CALCINEURIN INHIBITORS, PDE-4 INHIBITORS, JAK INHIBITORS, AHR AGONISTS), 2) SYSTEMIC THERAPEUTIC BIOLOGICS, 3) OTHER JAK INHIBITORS, OR 4) POTENT IMMUNOSUPPRESSANTS (E.G., AZATHIOPRINE, CYCLOSPORINE). RENEWAL:

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	EXPERIENCED OR MAINTAINED IMPROVEMENT IN PRURITUS, RELAPSING-REMITTING DERMATITIS, OR FACIAL/INTERDIGITAL INVOLVEMENT.

Created: 10/25
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 01/26

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STANDARD PART D
PRIOR AUTHORIZATION GUIDELINES

ROFLUMILAST 0.3% CREAM (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ROFLUMILAST	ZORYVE		52657	GPI-14 (90230061003730)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of plaque psoriasis (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist
   - The patient has psoriasis covering 2 percent to 20 percent of body surface area (BSA) (excluding scalp, palms, and soles)
   - Zoryve will NOT be used concurrently with other systemic immunomodulating agents (e.g., Stelara [ustekinumab], Otezla [apremilast]), topical corticosteroids (e.g., betamethasone dipropionate, clobetasol propionate), or topical non-steroidals (e.g., calcitriol, tazarotene)

   If yes, continue to #2.
   If no, do no approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ROFLUMILAST 0.3% CREAM (PART D)

INITIAL CRITERIA (CONTINUED)

2. Has the patient had a trial of or contraindication to **TWO** of the following (from different categories)?
   - High potency topical corticosteroid (e.g., triamcinolone acetonide 0.5 percent cream or ointment, halobetasol propionate 0.01 percent lotion) or a super-high potency topical corticosteroid (e.g., fluocinonide 0.1 percent cream, clobetasol propionate 0.05 percent cream or ointment)
   - Topical vitamin D analog (e.g., calcipotriene cream, calcitriol ointment)
   - Topical calcineurin inhibitor (e.g., tacrolimus, pimecrolimus)
   - Topical retinoid (e.g., tazarotene cream/gel)
   - Topical aryl hydrocarbon receptor agonist (e.g., Vtama [tapinarof])

   If yes, **approve for 2 months by GPID or GPI-14.**
   If no, do not approve.

   INITIAL DENIAL TEXT: Our guideline named **ROFLUMILAST 0.3% CREAM (Zoryve)** requires the following rule(s) be met for approval:
   A. You have plaque psoriasis (a type of skin condition)
   B. You are 2 years of age or older
   C. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   D. You have psoriasis covering 2 percent to 20 percent of body surface area (BSA) (excluding scalp, palms, and soles)
   E. You will NOT use Zoryve concurrently (at the same time) with other systemic immunomodulating medications (such as Stelara [ustekinumab], Otezla [apremilast]), topical corticosteroids (such as betamethasone dipropionate, clobetasol propionate), or topical non-steroidals (such as calcitriol, tazarotene)
   F. You have tried or have a contraindication to (harmful for you to use) TWO of the following (from different categories):
      1. High potency topical corticosteroid (such as triamcinolone acetonide 0.5 percent cream or ointment, halobetasol propionate 0.01 percent lotion) or a super-high potency topical corticosteroid (such as fluocinonide 0.1 percent cream, clobetasol propionate 0.05 percent cream or ointment)
      2. Topical vitamin D analog (such as calcipotriene cream, calcitriol ointment)
      3. Topical calcineurin inhibitor (such as tacrolimus, pimecrolimus)
      4. Topical retinoid (such as tazarotene cream/gel)
      5. Topical aryl hydrocarbon receptor agonist (such as Vtama [tapinarof])

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STANDARD PART D
PRIOR AUTHORIZATION GUIDELINES

ROFLUMILAST 0.3% CREAM (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of plaque psoriasis (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient has achieved or maintained clear or minimal disease
   - Zoryve will NOT be used concurrently with other systemic immunomodulating agents (e.g., Stelara [ustekinumab], Otezla [apremilast]), topical corticosteroids (e.g., betamethasone dipropionate, clobetasol propionate), or topical non-steroidals (e.g., calcitriol, tazarotene)

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: Our guideline named **ROFLUMILAST 0.3% CREAM (Zoryve)** requires the following rule(s) be met for renewal:
   A. You have plaque psoriasis (a type of skin condition)
   B. You have achieved or maintained clear or minimal disease
   C. You will NOT use Zoryve concurrently (at the same time) with other systemic immunomodulating medications (such as Stelara [ustekinumab], Otezla [apremilast]), topical corticosteroids (such as betamethasone dipropionate, clobetasol propionate), or topical non-steroidals (such as calcitriol, tazarotene)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Zoryve.

REFERENCES
Zoryve [Prescribing Information]. Westlake Village, CA: Arcutis Biotherapeutics, Inc.; June 2026.

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STANDARD PART D
PRIOR AUTHORIZATION GUIDELINES

ROFLUMILAST 0.3% CREAM (PART D)

For Part D use only:

ROFLUMILAST 0.3% CREAM (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	PLAQUE PSORIASIS (PSO): INITIAL: PSORIASIS COVERING 2 TO 20 PERCENT OF BODY SURFACE AREA, (EXCLUDING SCALP, PALMS, AND SOLES).
Age Restrictions	N/A
Prescriber Restrictions	PSO: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST
Coverage Duration	INITIAL: 2 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	PSO: INITIAL: 1) NO CONCURRENT USE WITH OTHER SYSTEMIC IMMUNOMODULATING AGENTS (E.G., STELARA, OTEZLA), TOPICAL CORTICOSTEROIDS, OR TOPICAL NON-STEROIDALS (E.G., CALCITRIOL, TAZAROTENE), AND 2) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING (FROM DIFFERENT CATEGORIES): (A) HIGH OR SUPER-HIGH POTENCY TOPICAL CORTICOSTEROID, (B) TOPICAL VITAMIN D ANALOG, (C) TOPICAL CALCINEURIN INHIBITOR, (D) TOPICAL RETINOID (E.G., TAZAROTENE CREAM/GEL), (E) TOPICAL ARYL HYDROCARBON RECEPTOR AGONIST. RENEWAL: 1) ACHIEVED OR MAINTAINED CLEAR OR MINIMAL DISEASE, AND 2) NO CONCURRENT USE WITH OTHER SYSTEMIC IMMUNOMODULATING AGENTS (E.G., STELARA, OTEZLA), TOPICAL CORTICOSTEROIDS, OR TOPICAL NON-STEROIDALS (E.G., CALCITRIOL, TAZAROTENE).

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ROFLUMILAST 0.15% CREAM (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ROFLUMILAST	ZORYVE		55978	GPI-14 (90230061003720)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of mild to moderate atopic dermatitis (ICD-10 Group L20) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - The patient had a trial of or contraindication to a topical corticosteroid (e.g., triamcinolone 0.1% cream or ointment, mometasone furoate 0.1% ointment, fluocinonide 0.05% cream, halobetasol propionate 0.05% ointment) OR a topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus)
   - The patient had a trial of or contraindication to Eucrisa (crisaborole)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ROFLUMILAST 0.15% CREAM (PART D)

INITIAL CRITERIA (CONTINUED)

2. Will Zoryve be used concurrently with **ANY** of the following for the treatment of atopic dermatitis?
   - Other non-steroidal topicals (e.g., calcineurin inhibitors [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)], PDE-4 inhibitors [e.g., Eucrisa (crisaborole)], JAK inhibitors [e.g., Opzelura (ruxolitinib), delgocitinib], AhR agonists [e.g., Vtama (tapinarof)])
   - Systemic therapeutic biologics (e.g., Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
   - Other JAK inhibitors (e.g., Rinvoq [upadacitinib], Cibinqo [abrocitinib])
   - Potent immunosuppressants (e.g., azathioprine, cyclosporine)

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, **approve for 3 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ROFLUMILAST 0.15% CREAM (Zoryve)** requires the following rule(s) be met for approval:
   A. You have mild to moderate atopic dermatitis (a type of skin condition)
   B. You are 6 years of age or older
   C. You have tried or have a contraindication to (harmful for you to use) a topical corticosteroid (such as triamcinolone 0.1% cream or ointment, mometasone furoate 0.1% ointment, fluocinonide 0.05% cream, halobetasol propionate 0.05% ointment) OR a topical calcineurin inhibitor (such as pimecrolimus, tacrolimus)
   D. You have tried or have a contraindication (harmful for you to use) to Eucrisa (crisaborole)
   E. You will NOT use Zoryve concurrently (at the same time) with ANY of the following for the treatment of atopic dermatitis (a type of skin condition):
      1. Other non-steroidal topicals (such as calcineurin inhibitors [such as Elidel (pimecrolimus), Protopic (tacrolimus)], PDE-4 [phosphodiesterase-4] inhibitors [such as Eucrisa (crisaborole)], JAK [Janus kinase] inhibitors [such as Opzelura (ruxolitinib), delgocitinib], AhR [aryl hydrocarbon receptor] agonists [such as Vtama (tapinarof)])
      2. Systemic therapeutic biologics (such as Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
      3. Other JAK (Janus kinase) inhibitors (such as Rinvoq [upadacitinib], Cibinqo [abrocitinib])
      4. Potent immunosuppressants (such as azathioprine, cyclosporine)

   (Initial denial text continued on next page)

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ROFLUMILAST 0.15% CREAM (PART D)

INITIAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ROFLUMILAST 0.15% CREAM (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of mild to moderate atopic dermatitis (ICD-10 Group L20) **AND** meet the following criterion?
- The patient has experienced or maintained improvement in pruritus, relapsing-remitting dermatitis, or facial/interdigital involvement

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Will Zoryve be used concurrently with **ANY** of the following for the treatment of atopic dermatitis?
- Other non-steroidal topicals (e.g., calcineurin inhibitors [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)], PDE-4 inhibitors [e.g., Eucrisa (crisaborole)], JAK inhibitors [e.g., Opzelura (ruxolitinib), delgocitinib], AhR agonists [e.g., Vtama (tapinarof)])
- Systemic therapeutic biologics (e.g., Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
- Other JAK inhibitors (e.g., Rinvoq [upadacitinib], Cibinqo [abrocitinib])
- Potent immunosuppressants (e.g., azathioprine, cyclosporine)

If yes, do not approve.
DENIAL TEXT: See the renewal denial text at the end of the guideline.

If no, **approve for 12 months by GPID or GPI-14.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

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ROFLUMILAST 0.15% CREAM (PART D)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ROFLUMILAST 0.15% CREAM (Zoryve)** requires the following rule(s) be met for renewal:

A. You have mild to moderate atopic dermatitis (a type of skin condition)
B. You have experienced or maintained improvement in pruritus (itchiness), relapsing-remitting (disease returns and goes away) dermatitis, or facial/interdigital (between the fingers or toes) involvement
C. You will NOT use Zoryve concurrently (at the same time) with ANY of the following for the treatment of atopic dermatitis (a type of skin condition):
    1. Other non-steroidal topicals (such as calcineurin inhibitors [such as Elidel (pimecrolimus), Protopic (tacrolimus)], PDE-4 [phosphodiesterase-4] inhibitors [such as Eucrisa (crisaborole)], JAK [Janus kinase] inhibitors [such as Opzelura (ruxolitinib), delgocitinib], AhR [aryl hydrocarbon receptor] agonists [such as Vtama (tapinarof)])
    2. Systemic therapeutic biologics (such as Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
    3. Other JAK (Janus kinase) inhibitors (such as Rinvoq [upadacitinib], Cibinqo [abrocitinib])
    4. Potent immunosuppressants (such as azathioprine, cyclosporine)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zoryve.

REFERENCES

Zoryve [Prescribing Information]. Westlake Village, CA: Arcutis Biotherapeutics, Inc.; July 2024.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ROFLUMILAST 0.15% CREAM (PART D)

For Part D use only:

ROFLUMILAST 0.15% CREAM (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	INITIAL: 3 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	ATOPIC DERMATITIS: INITIAL: TRIAL OF OR CONTRAINDICATION TO 1) A TOPICAL CORTICOSTEROID OR A TOPICAL CALCINEURIN INHIBITOR, AND 2) EUCRISA. INITIAL/RENEWAL: NO CONCURRENT USE WITH ANY OF THE FOLLOWING FOR ATOPIC DERMATITIS: 1) NON-STEROIDAL TOPICALS (E.G., CALCINEURIN INHIBITORS, PDE-4 INHIBITORS, JAK INHIBITORS, AHR AGONISTS), 2) SYSTEMIC THERAPEUTIC BIOLOGICS, 3) OTHER JAK INHIBITORS, OR 4) POTENT IMMUNOSUPPRESSANTS (E.G., AZATHIOPRINE, CYCLOSPORINE). RENEWAL: EXPERIENCED OR MAINTAINED IMPROVEMENT IN PRURITUS, RELAPSING-REMITTING DERMATITIS, OR FACIAL/INTERDIGITAL INVOLVEMENT.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ROFLUMILAST - FOAM (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ROFLUMILAST	ZORYVE		55119	GPI-14 (90230061003920)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of seborrheic dermatitis (ICD-10 Group L21) and meet **ALL** of the following criteria?
   - The patient is 9 years of age or older
   - The patient's seborrheic dermatitis covers less than or equal to 20% of their body surface area (BSA) (may involve scalp, face, trunk, or intertriginous areas)

   If yes, continue to #2.
   If no, continue to #4.

2. Has the patient had a trial of or contraindication to **TWO** of the following (from different categories)?
   - High potency topical corticosteroid (e.g., triamcinolone acetonide 0.5% cream or ointment, halobetasol propionate 0.01% lotion) or a super-high potency topical corticosteroid (e.g., fluocinonide 0.1% cream, clobetasol propionate 0.05% cream or ointment)
   - Topical antifungal (e.g., ketoconazole, ciclopirox)

   If yes, **approve for 8 weeks by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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ROFLUMILAST - FOAM (PART D)

INITIAL CRITERIA (CONTINUED)

3. Has the patient had a prior successful treatment with roflumilast foam?

   If yes, **approve for 8 weeks by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have a diagnosis of plaque psoriasis (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist
   - The patient's plaque psoriasis covers at least 10% of total scalp OR does not exceed 20% BSA of non-scalp areas of the body
   - Zoryve will NOT be used concurrently with other systemic immunomodulating agents (e.g., Stelara [ustekinumab], Otezla [apremilast]), topical corticosteroids (e.g., betamethasone dipropionate, clobetasol propionate), or topical non-steroidals (e.g., calcitriol, tazarotene)

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

5. Has the patient had a trial of or contraindication to **TWO** of the following (from different categories)?
   - High potency topical corticosteroid (e.g., triamcinolone acetonide 0.5% cream or ointment, halobetasol propionate 0.01% lotion) or a super-high potency topical corticosteroid (e.g., fluocinonide 0.1% cream, clobetasol propionate 0.05% cream or ointment)
   - Topical vitamin D analog (e.g., calcipotriene cream, calcitriol ointment)

   If yes, **approve for 8 weeks by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ROFLUMILAST - FOAM (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ROFLUMILAST - FOAM (Zoryve)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Seborrheic dermatitis (a type of skin condition)
   2. Plaque psoriasis (a type of skin condition)

B. If you have seborrheic dermatitis, approval also requires:
   1. You are 9 years of age or older
   2. Your seborrheic dermatitis covers less than or equal to 20% of body surface area (BSA) (may involve scalp, face, trunk [the central part of your body], or intertriginous areas [between skin folds])
   3. You meet ONE of the following:
      a. You have tried or have a contraindication to (harmful for you to use) TWO of the following (from different categories):
         i. High potency topical corticosteroid (such as triamcinolone acetonide 0.5% cream or ointment, halobetasol propionate 0.01% lotion) or a super-high potency topical corticosteroid (such as fluocinonide 0.1% cream, clobetasol propionate 0.05% cream or ointment)
         ii. Topical antifungal (such as ketoconazole, ciclopirox)
      b. You previously had a successful treatment with roflumilast foam

(Initial denial text continued on next page)

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ROFLUMILAST - FOAM (PART D)

INITIAL CRITERIA (CONTINUED)

C. If you have plaque psoriasis, approval also requires:

1. You are 12 years of age or older
2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
3. Your plaque psoriasis covers at least 10% of your total scalp OR does not exceed 20% of your body surface area (BSA) in non-scalp areas of your body
4. You will NOT use Zoryve concurrently (at the same time) with other systemic immunomodulating agents (such as Stelara [ustekinumab], Otezla [apremilast]), topical corticosteroids (such as betamethasone dipropionate, clobetasol propionate), or topical non-steroidals (such as calcitriol, tazarotene)
5. You have tried or have a contraindication to (harmful for you to use) TWO of the following (from different categories):
   a. High potency topical corticosteroid (such as triamcinolone acetonide 0.5% cream or ointment, halobetasol propionate 0.01% lotion) or a super-high potency topical corticosteroid (such as fluocinonide 0.1% cream, clobetasol propionate 0.05% cream or ointment)
   b. Topical vitamin D analog (such as calcipotriene cream, calcitriol ointment)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ROFLUMILAST - FOAM (PART D)

RENEWAL CRITERIA

NOTE: For the diagnosis of seborrheic dermatitis, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of plaque psoriasis (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient's plaque psoriasis involves the scalp and/or body
   - The patient has achieved or maintained clear or minimal disease
   - Zoryve will NOT be used concurrently with other systemic immunomodulating agents (e.g., Stelara [ustekinumab], Otezla [apremilast]), topical corticosteroids (e.g., betamethasone dipropionate, clobetasol propionate), or topical non-steroidals (e.g., calcitriol, tazarotene)

   If yes, **approve for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ROFLUMILAST - FOAM (Zoryve)** requires the following rule(s) be met for renewal:
   A. You have plaque psoriasis (a type of skin condition)
   B. Your plaque psoriasis involves the scalp and/or body
   C. You have achieved or maintained clear or minimal disease
   D. You will NOT use Zoryve concurrently (at the same time) with other systemic immunomodulating medications (such as Stelara [ustekinumab], Otezla [apremilast]), topical corticosteroids (such as betamethasone dipropionate, clobetasol propionate), or topical non-steroidals (such as calcitriol, tazarotene)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ROFLUMILAST - FOAM (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zoryve.

REFERENCES

Zoryve [Prescribing Information]. Westlake Village, CA: Arcutis Biotherapeutics, Inc.; May 2025.

For Part D use only:

ROFLUMILAST - FOAM (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	INITIAL: SEBORRHEIC DERMATITIS: SEBORRHEIC DERMATITIS COVERING 20 PERCENT OR LESS OF BODY SURFACE AREA (BSA). PLAQUE PSORIASIS (PSO): PSORIASIS COVERING AT LEAST 10 PERCENT OF SCALP OR DOES NOT EXCEED 20 PERCENT OF BSA IN NON-SCALP AREAS.
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: PSO: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST.
Coverage Duration	INITIAL: SEBORRHEIC DERMATITIS, PSO: 8 WEEKS. RENEWAL: PSO: 12 MONTHS.
Other Criteria	SEBORRHEIC DERMATITIS: INITIAL: ONE OF THE FOLLOWING: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING (FROM DIFFERENT CATEGORIES): (A) HIGH OR SUPER-HIGH POTENCY TOPICAL CORTICOSTEROID, (B) TOPICAL ANTIFUNGAL, OR 2) PRIOR SUCCESSFUL TREATMENT WITH ROFLUMILAST FOAM. PSO: INITIAL: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING (FROM DIFFERENT CATEGORIES): (A) HIGH OR SUPER-HIGH POTENCY TOPICAL CORTICOSTEROID, (B) TOPICAL VITAMIN D ANALOG. INITIAL/RENEWAL: NO CONCURRENT USE WITH OTHER SYSTEMIC IMMUNOMODULATING AGENTS (E.G., STELARA, OTEZLA), TOPICAL CORTICOSTEROIDS, OR TOPICAL NON-STEROIDALS (E.G., CALCITRIOL, TAZAROTENE). RENEWAL: ACHIEVED OR MAINTAINED CLEAR OR MINIMAL DISEASE.

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Effective: 08/01/25 Client Approval: 06/25 P&T Approval: 04/25

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ROMIDEPSIN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ROMIDEPSIN	ISTODAX, ROMIDEPSIN	36898		GPI-10 (2153156000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of cutaneous T-cell lymphoma (CTCL) (ICD-10 Group C84.A), also known as Mycosis Fungoides (ICD Group C84.0) or Sezary Syndrome (ICD-10 Group C84.1) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient had a trial of or contraindication to Zolinza (vorinostat) AND is unable to tolerate oral medications
   - The patient has tried at least one form of systemic therapy (e.g., retinoids, interferons, extracorporeal photopheresis, denileukin diftitox, methotrexate, liposomal doxorubicin, gemcitabine, chlorambucil, pentostatin, etoposide, cyclophosphamide, temozolomide, bortezomib) AND is able to tolerate oral medications

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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ROMIDEPSIN (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ROMIDEPSIN (Istodax)** requires the following rule(s) be met for approval:

A. You have cutaneous T-cell lymphoma (CTCL: a type of blood cancer that affects the skin) also known as Mycosis Fungoides/Sezary Syndrome
B. You are 18 years of age or older
C. You meet ONE of the following:
    1. You have tried or have a contraindication to (harmful for you to use) Zolinza (vorinostat) AND you are not able to tolerate oral medications
    2. You have tried at least one form of systemic therapy (treatment that targets the entire body such as retinoids, interferons, extracorporeal photopheresis, denileukin diftitox, methotrexate, liposomal doxorubicin, gemcitabine, chlorambucil, pentostatin, etoposide, cyclophosphamide, temozolomide, bortezomib) AND you are able to tolerate oral medications

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Istodax.

REFERENCES

Istodax [Prescribing Information]. Celgene Corporation: Summit, NJ. December 2021.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ROMIDEPSIN (PART D)

For Part D use only:

ROMIDEPSIN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS.
Other Criteria	CUTANEOUS T CELL LYMPHOMA (CTCL): 1) TRIAL OF OR CONTRAINDICATION TO ZOLINZA AND UNABLE TO TOLERATE ORAL MEDICATIONS, OR 2) ABLE TO TOLERATE ORAL MEDICATIONS AND HAS TRIED AT LEAST ONE SYSTEMIC THERAPY (E.G., RETINOID, INTERFERON, EXTRACORPOREAL PHOTOPHERESIS, DENILEUKIN DIFTITOX, METHOTREXATE, LIPOSOMAL DOXORUBICIN, GEMCITABINE, CHLORAMBUCIL, PENTOSTATIN, ETOPOSIDE, CYCLOPHOSPHAMIDE, TEMOZOLOMIDE, BORTEZOMIB)

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 02/10
Client Approval: 06/24
P&T Approval: 10/21

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ROMIPLOSTIM (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ROMIPLOSTIM	NPLATE	35798		GPI-10 (8240506000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of immune thrombocytopenia (ITP) (ICD-10 D69.3) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hematologist or immunologist
   - The patient had a trial of or contraindication to one corticosteroid (e.g., prednisone) or immunoglobulin (e.g., Panzyga [immune globulin]), OR had an insufficient responseto splenectomy
   - Nplate will NOT be used concurrently with other thrombopoietin receptor agonists (TPO-RAs) (e.g., Doptelet [avatrombopag], Promacta [eltrombopag])

   If yes, continue to #2.
   If no, continue to #4.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has a platelet count of less than 30 x10^9/L
   - The patient has a platelet count of less than 50 x 10^9/L AND a prior bleeding event

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ROMIPLOSTIM (PART D)

INITIAL CRITERIA (CONTINUED)

3. Does the patient meet **ONE** of the following criteria?
   - The patient is between 1 to 17 years of age AND has a diagnosis of immune thrombocytopenia (ITP) for at least 6 months
   - The patient is 18 years of age or older

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have a diagnosis of hematopoietic syndrome of acute radiation syndrome (the patient was acutely exposed to myelosuppressive doses of radiation)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ROMIPLOSTIM (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ROMIPLOSTIM (Nplate)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Immune thrombocytopenia (ITP: a type of blood disorder)
   2. Hematopoietic syndrome of acute radiation syndrome (an illness that happens after you have been acutely exposed to myelosuppressive doses of radiation [a type of treatment])

B. If you have immune thrombocytopenia, approval also requires:
   1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or immunologist (a type of immune system doctor)
   2. You have tried or have a contraindication to (harmful for you to use) one corticosteroid (such as prednisone) or immunoglobulin (such as Panzyga [immune globulin]), OR you had an insufficient response to a splenectomy (surgical removal of spleen did not work)
   3. You meet ONE of the following:
      a. You have a platelet (a type of blood cell) count of less than 30 x10^9/L
      b. You have a platelet count (a type of blood cell) of less than 50 x 10^9/L AND a prior bleeding event
   4. You will NOT us Nplate concurrently (at the same time) with other thrombopoietin receptor agonists (TPO-RAs, such as Doptelet [avatrombopag], Promacta [eltrombopag])
   5. You meet ONE of the following:
      a. You are between 1 and 17 years old AND you have immune thrombocytopenia (ITP) for at least 6 months
      b. You are 18 years of age or older

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ROMIPLOSTIM (PART D)

RENEWAL CRITERIA

NOTE: For the diagnoses of hematopoietic syndrome of acute radiation syndrome, please refer to the Initial Criteria section.

1. Is the patient being treated for immune thrombocytopenia (ITP) (ICD-10 D69.3) and meet **ALL** of the following criteria?
   - The patient has improvement in platelet counts from baseline or reduction in bleeding events
   - Nplate will NOT be used concurrently with other thrombopoietin receptor agonists (TPO-RAs) (e.g., Doptelet [avatrombopag], Promacta [eltrombopag])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ROMIPLOSTIM (Nplate)** requires the following rule(s) be met for renewal:
   A. You have immune thrombocytopenia (ITP: a type of blood disorder)
   B. You had improvement in platelet (a type of blood cell) counts from baseline or reduction in bleeding events
   C. You will NOT us Nplate concurrently (at the same time) with other thrombopoietin receptor agonists (TPO-Ras, such as Doptelet [avatrombopag], Promacta [eltrombopag])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Nplate.

REFERENCES
Nplate [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; February 2022.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ROMIPLOSTIM (PART D)

For Part D use only:

ROMIPLOSTIM (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	IMMUNE THROMBOCYTOPENIA (ITP): INITIAL: 1) PLATELET COUNT OF LESS THAN 30 X 10^9/L, OR 2) PLATELET COUNT OF LESS THAN 50 X 10^9/L AND A PRIOR BLEEDING EVENT.
Age Restrictions	N/A
Prescriber Restrictions	ITP: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR IMMUNOLOGIST.
Coverage Duration	ITP: INITIAL: 6 MO, RENEWAL: 12 MO. HEMATOPOIETIC SYNDROME OF ACUTE RADIATION SYNDROME: 12 MO.
Other Criteria	ITP: INITIAL: 1) TRIAL OF OR CONTRAINDICATION TO ONE CORTICOSTEROID OR IMMUNOGLOBULIN, OR HAD AN INSUFFICIENT RESPONSE TO SPLENECTOMY, AND 2) NO CONCURRENT USE WITH OTHER THROMBOPOIETIN RECEPTOR AGONISTS (TPO-RAS). RENEWAL: 1) IMPROVEMENT IN PLATELET COUNTS FROM BASELINE OR REDUCTION IN BLEEDING EVENTS, AND 2) NO CONCURRENT USE WITH OTHER TPO-RAS.

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Effective: 09/01/25 Client Approval: 08/25 P&T Approval: 07/25

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ROMOSOZUMAB-AQQG BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ROMOSOZUMAB-AQQG	EVENITY	45681		GPI-10 (3004486010)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	Yes	No	No	Yes	No	No	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #5.

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ROMOSOZUMAB-AQQG BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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ROMOSOZUMAB-AQQG BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of postmenopausal osteoporosis (ICD-10 M81.0; Group M80.0)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the patient at high risk for fractures defined as **ONE** of the following criteria?
   - The patient has a history of osteoporotic (i.e., fragility, low trauma) fracture(s)
   - The patient has at least 2 risk factors for fracture (e.g., history of multiple recent lowtrauma fractures, bone marrow density [BMD] T-score or -2.5 or less, corticosteroid use [e.g., prednisone], use of GnRH analogs [e.g., Synarel (nafarelin)])
   - The patient has no prior treatment for osteoporosis AND FRAX score is at least 20 percent for any major fracture OR at least 3 percent for hip fracture

   If yes, continue to #4.
   If no, continue to #3.

3. Does the patient meet **ONE** of the following criteria?
   - The patient is unable to use oral therapy for any of the following reasons: unable to tolerate oral medications due to upper gastrointestinal (GI) problems, unable to absorb oral medications due to lower GI problems, trouble remembering to take oral medications, or trouble coordinating an oral bisphosphonate with other oral medications or their daily routine
   - The patient had a trial of, intolerance to, or a contraindication to a bisphosphonate (e.g., Fosamax [alendronate], Actonel [risedronate])

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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ROMOSOZUMAB-AQQG BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

4. Has the patient received a total of 12 months of Evenity therapy?

If yes, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

If no, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ROMOSOZUMAB-AQQG (Evenity)** requires the following rule(s) be met for approval:

A. You have postmenopausal osteoporosis (a type of bone condition in women after menopause)
B. You have not received a total of 12 months of Evenity therapy
C. You meet ONE of the following:
    1. You are at high risk for fractures defined as ONE of the following:
        a. You have a history of osteoporotic (fragility, low trauma) fracture(s) (a type of complete or partial break in a bone)
        b. You have at least 2 risk factors for fracture (such as history of multiple recent low trauma fractures, bone marrow density [BMD] T-score (a type of lab test) of -2.5 or less, corticosteroid use [such as prednisone], use of gonadotropin-releasing hormone [GnRH] analogs (such as Synarel [nafarelin])
        c. You have no prior treatment for osteoporosis AND your Fracture Risk Assessment Tool (FRAX: a type of test) score is at least 20 percent for any major fracture OR at least 3 percent for hip fracture
    2. You are unable to use oral therapy for any of the following reasons: unable to tolerate oral medication due to upper gastrointestinal (GI: digestive system) problems, unable to absorb oral medications due to lower GI problems, trouble remembering to take oral medications, or trouble coordinating an oral bisphosphonate with other oral medications or your daily routine
    3. You have tried, have an intolerance (side effect) to, or have a contraindication to (harmful for you to use) a bisphosphonate (such as Fosamax [alendronate], Actonel [risedronate])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ROMOSOZUMAB-AQQG BvD (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Evenity. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Evenity [Prescribing Information]. Thousand Oaks, CA: Amgen, Inc; April 2020.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed April 4, 2024].

For Part D use only:

ROMOSOZUMAB-AQQG (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	POSTMENOPAUSAL OSTEOPOROSIS: 1) HAS NOT RECEIVED A TOTAL OF 12 MONTHS OF EVENITY TREATMENT, 2) ONE OF THE FOLLOWING: (A) HIGH RISK FOR FRACTURES DEFINED AS: (I) HISTORY OF OSTEOPOROTIC (I.E., FRAGILITY, LOW TRAUMA) FRACTURE(S), (II) AT LEAST 2 RISK FACTORS FOR FRACTURE (E.G., HISTORY OF MULTIPLE RECENT LOW TRAUMA FRACTURES, BMD T-SCORE OF -2.5 OR LESS, CORTICOSTEROID USE, USE OF GNRH ANALOGS), OR (III) NO PRIOR TREATMENT FOR OSTEOPOROSIS AND FRAX SCORE OF AT LEAST 20% FOR ANY MAJOR FRACTURE OR AT LEAST 3% FOR HIP FRACTURE, (B) UNABLE TO USE ORAL THERAPY (I.E., UNABLE TO TOLERATE ORAL MEDICATION DUE TO UPPER GASTROINTESTINAL PROBLEMS, UNABLE TO ABSORB ORAL MEDICATIONS DUE TO LOWER GASTROINTESTINAL PROBLEMS, TROUBLE REMEMBERING TO TAKE ORAL MEDICATIONS OR COORDINATING AN ORAL BISPHOSPHONATE WITH OTHER ORAL MEDICATIONS OR THEIR DAILY ROUTINE), OR (C) TRIAL OF, INTOLERANCE TO, OR A CONTRAINDICATION TO A BISPHOSPHONATE.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ROPEGINTERFERON ALFA-2B-NJFT (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ROPEGINTERFERON ALFA-2B-NJFT	BESREMI	47669		GPI-10 (2170007750)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of polycythemia vera (ICD-10 D45) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of essential thrombocythemia (ICD-10 D47.3) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a hematologist or an oncologist
   - Besremi will NOT be used concurrently with another interferon (e.g., Pegasys [peginterferon alfa-2a]) or anagrelide

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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ROPEGINTERFERON ALFA-2B-NJFT (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ROPEGINTERFERON ALFA-2B-NJFT (Besremi)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Polycythemia vera (a type of blood cancer)
   2. Essential thrombocythemia (a rare type of blood cancer)

B. If you have polycythemia vera, approval also requires:
   1. You are 18 years of age or older

C. If you have essential thrombocythemia, approval also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or an oncologist (a type of cancer doctor)
   3. You will NOT use Besremi concurrently (at the same time) with another interferon (such as Pegasys [peginterferon alfa-2a]) or anagrelide

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Besremi.

REFERENCES

Besremi [Prescribing Information]. Burlington, MA: PharmaEssentia, Corp.; August 2026.

For Part D use only:

ROPEGINTERFERON ALFA-2B-NJFT (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	ESSENTIAL THROMBOCYTHEMIA: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR AN ONCOLOGIST.
Coverage Duration	12 MONTHS
Other Criteria	ESSENTIAL THROMBOCYTHEMIA: NO CONCURRENT USE WITH ANOTHER INTERFERON OR ANAGRELIDE.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ROZANOLIXIZUMAB-NOLI BVD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ROZANOLIXIZUMAB-NOLI	RYSTIGGO	49035		GPI-10 (9939827055)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	Yes	No	No	Yes	No	No	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit).**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, continue to #6.
   If no, continue to #4.

4. Will the patient or caregiver pick up the medication from the pharmacy OR will the medication be shipped directly to the member, who then brings it to the healthcare provider's clinic/office for administration?

   If yes, continue to #6.
   If no, continue to #5.

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ROZANOLIXIZUMAB-NOLI BVD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision).**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

6. Is the drug administered via an implantable pump?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, continue to #7.

7. Is the drug administered via an external pump?

   If yes, continue to #8.
   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

8. Is the drug specifically infused through an external infusion pump covered by Medicare?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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ROZANOLIXIZUMAB-NOLI BVD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of generalized myasthenia gravis (gMG) (ICD-10 Group G70.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is anti-acetylcholine receptor (AChR) antibody positive OR anti-muscle-specific tyrosine kinase antibody (MuSK-Ab) positive
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient is in Myasthenia Gravis Foundation of America class II, III, or IV
   - The patient had a trial of or contraindication to ONE corticosteroid (e.g., prednisone)
   - The patient had a trial of or contraindication to ONE non-steroidal immunosuppressive therapy (e.g., azathioprine, cyclophosphamide, methotrexate)
   - Rystiggo will NOT be used concurrently with another neonatal Fc receptor blocker (e.g., Vyvgart [efgartigimod alfa-fcab]) or complement inhibitor (e.g., Ultomiris [ravulizumab-cwvz], Zilbrysq [zilucoplan]) for the treatment of gMG

     If yes, **approve for 6 months by HICL or GPI-10.**
     If no, do not approve.
     DENIAL TEXT: See the initial denial text at the end of the guideline.

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ROZANOLIXIZUMAB-NOLI BVD (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ROZANOLIXIZUMAB-NOLI (Rystiggo)** requires the following rule(s) be met for approval:

A. You have generalized myasthenia gravis (gMG: chronic autoimmune disorder)
B. You are 18 years of age or older
C. You are anti-acetylcholine receptor (AChR) antibody positive (an indicator of myasthenia gravis) OR anti-muscle-specific tyrosine kinase antibody (MuSK-Ab) positive (an indicator of myasthenia gravis)
D. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor)
E. You are in Myasthenia Gravis Foundation of America class II, III, or IV (types of severity of disease)
F. You have tried or have a contraindication to (harmful for you to use) ONE corticosteroid (such as prednisone)
G. You have tried or have a contraindication to ONE non-steroidal immunosuppressive therapy (such as azathioprine, cyclophosphamide, methotrexate)
H. You will NOT use Rystiggo concurrently (at the same time) with another neonatal Fc receptor blocker (such as Vyvgart [efgartigimod alfa-fcab]) or complement inhibitor (such as Ultomiris [ravulizumab-cwvz], Zilbrysq [zilucoplan]) for the treatment of generalized myasthenia gravis

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ROZANOLIXIZUMAB-NOLI BVD (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of generalized myasthenia gravis (gMG) (ICD-10 Group G70.0) and meet **ALL** of the following criteria?
   - The patient has had clinical benefit compared to baseline (e.g., Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool)
   - Rystiggo will NOT be used concurrently with another neonatal Fc receptor blocker (e.g., Vyvgart [efgartigimod alfa-fcab]) or complement inhibitor (e.g., Ultomiris [ravulizumab-cwvz], Zilbrysq [zilucoplan]) for the treatment of gMG

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ROZANOLIXIZUMAB-NOLI (Rystiggo)** requires the following rule(s) be met for approval:
   A. You have generalized myasthenia gravis (gMG: chronic autoimmune disorder)
   B. You have had clinical benefit compared to baseline (such as, as shown by the Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool)
   C. You will NOT use Rystiggo concurrently (at the same time) with another neonatal Fc receptor blocker (such as Vyvgart [efgartigimod alfa-fcab]) or complement inhibitor (such as Ultomiris [ravulizumab-cwvz], Zilbrysq [zilucoplan]) for the treatment of generalized myasthenia gravis

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ROZANOLIXIZUMAB-NOLI BVD (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rystiggo.

The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B. Drugs administered by an implantable pump are covered under Part B. Drugs administered via an external pump are covered under Part B if they are included under the local coverage policy of the applicable Medicare coverage policies (National and/or Local Coverage Policies). Drugs administered via an external pump that are not included under the applicable Medicare coverage policies are covered under Part D. A CMS website to assist with National and Local Coverage Determination for B versus D review is http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx.

REFERENCES

Rystiggo [Prescribing Information]. Smyrna, GA: UCB, Inc.; March 2025.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed July 21, 2025].

For Part D use only:

ROZANOLIXIZUMAB-NOLI (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	GENERALIZED MYASTHENIA GRAVIS (GMG): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST.
Coverage Duration	GMG: INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS
Other Criteria	GMG: INITIAL: 1) MYASTHENIA GRAVIS FOUNDATION OF AMERICA CLASS II, III, OR IV, 2) TRIAL OF OR CONTRAINDICATION TO ONE CORTICOSTEROID, 3) TRIAL OF OR CONTRAINDICATION TO ONE NON-STEROIDAL IMMUNOSUPPRESSIVE THERAPY, AND 4) NO CONCURRENT USE WITH ANOTHER NEONATAL FC RECEPTOR BLOCKER OR COMPLEMENT INHIBITOR FOR GMG. RENEWAL: 1) CLINICAL BENEFIT COMPARED TO BASELINE, AND 2) NO CONCURRENT USE WITH ANOTHER NEONATAL FC RECEPTOR BLOCKER OR COMPLEMENT INHIBITOR FOR GMG.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ROZANOLIXIZUMAB-NOLI BVD (PART D)

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RUCAPARIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RUCAPARIB CAMSYLATE	RUBRACA	44002		GPI-10 (2153557020)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of recurrent epithelial ovarian (ICD-10 Groups C56, C79.6), fallopian tube (ICD-10 Group C57.0), or primary peritoneal cancer (ICD-10 Group C48), and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer has a deleterious BRCA mutation (germline and/or somatic)
   - The patient is in complete or partial response to platinum-based chemotherapy (e.g., cisplatin, carboplatin)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of metastatic castration-resistant prostate cancer (mCRPC) (ICD-10 Z19.2 and C61) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer has a deleterious BRCA mutation (germline and/or somatic) based on an FDA-approved companion diagnostic for Rubraca
   - The patient has been treated with an androgen receptor-directed therapy

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RUCAPARIB (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient meet **ONE** of the following criteria?
   - The patient previously had a bilateral orchiectomy
   - The patient has a castrate level of testosterone (i.e., less than 50 ng/dL)
   - Rubraca will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog (e.g., leuprolide, goserelin, histrelin)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RUCAPARIB (Rubraca)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer (types of reproductive system cancers that has returned)
      2. Metastatic castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and no longer responds to testosterone lowering treatment)

   B. If you have recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:
      1. You are 18 years of age or older
      2. Your cancer has a deleterious BRCA mutation (germline and/or somatic) (a type of gene mutation that is passed on from parent to child and/or acquired during life)
      3. You are in complete or partial response to platinum-based chemotherapy (such as cisplatin, carboplatin)

   (Denial text continued on next page)

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RUCAPARIB (PART D)

GUIDELINES FOR USE (CONTINUED)

C. If you have metastatic castration-resistant prostate cancer, approval also requires:

1. You are 18 years of age or older
2. Your cancer has a deleterious BRCA mutation (germline and/or somatic) (a type of gene mutation that is passed on from parent to child and/or acquired during life) based on a Food and Drug Administration (FDA)-approved companion diagnostic for Rubraca
3. You have been treated with an androgen receptor-directed therapy (type of therapy to treat cancer)
4. You meet ONE of the following:
   a. You previously received a bilateral orchiectomy (removal of both testicles)
   b. You have a castrate level of testosterone (blood testosterone levels are less than 50 ng/dL)
   c. Rubraca will be used concurrently (at the same time) with a gonadotropin-releasing hormone (GnRH) analog (such as leuprolide, goserelin, histrelin)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rubraca.

REFERENCES

Rubraca [Prescribing Information]. Boulder, CO: Clovis Oncology, Inc.; December 2025.

For Part D use only:

RUCAPARIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Medical Required Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	METASTATIC CASTRATION-RESISTANT PROSTATE CANCER: 1) RECEIVED A BILATERAL ORCHIECTOMY, 2) CASTRATE LEVEL OF TESTOSTERONE (I.E., LESS THAN 50 NG/DL), OR 3) CONCURRENT USE WITH A GONADOTROPIN RELEASING HORMONE (GNRH) ANALOG.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RUXOLITINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RUXOLITINIB PHOSPHATE	JAKAFI , JAKAFI XR	38202		GPI-10 (2153756020)	ROUTE ≠ TOPICAL

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of intermediate or high-risk myelofibrosis (ICD-10 D75.81), including primary myelofibrosis (ICD-10 D47.1), post-polycythemia vera myelofibrosis, and post-essential thrombocythemia myelofibrosis **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 6 months for all strengths of Jakafi and Jakafi XR by GPID or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of polycythemia vera (ICD-10 D45) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had an inadequate response or intolerance to hydroxyurea

   If yes, **approve for 12 months for all strengths of Jakafi and Jakafi XR by GPID or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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RUXOLITINIB (PART D)

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of steroid-refractory acute graft-versus-host disease (ICD-10 D89.810, D89.812) **AND** meet the following criterion?
   - The patient is 12 years of age or older

   If yes, **approve for 12 months for all strengths of Jakafi and Jakafi XR by GPID or GPI-10. APPROVAL TEXT (IF APPLICABLE):** The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

4. Does the patient have a diagnosis of chronic graft-versus-host disease (ICD-10 D89.811, D89.812) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient has failed at least ONE line of systemic therapy (e.g., prednisone, methotrexate)
   - The requested medication will NOT be used concurrently with Rezurock (belumosudil), Niktimvo (axatilimab-csfr), or Imbruvica (ibrutinib)

   If yes, **approve for 12 months for all strengths of Jakafi and Jakafi XR by GPID or GPI-10. APPROVAL TEXT (IF APPLICABLE):** The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RUXOLITINIB (Jakafi, Jakafi XR)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Intermediate or high-risk myelofibrosis, which includes primary myelofibrosis, post-polycythemia vera myelofibrosis, and post-essential thrombocythemia myelofibrosis (types of blood cancer)
      2. Polycythemia vera (a type of blood cancer)
      3. Steroid-refractory acute graft-versus-host disease (a type of short-term immune disorder that did not respond to a type of treatment)
      4. Chronic graft-versus-host disease (a type of long-term immune disorder)

   (Initial denial text continued on next page)

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RUXOLITINIB (PART D)

INITIAL CRITERIA (CONTINUED)

B. If you have intermediate or high-risk myelofibrosis, which includes primary myelofibrosis, post-polycythemia vera myelofibrosis, and post-essential thrombocythemia myelofibrosis, approval also requires:
1. You are 18 years of age or older

C. If you have polycythemia vera, approval also requires:
1. You are 18 years of age or older
2. You had an inadequate response to (drug did not work) or did not tolerate hydroxyurea

D. If you have steroid-refractory acute graft-versus-host disease, approval also requires:
1. You are 12 years of age or older

E. If you have chronic graft-versus-host disease, approval also requires:
1. You are 12 years of age or older
2. You have failed at least ONE line of systemic therapy (treatment that targets the entire body, such as prednisone, methotrexate)
3. You will NOT use the requested medication concurrently (at the same time) with Rezurock (belumosudil), Niktimvo (axatilimab-csfr), or Imbruvica (ibrutinib)

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RUXOLITINIB (PART D)

RENEWAL CRITERIA

NOTE: For the diagnoses of polycythemia vera or acute graft-versus-host disease, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of intermediate or high-risk myelofibrosis (ICD-10 D75.81), including primary myelofibrosis (ICD-10 D47.1), post-polycythemia vera myelofibrosis, and post-essential thrombocythemia myelofibrosis, **AND** meet the following criterion?
   - The patient continues to benefit from the medication

   If yes, **approve for 12 months for all strengths of Jakafi and Jakafi XR by GPID or GPI-10. APPROVAL TEXT (IF APPLICABLE):** The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of chronic graft-versus-host disease (ICD-10 D89.811, D89.812) **AND** meet the following criterion?
   - The requested medication will NOT be used concurrently with Rezurock (belumosudil), Niktimvo (axatilimab-csfr), or Imbruvica (ibrutinib)

   If yes, **approve for 12 months for all strengths of Jakafi and Jakafi XR by GPID or GPI-10. APPROVAL TEXT (IF APPLICABLE):** The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RUXOLITINIB (Jakafi, Jakafi XR)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Intermediate or high-risk myelofibrosis, which includes primary myelofibrosis, post-polycythemia vera myelofibrosis, and post-essential thrombocythemia myelofibrosis (types of blood cancer)
      2. Chronic graft-versus-host disease (a type of long-term immune disorder)

   B. If you have intermediate or high-risk myelofibrosis, which includes primary myelofibrosis, post-polycythemia vera myelofibrosis, and post-essential thrombocythemia myelofibrosis, approval also requires:
      1. You continue to benefit from the medication

   C. If you have chronic graft-versus-host disease, approval also requires:
      1. You will NOT use the requested medication concurrently (at the same time) with Rezurock (belumosudil), Niktimvo (axatilimab-csfr), or Imbruvica (ibrutinib)

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RUXOLITINIB (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Jakafi.

REFERENCES

Jakafi [Prescribing Information]. Wilmington, DE: Incyte Corporation; May 2026.

For Part D use only:

RUXOLITINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	MYELOFIBROSIS: INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS. POLYCYTHEMIA VERA, GVHD: 12 MONTHS.
Other Criteria	INITIAL: CHRONIC GRAFT VS HOST DISEASE (CGVHD): NO CONCURRENT USE WITH REZUROCK, NIKTIMVO, OR IMBRUVICA. RENEWAL: MYELOFIBROSIS: CONTINUES TO BENEFIT FROM THE MEDICATION. CGVHD: NO CONCURRENT USE WITH REZUROCK, NIKTIMVO, OR IMBRUVICA.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RUXOLITINIB TOPICAL (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RUXOLITINIB PHOSPHATE	OPZELURA	38202		GPI-10 (9027206050)	ROUTE ≠ ORAL

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of mild to moderate atopic dermatitis (ICD-10 Group L20) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - The patient is NOT immunocompromised
   - The patient had a trial of or contraindication to a topical corticosteroid (e.g., triamcinolone acetonide 0.1% cream or ointment; clobetasol propionate 0.05% cream or ointment; halobetasol propionate 0.01% lotion) OR a topical calcineurin inhibitor (e.g., Elidel [pimecrolimus], Protopic [tacrolimus])
   - The patient had a trial of or contraindication to Eucrisa (crisaborole)

   If yes, continue to #2.
   If no, continue to #3.

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RUXOLITINIB TOPICAL (PART D)

INITIAL CRITERIA (CONTINUED)

2. Will Opzelura be used concurrently with **ANY** of the following for the treatment of atopic dermatitis?
   - Other non-steroidal topicals (e.g., calcineurin inhibitors [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)], PDE-4 inhibitors [e.g., Eucrisa (crisaborole), Zoryve (roflumilast)], JAK inhibitors [e.g., delgocitinib], AhR agonists [e.g., Vtama (tapinarof)])
   - Systemic therapeutic biologics (e.g., Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
   - Other JAK inhibitors (e.g., Rinvoq [upadacitinib], Cibinqo [abrocitinib])
   - Potent immunosuppressants (e.g., azathioprine, cyclosporine)

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, **approve for 3 months by GPID or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

3. Does the patient have a diagnosis of nonsegmental vitiligo (ICD-10 L80) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
     - The patient has depigmented areas covering 10% or less of total body surface area
     - The patient had a trial of or contraindication to a topical corticosteroid (e.g., halobetasol, triamcinolone, fluocinonide) OR a topical calcineurin inhibitor (e.g., Protopic [tacrolimus])

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Will Opzelura be used concurrently with **ANY** of the following?
   - Other non-steroidal topicals (e.g., Elidel [pimecrolimus], Protopic [tacrolimus], Eucrisa [crisaborole ointment])
   - Systemic therapeutic biologics (e.g., Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
   - Other JAK inhibitors (e.g., Rinvoq [upadacitinib], Cibinqo [abrocitinib])
   - Potent immunosuppressants (e.g., azathioprine, cyclosporine)

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, **approve for 6 months by GPID or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

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RUXOLITINIB TOPICAL (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RUXOLITINIB TOPICAL (Opzelura)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Mild to moderate atopic dermatitis (a type of skin condition)
   2. Nonsegmental vitiligo (a type of skin condition)

B. If you have mild to moderate atopic dermatitis, approval also requires:
   1. You are 2 years of age or older
   2. You are NOT immunocompromised (low immune system)
   3. You have tried or have a contraindication to (harmful for you to use) a topical corticosteroid (such as triamcinolone acetonide 0.1% cream or ointment; clobetasol propionate 0.05% cream or ointment; halobetasol propionate 0.01% lotion) OR a topical calcineurin inhibitor (such as Elidel [pimecrolimus], Protopic [tacrolimus])
   4. You have tried or have a contraindication to Eucrisa (crisaborole)
   5. You will NOT use Opzelura concurrently (at the same time) with ANY of the following for the treatment of atopic dermatitis (a type of skin condition):
      a. Other non-steroid topicals (such as calcineurin inhibitors [such as Elidel (pimecrolimus), Protopic (tacrolimus)], PDE-4 [phosphodiesterase-4] inhibitors [such as Eucrisa (crisaborole), Zoryve (roflumilast)], JAK [Janus kinase] inhibitors [such as delgocitinib], AhR [aryl hydrocarbon receptor] agonists [such as Vtama (tapinarof)])
      b. Systemic therapeutic biologics (such as Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
      c. Other JAK inhibitors (such as Rinvoq [upadacitinib], Cibinqo [abrocitinib])
      d. Potent immunosuppressants (such as azathioprine, cyclosporine)

(Initial denial text continued on next page)

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RUXOLITINIB TOPICAL (PART D)

INITIAL CRITERIA (CONTINUED)

C. If you have nonsegmental vitiligo, approval also requires:

1. You are 12 years of age or older
2. You have depigmented (lightening of the skin or loss ofcolor) areas covering 10 percent or less of total body surface area
3. You have tried or have a contraindication to (harmful for you to use) a topical corticosteroid (such as halobetasol, triamcinolone, fluocinonide) OR a topical calcineurin inhibitor (such as Protopic [tacrolimus])
4. You will NOT use Opzelura concurrently (at the same time) with ANY of the following:
   a. Other non-steroid topicals (such as Elidel [pimecrolimus], Protopic [tacrolimus], Eucrisa [crisaborole ointment])
   b. Systemic therapeutic biologics (such as Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
   c. Other JAK inhibitors (such as Rinvoq [upadacitinib], Cibinqo [abrocitinib])
   d. Potent immunosuppressants (such as azathioprine, cyclosporine)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RUXOLITINIB TOPICAL (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of mild to moderate atopic dermatitis (ICD-10 Group L20) **AND** meet the following criterion?
- The patient has experienced or maintained improvement in pruritus, relapsing-remitting dermatitis, or facial/interdigital involvement

If yes, continue to #2.
If no, continue to #3.

2. Will Opzelura be used concurrently with **ANY** of the following for the treatment of atopic dermatitis?
- Other non-steroidal topicals (e.g., calcineurin inhibitors [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)], PDE-4 inhibitors [e.g., Eucrisa (crisaborole), Zoryve (roflumilast)], JAK inhibitors [e.g., delgocitinib], AhR agonist [e.g., Vtama (tapinarof)])
- Systemic therapeutic biologics (e.g., Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
- Other JAK inhibitors (e.g., Rinvoq [upadacitinib], Cibinqo [abrocitinib])
- Potent immunosuppressants (e.g., azathioprine, cyclosporine)

If yes, do not approve.
DENIAL TEXT: See the renewal denial text at the end of the guideline.

If no, **approve for 12 months by GPID or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

3. Does the patient have a diagnosis of nonsegmental vitiligo (ICD-10 L80) **AND** meet the following criterion?
- The patient has experienced or maintained clinically meaningful repigmentation

If yes, continue to #4.
If no, do not approve.
DENIAL TEXT: See the renewal denial text at the end of the guideline.

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RUXOLITINIB TOPICAL (PART D)

RENEWAL CRITERIA (CONTINUED)

4. Will Opzelura be used concurrently with **ANY** of the following?
   - Other non-steroid topicals (e.g., Elidel [pimecrolimus], Protopic [tacrolimus], Eucrisa [crisaborole ointment])
   - Systemic therapeutic biologics (e.g., Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
   - Other JAK inhibitors (e.g., Rinvoq [upadacitinib], Cibinqo [abrocitinib])
   - Potent immunosuppressants (e.g., azathioprine, cyclosporine)

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, **approve for 12 months by GPID or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RUXOLITINIB TOPICAL (Opzelura)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Mild to moderate atopic dermatitis (a type of skin condition)
      2. Nonsegmental vitiligo (a type of skin condition)
   B. If you have mild to moderate atopic dermatitis, renewal also requires:
      1. You have experienced or maintained improvement in pruritus (itchiness), relapsing-remitting (disease returns and goes away) dermatitis, or facial/interdigital (between the fingers or toes) involvement
      2. You will NOT use Opzelura concurrently (at the same time) with ANY of the following for the treatment of atopic dermatitis (a type of skin condition):
         a. Other non-steroid topicals (such as Elidel (pimecrolimus), Protopic (tacrolimus)], PDE-4 [phosphodiesterase-4] inhibitors [such as Eucrisa (crisaborole), Zoryve (roflumilast)], JAK [Janus kinase] inhibitors [such as delgocitinib], AhR [aryl hydrocarbon receptor] agonists [such as Vtama (tapinarof)])
         b. Systemic therapeutic biologics (such as Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
         c. Other JAK inhibitors (such as Rinvoq [upadacitinib], Cibinqo [abrocitinib])
         d. Potent immunosuppressants (such as azathioprine, cyclosporine)

   (Renewal denial text continued on next page)

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RUXOLITINIB TOPICAL (PART D)

RENEWAL CRITERIA (CONTINUED)

C. If you have nonsegmental vitiligo, renewal also requires:

1. You have experienced or maintained clinically meaningful repigmentation (recoloration of the skin after loss in color)
2. You will NOT use Opzelura concurrently (at the same time) with ANY of the following:
   a. Other non-steroid topicals (such as Elidel [pimecrolimus], Protopic [tacrolimus], Eucrisa [crisaborole ointment])
   b. Systemic therapeutic biologics (such as Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
   c. Other JAK inhibitors (such as Rinvoq [upadacitinib], Cibinqo [abrocitinib])
   d. Potent immunosuppressants (such as azathioprine, cyclosporine)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Opzelura.

REFERENCES

Opzelura [Prescribing Information]. Wilmington, DE: Incyte, Corp.; August 2024.

For Part D use only:

RUXOLITINIB TOPICAL (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	INITIAL: VITILIGO: DEPIGMENTED AREAS COVERING 10 PERCENT OR LESS OF TOTAL BODY SURFACE AREA.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	INITIAL: ATOPIC DERMATITIS: 3 MONTHS, VITILIGO: 6 MONTHS. RENEWAL: ALL INDICATIONS: 12 MONTHS.
Other Criteria	INITIAL: ATOPIC DERMATITIS: 1) NO CONCURRENT USE WITH NON-STEROIDAL TOPICALS (E.G., CALCINEURIN INHIBITORS, PDE-4 INHIBITORS, JAK INHIBITORS, AHR AGONISTS), SYSTEMIC THERAPEUTIC BIOLOGICS, OTHER JAK INHIBITORS, OR POTENT IMMUNOSUPPRESSANTS (E.G., AZATHIOPRINE, CYCLOSPORINE) FOR ATOPIC DERMATITIS, AND 2) TRIAL OF OR CONTRAINDICATION TO: (A) A TOPICAL CORTICOSTEROID OR A TOPICAL

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	CALCINEURIN INHIBITOR, AND (B) EUCRISA. VITILIGO: 1) NO CONCURRENT USE WITH NON-STEROIDAL TOPICALS, SYSTEMIC THERAPEUTIC BIOLOGICS, OTHER JAK INHIBITORS, OR POTENT IMMUNOSUPPRESSANTS, AND 2) TRIAL OF OR CONTRAINDICATION TO A TOPICAL CORTICOSTEROID OR A TOPICAL CALCINEURIN INHIBITOR. RENEWAL: ATOPIC DERMATITIS: 1) EXPERIENCED OR MAINTAINED IMPROVEMENT IN PRURITUS, RELAPSING-REMITTING DERMATITIS, OR FACIAL/INTERDIGITAL INVOLVEMENT, AND 2) NO CONCURRENT USE WITH NON-STEROIDAL TOPICALS, SYSTEMIC THERAPEUTIC BIOLOGICS, OTHER JAK INHIBITORS, OR POTENT IMMUNOSUPPRESSANTS FOR ATOPIC DERMATITIS. VITILIGO: 1) EXPERIENCED OR MAINTAINED CLINICALLY MEANINGFUL REPIGMENTATION, AND 2) NO CONCURRENT USE WITH NON-STEROIDAL TOPICALS, SYSTEMIC THERAPEUTIC BIOLOGICS, OTHER JAK INHIBITORS, OR POTENT IMMUNOSUPPRESSANTS.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SACITUZUMAB GOVITECAN-HZIY (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SACITUZUMAB GOVITECAN-HZIY	TRODELVY	46478		GPI-10 (2155106540)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable locally advanced or metastatic breast cancer (ICD-10 Group C50) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the patient's cancer triple-negative and the patient meets **ONE** of the following criteria?
   - The patient is not a candidate for programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor based therapy
   - Trodelvy will be used in combination with Keytruda (pembrolizumab) or Keytruda Qlex (pembrolizumab and berahyaluronidase alfa-pmph), AND the patient's tumor expresses programmed death-ligand 1 (PD-L1) [Combined Positive Score (CPS) of at least 10], as determined by an FDA-authorized test
   - The patient has received two or more prior systemic therapies (e.g., docetaxel, paclitaxel), at least one of them for metastatic disease

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

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SACITUZUMAB GOVITECAN-HZIY (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Is the patient's cancer hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative (IHC 0, IHC 1+ or IHC 2+/ISH-) and the patient meets **ALL** of the following criteria?
   - The patient has received endocrine-based therapy (e.g., tamoxifen, Arimidex [anastrozole])
   - The patient has received at least two additional systemic therapies (e.g., Enhertu [fam-trastuzumab deruxtecan-nxki], Talzenna [talazoparib]) in the metastatic setting

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: Our guideline named **SACITUZUMAB GOVITECAN-HZIY (Trodelvy)** requires the following rule(s) be met for approval:
   A. You have unresectable locally advanced or metastatic breast cancer (a type of breast cancer that cannot be surgically removed and has spread from where it started to nearby tissue or lymph nodes or to other parts of the body)
   B. You are 18 years of age or older
   C. You meet ONE of the following:
      1. Your breast cancer is triple negative (TNBC: a type of breast cancer that does not have three receptors); AND you are not a candidate for programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor based therapy (a type of cancer treatment)
      2. Your breast cancer is triple negative (TNBC: a type of breast cancer that does not have three receptors); Trodelvy will be used in combination with Keytruda (pembrolizumab) or Keytruda Qlex (pembrolizumab and berahyaluronidase alfa-pmph); AND your tumor has programmed death-ligand 1 (PD-L1: a type of protein) [Combined Positive Score (CPS) of at least 10], as determined by a Food and Drug Administration (FDA)-authorized test
      3. Your breast cancer is triple negative (TNBC: a type of breast cancer that does not have three receptors); AND you have tried two or more previous systemic therapies (treatment that targets the entire body such as docetaxel, paclitaxel), at least one of them for metastatic disease (disease that has spread to other parts of the body)
      4. Your breast cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative (IHC 0, IHC 1+ or IHC 2+/ISH- [a type of lab test]); you have received endocrine (hormone)-based therapy (such as tamoxifen, Arimidex [anastrozole]); AND you have received at least two additional systemic therapies (treatment that targets the entire body such as Enhertu [fam-trastuzumab deruxtecan-nxki], Talzenna [talazoparib]) in the metastatic setting (disease has spread to other parts of the body)

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SACITUZUMAB GOVITECAN-HZIY (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Trodelvy.

REFERENCES
Trodelvy [Prescribing Information]. Foster City, CA: Gilead Sciences, Inc.; June 2026.

For Part D Use Only:

SACITUZUMAB GOVITECAN-HZIY (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 06/20
Effective: 07/15/26 Client Approval: 07/26 DMC Approval: 07/26

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SACROSIDASE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SACROSIDASE	SUCRAID	18554		GPI-10 (5120006000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of genetically determined sucrase deficiency, which is part of congenital sucrase isomaltase deficiency (CSID) (ICD-10 E74.31), **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with a gastroenterologist or medical geneticist

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient's diagnosis confirmed by **ONE** of the following?
   - Small bowel biopsy
   - Sucrose breath test
   - Genetic test

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SACROSIDASE (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SACROSIDASE (Sucraid)** requires the following rule(s) be met for approval:

A. You have genetically determined sucrase deficiency, which is part of congenital sucrase isomaltase deficiency (a type of genetic digestive condition)
B. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions) or medical geneticist (a doctor who treats gene disorders)
C. Your diagnosis is confirmed by ONE of the following:
    1. Small bowel biopsy (removal of cells or tissue from the body for examination)
    2. Sucrose (a type of sugar) breath test
    3. Genetic test

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SACROSIDASE (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of genetically determined sucrase deficiency, which is part of congenital sucrase isomaltase deficiency (CSID) (ICD-10 E74.31), **AND** meet the following criterion?
   - The patient has experienced or maintained improvement on treatment

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SACROSIDASE (Sucraid)** requires the following rule(s) be met for renewal:
   A. You have genetically determined sucrase deficiency, which is part of congenital sucrase isomaltase deficiency (a type of genetic digestive condition)
   B. You have experienced or maintained improvement on treatment

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Sucraid.

REFERENCES
Sucraid [Prescriber Information]. Vero Beach, FL: QOL Medical, LLC.; May 2022.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SACROSIDASE (PART D)

For Part D use only:

SACROSIDASE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	SUCRASE DEFICIENCY: INITIAL: DIAGNOSIS CONFIRMED BY: 1) SMALL BOWEL BIOPSY, 2) SUCROSE BREATH TEST, OR 3) GENETIC TEST.
Age Restrictions	N/A
Prescriber Restrictions	SUCRASE DEFICIENCY: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST OR MEDICAL GENETICIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	SUCRASE DEFICIENCY: RENEWAL: EXPERIENCED OR MAINTAINED IMPROVEMENT ON TREATMENT.

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 06/22
Client Approval: 06/24
P&T Approval: 04/22

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SAFINAMIDE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SAFINAMIDE MESYLATE	XADAGO	42752		GPI-10 (7330002820)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Parkinson's disease (ICD-10 Group G20) and meet **ALL** of the following criteria?
   - The patient is experiencing 'off' episodes
   - Xadago will be used concurrently with carbidopa/levodopa (e.g., Sinemet, Sinemet CR, Parcopa)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SAFINAMIDE (Xadago)** requires the following rule(s) be met for approval:
   A. You have Parkinson's disease (a type of movement disorder)
   B. You are experiencing 'off' episodes (period of symptoms between doses)
   C. Xadago will be used together with carbidopa/levodopa (such as Sinemet, Sinemet Controlled Release [CR], Parcopa)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SAFINAMIDE (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Xadago.

REFERENCES
Xadago [Prescribing Information]. Louisville, KY: US WorldMeds, LLC; August 2021.

For Part D use only:

SAFINAMIDE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
No	No	Yes

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SAPROPTERIN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SAPROPTERIN DIHYDROCHLORIDE	KUVAN, JAVYGTOR, SAPROPTERIN DIHYDROCHLORIDE	35266		GPI-10 (3090856510)	FDB: ROUTE = ORAL

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hyperphenylalaninemia (HPA) due to tetrahydrobiopterin (BH4)-responsive phenylketonuria (PKU) (ICD-10 E70.1) and meet **ALL** of the following criteria?
   - The patient is 1 month of age or older
   - The requested medication will NOT be used concurrently with Palynziq (pegvaliase-pqpz)

   If yes, **approve for 2 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SAPROPTERIN (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SAPROPTERIN (Kuvan, Javygtor)** requires the following rule(s) be met for approval:

A. You have hyperphenylalaninemia (HPA) due to tetrahydrobiopterin (BH4)-responsive phenylketonuria (PKU) (high levels of a type of amino acid phenylalanine and it can be lowered with a certain supplement tetrahydrobiopterin)
B. You are 1 month of age or older
C. You will NOT use the requested medication concurrently (at the same time) with Palynziq (pegvaliase-pqpz)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SAPROPTERIN (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hyperphenylalaninemia (HPA) due to tetrahydrobiopterin (BH4)-responsive phenylketonuria (PKU) (ICD-10 E70.1) and meet **ALL** of the following criteria?
   - The patient continues to benefit from treatment
   - The requested medication will NOT be used concurrently with Palynziq (pegvaliase-pqpz)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SAPROPTERIN (Kuvan, Javygtor)** requires the following rule(s) be met for renewal:
   A. You have hyperphenylalaninemia (HPA) due to tetrahydrobiopterin (BH4)-responsive phenylketonuria (PKU) (high levels of a type of amino acid phenylalanine and it can be lowered with a certain supplement tetrahydrobiopterin)
   B. You continue to benefit from treatment
   C. You will NOT use the requested medication concurrently (at the same time) with Palynziq (pegvaliase-pqpz)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Sapropterin (Kuvan, Javygtor).

REFERENCES
Kuvan [Prescribing Information]. Novato, CA: BioMarin Pharmaceutical Inc., February 2021.

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SAPROPTERIN (PART D)

For Part D use only:

SAPROPTERIN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	INITIAL: 2 MONTHS, RENEWAL 12 MONTHS.
Other Criteria	HYPERPHENYLALANINEMIA (HPA): INITIAL: NO CONCURRENT USE WITH PALYNZIQ. RENEWAL: 1) CONTINUES TO BENEFIT FROM TREATMENT, AND 2) NO CONCURRENT USE WITH PALYNZIQ.

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 10/22
Client Approval: 06/24
P&T Approval: 10/21

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SARGRAMOSTIM (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SARGRAMOSTIM	LEUKINE	06074		GPI-10 (8240205000)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Has the patient undergone or is undergoing induction chemotherapy treatment for acute myeloid leukemia (AML) (ICD-10 Group C92.0) and meet **ALL** of the following criteria?
   - The patient is 55 years of age or older
   - Therapy is prescribed by or in consultation with a hematologist or oncologist

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Is the patient undergoing autologous hematopoietic stem cell transplantation and meet **ALL** of the following?
   - The patient has cancer
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a hematologist or oncologist

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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SARGRAMOSTIM (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Has the patient undergone or is undergoing autologous peripheral blood progenitor cell (PBPC) or bone marrow transplantation and meet **ALL** of the following criteria?
   - The patient has non-Hodgkin's lymphoma (NHL) (ICD-10 Group C85), acute lymphoblastic leukemia (ALL) (ICD-10 Group C91.0), or Hodgkin's lymphoma (HL) (ICD-10 Group C81)
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a hematologist or oncologist

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

4. Is the patient undergoing allogeneic bone marrow transplantation from an HLA-matched related donor and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a hematologist or oncologist

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Has the patient undergone allogeneic or autologous bone marrow transplantation and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - The patient's neutrophil recovery is delayed or has failed
   - Therapy is prescribed by or in consultation with a hematologist or oncologist

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #6.

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SARGRAMOSTIM (PART D)

GUIDELINES FOR USE (CONTINUED)

6. Is the patient acutely exposed to myelosuppressive doses of radiation (hematopoietic syndrome of acute radiation syndrome [H-ARS]) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SARGRAMOSTIM (Leukine)** requires the following rule(s) be met for approval:

   A. You meet ONE of the following:
      1. You have undergone or are undergoing induction chemotherapy treatment (start of cancer treatment) for acute myeloid leukemia (AML: type of blood cancer)
      2. You are undergoing autologous hematopoietic stem cell transplantation (a type of procedure to replace damaged bone marrow with your own health blood-forming cells)
      3. You have undergone or are undergoing autologous peripheral blood progenitor cell (PBPC: a type of blood cancer treatment) or bone marrow transplantation (procedure to get healthy blood-forming cells)
      4. You are undergoing allogeneic bone marrow transplantation from a human leukocyte antigen (HLA)-matched related donor (a type of procedure to get healthy blood-forming cells)
      5. You have undergone allogeneic or autologous bone marrow transplantation
      6. You are acutely exposed to myelosuppressive doses of radiation (hematopoietic syndrome of acute radiation syndrome [H-ARS: an illness that happens after whole body radiation])

   B. If you have undergone or are undergoing induction chemotherapy treatment for acute myeloid leukemia, approval also requires:
      1. You are 55 years of age or older
      2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)

   (Denial text continued on next page)

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SARGRAMOSTIM (PART D)

GUIDELINES FOR USE (CONTINUED)

C. If you are undergoing autologous hematopoietic stem cell transplantation, approval also requires:
1. You have cancer
2. You are 18 years of age or older
3. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)

D. If you have undergone or are undergoing autologous peripheral blood progenitor cell or bone marrow transplantation, approval also requires:
1. You have non-Hodgkin's lymphoma (NHL), acute lymphoblastic leukemia (ALL), or Hodgkin's lymphoma (HL) (types of blood cancer)
2. You are 2 years of age or older
3. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)

E. If you are undergoing allogeneic bone marrow transplantation from a human leukocyte antigen-matched related donor, approval also requires:
1. You are 2 years of age or older
2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)

F. If you have undergone allogeneic or autologous bone marrow transplantation, approval also requires:
1. You are 2 years of age or older
2. Your neutrophil (a type of white blood cell) recovery is delayed or has failed
3. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)

G. If you are acutely exposed to myelosuppressive doses of radiation (hematopoietic syndrome of acute radiation syndrome), approval also requires:
1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SARGRAMOSTIM (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Leukine.

REFERENCES
Leukine [Prescribing Information]. Lexington, MA: Partner Therapeutics, Inc.; August 2023.

For Part D use only:

SARGRAMOSTIM (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	PRESCRIBED BY OR IN CONSULTATION WITH HEMATOLOGIST OR ONCOLOGIST.
Coverage Duration	12 MONTHS
Other Criteria	N/A

Part D Effective: 01/01/25 Created: 06/24
Commercial Effective: N/A Client Approval: 06/24 P&T Approval: 04/18

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SARILUMAB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SARILUMAB	KEVZARA	44183		GPI-10 (6650006000)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Kevzara will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Orencia (abatacept)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

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SARILUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of polymyalgia rheumatica (PMR) (ICD-10 M35.3) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- The patient had an inadequate response to a corticosteroid (e.g., prednisone) or cannot tolerate a corticosteroid taper
- Kevzara will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of PMR

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #3.

3. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (pJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
- The patient weighs at least 63 kg (138 lbs)
- Therapy is prescribed by or in consultation with a rheumatologist
- Kevzara will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of pJIA
- The patient had a trial of or contraindication to TWO of the following preferred agents:
  - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
  - Xeljanz (tofacitinib IR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
  - Orencia (abatacept)

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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SARILUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SARILUMAB (Kevzara)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Polymyalgia rheumatica (PMR: an inflammatory disorder causing muscle pain and stiffness)
   3. Polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition)

B. If you have moderate to severe rheumatoid arthritis, approval also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Kevzara concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
   4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      a. Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
      b. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
      c. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
      d. Orencia (abatacept)

C. If you have polymyalgia rheumatica, approval also requires:
   1. You are 18 years of age or older
   2. You had an inadequate response (drug did not work) to a corticosteroid (such as prednisone) or cannot tolerate a corticosteroid taper (slowly lower the dose)
   3. You will NOT use Kevzara concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polymyalgia rheumatica

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SARILUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

D. If you have polyarticular juvenile idiopathic arthritis, approval also requires:
1. You weigh at least 63 kg (138 pounds)
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You will NOT use Kevzara concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis
4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
   b. Xeljanz (tofacitinib immediate-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
   c. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
   d. Orencia (abatacept)

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SARILUMAB (PART D)

RENEWAL CRITERIA

NOTE: For the diagnosis of polymyalgia rheumatica, please refer to the initial criteria section.

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Kevzara will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (pJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Kevzara will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of pJIA

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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SARILUMAB (PART D)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SARILUMAB (Kevzara)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition)

B. If you have moderate to severe rheumatoid arthritis, renewal also requires:
   1. You continue to benefit from the medication
   2. You will NOT use Kevzara concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis

C. If you have polyarticular juvenile idiopathic arthritis, renewal also requires:
   1. You continue to benefit from the medication
   2. You will NOT use Kevzara concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kevzara.

REFERENCE

Kevzara [Prescribing Information]. Bridgewater, NJ: Sanofi-Aventis US LLC; June 2024.

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SARILUMAB (PART D)

For Part D use only:

SARILUMAB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	RHEUMATOID ARTHRITIS (RA), POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST.
Coverage Duration	RA, PJIA: INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS. POLYMYALGIA RHEUMATICA (PMR): 12 MONTHS.
Other Criteria	INITIAL: RA: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, XELJANZ, RINVOQ, ORENCIA. PJIA: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, XELJANZ IR, RINVOQ, ORENCIA. PMR: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR PMR. INITIAL/RENEWAL: RA, PJIA: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR THE SAME INDICATION. RENEWAL: RA, PJIA: CONTINUES TO BENEFIT FROM THE MEDICATION.

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Effective: 05/01/26 Client Approval: 04/26 P&T Approval: 01/25

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SATRALIZUMAB-MWGE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SATRALIZUMAB-MWGE	ENSPRYNG	46781		GPI-10 (9940507040)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of neuromyelitis optica spectrum disorder (NMOSD) (ICD-10 G36.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a positive serologic test for anti-aquaporin-4 (AQP4) antibodies
   - Therapy is prescribed by or in consultation with a neurologist or ophthalmologist
   - Enspryng will NOT be used concurrently with another NMOSD agent (e.g., Rituxan [rituximab], Uplizna [inebilizumab-cdon], Soliris [eculizumab])

   If yes, continue to #2.
   If no, do no approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SATRALIZUMAB-MWGE (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient have **ONE** of the following core clinical characteristics?
   - Optic neuritis
   - Acute myelitis
   - Area postrema syndrome
   - Acute brainstem syndrome
   - Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions
   - Symptomatic cerebral syndrome with NMOSD-typical brain lesions

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SATRALIZUMAB-MWGE (Enspryng)** requires the following rule(s) be met for approval:
   A. You have neuromyelitis optica spectrum disorder (NMOSD: a type of brain disorder)
   B. You are 18 years of age or older
   C. You have a positive serologic (blood) test for anti-aquaporin-4 (AQP4: type of protein) antibodies
   D. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor) or ophthalmologist (a type of eye doctor)
   E. You will NOT use Enspryng concurrently (at the same time) with another NMOSD medication (such as Rituxan [rituximab], Uplizna [inebilizumab-cdon], Soliris [eculizumab])

(Initial denial text continued on next page)

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SATRALIZUMAB-MWGE (PART D)

INITIAL CRITERIA (CONTINUED)

F. You have at least ONE of the following core clinical characteristics:
   1. Optic neuritis (inflammation that damages an eye nerve)
   2. Acute myelitis (sudden and severe inflammation of the spinal cord)
   3. Area postrema syndrome (attacks of uncontrollable nausea, vomiting, or hiccups)
   4. Acute brainstem syndrome (problems with vision, hearing, swallowing and muscle weakness in the head)
   5. Symptomatic narcolepsy (sudden attacks of sleep) or acute diencephalic clinical syndrome (rare disorder caused by a tumor above the brainstem) with NMOSD-typical diencephalic MRI (magnetic resonance imaging: a type of lab imaging lab) lesions (affected areas)
   6. Symptomatic cerebral syndrome with NMOSD-typical brain lesions

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SATRALIZUMAB-MWGE (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of neuromyelitis optica spectrum disorder (NMOSD) (ICD-10 G36.0) and meet **ALL** of the following criteria?
   - The patient had a reduction in relapse frequency from baseline
   - Enspryng will NOT be used concurrently with another NMOSD agent (e.g., Rituxan [rituximab], Uplizna [inebilizumab-cdon], Soliris [eculizumab])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SATRALIZUMAB-MWGE (Enspryng)** requires the following rule(s) be met for renewal:
   A. You have neuromyelitis optica spectrum disorder (NMOSD: a type of brain disorder)
   B. You had a reduction in relapse frequency from baseline
   C. You will NOT use Enspryng concurrently (at the same time) with another NMOSD medication (such as Rituxan [rituximab], Uplizna [inebilizumab-cdon], Soliris [eculizumab])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Enspryng.

REFERENCES
Enspryng [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; September 2022.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SATRALIZUMAB-MWGE (PART D)

For Part D use only:

SATRALIZUMAB-MWGE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	NEUROMYELITIS OPTICA SPECTRUM DISORDER (NMOSD): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST OR OPHTHALMOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	NMOSD: INITIAL: 1) ONE OF THE FOLLOWING CORE CLINICAL CHARACTERISTIC: (A) OPTIC NEURITIS, (B) ACUTE MYELITIS, (C) AREA POSTREMA SYNDROME, (D) ACUTE BRAINSTEM SYNDROME, (E) SYMPTOMATIC NARCOLEPSY OR ACUTE DIENCEPHALIC CLINICAL SYNDROME WITH NMOSD-TYPICAL DIENCEPHALIC MRI LESIONS, OR (F) SYMPTOMATIC CEREBRAL SYNDROME WITH NMOSD-TYPICAL BRAIN LESIONS, AND 2) NO CONCURRENT USE WITH ANOTHER NMOSD AGENT (E.G., RITUXIMAB, INEBILIZUMAB, ECULIZUMAB). RENEWAL: 1) REDUCTION IN RELAPSE FREQUENCY FROM BASELINE, AND 2) NO CONCURRENT USE WITH ANOTHER NMOSD AGENT (E.G., RITUXIMAB, INEBILIZUMAB, ECULIZUMAB).

Created: 08/20
Effective: 01/01/26 Client Approval: 11/25 P&T Approval: 10/25

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SEBELIPASE ALFA (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SEBELIPASE ALFA	KANUMA	42747		GPI-10 (3090636000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of lysosomal acid lipase (LAL) deficiency (ICD-10 E75.5) and meet **ALL** of the following criteria?
   - The diagnosis is confirmed by the presence of clinical features (e.g., hepatomegaly, elevated serum transaminases, dyslipidemia, splenomegaly)
   - Therapy is prescribed by or in consultation with an endocrinologist, hepatologist, gastroenterologist, medical geneticist, lipidologist, or metabolic specialist

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has a blood test indicating low or absent levels of LAL enzyme activity
   - The patient has a dried blood spot test indicating low or absent LAL enzyme activity
   - The patient has a genetic test indicating the bi-allelic presence of altered LIPA gene(s)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See initial denial text at the end of the guideline.

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SEBELIPASE ALFA (PART D)

INITIAL CRITERIA (CONTINUED)

3. Is lysosomal acid lipase (LAL) deficiency presenting within the first 6 months of life **AND** is rapidly progressive (also known as Wolman disease)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

4. Is lysosomal acid lipase (LAL) deficiency presenting after the first 6 months of life **AND** is NOT considered rapidly progressive (also known as cholesteryl ester storage disease [CESD])?

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SEBELIPASE ALFA (Kanuma)** requires the following rule(s) be met for approval:
   A. You have lysosomal acid lipase (LAL) deficiency (a type of genetic metabolic disorder)
   B. Your diagnosis is confirmed by the presence of clinical features such as hepatomegaly (enlarged liver), elevated serum transaminases (types of enzymes), dyslipidemia (abnormal levels of fats), splenomegaly (enlarged spleen)
   C. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor), hepatologist (a type of liver doctor), gastroenterologist (doctor who treats digestive conditions), medical geneticist, lipidologist (a type of cholesterol doctor) or metabolic specialist

   (Initial denial text continued on next page)

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SEBELIPASE ALFA (PART D)

INITIAL CRITERIA (CONTINUED)

D. You have ONE of the following:
   1. A blood test indicating low or absent levels of lysosomal acid lipase enzyme activity
   2. A dried blood spot test indicating low or absent lysosomal acid lipase enzyme activity
   3. A genetic test indicating the bi-allelic presence of altered LIPA gene(s) (you have a change in a gene that provides instructions for producing an enzyme called lysosomal acid lipase)

E. Your diagnosis either is presenting within the first 6 months of life and is rapidly progressive (quickly getting worse), OR is presenting after the first 6 months of life and is not considered rapidly progressive (not quickly getting worse)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SEBELIPASE ALFA (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of lysosomal acid lipase (LAL) deficiency (ICD-10 E75.5)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is lysosomal acid lipase (LAL) deficiency presenting within the first 6 months of life **AND** is rapidly progressive (also known as Wolman disease)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Is lysosomal acid lipase (LAL) deficiency presenting after the first 6 months of life **AND** not considered rapidly progressive?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Does the patient have improvement in **ONE** of the following clinical parameters during the past 6 months?
   - A relative reduction from baseline in LDL-c, non-HDL-c, OR triglycerides
   - Normalization of aspartate aminotransferase (AST) based on age- and gender-specific normal ranges
   - A decrease in liver fat content compared to baseline assessed by abdominal imaging (e.g., multi-echo gradient echo [MEGE] MRI)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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SEBELIPASE ALFA (PART D)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SEBELIPASE ALFA (Kanuma)** requires the following rule(s) be met for renewal:

A. You have lysosomal acid lipase (LAL) deficiency (a type of genetic metabolic disorder)
B. Your diagnosis either is presenting within the first 6 months of life and is rapidly progressive (quickly getting worse) OR is presenting after the first 6 months of life and is not considered rapidly progressive (not quickly getting worse)
C. If you have lysosomal acid lipase deficiency presenting after the first 6 months of life, renewal also requires:
    1. You have improvement in ONE of the following clinical parameters during the past 6 months:
        a. A relative reduction from baseline in LDL-c, non-HDL-c, OR triglycerides (types of fat lab measurements)
        b. Normalization of aspartate aminotransferase (AST: type of liver enzyme) based on age- and gender-specific normal ranges
        c. A decrease in liver fat content compared to baseline assessed by abdominal imaging such as multi-echo gradient echo [MEGE] MRI

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kanuma.

REFERENCES

Kanuma [Prescribing Information]. Cheshire, CT: Alexion Pharmaceuticals, Inc; November 2021.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SEBELIPASE ALFA (PART D)

For Part D use only:

SEBELIPASE ALFA (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	LYSOSOMAL ACID LIPASE (LAL) DEFICIENCY: INITIAL: DIAGNOSIS CONFIRMED BY 1) PRESENCE OF CLINICAL FEATURES (E.G., HEPATOMEGALY, ELEVATED SERUM TRANSAMINASES, DYSLIPIDEMIA, SPLENOMEGALY), AND 2) ONE OF THE FOLLOWING: (A) BLOOD TEST INDICATING LOW OR ABSENT LEVELS OF LAL ENZYME ACTIVITY, (B) DRIED BLOOD SPOT TEST INDICATING LOW OR ABSENT LAL ENZYME ACTIVITY, OR (C) GENETIC TEST INDICATING THE BI-ALLELIC PRESENCE OF ALTERED LIPA GENE(S).
Age Restrictions	N/A
Prescriber Restrictions	LAL DEFICIENCY: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST, HEPATOLOGIST, GASTROENTEROLOGIST, MEDICAL GENETICIST, LIPIDOLOGIST, OR METABOLIC SPECIALIST.
Coverage Duration	LAL DEFICIENCY: INITIAL: 6 OR 12 MONTHS, SEE OTHER CRITERIA. RENEWAL: 12 MONTHS
Other Criteria	LAL DEFICIENCY: INITIAL: RAPIDLY PROGRESSIVE LAL DEFICIENCY PRESENTING WITHIN THE FIRST 6 MONTHS OF LIFE: 12 MONTHS. LAL DEFICIENCY PRESENTING AFTER THE FIRST 6 MONTHS OF LIFE AND NOT CONSIDERED RAPIDLY PROGRESSIVE: 6 MONTHS. RENEWAL: LAL DEFICIENCY PRESENTING AFTER THE FIRST 6 MONTHS OF LIFE AND NOT CONSIDERED RAPIDLY PROGRESSIVE: IMPROVEMENT IN ONE OF THE FOLLOWING CLINICAL PARAMETERS DURING THE PAST 6 MONTHS: (1) A RELATIVE REDUCTION FROM BASELINE IN LDL-C, NON-HDL-C, OR TRIGLYCERIDES, (2) NORMALIZATION OF ASPARTATE AMINOTRANSFERASE (AST) BASED ON AGE- AND GENDER-SPECIFIC NORMAL RANGES, OR (3) DECREASE IN LIVER FAT CONTENT COMPARED TO BASELINE ASSESSED BY ABDOMINAL IMAGING.

Core	Advantage	Plus
No	No	Yes

Created: 12/15
Effective: 01/01/25 Client Approval: 08/24 P&T Approval: 11/16

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SEBETRALSTAT (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SEBETRALSTAT	EKTERLY	50678		GPI-10 (8584005000)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hereditary angioedema (HAE) (ICD-10 D84.1) and meet **ALL** of the following criteria?
- The patient is 12 years of age or older
- Ekterly will be used for the treatment of acute HAE attacks
- Therapy is prescribed by or in consultation with an allergist, immunologist, hematologist, or pulmonologist
- Ekterly will NOT be used concurrently with other agents used for the treatment of acute HAE attacks (e.g., Firazyr [icatibant], Berinert [C1 esterase inhibitor], Ruconest [C1 esterase inhibitor], Kalbitor [ecallantide])

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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SEBETRALSTAT (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient meet **ONE** of the following criteria?
   - The patient has Type I or II HAE, as confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q
   - The patient has Type III HAE

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SEBETRALSTAT (Ekterly)** requires the following rule(s) be met for approval:
   A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
   B. You are 12 years of age or older
   C. Ekterly will be used for the treatment of acute (sudden and severe) hereditary angioedema attacks
   D. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), immunologist (a type of immune system doctor), hematologist (a type of blood doctor), or pulmonologist (lung/breathing doctor)
   E. You will NOT use Ekterly concurrently (at the same time) with other medications used for the treatment of acute (sudden and severe) hereditary angioedema attacks (such as Firazyr [icatibant], Berinert [C1 esterase inhibitor], Ruconest [C1 esterase inhibitor], Kalbitor [ecallantide])
   F. You meet ONE of the following:
      1. You have Type I or II hereditary angioedema (a type of gene condition with severe body swelling), as confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q (types of lab tests)
      2. You have Type III hereditary angioedema (a type of gene condition with severe body swelling)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SEBETRALSTAT (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary angioedema (HAE) (ICD-10 D84.1) **AND** meet the following criterion?
   - Ekterly will NOT be used concurrently with other agents used for the treatment of acute HAE attacks (e.g., Firazyr [icatibant], Berinert [C1 esterase inhibitor], Ruconest [C1 esterase inhibitor], Kalbitor [ecallantide])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SEBETRALSTAT (Ekterly)** requires the following rule(s) be met for renewal:
   A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
   B. You will NOT use Ekterly concurrently (at the same time) with other medications used for the treatment of acute (sudden and severe) hereditary angioedema attacks (such as Firazyr [icatibant], Berinert [C1 esterase inhibitor], Ruconest [C1 esterase inhibitor], Kalbitor [ecallantide])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SEBETRALSTAT (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ekterly.

REFERENCES

Ekterly [Prescribing Information]. Cambridge, MA: KalVista Pharmaceuticals, Inc.; July 2025.

For Part D use only:

SEBETRALSTAT (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	HEREDITARY ANGIOEDEMA (HAE): INITIAL: 1) TYPE III HAE, OR 2) TYPE I OR II HAE CONFIRMED BY ONE OF THE FOLLOWING COMPLEMENT TESTS: C1-INH PROTEIN LEVELS, C4 PROTEIN LEVELS, C1-INH FUNCTIONAL LEVELS, C1Q.
Age Restrictions	N/A
Prescriber Restrictions	HAE: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH AN ALLERGIST, IMMUNOLOGIST, HEMATOLOGIST, OR PULMONOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	HAE: INITIAL/RENEWAL: NO CONCURRENT USE WITH OTHER MEDICATIONS FOR THE TREATMENT OF ACUTE HAE ATTACKS.

Created: 07/25
Effective: 03/01/26 Client Approval: 02/26 P&T Approval: 04/25

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SECUKINUMAB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SECUKINUMAB	COSENTYX	41715		GPI-10 (9025057500)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding for Cosentyx (secukinumab) intravenous infusion route.

Requests for subcutaneous (SC/SQ) Cosentyx (secukinumab) do not require Payment Determination.

1. Is the request for intravenous (IV) infusion of Cosentyx for the treatment of psoriatic arthritis, ankylosing spondylitis, or non-radiographic axial spondyloarthritis?

   If yes, continue to #2.
   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

2. Is this a pharmacy call?

   If yes, continue to #4.
   If no, continue to #3.

3. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #4.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

4. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #5.

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SECUKINUMAB (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #6.

6. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enterany override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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SECUKINUMAB (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist
   - The patient has psoriasis covering 3% or more of body surface area (BSA) OR psoriatic lesions affecting the hands, feet, genital area, scalp, or face
   - Cosentyx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy)
   - The patient has a contraindication or intolerance to both immunosuppressant and PUVA (phototherapy)
   - The patient is switching from a different biologic (e.g., Humira [adalimumab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SECUKINUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
- The patient is 2 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
- Cosentyx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #4.

4. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
- The patient is 12 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist
- Cosentyx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS
- The patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam)

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #5.

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SECUKINUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of non-radiographic axial spondyloarthritis (nr-axSpA) (ICD-10 Group M45.A) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient has C-reactive protein (CRP) levels above the upper limit of normal OR has sacroiliitis on magnetic resonance imaging (MRI)
   - Cosentyx will NOT be used concurrently with another systemic biologic (e.g., Taltz [ixekizumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of nr-axSpA
   - The patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #6.

6. Does the patient have a diagnosis of enthesitis-related arthritis (ERA) (ICD-10 M08.80) and meet **ALL** of the following criteria?
   - The patient is 4 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Cosentyx will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of ERA
   - The patient had a trial of or contraindication to ONE NSAID (e.g., ibuprofen, naproxen, meloxicam), sulfasalazine, OR methotrexate

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #7.

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SECUKINUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

7. Does the patient have a diagnosis of moderate to severe hidradenitis suppurativa (HS) (ICD-10 L73.2) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist
   - Cosentyx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of HS

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SECUKINUMAB (Cosentyx)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
      2. Psoriatic arthritis (PsA: a type of skin and joint condition)
      3. Ankylosing spondylitis (AS: a type of joint condition)
      4. Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)
      5. Enthesitis-related arthritis (ERA: a type of joint condition)
      6. Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)

   (Initial denial text continued on next page)

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SECUKINUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

B. If you have moderate to severe plaque psoriasis, approval also requires:
1. You are 6 years of age and older
2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
3. You have psoriasis covering 3% or more of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, genital area, scalp, or face
4. You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis
5. You meet ONE of the following:
   a. You have had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy)
   b. You have a contraindication (harmful for you to use) or intolerance (side effect) to both immunosuppressant (a type of drug that decreases the body's immune response) and PUVA (phototherapy)
   c. You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication

C. If you have psoriatic arthritis, approval also requires:
1. You are 2 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
3. You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

D. If you have ankylosing spondylitis, approval also requires:
1. You are 12 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis
4. You have tried or have a contraindication to (harmful for you to use) an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)

(Initial denial text continued on next page)

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SECUKINUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

E. If you have non-radiographic axial spondyloarthritis, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. Your C-reactive protein (CRP: a measure of how much inflammation is in the body) levels are above the upper limit of normal, OR you have sacroiliitis (type of inflammation where lower spine and pelvis connect) on magnetic resonance imaging (MRI: type of imaging lab)
4. You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic (such as Taltz [ixekizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-radiographic axial spondyloarthritis
5. You have tried or have a contraindication to (harmful for you to use) an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)

F. If you have enthesitis-related arthritis, approval also requires:
1. You are 4 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of enthesitis-related arthritis
4. You have tried or have a contraindication to (harmful for you to use) ONE NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam), sulfasalazine, or methotrexate

G. If you have moderate to severe hidradenitis suppurativa, approval also requires:
1. You are 12 years of age or older
2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
3. You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of hidradenitis suppurativa

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SECUKINUMAB (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Cosentyx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Cosentyx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Cosentyx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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SECUKINUMAB (PART D)

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of non-radiographic axial spondyloarthritis (nr-axSpA) (ICD-10 Group M45.A) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Cosentyx will NOT be used concurrently with another systemic biologic (e.g., Taltz [ixekizumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of nr-axSpA

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Does the patient have a diagnosis of enthesitis-related arthritis (ERA) (ICD-10 M08.80) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Cosentyx will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of ERA

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #6.

6. Does the patient have a diagnosis of moderate to severe hidradenitis suppurativa (HS) (ICD-10 L73.2) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Cosentyx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of HS

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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SECUKINUMAB (PART D)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SECUKINUMAB (Cosentyx)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   2. Psoriatic arthritis (PsA: a type of joint and skin condition)
   3. Ankylosing spondylitis (AS: a type of joint condition)
   4. Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)
   5. Enthesitis-related arthritis (ERA: a type of joint condition)
   6. Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)

B. If you have plaque psoriasis, renewal also requires:
   1. You continue to benefit from the medication
   2. You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis

C. If you have psoriatic arthritis, renewal also requires:
   1. You continue to benefit from the medication
   2. You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

D. If you have ankylosing spondylitis, renewal also requires:
   1. You continue to benefit from the medication
   2. You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis

E. If you have non-radiographic axial spondyloarthritis, renewal also requires:
   1. You continue to benefit from the medication
   2. You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic (such as Taltz [ixekizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-radiographic axial spondyloarthritis

(Renewal denial text continued on next page)

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SECUKINUMAB (PART D)

RENEWAL CRITERIA (CONTINUED)

F. If you have enthesitis-related arthritis, renewal also requires:
1. You continue to benefit from the medication
2. You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of enthesitis-related arthritis

G. If you have hidradenitis suppurativa, renewal also requires:
1. You continue to benefit from the medication
2. You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of hidradenitis suppurativa

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cosentyx.

The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Cosentyx [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2026.

Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed July 1, 2024].

For Part D use only:

SECUKINUMAB SQ (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	INITIAL: PLAQUE PSORIASIS (PSO): PSORIASIS COVERING 3 PERCENT OR MORE OF BODY SURFACE AREA OR PSORIATIC LESIONS AFFECTING THE HANDS, FEET, GENITAL AREA, SCALP, OR FACE. NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS (NR-AXSPA): 1) C-REACTIVE PROTEIN (CRP) LEVELS ABOVE THE UPPER LIMIT OF NORMAL, OR 2) SACROILIITIS ON MAGNETIC RESONANCE IMAGING (MRI).
Age Restrictions	N/A

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Prescriber Restrictions	INITIAL: PSO, HIDRADENITIS SUPPURATIVA (HS): PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST. PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST OR A DERMATOLOGIST. ANKYLOSING SPONDYLITIS (AS), NR-AXSPA, ENTHESITIS-RELATED ARTHRITIS (ERA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST.
Coverage Duration	INITIAL: HS: 12 MONTHS, ALL OTHER INDICATIONS: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: PSO: 1) AT LEAST A 3 MONTH TRIAL OF ONE ORAL IMMUNOSUPPRESSANT (CYCLOSPORINE, METHOTREXATE, TACROLIMUS) OR PUVA (PHOTOTHERAPY), 2) CONTRAINDICATION OR INTOLERANCE TO BOTH IMMUNOSUPPRESSANT AND PUVA, OR 3) PATIENT IS SWITCHING FROM A DIFFERENT BIOLOGIC, PDE-4 INHIBITOR, OR JAK INHIBITOR FOR THE SAME INDICATION. AS, NR-AXSPA: TRIAL OF OR CONTRAINDICATION TO AN NSAID. ERA: TRIAL OF OR CONTRAINDICATION TO ONE NSAID, SULFASALAZINE, OR METHOTREXATE. INITIAL/RENEWAL: ALL INDICATIONS: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION. RENEWAL: ALL INDICATIONS: CONTINUES TO BENEFIT FROM THE MEDICATION.

Created: 05/15
Effective: 06/10/26 Client Approval: 06/26 P&T Approval: 04/26

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SELADELPAR (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SELADELPAR LYSINE	LIVDELZI	49816		GPI-10 (5278007050)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of primary biliary cholangitis (PBC) (ICD-10 K74.3) as confirmed by at least **TWO** of the following criteria?
   - The patient has an elevated alkaline phosphatase (ALP) level
   - The patient has the presence of antimitochondrial antibodies (AMA) OR other PBC-specific autoantibodies, including sp100 or gp210, if AMA is negative
   - The patient has histologic evidence (obtained by liver biopsy) of non-suppurative destructive cholangitis and destruction of interlobular bile ducts

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SELADELPAR (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist or hepatologist
   - The patient does NOT have decompensated cirrhosis (Child-Pugh B or C)
   - Livdelzi will NOT be used concurrently with any other second-line PBC treatment (i.e., Ocaliva [obeticholic acid], Iqirvo [elafibranor])

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - Livdelzi will be used as monotherapy in a patient who is unable to tolerate ursodiol (ursodeoxycholic acid)
   - Livdelzi will be used in combination with ursodiol (ursodeoxycholic acid) in a patient who had an inadequate response to at least 1 year of treatment with ursodiol (ursodeoxycholic acid) monotherapy

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Is alleviation of pruritus a treatment goal?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Has the patient had a trial of or contraindication to ONE of the following preferred agents: Ocaliva (obeticholic acid), Iqirvo (elafibranor)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SELADELPAR (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SELADELPAR (Livdelzi)** requires the following rule(s) be met for approval:

A. You have primary biliary cholangitis (PBC: a type of immune system disorder that destroys the bile duct), as confirmed by TWO of the following:
   1. You have an elevated (high) alkaline phosphatase (ALP) level (a type of lab test)
   2. You have the presence of antimitochondrial antibodies (AMA: indicator of the body attacking its own cells) or other PBC-specific autoantibodies (indicator of the body attacking its own cells), including sp100 or gp210, if AMA is negative
   3. You have histologic evidence (lab data obtained by liver biopsy [removal of cells or tissue from the liver for examination]) of non-suppurative destructive cholangitis and destruction of interlobular bile ducts (symptoms of liver disease)

B. You are 18 years of age or older

C. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions) or hepatologist (a type of liver doctor)

D. You do NOT have decompensated cirrhosis (a condition where there is liver damage and scarring with major symptoms) (Child-Pugh B or C: a score that evaluates the severity of liver damage)

E. You will NOT use Livdelzi concurrently (at the same time) with any other second-line therapy for PBC (Ocaliva [obeticholic acid], Iqirvo [elafibranor])

F. You meet ONE of the following:
   1. Livdelzi will be used as monotherapy (one drug treatment) if you are unable to tolerate ursodiol (ursodeoxycholic acid)
   2. Livdelzi will be used in combination (together) with ursodiol (ursodeoxycholic acid) if you had an inadequate (poor) response to at least 1 year of treatment with ursodiol (ursodeoxycholic acid) monotherapy (one drug treatment)

G. You meet ONE of the following:
   1. Alleviation of (decreasing) your pruritus (itching) is a goal of treatment with Livdelzi
   2. You had a trial of or contraindication to (harmful for you to use) ONE of the following preferred medications: Ocaliva (obeticholic acid), Iqirvo (elafibranor)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SELADELPAR (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of primary biliary cholangitis (PBC) (ICD-10 K74.3) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Livdelzi will NOT be used concurrently with any other second-line PBC treatment (i.e., Ocaliva [obeticholic acid], Iqirvo [elafibranor])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SELADELPAR (Livdelzi)** requires the following rule(s) be met for renewal:
   A. You have primary biliary cholangitis (PBC: a type of immune system disorder that destroys the bile duct)
   B. You continue to benefit from the medication
   C. You will NOT use Livdelzi concurrently (at the same time) with any other second-line therapy for PBC (Ocaliva [obeticholic acid], Iqirvo [elafibranor])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Livdelzi.

REFERENCES
Livdelzi [Prescribing Information]. Foster City, CA: Gilead Sciences, Inc.; August 2024.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SELADELPAR (PART D)

For Part D use only:

SELADELPAR (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	PRIMARY BILIARY CHOLANGITIS (PBC): INITIAL: DIAGNOSIS CONFIRMED BY TWO OF THE FOLLOWING: 1) ELEVATED ALKALINE PHOSPHATASE LEVEL, 2) PRESENCE OF ANTIMITOCHONDRIAL ANTIBODIES OR OTHER PBC-SPECIFIC AUTOANTIBODIES, INCLUDING SP100 OR GP210, IF AMA IS NEGATIVE, OR 3) HISTOLOGIC EVIDENCE (OBTAINED BY LIVER BIOPSY) OF NON-SUPPURATIVE DESTRUCTIVE CHOLANGITIS AND DESTRUCTION OF INTERLOBULAR BILE DUCTS.
Age Restrictions	N/A
Prescriber Restrictions	PBC: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST OR HEPATOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	PBC: INITIAL: 1) NO CONCURRENT USE WITH ANOTHER SECOND-LINE THERAPY FOR PBC, 2) USED IN COMBINATION WITH URSODIOL IF INADEQUATE RESPONSE AFTER TREATMENT WITH URSODIOL MONOTHERAPY FOR AT LEAST 1 YEAR, OR USED AS MONOTHERAPY IF UNABLE TO TOLERATE URSODIOL, 3) DOES NOT HAVE DECOMPENSATED CIRRHOSIS (CHILD-PUGH B OR C), AND 4) TRIAL OF OR CONTRAINDICATION TO ONE OF THE FOLLOWING PREFERRED AGENTS: OCALIVA, IQIRVO. STEP NOT APPLICABLE FOR WHOM ALLEVIATION OF PRURITUS IS A TREATMENT GOAL. RENEWAL: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SECOND-LINE THERAPY FOR PBC.

Part D Effective: 11/11/24 Created: 08/24
Commercial Effective: N/A Client Approval: 11/24 P&T Approval: 07/24

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ADVANTAGE AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SELEXIPAG (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SELEXIPAG	UPTRAVI	42922		GPI-10 (4012007000)	

Do not review this guideline with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH)(World Health Organization Group 1) (ICD-10 I27.0, Group I27.2) and meet **ALL** of the following criteria?
   - The patient is at least 2 years of age
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist

   If yes, continue to #2.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient's PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of 15 mmHg or less
   - Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

   If yes, continue to #3.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Is the patient 2 to 17 years of age?

   If yes, **approve for 12 months by HICL or GPI-10.**

   If no, continue to #4.

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SELEXIPAG (PART D)

INITIAL CRITERIA (CONTINUED)

4. Is the patient at least 18 years of age and had a trial of or contraindication to **ONE** of the following agents?
   - Formulary version of an oral endothelin receptor antagonist (e.g., Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
   - Formulary version of an oral phosphodiesterase-5 inhibitor indicated for PAH (e.g., Revatio [sildenafil], Adcirca [tadalafil], Alyq [tadalafil], Tadliq [tadalafil])
   - Formulary version of an oral cGMP stimulator (e.g., Adempas [riociguat])

   If yes, **approve for 12 months by HICL or GPI-10.**

   If no, do not approve.

   INITIAL DENIAL TEXT:

   Our guideline named **SELEXIPAG (Uptravi)** requires the following rule(s) be met for approval:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1: a way to classify the severity of disease)
   B. You are 2 years of age or older
   C. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   D. Your pulmonary arterial hypertension diagnosis is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
      1. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
      2. Pulmonary capillary wedge pressure (PCWP) of 15 mmHg or less
      3. Pulmonary vascular resistance (PVR) greater than 2 Wood units
   E. If you are 18 years of age or older, approval also requires you have tried or have a contraindication to (harmful for you to use) ONE of the following medications:
      1. Formulary version of an oral endothelin receptor antagonist (such as Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
      2. Formulary version of an oral phosphodiesterase-5 inhibitor indicated for PAH (such as Adcirca [tadalafil], Alyq [tadalafil], Tadliq [tadalafil], Revatio [sildenafil])
      3. Formulary version of an oral cGMP stimulator (such as Adempas [riociguat])

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SELEXIPAG (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH)(World Health Organization Group 1) (ICD-10 I27.0, Group I27.2)?

   If yes, **approve for 12 months by HICL or GPI-10.**

   If no, do not approve.

   RENEWAL DENIAL TEXT:

   Our guideline named **SELEXIPAG (Uptravi)** requires the following rule(s) be met for renewal:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition)(World Health Organization [WHO] Group 1: a way to classify the severity of disease)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Uptravi.

REFERENCES
Uptravi [Prescribing Information]. Titusville, NJ : Actelion Pharmaceuticals US, Inc.; May 2026.

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SELEXIPAG (PART D)

For Part D use only:

SELEXIPAG (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	PULMONARY ARTERIAL HYPERTENSION (PAH): INITIAL: DIAGNOSIS CONFIRMED BY RIGHT HEART CATHETERIZATION WITH THE FOLLOWING PARAMETERS: 1) MEAN PULMONARY ARTERY PRESSURE (PAP) GREATER THAN 20 MMHG, 2) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF 15 MMHG OR LESS, AND 3) PULMONARY VASCULAR RESISTANCE (PVR) GREATER THAN 2 WOOD UNITS.
Age Restrictions	N/A
Prescriber Restrictions	PAH: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS
Other Criteria	PAH: INITIAL: AGES 18 YEARS OR OLDER: TRIAL OF OR CONTRAINDICATION TO ONE OF THE FOLLOWING AGENTS: 1) FORMULARY VERSION OF AN ORAL ENDOTHELIN RECEPTOR ANTAGONIST, 2) FORMULARY VERSION OF AN ORAL PHOSPHODIESTERASE TYPE-5 INHIBITOR FOR PAH, 3) FORMULARY VERSION OF AN ORAL CGMP STIMULATOR.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SELINEXOR (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SELINEXOR	XPOVIO	45854		GPI-10 (2156006000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of multiple myeloma (MM) (ICD-10 Group C90.0) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Will Xpovio be used in combination with Velcade (bortezomib) and dexamethasone **AND** the patient meets the following criterion?
   - The patient has received at least one prior therapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Has the patient's cancer relapsed or is refractory (RRMM) and the patient meets **ALL** of the following criteria?
   - Xpovio will be used in combination with dexamethasone
   - The patient has received at least four prior therapies for the treatment of RRMM

   If yes, continue to #4.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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SELINEXOR (PART D)

GUIDELINES FOR USE (CONTINUED)

4. Is the patient's disease refractory to **ALL** of the following?
   - Two proteasome inhibitors (e.g., Velcade [bortezomib], Kyprolis [carfilzomib])
   - Two immunomodulatory agents (e.g., Revlimid [lenalidomide], Pomalyst [pomalidomide])
   - One anti-CD38 monoclonal antibody (e.g., Darzalex [daratumumab])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SELINEXOR (Xpovio)** requires the following rule(s) be met for approval:
   A. You have multiple myeloma (MM: a type of blood cancer)
   A. You are 18 years of age or older
   B. You meet ONE of the following:
      1. Xpovio will be used in combination with Velcade (bortezomib) and dexamethasone; and you have received at least ONE prior therapy
      2. You have relapsed or refractory multiple myeloma (RRMM: a type of blood cancer that has returned or did not respond to treatment); Xpovio will be used in combination with dexamethasone; you have received at least four prior therapies for the treatment of RRMM; AND your disease is refractory (non-responsive) to ALL of the following:
         a. Two proteasome inhibitors (such as Velcade [bortezomib], Kyprolis [carfilzomib])
         b. Two immunomodulatory agents (such as Revlimid [lenalidomide], Pomalyst [pomalidomide])
         c. One anti-CD38 monoclonal antibody (such as Darzalex [daratumumab])

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SELINEXOR (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Xpovio.

REFERENCES
Xpovio [Prescribing Information]. Newton, MA: Karyopharm Therapeutics Inc.; April 2026.

For Part D use only:

SELINEXOR (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SELPERCATINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SELPERCATINIB	RETEVMO	46525		GPI-10 (2153577900)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer has a *RET* gene fusion, as detected by an FDA-approved test

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of advanced or metastatic medullary thyroid cancer (MTC) (ICD-10 C73) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - The patient's cancer has a *RET*-mutation, as detected by an FDA-approved test
   - The patient requires systemic therapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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SELPERCATINIB (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of advanced or metastatic thyroid cancer (ICD-10 C73) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - The patient's cancer has a *RET* gene fusion, as detected by an FDA-approved test
   - The patient requires systemic therapy
   - The thyroid cancer is refractory to radioactive iodine therapy (if radioactive iodine is appropriate)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

4. Does the patient have a diagnosis of locally advanced or metastatic solid tumor and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - The patient's tumor has a *RET* gene fusion, as detected by an FDA-approved test
   - The patient's tumor has progressed on or following prior systemic treatment OR the patient has no satisfactory alternative treatment options

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SELPERCATINIB (Retevmo)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Locally advanced or metastatic non-small cell lung cancer (a type of lung cancer that has spread to nearby tissue or lymph nodes or has spread to other parts of the body)
      2. Advanced or metastatic medullary thyroid cancer (a type of thyroid cancer that has progressed or has spread to other parts of the body)
      3. Advanced or metastatic thyroid cancer (thyroid cancer that has progressed or has spread to other parts of the body)
      4. Locally advanced or metastatic solid tumor (abnormal mass that has spread to nearby tissue or lymph nodes, or has spread to other parts of the body)

   (Denial text continued on next page)

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SELPERCATINIB (PART D)

GUIDELINES FOR USE (CONTINUED)

B. If you have locally advanced or metastatic non-small cell lung cancer, approval also requires:
1. You are 18 years of age or older
2. Your cancer has a rearranged during transfection (*RET:* type of gene) gene fusion, as detected by a Food and Drug Administration (FDA)-approved test

C. If you have advanced or metastatic medullary thyroid cancer, approval also requires:
1. You are 2 years of age or older
2. Your cancer has a rearranged during transfection (*RET*: type of gene) mutation, as detected by a Food and Drug Administration (FDA)-approved test
3. You require systemic therapy (treatment that travels through the entire body)

D. If you have advanced or metastatic thyroid cancer, approval also requires:
1. You are 2 years of age or older
2. You require systemic therapy (treatment that travels through the entire body)
3. Your cancer has a rearranged during transfection (*RET:* type of gene) gene fusion, as detected by a Food and Drug Administration (FDA)-approved test
4. Your thyroid cancer is refractory (has not responded) to radioactive iodine therapy, if radioactive iodine is appropriate

E. If you have a locally advanced or metastatic solid tumor, approval also requires:
1. You are 2 years of age or older
2. Your tumor has a rearranged during transfection (*RET:* type of gene) gene fusion, as detected by a Food and Drug Administration (FDA)-approved test
3. Your tumor has progressed on or following prior systemic treatment OR you have no satisfactory alternative treatment options

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Retevmo.

REFERENCES

Retevmo [Prescribing Information]. Indianapolis, IN: Lilly USA, LLC; May 2024.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SELPERCATINIB (PART D)

For Part D use only:

SELPERCATINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SELUMETINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SELUMETINIB SULFATE	KOSELUGO	46451		GPI-10 (2153356550)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of neurofibromatosis type 1 (NF1) (ICD-10 Q85.01) and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - The patient has symptomatic, inoperable plexiform neurofibromas (PN)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SELUMETINIB (Koselugo)** requires the following rule(s) be met for approval:
   A. You have neurofibromatosis type 1 (NF1: a type of skin and nervous system disorder)
   B. You are 1 year of age or older
   C. You have symptomatic, inoperable (cannot be treated by surgery) plexiform neurofibromas (PN: tumors that grow along the nerves)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SELUMETINIB (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Koselugo.

REFERENCES

Koselugo [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; November 2025.

For Part D use only:

SELUMETINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 04/20
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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SEMAGLUTIDE - WEGOVY DVE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SEMAGLUTIDE	WEGOVY	44675		GPI-10 (6125207000)	BRAND = WEGOVY

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	Yes	No	No	Yes	No	No	Yes	No	No	Yes

This is a DvE drug requiring a payment determination for "Part D" or "Non-Part D."

PAYMENT DETERMINATION CRITERIA

1. Is the request to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Wegovy will be used in combination with a reduced calorie diet and increased physical activity
   - The patient has established cardiovascular disease (e.g., prior myocardial infarction, prior stroke, symptomatic peripheral arterial disease [PAD])
   - The patient is obese (BMI of at least 30 kg/m[2] or the patient is Asian and has a BMI of at least 27.5 kg/m[2]), OR overweight (BMI of at least 27 kg/m[2] or the patient is Asian and has a BMI of at least 25 kg/m[2]) at baseline

   If yes, **set CMS_DVE_OVR to 'D' and approve all strengths and formulations for 12 months by GPID or GPI-10. Document in the PA comments: Part D Determination Override.**

   If no, continue to #2.

2. Does the patient have a diagnosis of noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH)/nonalcoholic steatohepatitis (NASH) (ICD-10 K75.81) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The request is for Wegovy injection
   - The patient has moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis)
   - Wegovy will be used in combination with a reduced calorie diet and increased physical activity

   If yes, **set CMS_DVE_OVR to 'D' and approve all strengths of the pen for 12 months by GPID or GPI-12. Document in the PA comments: Part D Determination Override.**

   If no, **set CMS_DVE_OVR to 'E' and approve for 12 months by GPID or GPI-10. Document in the PA comments: Payment Determination Override. This is not a Part D indication.**

   NOTE: If the claim rejects after analyzing, then follow the clinical authorization process within the HQ notes.

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SEMAGLUTIDE - WEGOVY DVE (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

RPH Review
Review for Part D compendial supported off-label indications. If yes for a Part D indication, **set CMS_DVE_OVR to 'D' and approve for 12 months for all strengths by GPID or GPI-10. Document in the PA comments: Part D Determination Override.**

If not a Part D indication, and you are denying other UM **Set CMS_DVE_OVR to 'E' within the denied PA for 12 months by GPID or GPI-10.**

If the diagnosis is UNKNOWN do not enter a DVE override; follow the criteria for any additional UM and decision the case accordingly. Provide the following PAC instruction: '**PAC: do not enter a DVE override**.'

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SEMAGLUTIDE - WEGOVY** requires the following rule(s) be met for approval:

A. The request is for ONE of the following:
   1. Lowering the risk of major adverse cardiovascular events (MACE: serious heart problems, such as death from heart disease, heart attack, or stroke).
   2. Treating noncirrhotic metabolic dysfunction-associated steatohepatitis /nonalcoholic steatohepatitis (MASH/NASH: severe forms of fatty liver disease)
B. You are 18 years of age or older
C. You will use Wegovy along with a lower-calorie diet and more physical activity
D. For lowering the risk of MACE, approval also requires:
   1. You have heart or blood vessel disease, such as a past heart attack, past stroke, or peripheral artery disease (a condition where narrowed blood vessels reduce blood flow to your arms or legs).
   2. Based on your body mass index (BMI: a tool for evaluating body fat) before treatment, you are ONE of the following:
      a. Obese: BMI of at least 30 kg/m[2] (or at least 27.5 kg/m[2] if you are Asian)
      b. Overweight: BMI of at least 27 kg/m[2] (or at least 25 kg/m[2]) if you are Asian)
E. For MASH/NASH, approval also requires:
   1. The request is for Wegovy injection
   2. You have moderate to advanced liver fibrosis (scarring) at stage F2 to F3.

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SEMAGLUTIDE - WEGOVY DVE (PART D)

RATIONALE

To limit the coverage of Wegovy to the Medicare Part D covered indications of reduction in risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) and the treatment of noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH)/nonalcoholic steatohepatitis (NASH), and to exclude coverage for the treatment of obesity. For further information, please refer to the Prescribing Information and/or Drug Monograph for Wegovy.

REFERENCES

Wegovy [Prescribing Information]. Plainsboro, NJ: Novo Nordisk Inc.; February 2026.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements. Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf. [Accessed March 2026].

For Part D use only:

SEMAGLUTIDE - WEGOVY (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	PART D DOES NOT COVER THIS DRUG WHEN USED FOR TREATMENT OF OBESITY.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 03/24
Effective: 09/18/26 Client Approval: 09/26 P&T Approval: 10/25

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SEPIAPTERIN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SEPIAPTERIN	SEPHIENCE	50760		GPI-10 (3090856800)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of sepiapterin-responsive phenylketonuria (PKU) with hyperphenylalaninemia (HPA) (ICD-10 E70.1) and meet **ALL** of the following criteria?
   - The patient is 1 month of age or older
   - Therapy is prescribed by or in consultation with a metabolic or genetic disease specialist
   - Sephience will NOT be used concurrently with another agent indicated for the treatment of phenylketonuria (PKU) (e.g., Kuvan [sapropterin], Palynziq [pegvaliase-pqpz])
   - The patient had a trial of or contraindication to the preferred agent: sapropterin/Javygtor

   If yes, **approve for 6 weeks by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SEPIAPTERIN (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SEPIAPTERIN (Sephience)** requires the following rule(s) be met for approval:

A. You have sepiapterin-responsive phenylketonuria (PKU: a type of genetic metabolic disorder) with hyperphenylalaninemia (HPA: high levels of a type of amino acid)
B. You are 1 month of age or older
C. Therapy is prescribed by or in consultation with a metabolic or genetic disease specialist (a doctor that treats metabolic or gene disorders)
D. You will NOT use Sephience concurrently (at the same time) with another medication indicated for the treatment of phenylketonuria (PKU) (such as Kuvan [sapropterin], Palynziq [pegvaliase-pqpz])
E. You have tried or have a contraindication to (harmful for you to use) the preferred medication: sapropterin/Javygtor

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SEPIAPTERIN (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of sepiapterin-responsive phenylketonuria (PKU) with hyperphenylalaninemia (HPA) (ICD-10 E70.1) and meet **ALL** of the following criteria?
   - The patient continues to benefit from treatment
   - Sephience will NOT be used concurrently with another agent indicated for the treatment of phenylketonuria (PKU) (e.g., Kuvan [sapropterin], Palynziq [pegvaliase-pqpz])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SEPIAPTERIN (Sephience)** requires the following rule(s) be met for renewal:
   A. You have sepiapterin-responsive phenylketonuria (PKU: a type of genetic metabolic disorder) with hyperphenylalaninemia (HPA: high levels of a type of amino acid)
   B. You continue to benefit from treatment
   C. You will NOT use Sephience concurrently (at the same time) with another medication indicated for the treatment of phenylketonuria (PKU) (such as Kuvan [sapropterin], Palynziq [pegvaliase-pqpz])

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Sephience.

REFERENCES
Sephience [Prescribing Information]. Warren, NJ: PTC Therapeutics, Inc.; July 2025.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SEPIAPTERIN (PART D)

For Part D use only:

SEPIAPTERIN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	SEPIAPTERIN-RESPONSIVE PHENYLKETONURIA (PKU) WITH HYPERPHENYLALANINEMIA (HPA): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A METABOLIC OR GENETIC DISEASE SPECIALIST.
Coverage Duration	INITIAL: 6 WEEKS. RENEWAL: 12 MONTHS.
Other Criteria	SEPIAPTERIN-RESPONSIVE PKU WITH HPA: INITIAL: TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT: SAPROPTERIN/JAVYGTOR. INITIAL/RENEWAL: NO CONCURRENT USE WITH ANOTHER AGENT INDICATED FOR THE TREATMENT OF PKU. RENEWAL: CONTINUES TO BENEFIT FROM TREATMENT.

Created: 12/25
Effective: 01/01/26 Client Approval: 12/25 P&T Approval: 10/25

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SEVABERTINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SEVABERTINIB	HYRNUO	51015		GPI-10 (2153305700)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has tumors with HER2 (ERBB2) tyrosine kinase domain (TKD) activating mutations, as detected by an FDA-authorized test

   If yes, **approve for 12 months by HICL or GPI-10.**

   If no, do not approve.

   DENIAL TEXT:

   Our guideline named **SEVABERTINIB (Hyrnuo)** requires the following rule(s) be met for approval:
   A. You have locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) (a type of lung cancer that has spread from where it started to nearby tissue, lymph nodes, or other parts of the body)
   B. You are 18 years of age or older
   C. Your tumors have HER2 (ERBB2) tyrosine kinase domain (TKD) activating mutations (abnormal changes in a type of gene), as detected by a Food and Drug Administration (FDA)-authorized test

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SEVABERTINIB (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Hyrnuo.

REFERENCES

Hyrnuo [Prescribing Information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals, Inc.; September 2026.

For Part D use only:

SEVABERTINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 12/25
Effective: 09/18/26 Client Approval: 09/26 DMC Approval: 09/22/26

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STANDARD PART D
PRIOR AUTHORIZATION GUIDELINES

SIBEPRENLIMAB-SZSI (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SIBEPRENLIMAB-SZSI	VOYXACT	51027		GPI-10 (5648055000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of primary immunoglobulin A nephropathy (IgAN) (ICD-10 Group N02.B) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is at risk for disease progression
   - Therapy is prescribed by or in consultation with a nephrologist
   - The patient's diagnosis is confirmed by a biopsy
   - The patient has proteinuria of at least 0.5 g/day
   - The patient has an eGFR of at least 30 mL/min/1.73 m(2)
   - The patient has tried an ACE inhibitor (e.g., benazepril, lisinopril) or an ARB (e.g., losartan, valsartan) for at least 3 months at a maximum tolerated dose and will continue use, OR has a contraindication to both drug classes

   If yes, **approve for 9 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SIBEPRENLIMAB-SZSI (PART D)

INITIAL CRITERIA (CONTINUED ON NEXT PAGE)

INITIAL DENIAL TEXT:

Our guideline named **SIBEPRENLIMAB-SZSI (Voyxact)** requires the following rule(s) be met for approval:

A. You have primary immunoglobulin A nephropathy (IgAN: a type of kidney disease)
B. You are 18 years of age or older
C. You are at risk for disease progression (worsening of disease)
D. Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor)
E. Your diagnosis is confirmed by a biopsy (removal of cells or tissue from the kidney for examination)
F. You have proteinuria (high levels of protein in the urine) of at least 0.5 g/day
G. You have an estimated glomerular filtration rate (eGFR: a tool for evaluating kidney function) of at least 30 mL/min/1.73 m(2)
H. You have tried an angiotensin converting enzyme inhibitor (ACE-I: a type of medication used to protect kidneys, such as benazepril, lisinopril) or an angiotensin receptor blocker (ARB: a type of medication used to protect kidneys, such as losartan, valsartan) for at least three months at a maximum tolerated dose and will continue use, OR you have a contraindication to (harmful for you to use) both of these medication classes

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STANDARD PART D
PRIOR AUTHORIZATION GUIDELINES

SIBEPRENLIMAB-SZSI (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of primary immunoglobulin A nephropathy (IgAN) (ICD-10 Group N02.B) and meet **ONE** of the following criteria?
   - The patient has had a reduction in proteinuria
   - The patient has improved or stable kidney function compared to baseline

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT:

   Our guideline named **SIBEPRENLIMAB-SZSI (Voyxact)** requires the following rule(s) be met for renewal:
   A. You have primary immunoglobulin A nephropathy (IgAN: a type of kidney disease)
   B. You meet ONE of the following:
      1. You have had a reduction (decrease) in proteinuria (a condition with high levels of protein in the urine)
      2. You have improved or stable kidney function compared to baseline (before starting Voyxact)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Voyxact.

REFERENCES

Voyxact [Prescribing Information]. Rockville, MD: Otsuka America Pharmaceutical, Inc.; November 2025.

Created: 07/26
Effective: 07/01/26 Client Approval: 07/26 DMC Approval: 06/30/26

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SILDENAFIL IV (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SILDENAFIL CITRATE	REVATIO, SILDENAFIL CITRATE		28273	GPI-14 (40143060102020)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (World Health Organization Group 1) (ICD-10 I27.0, Group I27.2) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   - The patient is NOT concurrently or intermittently taking oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
   - The requested medication will NOT be used concurrently with guanylate cyclase (GC) stimulators (e.g., Adempas [riociguat])

   If yes, continue to #2.
   If no, continue to #3.

2. Is the PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of 15 mmHg or less
   - Pulmonary vascular resistance (PVR) greater than 2 Wood units

   If yes, **approve for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SILDENAFIL IV (PART D)

INITIAL CRITERIA (CONTINUED)

3. Does the patient have **ONE** of the following?
   - Achalasia (ICD-10 K22.0, Q39.5)
   - Persistent pulmonary hypertension of the newborn (ICD-10 P29.30)
   - Secondary Raynaud's phenomenon (ICD-10 Group I73.0)
   - Nitric oxide withdrawal symptoms (e.g., rebound pulmonary hypertension)

   If yes, **approve for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SILDENAFIL IV (Revatio)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization Group 1: a way to classify the severity of disease)
      2. Achalasia (a rare disorder making it hard for food and liquid to pass into the stomach)
      3. Persistent pulmonary hypertension of the newborn (a condition where not enough blood or oxygen goes into the baby's lungs after birth)
      4. Secondary Raynaud's phenomenon (a type of blood vessel disorder caused by another condition)
      5. Nitric oxide withdrawal symptoms (such as rebound pulmonary hypertension [a type of lung condition])

   (Initial denial text continued on next page)

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SILDENAFIL IV (PART D)

INITIAL CRITERIA (CONTINUED)

B. If you have pulmonary arterial hypertension (World Health Organization Group 1), approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
3. Your pulmonary arterial hypertension diagnosis is confirmed by right heart catheterization (a test used to measure how well the heart is pumping) with ALL of the following lab values:
   a. Mean pulmonary artery pressure (PAP: a type of measurement for pulmonary arterial hypertension) greater than 20 mmHg
   b. Pulmonary capillary wedge pressure (PCWP: a type of measurement for pulmonary arterial hypertension) of 15 mmHg or less
   c. Pulmonary vascular resistance (PVR: a type of measurement for pulmonary arterial hypertension) greater than 2 Wood units
4. You are NOT concurrently (at the same time) or intermittently (off and on) taking oral erectile dysfunction agents (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
5. You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (drugs that also treat pulmonary hypertension such as Adempas [riociguat])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SILDENAFIL IV (PART D)

RENEWAL CRITERIA

NOTE: For the diagnoses of achalasia, persistent pulmonary hypertension of the newborn, secondary Raynaud's phenomenon, and nitric oxide withdrawal symptoms, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (World Health Organization Group 1) (ICD-10 I27.0, Group I27.2) and meet **ALL** of the following criteria?
   - The patient is NOT concurrently or intermittently taking oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
   - The requested medication will NOT be used concurrently with guanylate cyclase (GC) stimulators (e.g., Adempas [riociguat])

   If yes, **approve for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SILDENAFIL IV (Revatio)** requires the following rule(s) be met for renewal:
   A. You have pulmonary arterial hypertension (PAH; a type of heart and lung condition) (World Health Organization Group 1: a way to classify the severity of disease)
   B. You are NOT concurrently (at the same time) or intermittently (off and on) taking oral erectile dysfunction agents (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
   C. You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (drugs that also treat pulmonary hypertension such as Adempas [riociguat])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SILDENAFIL IV (PART D)

RATIONALE

Prior authorization on these drugs is required due to a high potential for non-Part D use. These drugs should NOT be used for non-medically accepted indications as defined in section 1860D-2(e)(4) of the Act. For further information, please refer to the Prescribing Information and/or Drug Monograph for Revatio.

REFERENCES

Revatio [Prescribing Information]. Morgantown, WV: Viatris Specialty LLC; January 2023.
Announcement of Calendar Year (CY) 2015 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. April 7, 2014. Section III – Part D: Appropriate Utilization of Prior Authorization Requirements to Determine Part D Drug Status. Page 112 – 114.

For Part D use only:

SILDENAFIL IV (PART D)	
Covered Uses	ALL MEDICALLY-ACCEPTED INDICATIONS.
Exclusion Criteria	N/A
Required Medical Information	PULMONARY ARTERIAL HYPERTENSION (PAH): INITIAL: DIAGNOSIS CONFIRMED BY RIGHT HEART CATHETERIZATION WITH THE FOLLOWING PARAMETERS: 1) MEAN PULMONARY ARTERY PRESSURE (PAP) GREATER THAN 20 MMHG, 2) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF 15 MMHG OR LESS, AND 3) PULMONARY VASCULAR RESISTANCE (PVR) GREATER THAN 2 WOOD UNITS.
Age Restrictions	N/A
Prescriber Restrictions	PAH: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	PAH: INITIAL/RENEWAL: 1) NOT CONCURRENTLY OR INTERMITTENTLY TAKING ORAL ERECTILE DYSFUNCTION AGENTS (E.G. CIALIS, VIAGRA) OR ANY ORGANIC NITRATES IN ANY FORM, AND 2) NO CONCURRENT USE WITH GUANYLATE CYCLASE STIMULATORS.

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25 Created: 01/08
Commercial Effective: N/A Client Approval: 06/24 P&T Approval: 01/24

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SILDENAFIL SUSPENSION-LIQREV TIRF (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SILDENAFIL CITRATE	LIQREV		54078	GPI-14 (40143060101825)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	Yes	No	No	Yes	No	No	Yes	No	Yes	Yes

These are TIRF-Like drugs requiring a payment determination for "Part D" or "Non-Part D".

PAYMENT DETERMINATION CRITERIA

1. Does the patient have **ONE** of the following diagnoses?
   - Pulmonary arterial hypertension (PAH) (World Health Organization Group 1) (ICD-10 I27.0, Group I27.2)
   - Achalasia (ICD-10 K22.0, Q39.5)
   - Persistent pulmonary hypertension of the newborn (ICD-10 P29.30)
   - Secondary Raynaud's phenomenon (ICD-10 Group I73.0)
   - Nitric oxide withdrawal symptoms (e.g., rebound pulmonary hypertension)

   If yes, **set MCARE_DRUG_DETERM_OVR to 'Y' and approve for 12 months by GPID or GPI-14. Document in the PA comments: Part D Determination Override and diagnosis.**

   If no, **do not enter an MCARE override. Then, process as follows:**
   CSR Note:
   - If the caller is a physician, member, and/or AOR, please initiate a verbal PA intake request in MR3.
   - If the caller is a pharmacy, please advise the pharmacy to contact the provider or member to pursue a payment determination and document the diagnosis provided in MedAccess.

   Please follow the clinical authorization process within the HQ notes.

   RPH Note:
   - Review for both FDA and Part D compendial supported off-label indications.
   - If the provided diagnosis is not FDA approved or compendial supported off-label use, **set MCARE_DRUG_DETERM_OVR to 'N' and enter override within the denied PA for 12 months by GPID or GPI-14.**
   - If the diagnosis is UNKNOWN do not enter an MCARE override; follow the criteria for any additional UM and decision the case accordingly. Provide the following PAC instruction**:** '**PAC: do not enter an MCARE override**.'

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SILDENAFIL SUSPENSION-LIQREV TIRF (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (World Health Organization Group 1) (ICD-10 I27.0, Group I27.2) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   - The patient is NOT concurrently or intermittently taking oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
   - Liqrev will NOT be used concurrently with guanylate cyclase (GC) stimulators (e.g., Adempas [riociguat])
   - The patient is unable to swallow Revatio (sildenafil) tablets
   - The patient had a trial of generic sildenafil powder for suspension

   If yes, continue to #2.
   If no, continue to #3.

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SILDENAFIL SUSPENSION-LIQREV TIRF (PART D)

INITIAL CRITERIA (CONTINUED)

2. Is the PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of 15 mmHg or less
   - Pulmonary vascular resistance (PVR) greater than 2 Wood units

   If yes, **approve for 12 months by GPID or GPI-14. NOTE: If the claim rejects for payment determination after analyzing, then follow the above TIRF-Like determination criteria.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   - **If indication is Part D, but other criteria not met: Set MCARE_DRUG_DETERM_OVR to 'Y' and enter override within the partially denied PA for 12 months by GPID or GPI-14.**

   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient have **ONE** of the following diagnoses?
   - Achalasia (ICD-10 K22.0, Q39.5)
   - Persistent pulmonary hypertension of the newborn (ICD-10 P29.30)
   - Secondary Raynaud's phenomenon (ICD-10 Group I73.0)
   - Nitric oxide withdrawal symptoms (e.g., rebound pulmonary hypertension)

   If yes, **approve for 12 months by GPID or GPI-14. NOTE: If the claim rejects for payment determination after analyzing, then follow the above TIRF-Like determination criteria.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   If not a Part D indication: Set MCARE_DRUG_DETERM_OVR to 'N' and enter override within the denied PA for 12 months by GPID or GPI-14.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SILDENAFIL SUSPENSION-LIQREV TIRF (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SILDENAFIL SUSPENSION-LIQREV** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization Group 1: a way to classify the severity of disease)
   2. Achalasia (a rare disorder making it hard for food and liquid to pass into the stomach)
   3. Persistent pulmonary hypertension of the newborn (a condition where not enough blood or oxygen goes into the baby's lungs after birth)
   4. Secondary Raynaud's phenomenon (a type of blood vessel disorder caused by another condition)
   5. Nitric oxide withdrawal symptoms (such as rebound pulmonary hypertension [a type of lung condition])

B. If you have pulmonary arterial hypertension (World Health Organization Group 1), approval also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   3. You are NOT concurrently (at the same time) or intermittently (off and on) taking oral erectile dysfunction agents (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
   4. You will NOT use Liqrev concurrently (at the same time) with guanylate cyclase (GC) stimulators (drugs that also treat pulmonary hypertension such as Adempas [riociguat])
   5. You are unable to swallow Revatio (sildenafil) tablets
   6. You have tried generic sildenafil powder for suspension
   7. Your pulmonary arterial hypertension diagnosis is confirmed by right heart catheterization (a test used to measure how well the heart is pumping) with ALL of the following lab values:
      a. Mean pulmonary artery pressure (PAP: a type of measurement for pulmonary arterial hypertension) greater than 20 mmHg
      b. Pulmonary capillary wedge pressure (PCWP: a type of measurement for pulmonary arterial hypertension) of 15 mmHg or less
      c. Pulmonary vascular resistance (PVR: a type of measurement for pulmonary arterial hypertension) greater than 2 Wood units

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SILDENAFIL SUSPENSION-LIQREV TIRF (PART D)

RENEWAL CRITERIA

NOTE: For the diagnoses of achalasia, persistent pulmonary hypertension of the newborn, secondary Raynaud's phenomenon, and nitric oxide withdrawal symptoms, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (World Health Organization Group 1) (ICD-10 I27.0, Group I27.2) and meet **ALL** of the following criteria?
   - The patient is NOT concurrently or intermittently taking oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
   - Liqrev will NOT be used concurrently with guanylate cyclase (GC) stimulators (e.g., Adempas [riociguat])

   If yes, **approve for 12 months by GPID or GPI-14. NOTE: If the claim rejects for payment determination after analyzing, then follow the above TIRF-Like determination criteria. APPROVAL TEXT (IF APPLICABLE):** The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   - **If not a Part D indication: Set MCARE_DRUG_DETERM_OVR to 'N' and enter override within the denied PA for 12 months by GPID or GPI-14.**
   - **If indication is Part D, but other criteria not met: Set MCARE_DRUG_DETERM_OVR to 'Y' and enter override within the partially denied PA for 12 months by GPID or GPI-14.**

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SILDENAFIL SUSPENSION-LIQREV** requires the following rule(s) be met for renewal:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization Group 1: a way to classify the severity of disease)
   B. You are NOT concurrently (at the same time) or intermittently (off and on) taking oral erectile dysfunction agents (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
   C. You will NOT use Liqrev concurrently (at the same time) with guanylate cyclase stimulators (drugs that also treat pulmonary hypertension such as Adempas [riociguat])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SILDENAFIL SUSPENSION-LIQREV TIRF (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Liqrev. Prior authorization on these drugs is required due to a high potential for non-Part D use. These drugs should NOT be used for non-medically accepted indications as defined in section 1860D-2(e)(4) of the Act.

REFERENCES

Liqrev [Prescribing Information]. Farmville, NC: CMP Pharma Inc.; April 2023.
Announcement of Calendar Year (CY) 2015 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. April 7, 2014. Section III – Part D: Appropriate Utilization of Prior Authorization Requirements to Determine Part D Drug Status. Page 112 – 114.

For Part D use only:

SILDENAFIL SUSPENSION-LIQREV (PART D)	
Covered Uses	ALL MEDICALLY-ACCEPTED INDICATIONS.
Exclusion Criteria	N/A
Required Medical Information	PULMONARY ARTERIAL HYPERTENSION (PAH): INITIAL: DIAGNOSIS CONFIRMED BY RIGHT HEART CATHETERIZATION WITH THE FOLLOWING PARAMETERS: 1) MEAN PULMONARY ARTERY PRESSURE (PAP) GREATER THAN 20 MMHG, 2) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF 15 MMHG OR LESS, AND 3) PULMONARY VASCULAR RESISTANCE (PVR) GREATER THAN 2 WOOD UNITS.
Age Restrictions	N/A
Prescriber Restrictions	PAH: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	PAH: INITIAL: 1) NOT CONCURRENTLY OR INTERMITTENTLY TAKING ORAL ERECTILE DYSFUNCTION AGENTS (E.G. CIALIS, VIAGRA) OR ANY ORGANIC NITRATES IN ANY FORM, 2) NO CONCURRENT USE WITH GUANYLATE CYCLASE STIMULATORS, 3) INABILITY TO SWALLOW SILDENAFIL TABLETS, AND 4) TRIAL OF GENERIC SILDENAFIL POWDER FOR SUSPENSION. RENEWAL: 1) NOT CONCURRENTLY OR INTERMITTENTLY TAKING ORAL ERECTILE DYSFUNCTION AGENTS (E.G. CIALIS, VIAGRA) OR ANY ORGANIC NITRATES IN ANY FORM, AND 2) NO CONCURRENT USE WITH GUANYLATE CYCLASE STIMULATORS.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SILDENAFIL SUSPENSION-REVATIO TIRF (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SILDENAFIL CITRATE	REVATIO, SILDENAFIL CITRATE		33186	GPI-14 (40143060101920)	

These are TIRF-Like drugs requiring a payment determination for "Part D" or "Non-Part D".

PAYMENT DETERMINATION CRITERIA

1. Does the patient have **ONE** of the following diagnoses?
   - Pulmonary arterial hypertension (PAH) (World Health Organization Group 1) (ICD-10 I27.0, Group I27.2)
   - Achalasia (ICD-10 K22.0, Q39.5)
   - Persistent pulmonary hypertension of the newborn (ICD-10 P29.30)
   - Secondary Raynaud's phenomenon (ICD-10 Group I73.0)
   - Nitric oxide withdrawal symptoms (e.g., rebound pulmonary hypertension)

   If yes, **set MCARE_DRUG_DETERM_OVR to 'Y' and approve for 12 months by GPID or GPI-14. Document in the PA comments: Part D Determination Override and diagnosis.**

   If no, **do not enter an MCARE override. Then, process as follows:**
   CSR Note:
   - If the caller is a physician, member, and/or AOR, please initiate a verbal PA intake request in MR3.
   - If the caller is a pharmacy, please advise the pharmacy to contact the provider or member to pursue a payment determination and document the diagnosis provided in MedAccess.

   Please follow the clinical authorization process within the HQ notes.

   RPH Note:
   - Review for both FDA and Part D compendial supported off-label indications.
   - If the provided diagnosis is not FDA approved or compendial supported off-label use, **set MCARE_DRUG_DETERM_OVR to 'N' and enter override within the denied PA for 12 months by GPID or GPI-14.**
   - If the diagnosis is UNKNOWN do not enter an MCARE override; follow the criteria for any additional UM and decision the case accordingly. Provide the following PAC instruction**:** '**PAC: do not enter an MCARE override**.'

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SILDENAFIL SUSPENSION-REVATIO TIRF (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (World Health Organization Group 1) (ICD-10 I27.0, Group I27.2) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   - The patient is unable to swallow tablets
   - The patient is NOT concurrently or intermittently taking oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
   - The requested medication will NOT be used concurrently with guanylate cyclase (GC) stimulators (e.g., Adempas [riociguat])

   If yes, continue to #2.
   If no, continue to #4.

2. Is the patient 1 to 17 years of age and the PAH diagnosis is confirmed by right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of 15 mmHg or less
   - Pulmonary vascular resistance (PVR) of 3 Wood units or greater

   If yes, **approve for 12 months by GPID or GPI-14. NOTE: If the claim rejects for payment determination after analyzing, then follow the above TIRF-Like determination criteria. APPROVAL TEXT (IF APPLICABLE):** The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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SILDENAFIL SUSPENSION-REVATIO TIRF (PART D)

INITIAL CRITERIA (CONTINUED)

3. Is the patient 18 years of age or older and the PAH diagnosis is confirmed by right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of 15 mmHg or less
   - Pulmonary vascular resistance (PVR) greater than 2 Wood units

   If yes, **approve for 12 months by GPID or GPI-14. NOTE: If the claim rejects for payment determination after analyzing, then follow the above TIRF-Like determination criteria.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   - **If indication is Part D, but other criteria not met: Set MCARE_DRUG_DETERM_OVR to 'Y' and enter override within the partially denied PA for 12 months by GPID or GPI-14.**

   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have **ONE** of the following?
   - Achalasia (ICD-10 K22.0, Q39.5)
   - Persistent pulmonary hypertension of the newborn (ICD-10 P29.30)
   - Secondary Raynaud's phenomenon (ICD-10 Group I73.0)
   - Nitric oxide withdrawal symptoms (e.g., rebound pulmonary hypertension)

   If yes, **approve for 12 months by GPID or GPI-14. NOTE: If the claim rejects for payment determination after analyzing, then follow the above TIRF-Like determination criteria.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   If not a Part D indication: Set MCARE_DRUG_DETERM_OVR to 'N' and enter override within the denied PA for 12 months by GPID or GPI-14.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SILDENAFIL SUSPENSION-REVATIO TIRF (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SILDENAFIL SUSPENSION-REVATIO** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization Group 1: a way to classify the severity of disease)
   2. Achalasia (a rare disorder making it hard for food and liquid to pass into the stomach)
   3. Persistent pulmonary hypertension of the newborn (a condition where not enough blood or oxygen goes into the baby's lungs after birth)
   4. Secondary Raynaud's phenomenon (a type of blood vessel disorder caused by another condition)
   5. Nitric oxide withdrawal symptoms (such as rebound pulmonary hypertension [a type of lung condition])

B. If you have pulmonary arterial hypertension (World Health Organization Group 1), approval also requires:
   1. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   2. You are unable to swallow tablets
   3. You are NOT concurrently (at the same time) or intermittently (off and on) taking oral erectile dysfunction agents (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
   4. You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (drugs that also treat pulmonary hypertension such as Adempas [riociguat])
   5. If you are 1 to 17 years of age, your pulmonary arterial hypertension diagnosis is confirmed by right heart catheterization (a test used to measure how well the heart is pumping) with ALL of the following lab values:
      a. Mean pulmonary artery pressure (PAP: a type of measurement for pulmonary arterial hypertension) greater than 20 mmHg
      b. Pulmonary capillary wedge pressure (PCWP: a type of measurement for pulmonary arterial hypertension) of 15 mmHg or less
      c. Pulmonary vascular resistance (PVR: a type of measurement for pulmonary arterial hypertension) of 3 Wood units or greater

(Initial denial text continued on next page)

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SILDENAFIL SUSPENSION-REVATIO TIRF (PART D)

INITIAL CRITERIA (CONTINUED)

6. If you are 18 years of age or older, your pulmonary arterial hypertension diagnosis is confirmed by right heart catheterization (a test used to measure how well the heart is pumping) with ALL of the following lab values:
   a. Mean pulmonary artery pressure (PAP: a type of measurement for pulmonary arterial hypertension) greater than 20 mmHg
   b. Pulmonary capillary wedge pressure (PCWP: a type of measurement for pulmonary arterial hypertension) of 15 mmHg or less
   c. Pulmonary vascular resistance (PVR: a type of measurement for pulmonary arterial hypertension) greater than 2 Wood units

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SILDENAFIL SUSPENSION-REVATIO TIRF (PART D)

RENEWAL CRITERIA

NOTE: For the diagnoses of achalasia, persistent pulmonary hypertension of the newborn, secondary Raynaud's phenomenon, and nitric oxide withdrawal symptoms, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (World Health Organization Group 1) (ICD-10 I27.0, Group I27.2) and meet **ALL** of the following criteria?
   - The patient is NOT concurrently or intermittently taking oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
   - The requested medication will NOT be used concurrently with guanylate cyclase (GC) stimulators (e.g., Adempas [riociguat])

   If yes, **approve for 12 months by GPID or GPI-14. NOTE: If the claim rejects for payment determination after analyzing, then follow the above TIRF-Like determination criteria. APPROVAL TEXT (IF APPLICABLE):** The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   - **If not a Part D indication: Set MCARE_DRUG_DETERM_OVR to 'N' and enter override within the denied PA for 12 months by GPID or GPI-14.**
   - **If indication is Part D, but other criteria not met: Set MCARE_DRUG_DETERM_OVR to 'Y' and enter override within the partially denied PA for 12 months by GPID or GPI-14.**

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SILDENAFIL SUSPENSION-REVATIO** requires the following rule(s) be met for renewal:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization Group 1: a way to classify the severity of disease)
   B. You are NOT concurrently (at the same time) or intermittently (off and on) taking oral erectile dysfunction agents (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
   C. You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (drugs that also treat pulmonary hypertension such as Adempas [riociguat])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request. **CONTINUED ON NEXT PAGE**

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SILDENAFIL SUSPENSION-REVATIO TIRF (PART D)

RATIONALE

Prior authorization on these drugs is required due to a high potential for non-Part D use. These drugs should NOT be used for non-medically accepted indications as defined in section 1860D-2(e)(4) of the Act. For further information, please refer to the Prescribing Information and/or Drug Monograph for Revatio.

REFERENCES

Revatio [Prescribing Information]. Morgantown, WV: Viatris Specialty LLC; January 2023.
Announcement of Calendar Year (CY) 2015 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. April 7, 2014. Section III – Part D: Appropriate Utilization of Prior Authorization Requirements to Determine Part D Drug Status. Page 112 – 114.

For Part D use only:

SILDENAFIL SUSPENSION-REVATIO (PART D)	
Covered Uses	ALL MEDICALLY-ACCEPTED INDICATIONS.
Exclusion Criteria	N/A
Required Medical Information	PULMONARY ARTERIAL HYPERTENSION (PAH): INITIAL: AGES 18 YEARS OR OLDER: DIAGNOSIS CONFIRMED BY RIGHT HEART CATHETERIZATION WITH THE FOLLOWING PARAMETERS: 1) MEAN PULMONARY ARTERY PRESSURE (PAP) GREATER THAN 20 MMHG, 2) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF 15 MMHG OR LESS, AND 3) PULMONARY VASCULAR RESISTANCE (PVR) GREATER THAN 2 WOOD UNITS. AGES 1 TO 17 YEARS: DIAGNOSIS CONFIRMED BY RIGHT HEART CATHETERIZATION WITH THE FOLLOWING PARAMETERS: 1) MEAN PAP GREATER THAN 20 MMHG, 2) PCWP OF 15 MMHG OR LESS, AND 3) PVR OF 3 WOOD UNITS OR GREATER.
Age Restrictions	N/A
Prescriber Restrictions	PAH: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	PAH: INITIAL: 1) NOT CONCURRENTLY OR INTERMITTENTLY TAKING ORAL ERECTILE DYSFUNCTION AGENTS (E.G. CIALIS, VIAGRA) OR ANY ORGANIC NITRATES IN ANY FORM, 2) NO CONCURRENT USE WITH GUANYLATE CYCLASE STIMULATORS, AND 3) INABILITY TO SWALLOW TABLETS. RENEWAL: 1) NOT CONCURRENTLY OR INTERMITTENTLY TAKING ORAL ERECTILE DYSFUNCTION AGENTS (E.G. CIALIS, VIAGRA) OR ANY ORGANIC NITRATES IN ANY FORM, AND 2) NO CONCURRENT USE WITH GUANYLATE CYCLASE STIMULATORS.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SILDENAFIL SUSPENSION-REVATIO TIRF (PART D)

Core	Advantage	Plus
Yes	Yes	Yes

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Effective: 05/17/25 Client Approval: 05/25 P&T Approval: 01/24

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SILDENAFIL TABLET TIRF (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SILDENAFIL CITRATE	REVATIO, SILDENAFIL CITRATE		24758	GPI-14 (40143060100320)	

These are TIRF-Like drugs requiring a payment determination for "Part D" or "Non-Part D".

PAYMENT DETERMINATION CRITERIA

1. Does the patient have **ONE** of the following diagnoses?
   - Pulmonary arterial hypertension (PAH) (World Health Organization Group 1) (ICD-10 I27.0, Group I27.2)
   - Achalasia (ICD-10 K22.0, Q39.5)
   - Persistent pulmonary hypertension of the newborn (ICD-10 P29.30)
   - Secondary Raynaud's phenomenon (ICD-10 Group I73.0)
   - Nitric oxide withdrawal symptoms (e.g., rebound pulmonary hypertension)

   If yes, **set MCARE_DRUG_DETERM_OVR to 'Y' and approve for 12 months by GPID or GPI-14. Document in the PA comments: Part D Determination Override and diagnosis.**

   If no, **do not enter an MCARE override. Then, process as follows:**
   CSR Note:
   - If the caller is a physician, member, and/or AOR, please initiate a verbal PA intake request in MR3.
   - If the caller is a pharmacy, please advise the pharmacy to contact the provider or member to pursue a payment determination and document the diagnosis provided in MedAccess.

   Please follow the clinical authorization process within the HQ notes.

   RPH Note:
   - Review for both FDA and Part D compendial supported off-label indications.
   - If the provided diagnosis is not FDA approved or compendial supported off-label use, **set MCARE_DRUG_DETERM_OVR to 'N' and enter override within the denied PA for 12 months by GPID or GPI-14.**
   - If the diagnosis is UNKNOWN do not enter an MCARE override; follow the criteria for any additional UM and decision the case accordingly. Provide the following PAC instruction**:** '**PAC: do not enter an MCARE override**.'

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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SILDENAFIL TABLET TIRF (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (World Health Organization Group 1) (ICD-10 I27.0, Group I27.2) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   - The patient is NOT concurrently or intermittently taking oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
   - The requested medication will NOT be used concurrently with guanylate cyclase (GC) stimulators (e.g., Adempas [riociguat])

   If yes, continue to #2.
   If no, continue to #4.

2. Is the patient 1 to 17 years of age and the PAH diagnosis is confirmed by right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of 15 mmHg or less
   - Pulmonary vascular resistance (PVR) of 3 Wood units or greater

   If yes, **approve for 12 months by GPID or GPI-14. NOTE: If the claim rejects for payment determination after analyzing, then follow the above TIRF-Like determination criteria.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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SILDENAFIL TABLET TIRF (PART D)

INITIAL CRITERIA (CONTINUED)

3. Is the patient 18 years of age or older and the PAH diagnosis is confirmed by right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of 15 mmHg or less
   - Pulmonary vascular resistance (PVR) greater than 2 Wood units

   If yes, **approve for 12 months by GPID or GPI-14. NOTE: If the claim rejects for payment determination after analyzing, then follow the above TIRF-Like determination criteria.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   - **If indication is Part D, but other criteria not met: Set MCARE_DRUG_DETERM_OVR to 'Y' and enter override within the partially denied PA for 12 months by GPID or GPI-14.**

   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have **ONE** of the following?
   - Achalasia (ICD-10 K22.0, Q39.5)
   - Persistent pulmonary hypertension of the newborn (ICD-10 P29.30)
   - Secondary Raynaud's phenomenon (ICD-10 Group I73.0)
   - Nitric oxide withdrawal symptoms (e.g., rebound pulmonary hypertension)

   If yes, **approve for 12 months by GPID or GPI-14. NOTE: If the claim rejects for payment determination after analyzing, then follow the above TIRF-Like determination criteria.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   If not a Part D indication: Set MCARE_DRUG_DETERM_OVR to 'N' and enter override within the denied PA for 12 months by GPID or GPI-14.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SILDENAFIL TABLET TIRF (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SILDENAFIL TABLET (Revatio)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization Group 1: a way to classify the severity of disease)
   2. Achalasia (a rare disorder making it hard for food and liquid to pass into the stomach)
   3. Persistent pulmonary hypertension of the newborn (a condition where not enough blood or oxygen goes into the baby's lungs after birth)
   4. Secondary Raynaud's phenomenon (a type of blood vessel disorder that is caused by another condition)
   5. Nitric oxide withdrawal symptoms (such as rebound pulmonary hypertension [a type of lung condition])

B. If you have pulmonary arterial hypertension (World Health Organization Group 1), approval also requires:
   1. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   2. You are NOT concurrently (at the same time) or intermittently (off and on) taking oral erectile dysfunction agents (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
   3. You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (drugs that also treat pulmonary hypertension such as Adempas [riociguat])
   4. If you are 1 to 17 years of age, your pulmonary arterial hypertension diagnosis is confirmed by right heart catheterization (a test used to measure how well the heart is pumping) with ALL of the following lab values:
      a. Mean pulmonary artery pressure (PAP: a type of measurement for pulmonary arterial hypertension) greater than 20 mmHg
      b. Pulmonary capillary wedge pressure (PCWP: a type of measurement for pulmonary arterial hypertension) of 15 mmHg or less
      c. Pulmonary vascular resistance (PVR: a type of measurement for pulmonary arterial hypertension) of 3 Wood units or greater

(Initial denial text continued on next page)

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SILDENAFIL TABLET TIRF (PART D)

INITIAL CRITERIA (CONTINUED)

5. If you are 18 years of age or older, your pulmonary arterial hypertension diagnosis is confirmed by right heart catheterization (a test used to measure how well the heart is pumping) with ALL of the following lab values:
   a. Mean pulmonary artery pressure (PAP: a type of measurement for pulmonary arterial hypertension) greater than 20 mmHg
   b. Pulmonary capillary wedge pressure (PCWP: a type of measurement for pulmonary arterial hypertension) of 15 mmHg or less
   c. Pulmonary vascular resistance (PVR: a type of measurement for pulmonary arterial hypertension) greater than 2 Wood units

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SILDENAFIL TABLET TIRF (PART D)

RENEWAL CRITERIA

NOTE: For the diagnoses of achalasia, persistent pulmonary hypertension of the newborn, secondary Raynaud's phenomenon, and nitric oxide withdrawal symptoms, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (World Health Organization Group 1) (ICD-10 I27.0, Group I27.2) and meet **ALL** of the following criteria?
   - The patient is NOT concurrently or intermittently taking oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
   - The requested medication will NOT be used concurrently with guanylate cyclase (GC) stimulators (e.g., Adempas [riociguat])

   If yes, **approve for 12 months by GPID or GPI-14. NOTE: If the claim rejects for payment determination after analyzing, then follow the above TIRF-Like determination criteria. APPROVAL TEXT (IF APPLICABLE):** The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   - **If not a Part D indication: Set MCARE_DRUG_DETERM_OVR to 'N' and enter override within the denied PA for 12 months by GPID or GPI-14.**
   - **If indication is Part D, but other criteria not met: Set MCARE_DRUG_DETERM_OVR to 'Y' and enter override within the partially denied PA for 12 months by GPID or GPI-14.**

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SILDENAFIL TABLET (Revatio)** requires the following rule(s) be met for renewal:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization Group 1: a way to classify the severity of disease)
   B. You are NOT concurrently (at the same time) or intermittently (off and on) taking oral erectile dysfunction agents (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
   C. You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (drugs that also treat pulmonary hypertension such as Adempas [riociguat])

   (Renewal denial text continued on next page)

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SILDENAFIL TABLET TIRF (PART D)

RENEWAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

Prior authorization on these drugs is required due to a high potential for non-Part D use. These drugs should NOT be used for non-medically accepted indications as defined in section 1860D-2(e)(4) of the Act. For further information, please refer to the Prescribing Information and/or Drug Monograph for Revatio.

REFERENCES

Revatio [Prescribing Information]. Morgantown, WV: Viatris Specialty LLC; January 2023.
Announcement of Calendar Year (CY) 2015 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. April 7, 2014. Section III – Part D: Appropriate Utilization of Prior Authorization Requirements to Determine Part D Drug Status. Page 112 – 114.

For Part D use only:

SILDENAFIL TABLET (PART D)	
Covered Uses	ALL MEDICALLY-ACCEPTED INDICATIONS.
Exclusion Criteria	N/A
Required Medical Information	PULMONARY ARTERIAL HYPERTENSION (PAH): INITIAL: AGES 18 YEARS OR OLDER: DIAGNOSIS CONFIRMED BY RIGHT HEART CATHETERIZATION WITH THE FOLLOWING PARAMETERS: 1) MEAN PULMONARY ARTERY PRESSURE (PAP) GREATER THAN 20 MMHG, 2) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF 15 MMHG OR LESS, AND 3) PULMONARY VASCULAR RESISTANCE (PVR) GREATER THAN 2 WOOD UNITS. AGES 1 TO 17 YEARS: DIAGNOSIS CONFIRMED BY RIGHT HEART CATHETERIZATION WITH THE FOLLOWING PARAMETERS: 1) MEAN PAP GREATER THAN 20 MMHG, 2) PCWP OF 15 MMHG OR LESS, AND 3) PVR OF 3 WOOD UNITS OR GREATER.
Age Restrictions	N/A
Prescriber Restrictions	PAH: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	PAH: INITIAL/RENEWAL: 1) NOT CONCURRENTLY OR INTERMITTENTLY TAKING ORAL ERECTILE DYSFUNCTION AGENTS (E.G. CIALIS, VIAGRA) OR ANY ORGANIC NITRATES

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	IN ANY FORM AND 2) NO CONCURRENT USE WITH GUANYLATE CYCLASE STIMULATORS.

Core	Advantage	Plus
Yes	Yes	Yes

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Effective: 05/17/25 Client Approval: 05/25 P&T Approval: 01/24

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SILTUXIMAB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SILTUXIMAB	SYLVANT	41101		GPI-10 (9947308000)	

Do not review Part D guidelines with physicians; if the caller wished to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of multi-centric Castleman's disease (MCD) (ICD-10 D47.Z2) and meet **ALL** of the following criteria?
   - The patient is human immunodeficiency virus (HIV) negative
   - The patient is human herpesvirus-8 (HHV-8) negative

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SILTUXIMAB (Sylvant)** requires the following rule(s) be met for approval:
   A. You have multi-centric Castleman's disease (MCD: a rare condition of lymph nodes and related tissues)
   B. You are negative for both human immunodeficiency virus (HIV: a type of immune system disease caused by a virus) and human herpes virus-8 (HHV-8: a type of viral infection)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SILTUXIMAB (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Sylvant.

REFERENCES
Sylvant [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc; December 2019.

For Part D use only:

SILTUXIMAB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A
Quantity Limit (from Formulary ASCII file)	N/A

Created: 6/14
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ADVANTAGE AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SIPONIMOD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SIPONIMOD	MAYZENT	45670		GPI-10 (6240707020)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), to include clinically isolated syndrome, relapsing-remitting disease, or secondary progressive multiple sclerosis, **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SIPONIMOD (Mayzent)** requires the following rule(s) be met for approval:
   A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease returns and goes away), or secondary progressive multiple sclerosis (advanced disease)
   B. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ADVANTAGE AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SIPONIMOD (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Mayzent.

REFERENCES

Mayzent [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; June 2024.

For Part D use only:

SIPONIMOD (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

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Effective: 03/01/25 Client Approval: 02/25 P&T Approval: 01/19

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SIROLIMUS PROTEIN-BOUND (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SIROLIMUS PROTEIN-BOUND	FYARRO	47680		GPI-10 (2153256020)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor (PEComa) (ICD-10 Group C49 except Group C49.A) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SIROLIMUS PROTEIN-BOUND (Fyarro)** requires the following rule(s) be met for approval:
   A. You have locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor (PEComa: a type of rare tumor, that cannot be completely removed with surgery and has spread to nearby tissue or lymph nodes, or that has spread to other parts of the body)
   B. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SIROLIMUS PROTEIN-BOUND (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Fyarro.

REFERENCES

Fyarro [Prescribing Information]. Pacific Palisades, CA: Aadi Bioscience, Inc.; November 2021.

For Part D use only:

SIROLIMUS PROTEIN-BOUND (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

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Effective: 01/01/25 Client Approval: 08/24 P&T Approval: 01/22

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SIROLIMUS TOPICAL (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SIROLIMUS	HYFTOR		52138	GPI-10 (9078407000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of facial angiofibroma associated with tuberous sclerosis (ICD-10 Q85.1) **AND** meet the following criterion?
   - The patient is 6 years of age or older

   If yes, **approve for 12 weeks by GPID or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SIROLIMUS TOPICAL (Hyftor)** requires the following rule(s) be met for approval:
   A. You have facial angiofibroma (a skin condition) associated with tuberous sclerosis (a rare type of tumor disorder)
   B. You are 6 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SIROLIMUS TOPICAL (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of facial angiofibroma associated with tuberous sclerosis (ICD-10 Q85.1)?

   If yes, **approve for 12 months by GPID or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SIROLIMUS TOPICAL (Hyftor)** requires the following rule(s) be met for renewal:
   A. You have facial angiofibroma (a skin condition) associated with tuberous sclerosis (a rare type of tumor disorder)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Hyftor.

REFERENCES
Hyftor [Prescribing Information]. Bethesda, MD: Nobelpharma America, LLC.; March 2022.

For Part D use only:

SIROLIMUS TOPICAL (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	INITIAL: 12 WEEKS. RENEWAL: 12 MONTHS
Other Criteria	N/A

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SIROLIMUS TOPICAL (PART D)

Core	Advantage	Plus
No	No	Yes

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Effective: 01/01/25 Client Approval: 08/24 P&T Approval: 07/22

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOD PHENYLBUTYRATE-TAURURSODIOL (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOD PHENYLBUTYRAT/ TAURURSODIOL	RELYVRIO	48081		GPI-10 (7450990270)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of amyotrophic lateral sclerosis (ALS) (ICD-10 G12.21) and meet **ALL** the following?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist or ALS specialist or being seen at an ALS Specialty Center or Care Clinic

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOD PHENYLBUTYRATE-TAURURSODIOL (Relyvrio)** requires the following rule(s) be met for approval:
   A. You have amyotrophic lateral sclerosis (ALS: a type of brain and nerve condition)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor) or ALS specialist or being seen at an ALS Specialty Center or Care Clinic

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOD PHENYLBUTYRATE-TAURURSODIOL (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of amyotrophic lateral sclerosis (ALS) (ICD-10 G12.21) and meet **ALL** of the following criteria?
   - The patient does not require invasive ventilation
   - The patient has improved or maintained baseline functional ability measured by functional assessments (e.g., Amyotrophic Lateral Sclerosis Functional Rating Scale [ALSFRS])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOD PHENYLBUTYRATE-TAURURSODIOL (Relyvrio)** requires the following rule(s) be met for renewal:
   A. You have amyotrophic lateral sclerosis (ALS: a type of brain and nerve condition)
   B. You do not require invasive ventilation (inserting a breathing tube into your throat)
   C. You have improved or maintained baseline functional ability measured by functional assessments (such as Amyotrophic Lateral Sclerosis Functional Rating Scale [ALSFRS: a tool for evaluating functional status])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Relyvrio.

REFERENCES
Relyvrio [Prescribing Information]. Cambridge, MA: Amylyx Pharmaceuticals, Inc., September 2022.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOD PHENYLBUTYRATE-TAURURSODIOL (PART D)

For Part D use only:

SOD PHENYLBUTYRATE-TAURURSODIOL (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	AMYOTROPHIC LATERAL SCLEROSIS (ALS): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST OR ALS SPECIALIST OR BEING SEEN AT AN ALS SPECIALTY CENTER OR CARE CLINIC
Coverage Duration	INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS.
Other Criteria	ALS: RENEWAL: 1) DOES NOT REQUIRE INVASIVE VENTILATION, AND 2) HAS IMPROVED OR MAINTAINED BASELINE FUNCTIONAL ABILITY MEASURED BY FUNCTIONAL ASSESSMENTS (E.G., AMYOTROPHIC LATERAL SCLEROSIS FUNCTIONAL RATING SCALE).

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 10/22
Client Approval: 06/24
P&T Approval: 04/22

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SODIUM OXYBATE - LUMRYZ (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SODIUM OXYBATE	LUMRYZ	12346		GPI-10 (6245006020)	FORM ≠ SOLUTION

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of cataplexy with narcolepsy (ICD-10 G47.411) and meet **ALL** of the following criteria?
   - The patient is 7 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist, psychiatrist, or specialist insleep medicine
   - Lumryz will NOT be used concurrently with a sedative hypnotic agent (e.g., Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant])
   - The patient had a trial of generic sodium oxybate

   If yes, **approve for 6 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.
   If no, continue to #2.

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SODIUM OXYBATE - LUMRYZ (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of excessive daytime sleepiness (EDS) with narcolepsy (ICD-10 G47.419) and meet **ALL** of the following criteria?
   - The patient is 7 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist, psychiatrist, or specialist insleep medicine
   - Lumryz will NOT be used concurrently with a sedative hypnotic agent (e.g., Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant])
   - The patient had a trial, failure, or contraindication to generic sodium oxybate
   - The patient had a trial, failure, or contraindication to armodafinil (Nuvigil), modafinil (Provigil), OR a generic typical stimulant indicated for EDS with narcolepsy (e.g., amphetamine sulfate [Evekeo], dextroamphetamine [Dexedrine], methylphenidate [Ritalin])

   If yes, **approve for 6 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SODIUM OXYBATE - LUMRYZ** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Cataplexy with narcolepsy (a type of sleep condition with extreme drowsiness with sudden and uncontrollable muscle weakness)
      2. Excessive daytime sleepiness (EDS) with narcolepsy (a type of sleep condition with overwhelming daytime drowsiness)

   B. If you have cataplexy with narcolepsy, approval also requires:
      1. You are 7 years of age or older
      2. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor), psychiatrist (a type of mental health doctor), or specialist in sleep medicine
      3. You will NOT use Lumryz concurrently (at the same time) with a sedative hypnotic agent (drugs that make you sleepy, such as Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant])
      4. You have tried generic sodium oxybate

   (Initial denial text continued on next page)

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SODIUM OXYBATE - LUMRYZ (PART D)

INITIAL CRITERIA (CONTINUED)

C. If you have excessive daytime sleepiness with narcolepsy, approval also requires:

1. You are 7 years of age or older
2. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor), psychiatrist (a type of mental health doctor), or specialist in sleep medicine
3. You will NOT use Lumryz concurrently (at the same time) with a sedative hypnotic agent (drugs that make you sleepy, such as Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant])
4. You have tried, failed (drug did not work), or have a contraindication to (harmful for you to use) generic sodium oxybate
5. You have tried, failed, or have a contraindication to armodafinil (Nuvigil), modafinil (Provigil), OR a generic stimulant indicated for excessive daytime sleepiness with narcolepsy (such as amphetamine sulfate [Evekeo], dextroamphetamine [Dexedrine], methylphenidate [Ritalin])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SODIUM OXYBATE - LUMRYZ (PART D)

RENEWAL CRITERIA

1. Does the patient have **ONE** of the following diagnoses?
   - Cataplexy with narcolepsy (ICD-10 G47.411)
   - Excessive daytime sleepiness (EDS) with narcolepsy (ICD-10 G47.419)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
   - The patient has sustained improvement of symptoms compared to baseline
   - Lumryz will NOT be used concurrently with a sedative hypnotic agent (e.g., Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant])

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SODIUM OXYBATE - LUMRYZ** requires the following rules be met for renewal:
   A. You have ONE of the following:
      1. Cataplexy with narcolepsy (a type of sleep condition with extreme drowsiness with sudden and uncontrollable muscle weakness)
      2. Excessive daytime sleepiness (EDS) with narcolepsy (a type of sleep condition with overwhelming daytime drowsiness)
   B. You have sustained improvement of symptoms compared to baseline
   C. You will NOT use Lumryz concurrently (at the same time) with a sedative hypnotic agent (such as Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SODIUM OXYBATE - LUMRYZ (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lumryz.

REFERENCES

Lumryz [Prescribing Information]. Chesterfield, MO: Avadel CNS Pharmaceuticals, LLC; October 2024.

For Part D use only:

SODIUM OXYBATE - LUMRYZ (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: CATAPLEXY IN NARCOLEPSY, EXCESSIVE DAYTIME SLEEPINESS (EDS) IN NARCOLEPSY: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST, PSYCHIATRIST, OR SPECIALIST IN SLEEP MEDICINE
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS
Other Criteria	INITIAL: CATAPLEXY IN NARCOLEPSY: 1) NO CONCURRENT USE WITH A SEDATIVE HYPNOTIC AGENT, AND 2) TRIAL OF GENERIC SODIUM OXYBATE. EDS IN NARCOLEPSY: 1) NO CONCURRENT USE WITH A SEDATIVE HYPNOTIC AGENT, 2) TRIAL, FAILURE OF, OR CONTRAINDICATION TO GENERIC SODIUM OXYBATE, AND 3) TRIAL, FAILURE OF, OR CONTRAINDICATION TO A GENERIC STIMULANT INDICATED FOR EDS IN NARCOLEPSY, MODAFINIL, OR ARMODAFINIL. RENEWAL: CATAPLEXY IN NARCOLEPSY, EDS IN NARCOLEPSY: 1) SUSTAINED IMPROVEMENT OF SYMPTOMS COMPARED TO BASELINE, AND 2) NO CONCURRENT USE WITH A SEDATIVE HYPNOTIC AGENT.

Created: 08/23
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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SODIUM OXYBATE-XYREM (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SODIUM OXYBATE	XYREM, SODIUM OXYBATE		18104	GPI-14 (62450060202020)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of cataplexy with narcolepsy (ICD-10 G47.411) and meet **ALL** of the following criteria?
   - The patient is 7 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
   - The requested medication will NOT be used concurrently with a sedative hypnotic agent (e.g., Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant])

   If yes, **approve for 6 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

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SODIUM OXYBATE-XYREM (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of excessive daytime sleepiness (EDS) with narcolepsy (ICD-10 G47.419) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
   - The requested medication will NOT be used concurrently with a sedative hypnotic agent (e.g., Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant])

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following?
   - The patient is 7 to 17 years of age
   - The patient is 18 years of age or older AND had a trial, failure, or contraindication to a formulary version of modafinil, armodafinil, or Sunosi (solriamfetol) AND one generic stimulant indicated for EDS with narcolepsy (e.g., amphetamine sulfate [Evekeo], dextroamphetamine [Dexedrine], methylphenidate [Ritalin])

   If yes, **approve for 6 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SODIUM OXYBATE-XYREM (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SODIUM OXYBATE (Xyrem)** requires the following rules be met for approval:

A. You have ONE of the following:
   1. Cataplexy with narcolepsy (a type of sleep condition with extreme drowsiness with sudden and uncontrollable muscle weakness)
   2. Excessive daytime sleepiness (EDS) with narcolepsy (a type of sleep condition with overwhelming daytime drowsiness)

B. If you have cataplexy with narcolepsy, approval also requires:
   1. You are 7 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor), psychiatrist (a type of mental health doctor), or specialist in sleep medicine
   3. You will NOT use the requested medication concurrently (at the same time) with a sedative hypnotic agent (drugs that make you sleepy, such as Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant])

C. If you have excessive daytime sleepiness with narcolepsy, approval also requires:
   1. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor), psychiatrist (a type of mental health doctor), or specialist in sleep medicine
   2. You will NOT use the requested medication concurrently (at the same time) with a sedative hypnotic agent (drugs that make you sleepy, such as Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant])
   3. You meet ONE of the following:
      a. You are 7 to 17 years old
      b. You are 18 years or older AND have tried, failed, or have a contraindication to a formulary version of modafinil, armodafinil, or Sunosi (solriamfetol) AND one generic stimulant indicated for excessive daytime sleepiness with narcolepsy (such as amphetamine sulfate [Evekeo], dextroamphetamine [Dexedrine], methylphenidate [Ritalin])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SODIUM OXYBATE-XYREM (PART D)

RENEWAL CRITERIA

1. Does the patient have **ONE** of the following diagnoses?
   - Cataplexy with narcolepsy (ICD-10 G47.411)
   - Excessive daytime sleepiness (EDS) with narcolepsy (ICD-10 G47.419)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
   - The patient has sustained improvement of symptoms compared to baseline
   - The requested medication will NOT be used concurrently with a sedative hypnotic agent (e.g., Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant])

   If yes, **approve for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SODIUM OXYBATE (Xyrem)** requires the following rules be met for renewal:
   A. You have ONE of the following:
      1. Cataplexy with narcolepsy (a type of sleep condition with extreme drowsiness with sudden and uncontrollable muscle weakness)
      2. Excessive daytime sleepiness (EDS) with narcolepsy (a type of sleep condition with overwhelming daytime drowsiness)
   B. You have sustained improvement of symptoms compared to baseline
   C. You will NOT use the requested medication concurrently (at the same time) with a sedative hypnotic agent (such as Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SODIUM OXYBATE-XYREM (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Xyrem.

REFERENCES
Xyrem [Prescribing Information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; April2023.

SODIUM OXYBATE-XYREM (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: CATAPLEXY IN NARCOLEPSY, EXCESSIVE DAYTIME SLEEPINESS (EDS) IN NARCOLEPSY: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST, PSYCHIATRIST, OR SPECIALIST IN SLEEP MEDICINE
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS
Other Criteria	INITIAL: EDS IN NARCOLEPSY: 1) NO CONCURRENT USE WITH A SEDATIVE HYPNOTIC AGENT, AND 2) AGES 18 YEARS OR OLDER: TRIAL, FAILURE OF, OR CONTRAINDICATION TO A FORMULARY VERSION OF MODAFINIL, ARMODAFINIL, OR SUNOSI AND ONE GENERIC STIMULANT INDICATED FOR EDS IN NARCOLEPSY. CATAPLEXY IN NARCOLEPSY: NO CONCURRENT USE WITH A SEDATIVE HYPNOTIC AGENT. RENEWAL: CATAPLEXY IN NARCOLEPSY, EDS IN NARCOLEPSY: 1) SUSTAINED IMPROVEMENT OF SYMPTOMS COMPARED TO BASELINE, AND 2) NO CONCURRENT USE WITH A SEDATIVE HYPNOTIC AGENT.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SODIUM/CALCIUM/MAG/POT OXYBATE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SODIUM, CALCIUM, MAG, POT OXYBATE	XYWAV	46743		GPI-10 (6245990420)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of cataplexy with narcolepsy (ICD-10 G47.411) and meet **ALL** of the following criteria?
   - The patient is 7 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
   - Xywav will NOT be used concurrently with a sedative hypnotic agent (e.g., Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant])
   - The patient requires a lower sodium formulation due to concurrent medical concerns OR had a sodium-related side effect from Xyrem (sodium oxybate)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

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SODIUM/CALCIUM/MAG/POT OXYBATE (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of excessive daytime sleepiness (EDS) with narcolepsy (ICD-10 G47.419) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
   - Xywav will NOT be used concurrently with a sedative hypnotic agent (e.g., Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant])
   - The patient requires a lower sodium formulation due to concurrent medical concerns OR had a sodium-related side effect from Xyrem (sodium oxybate)

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet **ONE** of the following criteria?
   - The patient is 7 to 17 years of age AND had a trial, failure, or contraindication to a generic stimulant indicated for EDS with narcolepsy (e.g., amphetamine sulfate [Evekeo], dextroamphetamine [Dexedrine], methylphenidate [Ritalin])
   - The patient is 18 years of age or older AND had a trial, failure, or contraindication to modafinil (Provigil), armodafinil (Nuvigil), or a generic stimulant indicated for EDS with narcolepsy (e.g., amphetamine sulfate [Evekeo], dextroamphetamine [Dexedrine], methylphenidate [Ritalin]) AND Sunosi (solriamfetol)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have a diagnosis of idiopathic hypersomnia (IH) (ICD-10 G47.11, G47.12) and diagnosis is confirmed by **ALL** of the following criteria?
   - The patient does not have cataplexy
   - The patient has had insufficient sleep syndrome ruled out, and there is no better explanation by another sleep/medical/psychiatric disorder or use of drugs/medications
   - The patient has experienced daily periods of irrepressible need to sleep or daytime lapses into sleep for at least three months

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SODIUM/CALCIUM/MAG/POT OXYBATE (PART D)

INITIAL CRITERIA (CONTINUED)

5. Does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
   - Xywav will NOT be used concurrently with a sedative hypnotic agent (e.g., Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant])

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SODIUM/CALCIUM/MAG/POT OXYBATE (Xywav)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      Cataplexy with narcolepsy (a type of sleep condition with extreme drowsiness with sudden and uncontrollable muscle weakness)
      Excessive daytime sleepiness (EDS) with narcolepsy (a type of sleep condition with overwhelming daytime drowsiness)
      Idiopathic hypersomnia (IH: a type of sleep disorder)

   B. If you have cataplexy in narcolepsy, approval also requires:
      1. You are 7 years of age or older
      2. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor), psychiatrist (a type of mental health doctor), or specialist in sleep medicine
      3. You will NOT use Xywav concurrently (at the same time) with a sedative hypnotic agent (drugs that make you sleepy, such as Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant])
      4. You require a lower sodium formulation due to concurrent (at the same time) medical concerns OR you had a sodium-related side effect from Xyrem (sodium oxybate)

   (Initial denial text continued on next page)

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SODIUM/CALCIUM/MAG/POT OXYBATE (PART D)

INITIAL CRITERIA (CONTINUED)

C. If you have excessive daytime sleepiness with narcolepsy, approval also requires:

1. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor), psychiatrist (a type of mental health doctor), or specialist in sleep medicine
2. You will NOT use Xywav concurrently (at the same time) with a sedative hypnotic agent (drugs that make you sleepy, such as Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant])
3. You require a lower sodium formulation due to concurrent (at the same time) medical concerns OR you had a sodium-related side effect from Xyrem (sodium oxybate)
4. You meet ONE of the following:
   a. You are 7 to 17 years old AND have tried, failed (drug did not work), or have a contraindication to (harmful for you to use) a generic stimulant indicated for excessive daytime sleepiness with narcolepsy (such as amphetamine sulfate [Evekeo], dextroamphetamine [Dexedrine], methylphenidate [Ritalin])
   b. You are 18 years or older AND have tried, failed, or have a contraindication to modafinil (Provigil), armodafinil (Nuvigil), or a generic stimulant indicated for excessive daytime sleepiness with narcolepsy (such as amphetamine sulfate [Evekeo], dextroamphetamine [Dexedrine], methylphenidate [Ritalin]) AND Sunosi (solriamfetol)

D. If you have idiopathic hypersomnia, approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor), psychiatrist (a type of mental health doctor), or specialist in sleep medicine
3. You will NOT use Xywav concurrently (at the same time) with a sedative hypnotic agent (drugs that make you sleepy, such as Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant])
4. Your diagnosis is confirmed by ALL of the following:
   a. You do not have cataplexy (uncontrollable muscle weakness)
   b. You have had insufficient sleep syndrome ruled out and there is no better explanation by another sleep/medical/psychiatric disorder or use of drugs/medications
   c. You have experienced daily periods of irrepressible need to sleep or daytime lapses into sleep for at least three months

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SODIUM/CALCIUM/MAG/POT OXYBATE (PART D)

RENEWAL CRITERIA

1. Does the patient have **ONE** of the following diagnoses?
   Cataplexy with narcolepsy (ICD-10 G47.411)
   Excessive daytime sleepiness (EDS) with narcolepsy (ICD-10 G47.419)

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ALL** of the following criteria?
   - The patient has sustained improvement of symptoms compared to baseline
   - Xywav will NOT be used concurrently with a sedative hypnotic agent (e.g., Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

3. Does the patient have a diagnosis of idiopathic hypersomnia (ICD-10 G47.11, G47.12) and meet **ALL** of the following criteria?
   - The patient has demonstrated improvement of symptoms compared to baseline
   - Xywav will NOT be used concurrently with a sedative hypnotic agent (e.g., Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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SODIUM/CALCIUM/MAG/POT OXYBATE (PART D)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SODIUM/CALCIUM/MAG/POT OXYBATE (Xywav)** requires the following rules be met for renewal:

A. You have ONE of the following:
   1. Cataplexy with narcolepsy (a type of sleep condition with extreme drowsiness with sudden and uncontrollable muscle weakness)
   2. Excessive daytime sleepiness (EDS) with narcolepsy (a type of sleep condition with overwhelming daytime drowsiness)
   3. Idiopathic hypersomnia (IH: a type of sleep disorder)

B. If you have cataplexy or excessive daytime sleepiness with narcolepsy, renewal also requires:
   1. You have experienced sustained improvement of symptoms compared to baseline
   2. You will NOT use Xywav concurrently (at the same time) with a sedative hypnotic agent (drugs that make you sleepy, such as Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant])

C. If you have idiopathic hypersomnia, renewal also requires:
   1. You have demonstrated improvement of symptoms compared to baseline
   2. You will NOT use Xywav concurrently (at the same time) with a sedative hypnotic agent (drugs that make you sleepy, such as Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xywav.

REFERENCES

Xywav [Prescribing Information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; April 2023.

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SODIUM/CALCIUM/MAG/POT OXYBATE (PART D)

For Part D Use Only:

SODIUM/CALCIUM/MAG/POT OXYBATE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: CATAPLEXY IN NARCOLEPSY, EXCESSIVE DAYTIME SLEEPINESS (EDS) IN NARCOLEPSY, IDIOPATHIC HYPERSOMNIA (IH): PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST, PSYCHIATRIST, OR SPECIALIST IN SLEEP MEDICINE.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: CATAPLEXY IN NARCOLEPSY: 1) LOWER SODIUM FORMULATION REQUIRED DUE TO CONCURRENT MEDICAL CONCERNS OR HAS A SODIUM RELATED SIDE EFFECT FROM XYREM, AND 2) NO CONCURRENT USE WITH A SEDATIVE HYPNOTIC AGENT. EDS IN NARCOLEPSY: 1) LOWER SODIUM FORMULATION REQUIRED DUE TO CONCURRENT MEDICAL CONCERNS OR HAS A SODIUM RELATED SIDE EFFECT FROM XYREM, 2) AGES 18 YEARS OR OLDER: TRIAL, FAILURE OF, OR CONTRAINDICATION TO: (A) MODAFINIL, ARMODAFINIL OR A GENERIC STIMULANT INDICATED FOR EDS IN NARCOLEPSY, AND (B) SUNOSI, 3) AGES 7 TO 17 YEARS: TRIAL, FAILURE OF, OR CONTRAINDICATION TO ONE GENERIC STIMULANT INDICATED FOR EDS IN NARCOLEPSY, AND 4) NO CONCURRENT USE WITH A SEDATIVE HYPNOTIC AGENT. IH: 1) CATAPLEXY IS ABSENT, 2) INSUFFICIENT SLEEP SYNDROME IS RULED OUT AND THERE IS NO BETTER EXPLANATION BY ANOTHER SLEEP/MEDICAL/PSYCHIATRIC DISORDER OR USE OF DRUGS/MEDICATIONS, 3) HAS EXPERIENCED DAILY PERIODS OF IRREPRESSIBLE NEED TO SLEEP OR DAYTIME LAPSES INTO SLEEP FOR AT LEAST THREE MONTHS, AND 4) NO CONCURRENT USE WITH A SEDATIVE HYPNOTIC AGENT. RENEWAL: CATAPLEXY IN NARCOLEPSY, EDS IN NARCOLEPSY: 1) NO CONCURRENT USE WITH A SEDATIVE HYPNOTIC AGENT, AND 2) SUSTAINED IMPROVEMENT OF SYMPTOMS COMPARED TO BASELINE. IH: 1) NO CONCURRENT USE WITH A SEDATIVE HYPNOTIC AGENT, AND 2) IMPROVEMENT OF SYMPTOMS COMPARED TO BASELINE.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SODIUM/CALCIUM/MAG/POT OXYBATE (PART D)

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 09/20
Client Approval: 06/24
P&T Approval: 10/21

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SODIUM PHENYLBUTYRATE GRANULES (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SODIUM PHENYLBUTYRATE	PHEBURANE		36733	GPI-14 (30908060008920)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of a urea cycle disorder (UCD) (ICD-10 E72.2) and meet **ALL** of the following criteria?
   - The patient's UCD is confirmed via enzymatic, biochemical or genetic testing
   - Pheburane will be used in combination with standard of care therapy (e.g., dietary management)
   - The patient had a trial of or contraindication to generic sodium phenylbutyrate powder
   - The patient is unable to swallow sodium phenylbutyrate tablets

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of guideline.

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SODIUM PHENYLBUTYRATE GRANULES (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SODIUM PHENYLBUTYRATE GRANULES (Pheburane)** requires the following rule(s) be met for approval:

A. You have a urea cycle disorder (a genetic disorder that causes high ammonia levels in the blood)
B. Your disorder is confirmed by enzymatic, biochemical or genetic testing (types of lab tests)
C. Pheburane will be used together with standard of care therapy (such as dietary management)
D. You have tried or have a contraindication to (harmful for you to use) generic sodium phenylbutyrate powder
E. You are unable to swallow sodium phenylbutyrate tablets

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SODIUM PHENYLBUTYRATE GRANULES (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of a urea cycle disorder (UCD) (ICD-10 E72.2) **AND** meet the following criterion?
   - The patient has experienced clinical benefit from baseline (e.g., normal fasting glutamine, low-normal fasting ammonia levels, mental status clarity)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SODIUM PHENYLBUTYRATE GRANULES (Pheburane)** requires the following rule(s) be met for renewal:
   A. You have a urea cycle disorder (a genetic disorder that causes high ammonia levels in the blood)
   B. You have experienced clinical benefit from baseline (such as normal fasting glutamine, low-normal fasting ammonia levels, mental status clarity)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Pheburane.

REFERENCES
Pheburane [Prescribing Information]. Bryn Mawr, PA: Medunik USA, Inc.; June 2022.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SODIUM PHENYLBUTYRATE GRANULES (PART D)

For Part D use only:

SODIUM PHENYLBUTYRATE GRANULES (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	UREA CYCLE DISORDER (UCD): INITIAL: UCD IS CONFIRMED VIA ENZYMATIC, BIOCHEMICAL, OR GENETIC TESTING.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	UCD: INITIAL: 1) TRIAL OF OR CONTRADICTION TO GENERIC SODIUM PHENYLBUTYRATE POWDER, AND 2) UNABLE TO SWALLOW SODIUM PHENYLBUTYRATE TABLETS. RENEWAL: CLINICAL BENEFIT FROM BASELINE.

Created: 07/23
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 10/22

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SODIUM PHENYLBUTYRATE PELLETS (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SODIUM PHENYLBUTYRATE	OLPRUVA	11317		GPI-10 (3090806000)	BRAND = OLPRUVA

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of a urea cycle disorder (UCD) (ICD-10 E72.2) and meet **ALL** of the following criteria?
   - The patient's UCD is confirmed via enzymatic, biochemical or genetic testing
   - Olpruva will be used in combination with standard of care therapy (e.g., dietary management)
   - The patient had a trial of or contraindication to generic sodium phenylbutyrate powder
   - The patient is unable to swallow Buphenyl (sodium phenylbutyrate) tablets

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SODIUM PHENYLBUTYRATE PELLETS (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SODIUM PHENYLBUTYRATE PELLETS (Olpruva)** requires the following rule(s) be met for approval:

A. You have a urea cycle disorder (a genetic disorder that causes high ammonia levels in the blood)
B. Your disorder is confirmed by enzymatic, biochemical or genetic testing (types of lab tests)
C. Olpruva will be used together with standard of care therapy (such as dietary management)
D. You have tried or have a contraindication to (harmful for you to use) generic sodium phenylbutyrate powder
E. You are unable to swallow Buphenyl (sodium phenylbutyrate) tablets

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SODIUM PHENYLBUTYRATE PELLETS (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of a urea cycle disorder (UCD) (ICD-10 E72.2) **AND** meet the following criterion?
   - The patient has experienced clinical benefit from baseline (e.g., normal fasting glutamine, low-normal fasting ammonia levels, mental status clarity)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SODIUM PHENYLBUTYRATE PELLETS (Olpruva)** requires the following rule(s) be met for renewal:
   A. You have a urea cycle disorder (a genetic disorder that causes high ammonia levels in the blood)
   B. You have experienced clinical benefit from baseline (such as normal fasting glutamine levels, low-normal fasting ammonia levels, mental clarity)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Olpruva.

REFERENCES
Olpruva [Prescribing Information]. Newton, MA: Acer Therapeutics Inc.; December 2022.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SODIUM PHENYLBUTYRATE PELLETS (PART D)

For Part D use only:

SODIUM PHENYLBUTYRATE PELLETS (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	UREA CYCLE DISORDER (UCD): INITIAL: UCD IS CONFIRMED VIA ENZYMATIC, BIOCHEMICAL, OR GENETIC TESTING.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	UCD: INITIAL: 1) TRIAL OF OR CONTRADICTION TO GENERIC SODIUM PHENYLBUTYRATE POWDER, AND 2) UNABLE TO SWALLOW SODIUM PHENYLBUTYRATE TABLETS. RENEWAL: CLINICAL BENEFIT FROM BASELINE.

Created: 07/23
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 07/23

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SODIUM PHENYLBUTYRATE POWDER (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/ Other
SODIUM PHENYLBUTYRATE	BUPHENYL, SODIUM PHENYLBUTYRATE		43370	GPI-14 (30908060002950)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of a urea cycle disorder (UCD) (ICD-10 E72.2) and meet **ALL** of the following criteria?
   - The patient's UCD is confirmed via enzymatic, biochemical, or genetic testing
   - The requested medication will be used in combination with standard of care therapy (e.g., dietary management)

   If yes, **approve for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SODIUM PHENYLBUTYRATE POWDER (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SODIUM PHENYLBUTYRATE POWDER (Buphenyl)** requires the following rule(s) be met for approval:

A. You have a urea cycle disorder (a genetic disorder that causes high ammonia levels in the blood)
B. Your disorder is confirmed by enzymatic, biochemical or genetic testing (types of lab tests)
C. The requested medication will be used together with standard of care therapy (such as dietary management)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SODIUM PHENYLBUTYRATE POWDER (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of a urea cycle disorder (UCD) (ICD-10 E72.2) **AND** meet the following criterion?
   - The patient has experienced clinical benefit from baseline (e.g., normal fasting glutamine, low-normal fasting ammonia levels, mental status clarity)

   If yes, **approve for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SODIUM PHENYLBUTYRATE POWDER (Buphenyl)** requires the following rule(s) be met for renewal:
   A. You have a urea cycle disorder (a genetic disorder that causes high ammonia levels in the blood)
   B. You have experienced clinical benefit from baseline (such as normal fasting glutamine, low-normal fasting ammonia levels, mental status clarity)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Buphenyl.

REFERENCES

Buphenyl [Prescribing Information]. Deerfield, IL: Horizon Therapeutics USA, Inc.; July 2022.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SODIUM PHENYLBUTYRATE POWDER (PART D)

For Part D use only:

SODIUM PHENYLBUTYRATE POWDER (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	UREA CYCLE DISORDER (UCD): INITIAL: UCD IS CONFIRMED VIA ENZYMATIC, BIOCHEMICAL OR GENETIC TESTING.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	UCD: RENEWAL: CLINICAL BENEFIT FROM BASELINE.

Core	Advantage	Plus
No	No	Yes

Created: 07/23
Effective: 01/01/25 Client Approval: 08/24 P&T Approval: 07/19

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SODIUM PHENYLBUTYRATE TABLETS (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/ Other
SODIUM PHENYLBUTYRATE	BUPHENYL, SODIUM PHENYLBUTYRATE		43371	GPI-14 (30908060000320)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of a urea cycle disorder (UCD) (ICD-10 E72.2) and meet **ALL** of the following criteria?
   - The patient's UCD is confirmed via enzymatic, biochemical or genetic testing
   - The requested medication will be used in combination with standard of care therapy (e.g., dietary management)

   If yes, **approve for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SODIUM PHENYLBUTYRATE TABLETS (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SODIUM PHENYLBUTYRATE TABLETS (Buphenyl)** requires the following rule(s) be met for approval:

A. You have a urea cycle disorder (a genetic disorder that causes high ammonia levels in the blood)
B. Your disorder is confirmed by enzymatic, biochemical or genetic testing (types of lab tests)
C. The requested medication will be used together with standard of care therapy (such as dietary management)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SODIUM PHENYLBUTYRATE TABLETS (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of a urea cycle disorder (UCD) (ICD-10 E72.2) **AND** meet the following criterion?
   - The patient has experienced clinical benefit from baseline (e.g., normal fasting glutamine, low-normal fasting ammonia levels, mental status clarity)

   If yes, **approve for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SODIUM PHENYLBUTYRATE TABLETS (Buphenyl)** requires the following rule(s) be met for renewal:
   A. You have a urea cycle disorder (a genetic disorder that causes high ammonia levels in the blood)
   B. You have experienced clinical benefit from baseline (such as normal fasting glutamine, low-normal fasting ammonia levels, mental status clarity)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Buphenyl.

REFERENCES

Buphenyl [Prescribing Information]. Deerfield, IL: Horizon Therapeutics USA, Inc.; July 2022.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SODIUM PHENYLBUTYRATE TABLETS (PART D)

For Part D use only:

SODIUM PHENYLBUTYRATE TABLETS (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	UREA CYCLE DISORDER (UCD): INITIAL: UCD IS CONFIRMED VIA ENZYMATIC, BIOCHEMICAL OR GENETIC TESTING.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	UCD: RENEWAL: CLINICAL BENEFIT FROM BASELINE.

Created: 07/23
Effective: 01/01/26 Client Approval: 01/26 P&T Approval: 07/19

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOFOSBUVIR (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOFOSBUVIR	SOVALDI	40795		GPI-10 (1235308000)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guideline with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed (see the MedImpact Standard MRF for HepC).

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic hepatitis C virus (HCV) (ICD-10 B18.2) and meet **ONE** of the following criteria?
- The patient has genotype 2 or 3 infection AND is 3 to 17 years of age
- The patient has genotype 1, 2, 3, or 4 infection AND is 18 years of age or older

If yes, continue to #2.
If no, continue to #13.

2. Will Sovaldi be used concurrently with Epclusa (velpatasvir/sofosbuvir), Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir), or Vosevi (velpatasvir/sofosbuvir/voxilaprevir)?

If yes, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

If no, continue to #3.

3. Does the patient have genotype 2 infection and meet **ALL** of the following criteria?
- The patient has compensated cirrhosis (Child-Pugh A) OR does not have cirrhosis
- Sovaldi will be used with ribavirin

If yes, continue to #4.
If no, continue to #5.

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SOFOSBUVIR (PART D)

GUIDELINES FOR USE (CONTINUED)

4. Does the patient meet **ONE** of the following criteria?
   - The patient is 3 to 17 years of age
   - The patient is 18 years of age or older AND has an intolerance or contraindication to the preferred agent: Epclusa

   If yes, **approve for 12 weeks by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Does the patient have genotype 3 infection and meet **ALL** of the following criteria?
   - The patient has compensated cirrhosis (Child-Pugh A) OR does not have cirrhosis
   - Sovaldi will be used with ribavirin

   If yes, continue to #6.
   If no, continue to #7.

6. Does the patient meet **ONE** of the following criteria?
   - The patient is 3 to 17 years of age
   - The patient is 18 years of age or older AND has an intolerance or contraindication to the preferred agent: Epclusa

   If yes, **approve for 24 weeks by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

7. Does the patient have genotype 1 or 4 infection and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is treatment-naïve
   - The patient has compensated cirrhosis (Child-Pugh A) OR does not have cirrhosis
   - Sovaldi will be used with peginterferon alfa and ribavirin

   If yes, continue to #8.
   If no, continue to #9.

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SOFOSBUVIR (PART D)

GUIDELINES FOR USE (CONTINUED)

8. Does the patient have an intolerance or contraindication to ONE of the following preferred agents: Harvoni, Epclusa?

   If yes, **approve for 12 weeks by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

9. Does the patient have genotype 1 infection and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is treatment-naïve
   - The patient has compensated cirrhosis (Child-Pugh A) OR does not have cirrhosis
   - Sovaldi will be used with ribavirin
   - The patient has a contraindication to interferon (interferon ineligible)

   If yes, continue to #10.
   If no, continue to #11.

10. Does the patient have an intolerance or contraindication to ONE of the following preferred agents: Harvoni, Epclusa?

    If yes, **approve for 24 weeks by HICL or GPI-10.**
    APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

11. Is the request to prevent post-transplant HCV reinfection and the patient meets **ALL** of the following criteria?
    - The patient has hepatocellular carcinoma (ICD-10 C22.0)
    - The patient is awaiting liver transplantation
    - Sovaldi will be used with ribavirin as pre-transplant treatment

    If yes, **approve for 48 weeks by HICL or GPI-10.**
    APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

    If no, continue to #12.

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SOFOSBUVIR (PART D)

GUIDELINES FOR USE (CONTINUED)

12. Has the patient previously failed treatment with Mavyret (glecaprevir/pibrentasvir) OR Vosevi (sofosbuvir/velpatasvir/voxilaprevir) and meets **ALL** of the following criteria?
    - The patient has compensated cirrhosis OR does not have cirrhosis
    - Sovaldi will be used with Mavyret (glecaprevir/pibrentasvir) AND ribavirin

    If yes, **approve for 16 weeks by HICL or GPI-10.**
    APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

    If no, continue to #13.

13. Is the requested regimen recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment?

    If yes, **approve as indicated per guidance in AASLD/IDSA.**
    If no, do not approve.

    DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

    Our guideline named **SOFOSBUVIR (Sovaldi)** requires the following rule(s) be met for approval:
    A. You have chronic hepatitis C virus (HCV: liver inflammation caused by a type of virus)
    B. You have genotype 2 or 3 infection (types of hepatitis C virus) and are 3 to 17 years of age OR you have genotype 1, 2, 3, or 4 infection (types of hepatitis C virus) and are 18 years of age or older
    C. You will NOT use Sovaldi concurrently (at the same time) with Epclusa (velpatasvir/sofosbuvir), Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir), or Vosevi (velpatasvir/sofosbuvir/voxilaprevir)

    (Denial text continued on the next page)

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SOFOSBUVIR (PART D)

GUIDELINES FOR USE (CONTINUED)

D. If you have genotype 2 infection, approval also requires:
1. You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage) OR you do not have cirrhosis (liver damage and scarring)
2. Sovaldi will be used with ribavirin
3. You meet ONE of the following:
   a. You are 3 to 17 years of age
   b. You are 18 years of age or older AND have an intolerance (side effect) or contraindication to (harmful for you to use) the preferred medication: Epclusa

E. If you have genotype 3 infection, approval also requires:
1. You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage) OR you do not have cirrhosis (liver damage and scarring)
2. Sovaldi will be used with ribavirin
3. You meet ONE of the following:
   a. You are 3 to 17 years of age
   b. You are 18 years of age or older AND have an intolerance (side effect) or contraindication to (harmful for you to use) the preferred medication: Epclusa

F. If you have genotype 1 infection, approval also requires:
1. You are 18 years of age or older
2. You are treatment-naive (no prior treatment)
3. You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage) OR you do not have cirrhosis (liver damage and scarring)
4. Sovaldi will be used with peginterferon alfa and ribavirin OR Sovaldi will be used with ribavirin if you have a contraindication to (harmful for you to use) interferon
5. You have an intolerance (side effect) or contraindication to ONE of the following preferred medications: Harvoni, Epclusa

(Denial text continued on the next page)

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SOFOSBUVIR (PART D)

GUIDELINES FOR USE (CONTINUED)

G. If you have genotype 4 infection, approval also requires:
1. You are 18 years of age or older
2. You are treatment-naive (no prior treatment)
3. You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage) OR you do not have cirrhosis (liver damage and scarring)
4. Sovaldi will be used with peginterferon alfa and ribavirin
5. You have an intolerance (side effect) or contraindication to (harmful for you to use) ONE of the following preferred medications: Harvoni, Epclusa

H. If Sovaldi will be used to prevent post-transplant HCV reinfection (getting infected again with HCV after transplant), approval also requires:
1. You have hepatocellular carcinoma (HCC: a type of liver cancer)
2. You are waiting for your liver transplant
3. Sovaldi will be used with ribavirin as pre-transplant (before transplant) treatment

I. If you had a previous treatment failure with Mavyret (glecaprevir/pibrentasvir) OR Vosevi (sofosbuvir/velpatasvir/voxilaprevir), approval also requires:
1. You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) OR you do not have cirrhosis (liver damage and scarring)
2. Sovaldi will be used with Mavyret (glecaprevir/pibrentasvir) AND ribavirin

J. Sovaldi will also be approved for any other regimen/condition not listed above that is recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOFOSBUVIR (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sovaldi.

REFERENCES

Sovaldi [Prescribing Information]. Foster City, CA: Gilead Sciences; March 2020.
Guidance from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) Recommendations for Testing, Managing, Accessed October 2023.

For Part D use only:

SOFOSBUVIR (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	CRITERIA WILL BE APPLIED CONSISTENT WITH CURRENT AASLD/IDSA GUIDANCE
Other Criteria	1) CRITERIA WILL BE APPLIED CONSISTENT WITH CURRENT AASLD/IDSA GUIDANCE, 2) NO CONCURRENT USE WITH EPCLUSA, HARVONI, ZEPATIER, OR VOSEVI, AND 3) INTOLERANCE OR CONTRAINDICATION TO ONE OF THE PREFERRED FORMULARY AGENTS: HARVONI OR EPCLUSA, WHEN THESE AGENTS ARE CONSIDERED ACCEPTABLE FOR TREATMENT OF THE SPECIFIC GENOTYPE PER AASLD/IDSA GUIDANCE.

Created: 01/14
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 04/24

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOFOSBUVIR/VELPATASVIR (PART D)

Generic	Brand	HICL	GCN	Exception/Other
SOFOSBUVIR/ VELPATASVIR	EPCLUSA	43561		BRAND ONLY

Do not review this guideline with physicians; if the caller wishes to initiate a request, then a MRF must be completed (see the MedImpact Standard MRF for HepC).

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic hepatitis C virus (HCV) (ICD-10 B18.2) and meet **ALL** of the following criteria?
   - The patient is 3 years of age or older
   - The patient has genotype 1, 2, 3, 4, 5, or 6 infection

   If yes, continue to #2.
   If no, continue to #6.

2. Does the patient have an HCV RNA level within the past 6 months?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Will Epclusa be used concurrently with **ANY** of the following medications?
   - Amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, Priftin (rifapentine), efavirenz (e.g., Atripla, Sustiva), rosuvastatin at doses greater than 10mg daily, Aptivus (tipranavir)/ritonavir, topotecan, Sovaldi (sofosbuvir; as a single agent), Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir), Mavyret (pibrentasvir/glecaprevir), or Vosevi (velpatasvir/sofosbuvir/voxilaprevir)

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #4.

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SOFOSBUVIR/VELPATASVIR (PART D)

GUIDELINES FOR USE (CONTINUED)

4. Does the patient meet **ONE** of the following criteria?
   - The patient does not have cirrhosis
   - The patient has compensated cirrhosis (Child-Pugh A)
   - The patient has decompensated cirrhosis (moderate or severe hepatic impairment; Child-Pugh B or C) AND Epclusa will be used with ribavirin

   If yes, **approve for 12 weeks by HICL.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Does the patient have decompensated cirrhosis and meet **ONE** of the following criteria?
   - The patient has a contraindication to ribavirin (ribavirin ineligible)
   - The patient has failed prior treatment with a sofosbuvir-based regimen (e.g., sofosbuvir/ribavirin) AND Epclusa will be used with ribavirin
   - The patient has failed prior treatment with an NS5A inhibitor-based regimen (e.g., Harvoni [ledipasvir/sofosbuvir]) AND Epclusa will be used with ribavirin
   - The patient is post-liver transplant, treatment-experienced, AND Epclusa will be used with ribavirin

   If yes, **approve for 24 weeks by HICL.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #6.

6. Is the requested regimen recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment?

   If yes, **approve as indicated per guidance in AASLD/IDSA.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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SOFOSBUVIR/VELPATASVIR (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOFOSBUVIR/VELPATASVIR (Epclusa)** requires the following rule(s) be met for approval:

A. You have chronic hepatitis C virus (HCV: liver inflammation caused by a type of virus)
B. You are 3 years of age or older
C. You have genotype 1, 2, 3, 4, 5, or 6 hepatitis C infection (types of hepatitis C virus)
D. You have an HCV RNA level (a measure of the amount of hepatitis C virus in the blood) within the past 6 months
E. You will NOT use Epclusa concurrently (at the same time) with any of the following medications: amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, Priftin (rifapentine), efavirenz (such as Atripla, Sustiva), rosuvastatin at doses greater than 10mg daily, Aptivus (tipranavir)/ritonavir, topotecan, Sovaldi (sofosbuvir; as a single agent), Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir), Mavyret (pibrentasvir/glecaprevir), or Vosevi (velpatasvir/sofosbuvir/voxilaprevir)
F. You meet ONE of the following:
    1. You do not have cirrhosis (liver damage and scarring)
    2. You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage)
    3. You have decompensated cirrhosis (a condition where there is liver damage and scarring with major symptoms) (moderate or severe liver impairment; Child-Pugh B or C [a score that evaluates the severity of liver damage]), and you meet ONE of the following:
        a. You will use Epclusa with ribavirin
        b. You have a contraindication to (harmful for you to use) ribavirin
        c. You have failed prior treatment with a sofosbuvir-based regimen (such as sofosbuvir/ribavirin) AND Epclusa will be used with ribavirin
        d. You have failed prior treatment with an NS5A inhibitor-based regimen (such as Harvoni [ledipasvir/sofosbuvir]) AND Epclusa will be used with ribavirin
        e. You received a liver transplant (replaced your liver), are treatment-experienced (failed prior treatment), AND Epclusa will be used with ribavirin
G. Epclusa will also be approved for any other regimen/condition not listed above that is recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOFOSBUVIR/VELPATASVIR (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Epclusa.

REFERENCES

Guidance from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) Recommendations for Testing, Managing, and Treating hepatitis C. Available online at http://www.hcvguidelines.org/full-report-view Accessed November 27, 2023.

Epclusa [Prescribing Information]. Foster City, CA: Gilead Sciences; April 2022.

For Part D use only:

SOFOSBUVIR/VELPATASVIR (PART D)	
Covered uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	HCV RNA LEVEL WITHIN PAST 6 MONTHS.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	CRITERIA WILL BE APPLIED CONSISTENT WITH CURRENT AASLD/IDSA GUIDANCE.
Other Criteria	1) CRITERIA WILL BE APPLIED CONSISTENT WITH CURRENT AASLD/IDSA GUIDANCE, 2) NOT CONCURRENTLY TAKING ANY OF THE FOLLOWING MEDICATIONS: AMIODARONE, CARBAMAZEPINE, PHENYTOIN, PHENOBARBITAL, OXCARBAZEPINE, RIFAMPIN, RIFABUTIN, RIFAPENTINE, HIV REGIMEN THAT CONTAINS EFAVIRENZ, ROSUVASTATIN AT DOSES ABOVE 10MG, TIPRANAVIR/RITONAVIR, TOPOTECAN, SOVALDI (AS A SINGLE AGENT), HARVONI, ZEPATIER, MAVYRET, OR VOSEVI, AND 3) PATIENTS WITH DECOMPENSATED CIRRHOSIS REQUIRE CONCURRENT RIBAVIRIN UNLESS RIBAVIRIN INELIGIBLE.

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 07/22/24
Commercial Effective: N/A
Created: 06/16
Client Approval: 06/24
P&T Approval: 04/24

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOFOSBUVIR/ VELPATASVIR/ VOXILAPREVIR	VOSEVI	44428		GPI-10 (1235990380)	

Do not review this guideline with physicians; if the caller wishes to initiate a request, then a MRF must be completed (see the MedImpact Standard MRF for HepC).

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic hepatitis C virus (HCV) (ICD-10 B18.2) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- The patient has genotype 1, 2, 3, 4, 5, or 6 infection

If yes, continue to #2.
If no, continue to #8.

2. Does the patient have an HCV RNA level within the past 6 months?

If yes, continue to #3.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient meet **ANY** of the following criteria?
   - The patient has moderate or severe hepatic impairment (decompensated cirrhosis; Child-Pugh B or C)
   - Vosevi will be used concurrently with any of the following medications: amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, Priftin (rifapentine), cyclosporine, pitavastatin, pravastatin (at doses above 40mg), rosuvastatin, methotrexate, mitoxantrone, imatinib, irinotecan, lapatinib, sulfasalazine, topotecan, an HIV regimen containing efavirenz, atazanavir, or lopinavir, Aptivus (tipranavir)/ritonavir, Sovaldi (sofosbuvir; as a single agent), Epclusa (velpatasvir/sofosbuvir), Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir), or Mavyret (pibrentasvir/glecaprevir)

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #4.

4. Is the patient treatment naive and meets **ALL** of the following criteria?
   - The patient has genotype 3
   - The patient has compensated cirrhosis
   - The patient has NS5A RAS Y93H polymorphism

   If yes, **approve for 12 weeks by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Is the patient treatment-experienced and meets **ALL** of the following criteria?
   - The patient has compensated cirrhosis (Child-Pugh A) OR does not have cirrhosis
   - The patient has failed prior treatment with a full course of an HCV regimen containing an NS5A inhibitor (e.g., Harvoni [ledipasvir/sofosbuvir], Mavyret [pibrentasvir/glecaprevir]) or a DAA (e.g., Olysio [simeprevir]/peginterferon/ribavirin, Epclusa [velpatasvir/sofosbuvir]) if post-liver or kidney transplant

   If yes, **approve for 12 weeks by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #6.

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SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR (PART D)

GUIDELINES FOR USE (CONTINUED)

6. Is the patient treatment-experienced and meets **ALL** of the following criteria?
   - The patient has compensated cirrhosis (Child-Pugh A) OR does not have cirrhosis
   - The patient has failed prior treatment with a sofosbuvir-based regimen (e.g., Epclusa [sofosbuvir/velpatasvir], sofosbuvir with ribavirin, sofosbuvir with Olysio [simeprevir])

   If yes, **approve for 12 weeks by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #7.

7. Is the patient treatment-experienced and meets **ALL** of the following criteria?
   - The patient has compensated cirrhosis (Child-Pugh A) OR does not have cirrhosis
   - The patient failed prior treatment with Vosevi
   - Vosevi will be used with ribavirin

   If yes, **approve for 24 weeks by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #8.

8. Is the requested regimen recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment?

   If yes, **approve as indicated per guidance in AASLD/IDSA.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR (Vosevi)** requires the following rule(s) be met for approval:

A. You have chronic hepatitis C virus (HCV: liver inflammation caused by a type of virus)
B. You are 18 years of age or older
C. You have genotype 1, 2, 3, 4, 5 or 6 infection (types of hepatitis C virus)
D. You have an HCV RNA level (a measure of the amount of hepatitis C virus in the blood) within the past 6 months
E. You do NOT have moderate or severe liver impairment (decompensated cirrhosis [a condition where there is liver damage and scarring with major symptoms]; Child-Pugh B or C [a score that evaluates the severity of liver damage])
F. You will NOT use Vosevi concurrently (at the same time) with any of the following: amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, Priftin (rifapentine), cyclosporine, pitavastatin, pravastatin (at doses above 40mg), rosuvastatin, methotrexate, mitoxantrone, imatinib, irinotecan, lapatinib, sulfasalazine, topotecan, an HIV (human immunodeficiency virus: an immune system disease caused by a virus) regimen containing efavirenz, atazanavir, or lopinavir, Aptivus (tipranavir)/ritonavir, Sovaldi (sofosbuvir; as a single agent), Epclusa (velpatasvir/sofosbuvir), Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir), or Mavyret (pibrentasvir/glecaprevir)
G. If you are treatment naive (no prior treatment), approval also requires:
    1. You have genotype 3
    2. You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms)
    3. You have NS5A resistance-associated substitution (RAS) Y93H polymorphism (variations in a type of hepatitis C virus protein)
H. If you are treatment-experienced (failed prior treatment), approval also requires:
    1. You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage) OR you do not have cirrhosis (liver damage and scarring)
    2. You meet ONE of the following:
        a. You have failed a full course of a regimen containing an NS5A inhibitor (such as Harvoni [ledipasvir/sofosbuvir], Mavyret [pibrentasvir/glecaprevir]) or a direct-acting antiviral (such as Olysio [simeprevir]/peginterferon/ribavirin, Epclusa [velpatasvir/sofosbuvir]) if post-liver or kidney transplant (replaced your liver or kidney)
        b. You have failed prior treatment with a sofosbuvir-based regimen (such as Epclusa [sofosbuvir/velpatasvir], sofosbuvir with ribavirin, sofosbuvir with Olysio [simeprevir])
        c. You have failed prior treatment with Vosevi AND Vosevi will be used with ribavirin

(Denial text continued on next page)

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SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR (PART D)

GUIDELINES FOR USE (CONTINUED)

I. Vosevi will also be approved for any other regimen/condition not listed above that is recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vosevi.

REFERENCES

Guidance from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) Recommendations for Testing, Managing, and Treating hepatitis C. Available online at http://www.hcvguidelines.org/full-report-view Accessed January 31, 20243.

Vosevi [Prescribing Information]. Foster City, CA: Gilead Sciences; November 2019.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR (PART D)

For Part D use only:

SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	HCV RNA LEVEL WITHIN PAST 6 MONTHS
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	CRITERIA WILL BE APPLIED CONSISTENT WITH CURRENT AASLD/IDSA GUIDANCE.
Other Criteria	CRITERIA WILL BE APPLIED CONSISTENT WITH CURRENT AASLD/IDSA GUIDANCE, 2) NOT CONCURRENTLY TAKING ANY OF THE FOLLOWING MEDICATIONS: AMIODARONE, CARBAMAZEPINE, PHENYTOIN, PHENOBARBITAL, OXCARBAZEPINE, RIFAMPIN, RIFABUTIN, RIFAPENTINE, CYCLOSPORINE, PITAVASTATIN, PRAVASTATIN (DOSES ABOVE 40MG), ROSUVASTATIN, METHOTREXATE, MITOXANTRONE, IMATINIB, IRINOTECAN, LAPATINIB, SULFASALAZINE, TOPOTECAN, OR HIV REGIMEN THAT CONTAINS EFAVIRENZ, ATAZANAVIR, LOPINAVIR, TIPRANAVIR/RITONAVIR, SOVALDI (AS A SINGLE AGENT), EPCLUSA, HARVONI, ZEPATIER, OR MAVYRET, AND 3) DOES NOT HAVE MODERATE OR SEVERE HEPATIC IMPAIRMENT (CHILD-PUGH B OR C).

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25 Created: 06/17
Commercial Effective: N/A Client Approval: 06/24 P&T Approval: 04/24

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOFPIRONIUM (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOFPIRONIUM BROMIDE	SOFDRA	49707		GPI-10 (9097008320)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of primary axillary hyperhidrosis (ICD-10 L74.510) and meet **ALL** of the following criteria?
   - The patient is 9 years of age or older
   - The patient has primary axillary hyperhidrosis as evidenced by focal, visible, excessive sweating of at least 6 months duration with all secondary causes ruled out
   - Sofdra will NOT be used concurrently with other topical anticholinergics indicated for primary axillary hyperhidrosis (e.g., Qbrexza [glycopyrronium tosylate])

   If yes, continue to #2.
   If no, do not approve.

2. Does the patient meet at least **TWO** of the following criteria?
   - Symptoms occur bilaterally
   - Symptoms impair daily activities
   - The patient has at least one episode per week
   - Onset occurred prior to the patient turning 25 years of age
   - The patient has a family history of primary axillary hyperhidrosis
   - Symptoms do not occur during sleep

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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SOFPIRONIUM (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOFPIRONIUM (Sofdra)** requires the following rule(s) be met for approval:

A. You have primary axillary hyperhidrosis (excessive underarm sweating)
B. You are 9 years of age or older
C. You have primary axillary hyperhidrosis (excessive underarm sweating) as shown by focal (limited to a particular area of the body), visible, excessive sweating of at least 6 months duration with all secondary causes (caused by another medical condition) ruled out
D. You will NOT use Sofdra concurrently (at the same time) with other topical anticholinergics used for primary axillary hyperhidrosis (excessive underarm sweating) (such as Qbrexza [glycopyrronium tosylate])
E. You have at least two of the following:
    1. Symptoms occur bilaterally (on both sides of the body)
    2. Symptoms impair daily activities
    3. You have at least one episode per week
    4. Onset occurred before you turn(ed) 25 years old
    5. You have a family history of primary axillary hyperhidrosis (excessive underarm sweating)
    6. Symptoms do not occur during sleep

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sofdra.

REFERENCES

Sofdra [Prescribing Information]. Wayne, PA: Botanix SB Inc.; June 2024.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOFPIRONIUM (PART D)

For Part D use only:

SOFPIRONIUM (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	PRIMARY AXILLARY HYPERHIDROSIS: 1) FOCAL, VISIBLE, EXCESSIVE SWEATING FOR AT LEAST 6 MONTHS WITH ALL SECONDARY CAUSES RULED OUT, 2) NO CONCURRENT USE WITH OTHER TOPICAL ANTICHOLINERGICS INDICATED FOR PRIMARY AXILLARY HYPERHIDROSIS, AND 3) HAS TWO OF THE FOLLOWING: (A) OCCURS BILATERALLY, (B) IMPAIRS DAILY ACTIVITIES, (C) AT LEAST ONE EPISODE PER WEEK, (D) ONSET BEFORE 25 YEARS OF AGE, (E) FAMILY HISTORY OF PRIMARY AXILLARY HYPERHIDROSIS, OR (F) SYMPTOMS DO NOT OCCUR DURING SLEEP.

Created: 01/26
Effective: 01/26/26 Client Approval: 01/26 P&T Approval: 10/23

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOLRIAMFETOL (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOLRIAMFETOL HCL	SUNOSI	45666		GPI-10 (6137007020)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of excessive daytime sleepiness (EDS) with narcolepsy (ICD-10 G47.419) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist, psychiatrist, or specialist insleep medicine
   - The patient had a trial of a formulary version of modafinil or armodafinil AND one other generic stimulant indicated for (EDS) with narcolepsy (e.g., amphetamine sulfate [Evekeo], dextroamphetamine [Dexedrine], methylphenidate [Ritalin])

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of excessive daytime sleepiness (EDS) (ICD-10 G47.10) with obstructive sleep apnea (OSA) (ICD-10 G47.33) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of a formulary version of modafinil OR armodafinil

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SOLRIAMFETOL (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOLRIAMFETOL (Sunosi)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Excessive daytime sleepiness (EDS) with narcolepsy (a type of sleep condition with overwhelming daytime drowsiness)
   2. Excessive daytime sleepiness (EDS) with obstructive sleep apnea (OSA: a type of sleep condition due to a disorder where airflow is blocked during sleep)

B. If you have excessive daytime sleepiness with narcolepsy, approval also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor), psychiatrist (a type of mental health doctor), or specialist in sleep medicine
   3. You have tried a formulary version of modafinil or armodafinil AND one other generic stimulant indicated for excessive daytime sleepiness with narcolepsy (such as amphetamine sulfate [Evekeo], dextroamphetamine [Dexedrine], methylphenidate [Ritalin])

C. If you have excessive daytime sleepiness with obstructive sleep apnea, approval also requires:
   1. You are 18 years of age or older
   2. You have tried a formulary version of modafinil OR armodafinil

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOLRIAMFETOL (PART D)

RENEWAL CRITERIA

1. Does the patient have **ONE** of the following diagnoses?
   Excessive daytime sleepiness (EDS) with narcolepsy (ICD-10 G47.419)
   Excessive daytime sleepiness (EDS) (ICD-10 G47.10) with obstructive sleep apnea (OSA) (ICD-10 G47.33)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Has the patient had a sustained improvement of symptoms compared to baseline?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOLRIAMFETOL (Sunosi)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Excessive daytime sleepiness (EDS) with narcolepsy (a type of sleep condition with overwhelming daytime drowsiness)
      2. Excessive daytime sleepiness (EDS) with obstructive sleep apnea (OSA: a type of sleep condition due to a disorder where airflow is blocked during sleep)
   B. You have sustained improvement of symptoms compared to baseline

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Sunosi.

REFERENCES
Sunosi [Prescribing Information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; June 2023.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOLRIAMFETOL (PART D)

For Part D use only:

SOLRIAMFETOL (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: EXCESSIVE DAYTIME SLEEPINESS (EDS) IN NARCOLEPSY: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST, PSYCHIATRIST, OR SPECIALIST IN SLEEP MEDICINE.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: EDS IN NARCOLEPSY: 1) TRIAL OF A FORMULARY VERSION OF MODAFINIL OR ARMODAFINIL, AND 2) TRIAL OF ONE GENERIC STIMULANT INDICATED FOR EDS IN NARCOLEPSY. EDS IN OBSTRUCTIVE SLEEP APNEA (OSA): TRIAL OF A FORMULARY VERSION OF MODAFINIL OR ARMODAFINIL. RENEWAL: EDS IN NARCOLEPSY OR OSA: SUSTAINED IMPROVEMENT OF SYMPTOMS COMPARED TO BASELINE.

Created: 08/19
Effective: 01/01/26 Client Approval: 01/26 P&T Approval: 10/19

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOMAPACITAN-BECO (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOMAPACITAN-BECO	SOGROYA	46831		GPI-10 (3010000720)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the requested medication being used for **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, continue to #2.

2. Is the request for a pediatric patient with a diagnosis of growth failure due to inadequate secretion of endogenous growth hormone (GH) (ICD-10 Group E34.3), and does the patient meet **ALL** of the following criteria?
   - The patient is 2.5 to 17 years of age
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has open epiphyses (as confirmed by radiograph of the wrist and hand)
   - The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   - Sogroya will NOT be used concurrently with Increlex (mecasermin)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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SOMAPACITAN-BECO (PART D)

INITIAL CRITERIA (CONTINUED)

3. Is the request for an adult patient with a diagnosis of growth hormone deficiency (GHD) (ICD-10 Group E34.3, E23.0), and does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist
   - Sogroya will NOT be used concurrently with Increlex (mecasermin)

   If yes, continue to #4.
   If no, continue to #6.

4. Does the patient have a congenital, genetic, or organic disease (e.g., craniopharyngioma [tumor], pituitary hypoplasia, ectopic posterior pituitary, previous cranial irradiation)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Is the patient's GHD diagnosis confirmed by **ONE** of the following growth hormone stimulation tests?
   - Insulin tolerance test (peak growth hormone of 5 ng/mL or less)
   - Glucagon-stimulation test (peak response of 3 ng/mL or less AND the patient's BMI is less than 25 kg/m2; OR peak response of 3 ng/mL or less AND the patient's BMI is between 25 and 30 kg/m2 with a high pre-test probability; OR peak response of 1 ng/mL or less AND the patient's BMI is between 25 and 30 kg/m2 with a low test probability; OR peak response of 1 ng/mL or less AND the patient's BMI is greater than 30 kg/m2)
   - Macimorelin test (peak growth hormone of 2.8 ng/mL or less)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SOMAPACITAN-BECO (PART D)

INITIAL CRITERIA (CONTINUED)

6. Does the patient have a diagnosis of short stature born small for gestational age (SGA)(ICD-10 R62.52; Group P05.1) and meet **ALL** of the following criteria?
   - The patient is 2.5 to 17 years of age
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has open epiphyses (as confirmed by radiograph of the wrist and hand)
   - The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   - Sogroya will NOT be used concurrently with Increlex (mecasermin)

   If yes, **approve for 12 months by HICL or GPI-10**.
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #7.

7. Does the patient have a diagnosis of growth failure associated with Noonan syndrome (ICD-10 Q87.19) and meet **ALL** of the following criteria?
   - The patient is 2.5 to 17 years of age
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has open epiphyses (as confirmed by radiograph of the wrist and hand)
   - The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   - Sogroya will NOT be used concurrently with Increlex (mecasermin)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #8.

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SOMAPACITAN-BECO (PART D)

INITIAL CRITERIA (CONTINUED)

8. Does the patient have a diagnosis of idiopathic short stature (ISS) (ICD-10 R62.52) and meet **ALL** of the following criteria?

- The patient is 2.5 to 17 years of age
- Therapy is prescribed by or in consultation with an endocrinologist
- The patient has open epiphyses (as confirmed by radiograph of the wrist and hand)
- The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOMAPACITAN-BECO (Sogroya)** requires the following rule(s) be met for approval:

A. You meet ONE of the following:
   1. You are a pediatric patient with growth failure due to inadequate secretion (release) of endogenous (produced inside the body) growth hormone (GH)
   2. You are an adult patient with growth hormone deficiency (GHD: a type of hormone disorder with low growth hormone)
   3. You have short stature born small for gestational age (SGA: birth weight is lower than expected for the number of weeks of pregnancy)
   4. You have growth failure associated with Noonan syndrome (a type of genetic disorder)
   5. You have idiopathic short stature (ISS: short height due to unknown cause)

B. If you are a pediatric patient with growth failure due to inadequate secretion of endogenous growth hormone, approval also requires:
   1. You are 2.5 to 17 years of age
   2. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
   3. You have open epiphyses (end part of long bone) as confirmed by radiograph (a type of imaging test) of the wrist and hand
   4. Your height is at least 2 standard deviations (SD: a measure of variation from the average) below the mean (average) height for children of the same age and gender
   5. You will NOT use Sogroya concurrently (at the same time) with Increlex (mecasermin)

(Initial denial text continued on next page)

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SOMAPACITAN-BECO (PART D)

INITIAL CRITERIA (CONTINUED)

C. If you are an adult patient with growth hormone deficiency, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
3. You will NOT use Sogroya concurrently (at the same time) with Increlex (mecasermin)
4. You meet ONE of the following:
   a. You have congenital (at birth), genetic, or organic disease (such as craniopharyngioma [tumor], pituitary hypoplasia [a type of brain condition], ectopic posterior pituitary [a type of brain condition], previous cranial irradiation [radiation to the brain])
   b. Your diagnosis is confirmed by ONE of the following growth hormone stimulation tests:
      i. Insulin tolerance test (peak growth hormone of 5 ng/mL or less)
      ii. Glucagon-stimulation test (peak response of 3 ng/mL or less AND your body mass index [BMI: a tool for evaluating body fat] is less than 25 kg/m2 OR peak response of 3 ng/mL or less AND your BMI is between 25 and 30 kg/m2 with a high pre-test probability OR peak response of 1 ng/mL or less AND your BMI is between 25 and 30 kg/m2 with a low test probability OR peak response of 1 ng/mL or less AND your BMI is greater than 30 kg/m2)
      iii. Macimorelin test (peak growth hormone of 2.8 ng/mL or less)

D. If you have short stature born small for gestational age, approval also requires:
1. You are 2.5 to 17 years of age
2. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
3. You have open epiphyses (end part of long bone) as confirmed by radiograph (a type of imaging test) of the wrist and hand
4. Your height is at least 2 standard deviations (SD: a measure of variation from the average) below the mean (average) height for children of the same age and gender
5. You will NOT use Sogroya concurrently (at the same time) with Increlex (mecasermin)

E. If you have growth failure associated with Noonan syndrome, approval also requires:
1. You are 2.5 to 17 years of age
2. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
3. You have open epiphyses (end part of long bone) as confirmed by radiograph (a type of imaging test) of the wrist and hand
4. Your height is at least 2 standard deviations (SD: a measure of variation from the average) below the mean (average) height for children of the same age and gender
5. You will NOT use Sogroya concurrently (at the same time) with Increlex (mecasermin)

F. Request for Sogroya will NOT be approved for athletic enhancement (to perform better in sports) or anti-aging purposes.

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SOMAPACITAN-BECO (PART D)

RENEWAL CRITERIA

1. Is the requested medication being used for **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, continue to #2.

2. Is the request for a pediatric patient with a diagnosis of growth failure due to inadequate secretion of endogenous growth hormone (GH) (ICD-10 Group E34.3), and does the patient meet **ALL** of the following criteria?
   - The patient is 2.5 to 17 years of age
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has open epiphyses (as confirmed by radiograph of the wrist and hand OR the patient has not completed prepubertal growth)
   - The patient has shown improvement (increased height or increased growth velocity) on therapy
   - Sogroya will NOT be used concurrently with Increlex (mecasermin)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Is the request for an adult patient with a diagnosis of growth hormone deficiency (GHD) (ICD-10 Group E34.3, E23.0), and does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has achieved or maintained a response to therapy as evidenced by clinical treatment goals (e.g., improved body composition, lipid panel, bone health)
   - Sogroya will NOT be used concurrently with Increlex (mecasermin)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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SOMAPACITAN-BECO (PART D)

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have **ONE** of the following diagnoses?
   - Short stature born small for gestational age (SGA) (ICD-10 R62.52; Group P05.1)
   - Growth failure associated with Noonan syndrome (ICD-10 Q87.19)

   If yes, continue to #5.
   If no, continue to #6.

5. Does the patient meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has open epiphyses (as confirmed by radiograph of the wrist and hand ORthe patient has not completed prepubertal growth)
   - The patient has shown improvement (increased height or increased growth velocity)
   - Sogroya will NOT be used concurrently with Increlex (mecasermin)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

6. Does the patient have a diagnosis of idiopathic short stature (ISS) (ICD-10 R62.52) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has open epiphyses (as confirmed by radiograph of the wrist and hand)
   - The patient has shown improvement (increased height or increased growth velocity)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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SOMAPACITAN-BECO (PART D)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOMAPACITAN-BECO (Sogroya)** requires the following rule(s) be met for renewal:

A. You meet ONE of the following:
   1. You are a pediatric patient with growth failure due to inadequate secretion (release) of endogenous (produced inside the body) growth hormone (GH)
   2. You are an adult patient with growth hormone deficiency (GHD: a type of hormone disorder with low growth hormone)
   3. You have short stature born small for gestational age (SGA: birth weight is lower than expected for the number of weeks of pregnancy)
   4. You have growth failure associated with Noonan syndrome (a type of genetic disorder)
   5. You have idiopathic short stature (ISS: short height due to unknown cause)

B. If you are a pediatric patient with growth failure due to inadequate secretion of endogenous growth hormone, renewal also requires:
   1. You are 2.5 to 17 years of age
   2. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
   3. You have open epiphyses (end part of long bone) (as confirmed by radiograph [type of imaging test] of the wrist and hand OR you have not completed prepubertal growth)
   4. You have experienced improvement (increased height or increased growth velocity [rate]) on therapy
   5. You will NOT use Sogroya concurrently (at the same time) with Increlex (mecasermin)

C. If you are an adult patient with growth hormone deficiency, renewal also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
   3. You have achieved or maintained a response to therapy as evidenced by clinical treatment goals (such as improved body composition, lipid [fat] panel, bone health)
   4. You will NOT use Sogroya concurrently (at the same time) with Increlex (mecasermin)

(Renewal denial text continued on next page)

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SOMAPACITAN-BECO (PART D)

RENEWAL CRITERIA (CONTINUED)

D. If you have short stature born small for gestational age OR growth failure associated with Noonan syndrome, renewal also requires:
1. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
2. You have open epiphyses (end part of long bone) (as confirmed by radiograph [type of imaging test] of the wrist and hand OR you have not completed prepubertal growth)
3. You have experienced improvement (increased height or increased growth velocity [rate]) on therapy
4. You will NOT use Sogroya concurrently (at the same time) with Increlex (mecasermin)

E. If you have idiopathic short stature, renewal also requires:
1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
2. You have open epiphyses (end part of long bone) as confirmed by radiograph (type of imaging test) of the wrist and hand
3. You have experienced improvement (increased height or increased growth velocity [rate]) on therapy

F. Request for Sogroya will NOT be approved for athletic enhancement (to perform better in sports) or anti-aging purposes.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Sogroya.

REFERENCES
Sogroya [Prescribing Information]. Plainsboro, NJ: Novo Nordisk Inc.; February 2026.

For Part D use only:

SOMAPACITAN-BECO (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	INITIAL/RENEWAL: ATHLETIC ENHANCEMENT, ANTI-AGING PURPOSES.
Required Medical Information	INITIAL: PEDIATRIC GROWTH HORMONE DEFICIENCY (GHD), SMALL FOR GESTATIONAL AGE (SGA), NOONAN SYNDROME, IDIOPATHIC SHORT STATURE (ISS): HEIGHT AT LEAST 2 STANDARD DEVIATIONS BELOW THE MEAN HEIGHT FOR CHILDREN OF THE SAME AGE AND GENDER. ADULT GHD: 1) HAS A CONGENITAL, GENETIC, OR ORGANIC DISEASE (E.G., CRANIOPHARYNGIOMA, PITUITARY HYPOPLASIA, ECTOPIC POSTERIOR PITUITARY, PREVIOUS CRANIAL IRRADIATION), OR 2) GHD CONFIRMED BY ONE OF THE FOLLOWING GROWTH HORMONE (GH) STIMULATION TESTS: (A) INSULIN TOLERANCE TEST (PEAK GH OF 5 NG/ML OR LESS), (B) GLUCAGON-STIMULATION TEST (ONE OF THE FOLLOWING: (I) PEAK RESPONSE OF 3 NG/ML OR LESS AND BMI LESS THAN

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	25 KG/M2, (II) PEAK RESPONSE OF 3 NG/ML OR LESS AND BMI IS BETWEEN 25 - 30 KG/M2 WITH A HIGH PRE-TEST PROBABILITY, (III) PEAK RESPONSE OF 1 NG/ML OR LESS AND BMI IS BETWEEN 25 - 30 KG/M2 WITH LOW TEST PROBABILITY, OR (IV) PEAK RESPONSE OF 1 NG/ML OR LESS AND BMI IS GREATER THAN 30 KG/M2), OR (C) MACIMORELIN TEST (PEAK GH OF 2.8 NG/ML OR LESS).
Age Restrictions	N/A
Prescriber Restrictions	INITIAL/RENEWAL: ALL INDICATIONS: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: PEDIATRIC GHD, SGA, NOONAN SYNDROME, ISS: OPEN EPIPHYSES AS CONFIRMED BY RADIOGRAPH OF THE WRIST AND HAND. INITIAL/RENEWAL: PEDIATRIC GHD, ADULT GHD, SGA, NOONAN SYNDROME: NO CONCURRENT USE WITH INCRELEX. RENEWAL: PEDIATRIC GHD, SGA, NOONAN SYNDROME: 1) IMPROVEMENT WHILE ON THERAPY (INCREASED HEIGHT OR INCREASED GROWTH VELOCITY), AND 2) OPEN EPIPHYSES AS CONFIRMED BY RADIOGRAPH OF THE WRIST AND HAND OR HAS NOT COMPLETED PREPUBERTAL GROWTH. ADULT GHD: ACHIEVED OR MAINTAINED A RESPONSE TO THERAPY (E.G., IMPROVED BODY COMPOSITION, LIPID PANEL, BONE HEALTH). ISS: 1) IMPROVEMENT WHILE ON THERAPY (INCREASED HEIGHT OR INCREASED GROWTH VELOCITY), AND 2) OPEN EPIPHYSES AS CONFIRMED BY RADIOGRAPH OF THE WRIST AND HAND.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOMATROGON-GHLA (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOMATROGON-GHLA	NGENLA	47896		GPI-10 (3010001500)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the requested medication being used for **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.
   If no, continue to #2.

2. Is the request for a pediatric patient with a diagnosis of growth failure due to inadequate secretion of endogenous growth hormone (ICD-10 Group E34.3), and does the patient meet **ALL** of the following criteria?
   - The patient is 3 to 17 years of age
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has open epiphyses (as confirmed by radiograph of the wrist and hand)
   - The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   - Ngenla will NOT be used concurrently with Increlex (mecasermin)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SOMATROGON-GHLA (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOMATROGON-GHLA (Ngenla)** requires the following rule(s) be met for approval:

A. You are a pediatric patient with growth failure due to inadequate secretion (release) of endogenous (produced inside the body) growth hormone
B. You are 3 to 17 years of age
C. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
D. You have open epiphyses (end part of long bone) as confirmed by radiograph (type of imaging test) of the wrist and hand
E. Your height is at least 2 standard deviations (SD: a measure of variation from the average) below the mean (average) height for children of the same age and gender
F. You will NOT use Ngenla concurrently (at the same time) with Increlex (mecasermin)
G. Request for Ngenla will NOT be approved for athletic enhancement (to perform better in sports) or anti-aging purposes

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOMATROGON-GHLA (PART D)

RENEWAL CRITERIA

1. Is the requested medication being used for **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.
   If no, continue to #2.

2. Is the request for a pediatric patient with a diagnosis of growth failure due to inadequate secretion of endogenous growth hormone (ICD-10 Group E34.3), and does the patient meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has open epiphyses (as confirmed by radiograph of the wrist and hand) OR the patient has not completed prepubertal growth
   - The patient has shown improvement (increased height or increased growth velocity) while on therapy
   - Ngenla will NOT be used concurrently with Increlex (mecasermin)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOMATROGON-GHLA (Ngenla)** requires the following rule(s) be met for renewal:
   A. You are a pediatric patient with growth failure due to inadequate secretion (release) of endogenous (produced inside the body) growth hormone
   B. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
   C. You have open epiphyses (end part of long bone) as confirmed by a radiograph (type of imaging test) of the wrist and hand OR you have not completed prepubertal growth
   D. You have shown improvement (increased height or increased growth velocity [rate of growth]) while on therapy
   E. Renewal request for Ngenla will NOT be approved for athletic enhancement (to perform better in sports) or anti-aging purposes
   F. You will NOT use Ngenla concurrently (at the same time) with Increlex (mecasermin)

(Renewal denial text continued on next page)
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SOMATROGON-GHLA (PART D)

RENEWAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ngenla.

REFERENCES

Ngenla [Prescribing Information]. New York, NY: Pfizer Laboratories; July 2025.

For Part D use only:

SOMATROGON-GHLA (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	INITIAL/RENEWAL: ATHLETIC ENHANCEMENT, ANTI-AGING PURPOSES.
Required Medical Information	PEDIATRIC GROWTH HORMONE DEFICIENCY (GHD): INITIAL: HEIGHT IS AT LEAST 2 STANDARD DEVIATIONS BELOW THE MEAN HEIGHT FOR CHILDREN OF THE SAME AGE AND GENDER.
Age Restrictions	N/A
Prescriber Restrictions	PEDIATRIC GHD: INITIAL/RENEWAL: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS
Other Criteria	PEDIATRIC GHD: INITIAL: OPEN EPIPHYSES AS CONFIRMED BY RADIOGRAPH OF WRIST AND HAND. INITIAL/RENEWAL: NO CONCURRENT USE WITH INCRELEX. RENEWAL: 1) OPEN EPIPHYSES AS CONFIRMED BY RADIOGRAPH OF WRIST AND HAND, OR HAS NOT COMPLETED PREPUBERTAL GROWTH, AND 2) IMPROVEMENT WHILE ON THERAPY (INCREASED HEIGHT OR INCREASED GROWTH VELOCITY).

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOMATROPIN - GENOTROPIN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOMATROPIN	GENOTROPIN	02824		GPI-10 (3010002000)	BRAND = GENOTROPIN%

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for treatment of **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, continue to #2.

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SOMATROPIN - GENOTROPIN (PART D)

INITIAL CRITERIA (CONTINUED)

2. Is the request for a pediatric patient with a diagnosis of growth failure due to inadequate secretion of endogenous growth hormone (GH) (ICD-10 Group E34.3), and does the patient meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   - The patient has open epiphyses (as confirmed by radiograph of the wrist and hand)
   - Genotropin will NOT be used concurrently with Increlex (mecasermin)
   - The patient had a trial of or contraindication to the preferred agent: Norditropin

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Does the patient have a diagnosis of Prader-Willi syndrome (PWS) (ICD-10 Q87.11) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has a confirmed genetic diagnosis of PWS
   - Genotropin will NOT be used concurrently with Increlex (mecasermin)
   - The patient had a trial of or contraindication to the preferred agent: Norditropin

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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SOMATROPIN - GENOTROPIN (PART D)

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of growth failure born small for gestational age (SGA) (ICD-10 R62.52; Group P05.1) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   - The patient has open epiphyses (as confirmed by radiograph of the wrist and hand)
   - Genotropin will NOT be used concurrently with Increlex (mecasermin)
   - The patient had a trial of or contraindication to the preferred agent: Norditropin

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Does the patient have a diagnosis of growth failure associated with Turner syndrome (ICD-10 Group Q96) and meet **ALL** of the following criteria?
   - The patient's diagnosis is confirmed by chromosomal analysis (karyotyping)
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has open epiphyses (as confirmed by radiograph of the wrist and hand)
   - Genotropin will NOT be used concurrently with Increlex (mecasermin)
   - The patient had a trial of or contraindication to the preferred agent: Norditropin

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #6.

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SOMATROPIN - GENOTROPIN (PART D)

INITIAL CRITERIA (CONTINUED)

6. Does the patient have a diagnosis of idiopathic short stature (ISS) (ICD-10 R62.52) and meet **ALL** of the following criteria?
- Therapy is prescribed by or in consultation with an endocrinologist
- The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
- The patient has open epiphyses (as confirmed by radiograph of the wrist and hand)
- The patient had a trial of or contraindication to the preferred agent: Norditropin

If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #7.

7. Is the request for an adult patient with a diagnosis of growth hormone deficiency (GHD) (ICD-10 E23.0; Group E34.3), and does the patient meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with an endocrinologist
- Genotropin will NOT be used concurrently with Increlex (mecasermin)
- The patient had a trial of or contraindication to the preferred agent: Norditropin

If yes, continue to #8.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

8. Does the patient have a congenital, genetic, or organic disease (e.g., craniopharyngioma [tumor], pituitary hypoplasia, ectopic posterior pituitary, previous cranial irradiation)?

If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #9.

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SOMATROPIN - GENOTROPIN (PART D)

INITIAL CRITERIA (CONTINUED)

9. Is the patient's diagnosis confirmed by **ONE** of the following growth hormone stimulation tests?
   - Insulin tolerance test (peak growth hormone of 5 ng/mL or less)
   - Glucagon-stimulation test (peak response of 3 ng/mL or less AND the patient's BMI is less than 25 kg/m2; OR peak response of 3 ng/mL or less AND the patient's BMI is between 25 and 30 kg/m2 with a high pre-test probability; OR peak response of 1 ng/mL or less AND the patient's BMI is between 25 and 30 kg/m2 with a low test probability; OR peak response of 1 ng/mL or less AND the patient's BMI is greater than 30 kg/m2)
   - Macimorelin test (peak growth hormone of 2.8 ng/mL or less)

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOMATROPIN - GENOTROPIN** requires the following rule(s) be met for approval:
   A. You meet ONE of the following:
      1. You are a pediatric patient with growth failure due to inadequate secretion (release) of endogenous (produced inside the body) growth hormone (GH)
      2. You have Prader-Willi syndrome (PWS: type of genetic disorder)
      3. You have growth failure born small for gestational age (SGA: birth weight is lower than expected for the number of weeks of pregnancy)
      4. You have growth failure associated with Turner syndrome (type of genetic disorder)
      5. You have idiopathic short stature (ISS: short height due to unknown cause)
      6. You are an adult patient with growth hormone deficiency (GHD: type of hormone disorder with low growth hormone)

   (Initial denial text continued on next page)

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SOMATROPIN - GENOTROPIN (PART D)

INITIAL CRITERIA (CONTINUED)

B. If you are a pediatric patient with growth failure due to inadequate secretion of endogenous growth hormone, approval also requires:
1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
2. Your height is at least 2 standard deviations (SD: a measure of variation from the average) below the mean (average) height for children of the same age and gender
3. You have open epiphyses (end part of long bone) as confirmed by radiograph (a type of imaging test) of the wrist and hand
4. You will NOT use Genotropin concurrently (at the same time) with Increlex (mecasermin)
5. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Norditropin

C. If you have Prader-Willi syndrome, approval also requires:
1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
2. You have a confirmed genetic diagnosis of Prader-Willi syndrome
3. You will NOT use Genotropin concurrently (at the same time) with Increlex (mecasermin)
4. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Norditropin

D. If you have growth failure born small for gestational age, approval also requires:
1. You are 2 years of age or older
2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
3. Your height is at least 2 standard deviations (SD: a measure of variation from the average) below the mean (average) height for children of the same age and gender
4. You have open epiphyses (end part of long bone) as confirmed by radiograph (a type of imaging test) of the wrist and hand
5. You will NOT use Genotropin concurrently (at the same time) with Increlex (mecasermin)
6. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Norditropin

E. If you have growth failure associated with Turner syndrome, approval also requires:
1. Your diagnosis is confirmed by chromosomal analysis (karyotyping: a lab test used to examine your genetic information)
2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
3. You have open epiphyses (end part of long bone) as confirmed by radiograph (a type of imaging test) of the wrist and hand
4. You will NOT use Genotropin concurrently (at the same time) with Increlex (mecasermin)
5. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Norditropin

(Initial denial text continued on next page)

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SOMATROPIN - GENOTROPIN (PART D)

INITIAL CRITERIA (CONTINUED)

F. If you have idiopathic short stature, approval also requires:
1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
2. Your height is at least 2 standard deviations (SD: a measure of variation from the average) below the mean (average) height for children of the same age and gender
3. You have open epiphyses (end part of long bone) as confirmed by radiograph (a type of imaging test) of the wrist and hand
4. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Norditropin

G. If you are an adult patient with growth hormone deficiency, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
3. You will NOT use Genotropin concurrently (at the same time) with Increlex (mecasermin)
4. You meet ONE of the following:
   a. You have congenital (at birth), genetic, or organic disease (such as craniopharyngioma [tumor], pituitary hypoplasia [a type of brain condition], ectopic posterior pituitary [a type of brain condition], previous cranial irradiation [radiation to the brain])
   b. Your diagnosis is confirmed by ONE of the following growth hormone stimulation tests:
      i. Insulin tolerance test (peak growth hormone of 5 ng/mL or less)
      ii. Glucagon-stimulation test (peak response of 3 ng/mL or less AND your body mass index [BMI: a tool for evaluating body fat] is less than 25 kg/m2 OR peak response of 3 ng/mL or less AND your BMI is between 25 and 30 kg/m2 with a high pre-test probability OR peak response of 1 ng/mL or less AND your BMI is between 25 and 30 kg/m2 with a low test probability OR peak response of 1 ng/mL or less AND your BMI is greater than 30 kg/m2)
      iii. Macimorelin test (peak growth hormone of 2.8 ng/mL or less)
5. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Norditropin

H. Request for Genotropin will NOT be approved for athletic enhancement (to perform better in sports) or anti-aging purposes.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOMATROPIN - GENOTROPIN (PART D)

RENEWAL CRITERIA

1. Is the request for treatment of **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, continue to #2.

2. Is the request for a pediatric patient with a diagnosis of growth failure due to inadequate secretion of endogenous growth hormone (GH) (ICD-10 Group E34.3), and does the patient meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has open epiphyses (as confirmed by radiograph of the wrist and hand ORthe patient has not completed prepubertal growth)
   - The patient has shown improvement (increased height or increased growth velocity)
   - Genotropin will NOT be used concurrently with Increlex (mecasermin)

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Does the patient have a diagnosis of Prader-Willi syndrome (PWS) (ICD-10 Q87.11) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has shown improvement in body composition
   - Genotropin will NOT be used concurrently with Increlex (mecasermin)

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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SOMATROPIN - GENOTROPIN (PART D)

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of idiopathic short stature (ISS) (ICD-10 R62.52) and meet **ALL** of the following criteria?
- Therapy is prescribed by or in consultation with an endocrinologist
- The patient has open epiphyses (as confirmed by radiograph of the wrist and hand)
- The patient has shown improvement (increased height or increased growth velocity

If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #5.

5. Does the patient have **ONE** of the following diagnoses?
- Growth failure born small for gestational age (SGA) (ICD-10 R62.52; Group P05.1)
- Growth failure associated with Turner syndrome (ICD-10 Group Q96)

If yes, continue to #6.
If no, continue to #7.

6. Does the patient meet **ALL** of the following criteria?
- Therapy is prescribed by or in consultation with an endocrinologist
- The patient has open epiphyses (as confirmed by radiograph of the wrist and hand OR the patient has not completed prepubertal growth)
- The patient has shown improvement (increased height or increased growth velocity)
- Genotropin will NOT be used concurrently with Increlex (mecasermin)

If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the renewal denial text at the end of the guideline.

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SOMATROPIN - GENOTROPIN (PART D)

RENEWAL CRITERIA (CONTINUED)

7. Is the request for an adult patient with a diagnosis of growth hormone deficiency (GHD) (ICD-10 E23.0; Group E34.3), and does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist
   - Genotropin will NOT be used concurrently with Increlex (mecasermin)

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOMATROPIN - GENOTROPIN** requires the following rule(s) be met for renewal:

   A. You meet ONE of the following:
      1. You are a pediatric patient with growth failure due to inadequate secretion (release) of endogenous (produced inside the body) growth hormone (GH)
      2. You have Prader-Willi syndrome (PWS: type of genetic disorder)
      3. You have growth failure born small for gestational age (SGA: birth weight is lower than expected for the number of weeks of pregnancy)
      4. You have growth failure associated with Turner syndrome (type of genetic disorder)
      5. You have idiopathic short stature (ISS: short height due to unknown cause)
      6. You are an adult patient with growth hormone deficiency (GHD: type of hormone disorder with low growth hormone)

   B. If you are a pediatric patient with growth failure due to inadequate secretion of endogenous growth hormone, renewal also requires:
      1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
      2. You have open epiphyses (end part of long bone) as confirmed by radiograph (type of imaging test) of the wrist and hand OR you have not completed prepubertal growth
      3. You have experienced improvement (increased height or increased growth velocity [rate]) on therapy
      4. You will NOT use Genotropin concurrently (at the same time) with Increlex (mecasermin)

   (Renewal denial text continued on next page)

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SOMATROPIN - GENOTROPIN (PART D)

RENEWAL CRITERIA (CONTINUED)

C. If you have Prader-Willi syndrome, renewal also requires:
1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
2. You have experienced improvement in body composition
3. You will NOT use Genotropin concurrently (at the same time) with Increlex (mecasermin)

D. If you have idiopathic short stature, renewal also requires:
1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
2. You have open epiphyses (end part of long bone) as confirmed by radiograph (type of imaging test) of the wrist and hand
3. You have experienced improvement (increased height or increased growth velocity [rate]) on therapy

E. If you have growth failure born small for gestational age, growth failure associated with Turner syndrome, renewal also requires:
1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
2. You have open epiphyses (end part of long bone) as confirmed by radiograph (type of imaging test) of the wrist and hand OR you have not completed prepubertal growth
3. You have experienced improvement (increased height or increased growth velocity [rate]) on therapy
4. You will NOT use Genotropin concurrently (at the same time) with Increlex (mecasermin)

F. If you are an adult patient with growth hormone deficiency, renewal also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
3. You will NOT use Genotropin concurrently (at the same time) with Increlex (mecasermin)

G. Request for Genotropin will NOT be approved for athletic enhancement (to perform better in sports) or anti-aging purposes.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph Genotropin.

REFERENCES
Genotropin [Prescribing Information]. New York, NY: Pfizer Laboratories; July 2025.

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SOMATROPIN - GENOTROPIN (PART D)

For Part D use only:

SOMATROPIN - GENOTROPIN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	INITIAL/RENEWAL: ATHLETIC ENHANCEMENT, ANTI-AGING PURPOSES.
Required Medical Information	INITIAL: PEDIATRIC GROWTH HORMONE DEFICIENCY (GHD), IDIOPATHIC SHORT STATURE (ISS), SMALL FOR GESTATIONAL AGE (SGA): HEIGHT AT LEAST 2 STANDARD DEVIATIONS BELOW THE MEAN HEIGHT FOR CHILDREN OF THE SAME AGE AND GENDER. TURNER SYNDROME (TS): CONFIRMED BY CHROMOSOMAL ANALYSIS (KAROTYPING). PRADER WILLI SYNDROME (PWS): CONFIRMED GENETIC DIAGNOSIS OF PWS. ADULT GHD: 1) HAS A CONGENITAL, GENETIC, OR ORGANIC DISEASE (E.G., CRANIOPHARYNGIOMA, PITUITARY HYPOPLASIA, ECTOPIC POSTERIOR PITUITARY, PREVIOUS CRANIAL IRRADIATION), OR 2) GHD CONFIRMED BY ONE OF THE FOLLOWING GROWTH HORMONE (GH) STIMULATION TESTS: (A) INSULIN TOLERANCE TEST (PEAK GH OF 5 NG/ML OR LESS), (B) GLUCAGON-STIMULATION TEST (ONE OF THE FOLLOWING: (I) PEAK RESPONSE OF 3 NG/ML OR LESS AND BMI LESS THAN 25 KG/M2, (II) PEAK RESPONSE OF 3 NG/ML OR LESS AND BMI IS BETWEEN 25 - 30 KG/M2 WITH A PRE-TEST PROBABILITY, (III) PEAK RESPONSE OF 1 NG/ML OR LESS AND BMI IS BETWEEN 25 - 30 KG/M2 WITH LOW TEST PROBABILITY, OR (IV) PEAK RESPONSE OF 1 NG/ML OR LESS AND BMI IS GREATER THAN 30 KG/M2), OR (C) MACIMORELIN TEST (PEAK GH OF 2.8 NG/ML OR LESS).
Age Restrictions	SGA: 2 YEARS OF AGE OR OLDER.
Prescriber Restrictions	INITIAL/RENEWAL: ALL INDICATIONS: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT: NORDITROPIN. PEDIATRIC GHD, ISS, SGA, TS: OPEN EPIPHYSES AS CONFIRMED BY RADIOGRAPH OF THE WRIST AND HAND. INITIAL/RENEWAL: ADULT GHD, PEDIATRIC GHD, SGA, TS, PWS: NO CONCURRENT USE WITH INCRELEX. RENEWAL: ISS: 1) IMPROVEMENT WHILE ON THERAPY (INCREASED HEIGHT OR INCREASED GROWTH VELOCITY), AND 2) OPEN EPIPHYSES AS CONFIRMED BY RADIOGRAPH OF THE WRIST AND HAND. PEDIATRIC GHD, SGA, TS: 1) IMPROVEMENT WHILE ON THERAPY (INCREASED HEIGHT OR INCREASED GROWTH VELOCITY), AND 2) OPEN

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	EPIPHYSES AS CONFIRMED BY RADIOGRAPH OF THE WRIST AND HAND OR HAS NOT COMPLETED PREPUBERTAL GROWTH. PWS: IMPROVEMENT IN BODY COMPOSITION.

Created: 10/22
Effective: 02/01/26 Client Approval: 01/26 P&T Approval: 04/25

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOMATROPIN - HUMATROPE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOMATROPIN	HUMATROPE	02824		GPI-10 (3010002000)	BRAND = HUMATROPE

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, continue to #2.

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SOMATROPIN - HUMATROPE (PART D)

INITIAL CRITERIA (CONTINUED)

2. Is the request for a pediatric patient with a diagnosis of growth failure due to inadequate secretion of endogenous growth hormone (GH) (ICD-10 Group E34.3), and does the patient meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   - The patient has open epiphyses (as confirmed by radiograph of the wrist and hand)
   - Humatrope will NOT be used concurrently with Increlex (mecasermin)
   - The patient had a trial of or contraindication to the preferred agent: Norditropin

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Does the patient have a diagnosis of short stature associated with Turner syndrome (ICD-10 Group Q96) and meet **ALL** of the following criteria?
   - The patient's diagnosis is confirmed by chromosomal analysis (karyotyping)
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has open epiphyses (as confirmed by radiograph of the wrist and hand)
   - Humatrope will NOT be used concurrently with Increlex (mecasermin)
   - The patient had a trial of or contraindication to the preferred agent: Norditropin

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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SOMATROPIN - HUMATROPE (PART D)

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of idiopathic short stature (ISS) (ICD-10 R62.52) and meet **ALL** of the following criteria?
- Therapy is prescribed by or in consultation with an endocrinologist
- The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
- The patient has open epiphyses (as confirmed by radiograph of the wrist and hand)
- The patient had a trial of or contraindication to the preferred agent: Norditropin

If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #5.

5. Does the patient have a diagnosis of short stature or growth failure with short stature homeobox-containing gene (SHOX) deficiency (ICD-10 E34.328) and meet **ALL** of the following criteria?
- Therapy is prescribed by or in consultation with an endocrinologist
- The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
- The patient has open epiphyses (as confirmed by radiograph of the wrist and hand)
- Humatrope will NOT be used concurrently with Increlex (mecasermin)

If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #6.

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SOMATROPIN - HUMATROPE (PART D)

INITIAL CRITERIA (CONTINUED)

6. Does the patient have a diagnosis of short stature born small for gestational age (SGA) (ICD-10 R62.52; Group P05.1) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   - The patient has open epiphyses (as confirmed by radiograph of the wrist and hand)
   - Humatrope will NOT be used concurrently with Increlex (mecasermin)
   - The patient had a trial of or contraindication to the preferred agent: Norditropin

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #7.

7. Is the request for an adult patient with a diagnosis of growth hormone deficiency (GHD) (ICD-10 E23.0; Group E34.3), and does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist
   - Humatrope will NOT be used concurrently with Increlex (mecasermin)
   - The patient had a trial of or contraindication to the preferred agent: Norditropin

   If yes, continue to #8.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

8. Does the patient have a congenital, genetic, or organic disease (e.g., craniopharyngioma [tumor], pituitary hypoplasia, ectopic posterior pituitary, previous cranial irradiation)?

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #9.

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SOMATROPIN - HUMATROPE (PART D)

INITIAL CRITERIA (CONTINUED)

9. Is the patient's diagnosis confirmed by **ONE** of the following growth hormone stimulation tests?
   - Insulin tolerance test (peak growth hormone of 5 ng/mL or less)
   - Glucagon-stimulation test (peak response of 3 ng/mL or less AND the patient's BMI is less than 25 kg/m2; OR peak response of 3 ng/mL or less AND the patient's BMI is between 25 and 30 kg/m2 with a high pre-test probability; OR peak response of 1 ng/mL or less AND the patient's BMI is between 25 and 30 kg/m2 with a low test probability; OR peak response of 1 ng/mL or less AND the patient's BMI is greater than 30 kg/m2)
   - Macimorelin test (peak growth hormone of 2.8 ng/mL or less)

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOMATROPIN - HUMATROPE** requires the following rule(s) be met for approval:
   A. You meet ONE of the following:
      1. You are a pediatric patient with growth failure due to inadequate secretion (release) of endogenous (produced inside the body) growth hormone (GH)
      2. You have short stature associated with Turner syndrome (type of genetic disorder)
      3. You have idiopathic short stature (ISS: short height due to unknown cause)
      4. You have short stature or growth failure with short stature homeobox-containing gene (SHOX) deficiency (type of genetic disorder)
      5. You have short stature born small for gestational age (SGA: birth weight is lower than expected for the number of weeks of pregnancy)
      6. You are an adult patient with growth hormone deficiency (GHD: type of hormone disorder with low growth hormone)

   (Initial denial text continued on next page)

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SOMATROPIN - HUMATROPE (PART D)

INITIAL CRITERIA (CONTINUED)

B. If you are a pediatric patient with growth failure due to inadequate secretion of endogenous growth hormone, approval also requires:
1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
2. Your height is at least 2 standard deviations (SD: a measure of variation from the average) below the mean (average) height for children of the same age and gender
3. You have open epiphyses (end part of long bone) as confirmed by radiograph (a type of imaging test) of the wrist and hand
4. You will NOT use Humatrope concurrently (at the same time) with Increlex (mecasermin)
5. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Norditropin

C. If you have short stature associated with Turner syndrome, approval also requires:
1. Your diagnosis is confirmed by chromosomal analysis (karyotyping: a lab test used to examine your genetic information)
2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
3. You have open epiphyses (end part of long bone) as confirmed by radiograph (a type of imaging test) of the wrist and hand
4. You will NOT use Humatrope concurrently (at the same time) with Increlex (mecasermin)
5. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Norditropin

D. If you have idiopathic short stature, approval also requires:
1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
2. Your height is at least 2 standard deviations (SD: a measure of variation from the average) below the mean (average) height for children of the same age and gender
3. You have open epiphyses (end part of long bone) as confirmed by radiograph (a type of imaging test) of the wrist and hand
4. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Norditropin

E. If you have short stature or growth failure with SHOX deficiency, approval also requires:
1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
2. Your height is at least 2 standard deviations (SD: a measure of variation from the average) below the mean (average) height for children of the same age and gender
3. You have open epiphyses (end part of long bone) as confirmed by radiograph (a type of imaging test) of the wrist and hand
4. You will NOT use Humatrope concurrently (at the same time) with Increlex (mecasermin)

(Initial denial text continued on next page)

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SOMATROPIN - HUMATROPE (PART D)

INITIAL CRITERIA (CONTINUED)

F. If you have short stature born small for gestational age, approval also requires:
1. You are 2 years of age or older
2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
3. Your height is at least 2 standard deviations (SD: a measure of variation from the average) below the mean (average) height for children of the same age and gender
4. You have open epiphyses (end part of long bone) as confirmed by radiograph (a type of imaging test) of the wrist and hand
5. You will NOT use Humatrope concurrently (at the same time) with Increlex (mecasermin)
6. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Norditropin

G. If you are an adult patient with growth hormone deficiency, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
3. You will NOT use Humatrope concurrently (at the same time) with Increlex (mecasermin)
4. You meet ONE of the following:
   a. You have congenital (at birth), genetic, or organic disease (such as craniopharyngioma [tumor], pituitary hypoplasia [a type of brain condition], ectopic posterior pituitary [a type of brain condition], previous cranial irradiation [radiation to the brain])
   b. Your diagnosis is confirmed by ONE of the following growth hormone stimulation tests:
      i. Insulin tolerance test (peak growth hormone of 5 ng/mL or less)
      ii. Glucagon-stimulation test (peak response of 3 ng/mL or less AND your body mass index [BMI: a tool for evaluating body fat] is less than 25 kg/m2 OR peak response of 3 ng/mL or less AND your BMI is between 25 and 30 kg/m2 with a high pre-test probability OR peak response of 1 ng/mL or less AND your BMI is between 25 and 30 kg/m2 with a low test probability OR peak response of 1 ng/mL or less AND your BMI is greater than 30 kg/m2)
      iii. Macimorelin test (peak growth hormone of 2.8 ng/mL or less)
5. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Norditropin

H. Request for Humatrope will NOT be approved for athletic enhancement (to perform better in sports) or anti-aging purposes.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOMATROPIN - HUMATROPE (PART D)

RENEWAL CRITERIA

1. Is the request for **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, continue to #2.

2. Is the request for a pediatric patient with a diagnosis of growth failure due to inadequate secretion of endogenous growth hormone (GH) (ICD-10 Group E34.3), and does the patient meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has shown improvement (increased height or increased growth velocity)
   - The patient has open epiphyses (as confirmed by radiograph of the wrist and hand ORthe patient has not completed prepubertal growth)
   - Humatrope will NOT be used concurrently with Increlex (mecasermin)

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Does the patient have a diagnosis of idiopathic short stature (ISS) (ICD-10 R62.52) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has open epiphyses (as confirmed by radiograph of the wrist and hand)
   - The patient has shown improvement (increased height or increased growth velocity)

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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SOMATROPIN - HUMATROPE (PART D)

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have **ONE** of the following diagnoses?
   - Short stature associated with Turner syndrome (ICD-10 Group Q96)
   - Short stature or growth failure with short stature homeobox-containing gene (SHOX) deficiency (ICD-10 E34.328)
   - Short stature born small for gestational age (SGA) (ICD-10 R62.52; Group P05.1)

   If yes, continue to #4.
   If no, continue to #5.

5. Does the patient meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has open epiphyses (as confirmed by radiograph of the wrist and hand) OR the patient has not completed prepubertal growth
   - The patient has shown improvement (increased height or increased growth velocity)
   - Humatrope will NOT be used concurrently with Increlex (mecasermin)

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

6. Is the request for an adult patient with a diagnosis of growth hormone deficiency (GHD) (ICD-10 E23.0; Group E34.3), and does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist
   - Humatrope will NOT be used concurrently with Increlex (mecasermin)

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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SOMATROPIN - HUMATROPE (PART D)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOMATROPIN - HUMATROPE** requires the following rule(s) be met for renewal:

A. You meet ONE of the following:
   1. You are a pediatric patient with growth failure due to an inadequate secretion (release) of endogenous (produced inside the body) growth hormone (GH)
   2. You have short stature associated with Turner syndrome (type of genetic disorder)
   3. You have idiopathic short stature (ISS: short height due to unknown cause)
   4. You have short stature or growth failure with short stature homeobox-containing gene (SHOX) deficiency (type of genetic disorder)
   5. You have short stature born small for gestational age (SGA: birth weight is lower than expected for the number of weeks of pregnancy)
   6. You are an adult patient with growth hormone deficiency (GHD: type of hormone disorder with low growth hormone)

B. If you are a pediatric patient with growth failure due to inadequate secretion of endogenous growth hormone, renewal also requires:
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You have experienced improvement (increased height or increased growth velocity [rate]) on therapy
   3. You have open epiphyses (end part of long bone) as confirmed by radiograph (type of imaging test) of the wrist and hand OR you have not completed prepubertal growth
   4. You will NOT use Humatrope concurrently (at the same time) with Increlex (mecasermin)

C. If you have idiopathic short stature, renewal also requires:
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You have open epiphyses (end part of long bone) as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. You have experienced improvement (increased height or increased growth velocity [rate]) on therapy

(Renewal denial text continued on the page)

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RENEWAL CRITERIA (CONTINUED)

D. If you have short stature associated with Turner syndrome, short stature or growth failure with SHOX deficiency, or short stature born small for gestational age, renewal also requires:
1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
2. You have open epiphyses (end part of long bone) as confirmed by radiograph (type of imaging test) of the wrist and hand OR you have not completed prepubertal growth
3. You have experienced improvement (increased height or increased growth velocity [rate]) on therapy
4. You will NOT use Humatrope concurrently (at the same time) with Increlex (mecasermin)

E. If you are an adult patient with growth hormone deficiency, renewal also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
3. You will NOT use Humatrope concurrently (at the same time) with Increlex (mecasermin)

F. Renewal request for Humatrope will NOT be approved for athletic enhancement (to perform better in sports) or anti-aging purposes.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Humatrope.

REFERENCES
Humatrope [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; November 2025.

For Part D use only:

SOMATROPIN - HUMATROPE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	INITIAL/RENEWAL: ATHLETIC ENHANCEMENT, ANTI-AGING PURPOSES.
Required Medical Information	INITIAL: PEDIATRIC GROWTH HORMONE DEFICIENCY (GHD), IDIOPATHIC SHORT STATURE (ISS), SMALL FOR GESTATIONAL AGE (SGA), SHORT STATURE HOMEOBOX-CONTAINING GENE (SHOX) DEFICIENCY: HEIGHT AT LEAST 2 STANDARD DEVIATIONS BELOW THE MEAN HEIGHT FOR CHILDREN OF THE SAME AGE AND GENDER. TURNER SYNDROME (TS): CONFIRMED BY CHROMOSOMAL ANALYSIS (KARYOTYPING). ADULT GHD: 1) HAS A CONGENITAL, GENETIC, OR ORGANIC DISEASE (E.G.,

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	CRANIOPHARYNGIOMA, PITUITARY HYPOPLASIA, ECTOPIC POSTERIOR PITUITARY, PREVIOUS CRANIAL IRRADIATION), OR 2) GHD CONFIRMED BY ONE OF THE FOLLOWING GROWTH HORMONE (GH) STIMULATION TESTS: (A) INSULIN TOLERANCE TEST (PEAK GH OF 5 NG/ML OR LESS), (B) GLUCAGON-STIMULATION TEST (ONE OF THE FOLLOWING: (I) PEAK RESPONSE OF 3 NG/ML OR LESS AND BMI LESS THAN 25 KG/M2, (II) PEAK RESPONSE OF 3 NG/ML OR LESS AND BMI IS BETWEEN 25 - 30 KG/M2 WITH A PRE-TEST PROBABILITY, (III) PEAK RESPONSE OF 1 NG/ML OR LESS AND BMI IS BETWEEN 25 - 30 KG/M2 WITH LOW TEST PROBABILITY, OR (IV) PEAK RESPONSE OF 1 NG/ML OR LESS AND BMI IS GREATER THAN 30 KG/M2), OR (C) MACIMORELIN TEST (PEAK GH OF 2.8 NG/ML OR LESS).
Age Restrictions	SGA: 2 YEARS OF AGE OR OLDER.
Prescriber Restrictions	INITIAL/RENEWAL: ALL INDICATIONS: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT: NORDITROPIN, WHERE INDICATIONS ALIGN. PEDIATRIC GHD, ISS, SGA, TS, SHOX DEFICIENCY: OPEN EPIPHYSES AS CONFIRMED BY RADIOGRAPH OF THE WRIST AND HAND. INITIAL/RENEWAL: ADULT GHD, PEDIATRIC GHD, SGA, TS, SHOX DEFICIENCY: NO CONCURRENT USE WITH INCRELEX. RENEWAL: ISS: 1) IMPROVEMENT WHILE ON THERAPY (INCREASED HEIGHT OR INCREASED GROWTH VELOCITY), AND 2) OPEN EPIPHYSES AS CONFIRMED BY RADIOGRAPH OF THE WRIST AND HAND. PEDIATRIC GHD, SGA, TS, SHOX DEFICIENCY: 1) IMPROVEMENT WHILE ON THERAPY (INCREASED HEIGHT OR INCREASED GROWTH VELOCITY), AND 2) OPEN EPIPHYSES AS CONFIRMED BY RADIOGRAPH OF THE WRIST AND HAND OR HAS NOT COMPLETED PREPUBERTAL GROWTH.

Created: 07/22
Effective: 02/01/26 Client Approval: 01/26 P&T Approval: 04/25

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOMATROPIN - NORDITROPIN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOMATROPIN	NORDITROPIN FLEXPRO	02824		GPI-10 (3010002000)	BRAND = NORDITROPIN FLEXPRO

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, continue to #2.

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SOMATROPIN - NORDITROPIN (PART D)

INITIAL CRITERIA (CONTINUED)

2. Is the request for a pediatric patient with a diagnosis of growth failure due to inadequate secretion of endogenous growth hormone (GH) (ICD-10 Group E34.3), and does the patient meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   - The patient has open epiphyses (as confirmed by radiograph of the wrist and hand)
   - Norditropin Flexpro will NOT be used concurrently with Increlex (mecasermin)

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Does the patient have a diagnosis of short stature associated with Noonan syndrome (ICD-10 Q87.19) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   - The patient has open epiphyses (as confirmed by radiograph of the wrist and hand)
   - Norditropin Flexpro will NOT be used concurrently with Increlex (mecasermin)

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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SOMATROPIN - NORDITROPIN (PART D)

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of short stature associated with Turner syndrome (ICD-10 Group Q96) and meet **ALL** of the following criteria?
   - The patient's diagnosis is confirmed by chromosomal analysis (karyotyping)
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has open epiphyses (as confirmed by radiograph of the wrist and hand)
   - Norditropin Flexpro will NOT be used concurrently with Increlex (mecasermin)

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Does the patient have a diagnosis of short stature born small for gestational age (SGA) (ICD-10 R62.52; Group P05.1) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   - The patient has open epiphyses (as confirmed by radiograph of the wrist and hand)
   - Norditropin Flexpro will NOT be used concurrently with Increlex (mecasermin)

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #6.

6. Does the patient have a diagnosis of idiopathic short stature (ISS) (ICD-10 R62.52) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   - The patient has open epiphyses (as confirmed by radiograph of the wrist and hand)

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #7.

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SOMATROPIN - NORDITROPIN (PART D)

INITIAL CRITERIA (CONTINUED)

7. Does the patient have a diagnosis of Prader-Willi syndrome (PWS) (ICD-10 Q87.11) and meet **ALL** of the following criteria?
- Therapy is prescribed by or in consultation with an endocrinologist
- The patient has a confirmed genetic diagnosis of PWS
- Norditropin Flexpro will NOT be used concurrently with Increlex (mecasermin)

If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #8.

8. Is the request for an adult patient with a diagnosis of growth hormone deficiency (GHD) (ICD-10 E23.0; Group E34.3), and does the patient meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with an endocrinologist
- Norditropin Flexpro will NOT be used concurrently with Increlex (mecasermin)

If yes, continue to #9.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

9. Does the patient have a congenital, genetic, or organic disease (e.g., craniopharyngioma [tumor], pituitary hypoplasia, ectopic posterior pituitary, previous cranial irradiation)?

If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #10.

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SOMATROPIN - NORDITROPIN (PART D)

INITIAL CRITERIA (CONTINUED)

10. Is the patient's diagnosis confirmed by **ONE** of the following growth hormone stimulation tests?
    - Insulin tolerance test (peak growth hormone of 5 ng/mL or less)
    - Glucagon-stimulation test (peak response of 3 ng/mL or less AND the patient's BMI is less than 25 kg/m2; OR peak response of 3 ng/mL or less AND the patient's BMI is between 25 and 30 kg/m2 with a high pre-test probability; OR peak response of 1 ng/mL or less AND the patient's BMI is between 25 and 30 kg/m2 with a low test probability; OR peak response of 1 ng/mL or less AND the patient's BMI is greater than 30 kg/m2)
    - Macimorelin test (peak growth hormone of 2.8 ng/mL or less)

    If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
    APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

    If no, do not approve.

    INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

    Our guideline named **SOMATROPIN - NORDITROPIN** requires the following rule(s) be met for approval:

    A. You meet ONE of the following:
        1. You are a pediatric patient with growth failure due to inadequate secretion (release) of endogenous (produced inside the body) growth hormone (GH)
        2. You have short stature associated with Noonan syndrome (type of genetic disorder)
        3. You have short stature associated with Turner syndrome (type of genetic disorder)
        4. You have short stature born small for gestational age (SGA: birth weight is lower than expected for the number of weeks of pregnancy)
        5. You have idiopathic short stature (ISS: short height due to unknown cause)
        6. You have Prader-Willi syndrome (PWS: type of genetic disorder)
        7. You are an adult patient with growth hormone deficiency (GHD: type of hormone disorder with low growth hormone)

    (Initial denial text continued on the next page)

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SOMATROPIN - NORDITROPIN (PART D)

INITIAL CRITERIA (CONTINUED)

B. If you are a pediatric patient with growth failure due to inadequate secretion of endogenous growth hormone, approval also requires:
1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
2. Your height is at least 2 standard deviations (SD: a measure of variation from the average) below the mean (average) height for children of the same age and gender
3. You have open epiphyses (end part of long bone) as confirmed by radiograph (a type of imaging test) of the wrist and hand
4. You will NOT use Norditropin Flexpro concurrently (at the same time) with Increlex (mecasermin)

C. If you have idiopathic short stature, approval also requires:
1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
2. Your height is at least 2 standard deviations (SD: a measure of variation from the average) below the mean (average) height for children of the same age and gender
3. You have open epiphyses (end part of long bone) as confirmed by radiograph (a type of imaging test) of the wrist and hand

D. If you have short stature associated with Noonan syndrome, approval also requires:
1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
2. Your height is at least 2 standard deviations (SD: a measure of variation from the average) below the mean (average) height for children of the same age and gender
3. You have open epiphyses (end part of long bone) as confirmed by radiograph (a type of imaging test) of the wrist and hand
4. You will NOT use Norditropin Flexpro concurrently (at the same time) with Increlex (mecasermin)

E. If you have Turner syndrome, approval also requires:
1. Your diagnosis is confirmed by chromosomal analysis (karyotyping: a lab test used to examine your genetic information)
2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
3. You have open epiphyses (end part of long bone) as confirmed by radiograph (a type of imaging test) of the wrist and hand
4. You will NOT use Norditropin Flexpro concurrently (at the same time) with Increlex (mecasermin)

(Initial denial text continued on the next page)

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SOMATROPIN - NORDITROPIN (PART D)

INITIAL CRITERIA (CONTINUED)

F. If you have short stature born small for gestational age, approval also requires:
1. You are 2 years of age or older
2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
3. Your height is at least 2 standard deviations (SD: a measure of variation from the average) below the mean (average) height for children of the same age and gender
4. You have open epiphyses (end part of long bone) as confirmed by radiograph (a type of imaging test) of the wrist and hand
5. You will NOT use Norditropin Flexpro concurrently (at the same time) with Increlex (mecasermin)

G. If you have Prader-Willi syndrome, approval also requires:
1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
2. You have a confirmed genetic diagnosis of Prader-Willi syndrome
3. You will NOT use Norditropin Flexpro concurrently (at the same time) with Increlex (mecasermin)

H. If you are an adult patient with growth hormone deficiency, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
3. You will NOT use Norditropin Flexpro concurrently (at the same time) with Increlex (mecasermin)
4. You meet ONE of the following:
   a. You have congenital (at birth), genetic, or organic disease (such as craniopharyngioma [tumor], pituitary hypoplasia [a type of brain condition], ectopic posterior pituitary [a type of brain condition], previous cranial irradiation [radiation to the brain])
   b. Your diagnosis is confirmed by ONE of the following growth hormone stimulation tests:
      i. Insulin tolerance test (peak growth hormone of 5 ng/mL or less)
      ii. Glucagon-stimulation test (peak response of 3 ng/mL or less AND your body mass index [BMI: a tool for evaluating body fat] is less than 25 kg/m2 OR peak response of 3 ng/mL or less AND your BMI is between 25 and 30 kg/m2 with a high pre-test probability OR peak response of 1 ng/mL or less AND your BMI is between 25 and 30 kg/m2 with a low test probability OR peak response of 1 ng/mL or less AND your BMI is greater than 30 kg/m2)
      iii. Macimorelin test (peak growth hormone of 2.8 ng/mL or less)

I. Request for Norditropin Flexpro will NOT be approved for athletic enhancement (to perform better in sports) or anti-aging purposes.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOMATROPIN - NORDITROPIN (PART D)

RENEWAL CRITERIA

1. Is the request for **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, continue to #2.

2. Is the request for a pediatric patient with a diagnosis of growth failure due to inadequate secretion of endogenous growth hormone (GH) (ICD-10 Group E34.3), and does the patient meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has open epiphyses (as confirmed by radiograph of the wrist and hand ORthe patient has not completed prepubertal growth)
   - The patient has shown improvement (increased height or increased growth velocity)
   - Norditropin Flexpro will NOT be used concurrently with Increlex (mecasermin)

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Does the patient have a diagnosis of Idiopathic short stature (ISS) (ICD-10 R62.52) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has open epiphyses (as confirmed by radiograph of the wrist and hand)
   - The patient has shown improvement (increased height or increased growth velocity)

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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SOMATROPIN - NORDITROPIN (PART D)

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have **ONE** of the following diagnoses?
   - Short stature associated with Noonan syndrome (ICD-10 Q87.19)
   - Short stature associated with Turner syndrome (ICD-10 Group Q96)
   - Short stature born small for gestational age (SGA) (ICD-10 R62.52; Group P05.1)

   If yes, continue to #5.
   If no, continue to #6.

5. Does the patient meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has open epiphyses (as confirmed by radiograph of the wrist and hand OR the patient has not completed prepubertal growth)
   - The patient has shown improvement (increased height or increased growth velocity)
   - Norditropin Flexpro will NOT be used concurrently with Increlex (mecasermin)

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

6. Does the patient have a diagnosis of Prader-Willi syndrome (PWS) (ICD-10 Q87.11) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has shown improvement in body composition
   - Norditropin Flexpro will NOT be used concurrently with Increlex (mecasermin)

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #7.

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SOMATROPIN - NORDITROPIN (PART D)

RENEWAL CRITERIA (CONTINUED)

7. Is the request for an adult patient with a diagnosis of growth hormone deficiency (GHD) (ICD-10 E23.0; Group E34.3), and does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist
   - Norditropin Flexpro will NOT be used concurrently with Increlex (mecasermin)

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOMATROPIN - NORDITROPIN** requires the following rule(s) be met for renewal:

   A. You meet ONE of the following:
      1. You are a pediatric patient with growth failure due to inadequate secretion (release) of endogenous (produced inside the body) growth hormone (GH)
      2. You have short stature associated with Noonan syndrome (type of genetic disorder)
      3. You have short stature associated with Turner syndrome (type of genetic disorder)
      4. You have short stature born small for gestational age (SGA: birth weight is lower than expected for the number of weeks of pregnancy)
      5. You have idiopathic short stature (ISS: short height due to unknown cause)
      6. You have Prader-Willi syndrome (PWS: type of genetic disorder)
      7. You are an adult patient with growth hormone deficiency (GHD: type of hormone disorder with low growth hormone)

   B. If you are a pediatric patient with growth failure due to inadequate secretion of endogenous growth hormone, renewal also requires:
      1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
      2. You have open epiphyses (end part of long bone) as confirmed by radiograph (type of imaging test) of the wrist and hand OR you have not completed prepubertal growth
      3. You have experienced improvement (increased height or increased growth velocity [rate]) on therapy
      4. You will NOT use Norditropin Flexpro concurrently (at the same time) with Increlex (mecasermin)

   (Renewal denial text continued on the next page)

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SOMATROPIN - NORDITROPIN (PART D)

RENEWAL CRITERIA (CONTINUED)

C. If you have idiopathic short stature, renewal also requires:
1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
2. You have open epiphyses (end part of long bone) as confirmed by radiograph (type of imaging test) of the wrist and hand
3. You have experienced improvement (increased height or increased growth velocity [rate]) on therapy

D. If you have short stature associated with Noonan syndrome, short stature associated with Turner syndrome, or short stature born small for gestational age, renewal also requires:
1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
2. You have open epiphyses (end part of long bone) as confirmed by radiograph (type of imaging test) of the wrist and hand OR you have not completed prepubertal growth
3. You have experienced improvement (increased height or increased growth velocity [rate]) on therapy
4. You will NOT use Norditropin Flexpro concurrently (at the same time) with Increlex (mecasermin)

E. If you have Prader-Willi syndrome, renewal also requires:
1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
2. You have experienced improvement in body composition
3. You will NOT use Norditropin Flexpro concurrently (at the same time) with Increlex (mecasermin)

F. If you are an adult patient with growth hormone deficiency, renewal also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
3. You will NOT use Norditropin Flexpro concurrently (at the same time) with Increlex (mecasermin)

G. Request for Norditropin Flexpro will NOT be approved for athletic enhancement (to perform better in sports) or anti-aging purposes.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Norditropin.

REFERENCES
Norditropin [Prescribing Information]. Plainsboro, NJ: Novo Nordisk, Inc.; July 2025.

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SOMATROPIN - NORDITROPIN (PART D)

For Part D use only:

SOMATROPIN - NORDITROPIN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	INITIAL/RENEWAL: ATHLETIC ENHANCEMENT, ANTI-AGING PURPOSES.
Required Medical Information	INITIAL: PEDIATRIC GROWTH HORMONE DEFICIENCY (GHD), IDIOPATHIC SHORT STATURE (ISS), SMALL FOR GESTATIONAL AGE (SGA), NOONAN SYNDROME: HEIGHT AT LEAST 2 STANDARD DEVIATIONS BELOW THE MEAN HEIGHT FOR CHILDREN OF THE SAME AGE AND GENDER. TURNER SYNDROME (TS): CONFIRMED BY CHROMOSOMAL ANALYSIS (KARYOTYPING). PRADER WILLI SYNDROME (PWS): CONFIRMED GENETIC DIAGNOSIS OF PWS. ADULT GHD: 1) HAS A CONGENITAL, GENETIC, OR ORGANIC DISEASE (E.G., CRANIOPHARYNGIOMA, PITUITARY HYPOPLASIA, ECTOPIC POSTERIOR PITUITARY, PREVIOUS CRANIAL IRRADIATION), OR 2) GHD CONFIRMED BY ONE OF THE FOLLOWING GROWTH HORMONE (GH) STIMULATION TESTS: (A) INSULIN TOLERANCE TEST (PEAK GH OF 5 NG/ML OR LESS), (B) GLUCAGON-STIMULATION TEST (ONE OF THE FOLLOWING: (I) PEAK RESPONSE OF 3 NG/ML OR LESS AND BMI LESS THAN 25 KG/M2, (II) PEAK RESPONSE OF 3 NG/ML OR LESS AND BMI IS BETWEEN 25 - 30 KG/M2 WITH A PRE-TEST PROBABILITY, (III) PEAK RESPONSE OF 1 NG/ML OR LESS AND BMI IS BETWEEN 25 - 30 KG/M2 WITH LOW TEST PROBABILITY, OR (IV) PEAK RESPONSE OF 1 NG/ML OR LESS AND BMI IS GREATER THAN 30 KG/M2), OR (C) MACIMORELIN TEST (PEAK GH OF 2.8 NG/ML OR LESS).
Age Restrictions	SGA: 2 YEARS OF AGE OR OLDER.
Prescriber Restrictions	INITIAL/RENEWAL: ALL INDICATIONS: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: PEDIATRIC GHD, ISS, SGA, TS, NOONAN SYNDROME: OPEN EPIPHYSES AS CONFIRMED BY RADIOGRAPH OF THE WRIST AND HAND. INITIAL/RENEWAL: ADULT GHD, PEDIATRIC GHD, SGA, TS, PWS, NOONAN SYNDROME: NO CONCURRENT USE WITH INCRELEX. RENEWAL: ISS: 1) IMPROVEMENT WHILE ON THERAPY (INCREASED HEIGHT OR INCREASED GROWTH VELOCITY), AND 2) OPEN EPIPHYSES AS CONFIRMED BY RADIOGRAPH OF THE WRIST AND HAND. PEDIATRIC GHD, SGA, TS, NOONAN SYNDROME: 1) IMPROVEMENT WHILE ON THERAPY (INCREASED HEIGHT OR INCREASED GROWTH VELOCITY), AND 2) OPEN EPIPHYSES AS CONFIRMED BY

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	RADIOGRAPH OF THE WRIST AND HAND OR HAS NOT COMPLETED PREPUBERTAL GROWTH. PWS: IMPROVEMENT IN BODY COMPOSITION.

Created: 07/22
Effective: 02/01/26 Client Approval: 01/26 P&T Approval: 04/25

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOMATROPIN - NUTROPIN AQ (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOMATROPIN	NUTROPIN AQ NUSPIN	02824		GPI-10 (3010002000)	BRAND = NUTROPIN AQ NUSPIN%

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, continue to #2.

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SOMATROPIN - NUTROPIN AQ (PART D)

INITIAL CRITERIA (CONTINUED)

2. Is the request for a pediatric patient with a diagnosis of growth failure due to inadequate secretion of endogenous growth hormone (GH) (ICD-10 Group E34.3), and does the patient meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   - The patient has open epiphyses (as confirmed by radiograph of the wrist and hand)
   - Nutropin AQ will NOT be used concurrently with Increlex (mecasermin)
   - The patient had a trial of or contraindication to the preferred agent: Norditropin

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Does the patient have a diagnosis of growth failure secondary to chronic kidney disease (CKD) (ICD-10 R62.52; Group N18) and meet **ALL** of the following criteria?
   - The request is for a pediatric patient
   - Therapy is prescribed by or in consultation with an endocrinologist or nephrologist
   - The patient has not had a renal transplant OR it has been at least one year since the patient's renal transplant
   - The patient has persistent growth failure (height below the tenth percentile) and has persistent low height velocity (height velocity below the twenty-fifth percentile)
   - Nutropin AQ will NOT be used concurrently with Increlex (mecasermin)

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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SOMATROPIN - NUTROPIN AQ (PART D)

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of idiopathic short stature (ISS) (ICD-10 R62.52) and meet **ALL** of the following criteria?
- Therapy is prescribed by or in consultation with an endocrinologist
- The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
- The patient has open epiphyses (as confirmed by radiograph of the wrist and hand)
- The patient had a trial of or contraindication to the preferred agent: Norditropin

If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #5.

5. Does the patient have a diagnosis of short stature associated with Turner syndrome (ICD-10 Group Q96) and meet **ALL** of the following criteria?
- The patient's diagnosis is confirmed by chromosomal analysis (karyotyping)
- Therapy is prescribed by or in consultation with an endocrinologist
- The patient has open epiphyses (as confirmed by radiograph of the wrist and hand)
- Nutropin AQ will NOT be used concurrently with Increlex (mecasermin)
- The patient had a trial of or contraindication to the preferred agent: Norditropin

If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #6.

6. Is the request for an adult patient with a diagnosis of growth hormone deficiency (GHD) (ICD-10 E23.0; Group E34.3), and does the patient meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with an endocrinologist
- Nutropin AQ will NOT be used concurrently with Increlex (mecasermin)
- The patient had a trial of or contraindication to the preferred agent: Norditropin

If yes, continue to #7.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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SOMATROPIN - NUTROPIN AQ (PART D)

INITIAL CRITERIA (CONTINUED)

7. Does the patient have a congenital, genetic, or organic disease (e.g., craniopharyngioma [tumor], pituitary hypoplasia, ectopic posterior pituitary, previous cranial irradiation)?

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #8.

8. Is the patient's diagnosis confirmed by **ONE** of the following growth hormone stimulation tests?
   - Insulin tolerance test (peak growth hormone of 5 ng/mL or less)
   - Glucagon-stimulation test (peak response of 3 ng/mL or less AND the patient's BMI is less than 25 kg/m2; OR peak response of 3 ng/mL or less AND the patient's BMI is between 25 and 30 kg/m2 with a high pre-test probability; OR peak response of 1 ng/mL or less AND the patient's BMI is between 25 and 30 kg/m2 with a low test probability; OR peak response of 1 ng/mL or less AND the patient's BMI is greater than 30 kg/m2)
   - Macimorelin test (peak growth hormone of 2.8 ng/mL or less)

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOMATROPIN - NUTROPIN AQ (Nutropin AQ Nuspin)** requires the following rule(s) be met for approval:
   A. You meet ONE of the following:
      1. You are a pediatric patient with growth failure due to inadequate secretion (release) of endogenous (produced inside the body) growth hormone (GH)
      2. You have growth failure secondary to chronic (long-term) kidney disease
      3. You have idiopathic short stature (short height due to unknown cause)
      4. You have short stature associated with Turner syndrome (type of genetic disorder)
      5. You are an adult patient with growth hormone deficiency (GHD: type of hormone disorder with low growth hormone)

   (Initial denial text continued on next page)

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SOMATROPIN - NUTROPIN AQ (PART D)

INITIAL CRITERIA (CONTINUED)

B. If you are a pediatric patient with growth failure due to inadequate secretion of endogenous growth hormone, approval also requires:
1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
2. Your height is at least 2 standard deviations (a measure of variation from the average) below the mean (average) height for children of the same age and gender
3. You have open epiphyses (end part of long bone) as confirmed by radiograph (a type of imaging test) of the wrist and hand
4. You will NOT use Nutropin AQ concurrently (at the same time) with Increlex (mecasermin)
5. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Norditropin

C. If you have growth failure secondary to chronic kidney disease, approval also requires:
1. You are a pediatric patient
2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor) or a nephrologist (kidney doctor)
3. You have not had a renal (kidney) transplant OR it has been at least one year since your renal transplant
4. You have persistent growth failure (a height below the tenth percentile) and you have persistent low height velocity (height velocity below the twenty-fifth percentile)
5. You will NOT use Nutropin AQ concurrently (at the same time) with Increlex (mecasermin)

D. If you have idiopathic short stature, approval also requires:
1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
2. Your height is at least 2 standard deviations (a measure of variation from the average) below the mean (average) height for children of the same age and gender
3. You have open epiphyses (end part of long bone) as confirmed by radiograph (a type of imaging test) of the wrist and hand
4. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Norditropin

(Initial denial text continued on next page)

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SOMATROPIN - NUTROPIN AQ (PART D)

INITIAL CRITERIA (CONTINUED)

E. If you have short stature associated with Turner syndrome, approval also requires:
1. Your diagnosis is confirmed by chromosomal analysis (karyotyping: a lab test used to examine your genetic information)
2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
3. You have open epiphyses (end part of long bone) as confirmed by radiograph (a type of imaging test) of the wrist and hand
4. You will NOT use Nutropin AQ concurrently (at the same time) with Increlex (mecasermin)
5. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Norditropin

F. If you are an adult patient with growth hormone deficiency, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
3. You will NOT use Nutropin AQ concurrently (at the same time) with Increlex (mecasermin)
4. You meet ONE of the following:
   a. You have congenital (at birth), genetic, or organic disease (such as craniopharyngioma [tumor], pituitary hypoplasia [a type of brain condition], ectopic posterior pituitary [a type of brain condition], previous cranial irradiation [radiation to the brain])
   b. Your diagnosis is confirmed by ONE of the following growth hormone stimulation tests:
      i. Insulin tolerance test (peak growth hormone of 5 ng/mL or less)
      ii. Glucagon-stimulation test (peak response of 3 ng/mL or less AND your body mass index [BMI: a tool for evaluating body fat] is less than 25 kg/m2 OR peak response of 3 ng/mL or less AND your BMI is between 25 and 30 kg/m2 with a high pre-test probability OR peak response of 1 ng/mL or less AND your BMI is between 25 and 30 kg/m2 with a low test probability OR peak response of 1 ng/mL or less AND your BMI is greater than 30 kg/m2)
      iii. Macimorelin test (peak growth hormone of 2.8 ng/mL or less)
5. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Norditropin

G. Request for Nutropin AQ Nuspin will NOT be approved for athletic enhancement (to perform better in sports) or anti-aging purposes.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOMATROPIN - NUTROPIN AQ (PART D)

RENEWAL CRITERIA

1. Is the request for **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, continue to #2.

2. Is the request for a pediatric patient with a diagnosis of growth failure due to inadequate secretion of endogenous growth hormone (GH) (ICD-10 Group E34.3), and does the patient meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has open epiphyses (as confirmed by radiograph of the wrist and hand ORthe patient has not completed prepubertal growth)
   - The patient has shown improvement (increased height or increased growth velocity)
   - Nutropin AQ will NOT be used concurrently with Increlex (mecasermin)

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Does the patient have a diagnosis of growth failure secondary to chronic kidney disease (CKD) (ICD-10 R62.52; Group N18) and meet **ALL** of the following criteria?
   - The request is for a pediatric patient
   - Therapy is prescribed by or in consultation with an endocrinologist or nephrologist
   - The patient has not had a renal transplant within the past year
   - The patient has shown improvement (increased height or increased growth velocity)
   - The patient has open epiphyses (as confirmed by radiograph of the wrist and hand ORthe patient has not completed prepubertal growth)
   - Nutropin AQ will NOT be used concurrently with Increlex (mecasermin)

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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SOMATROPIN - NUTROPIN AQ (PART D)

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of idiopathic short stature (ISS) (ICD-10 R62.52) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has open epiphyses (as confirmed by radiograph of the wrist and hand)
   - The patient has shown improvement (increased height or increased growth velocity)

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Does the patient have a diagnosis of short stature associated with Turner syndrome (ICD-10 Group Q96) meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has open epiphyses (as confirmed by radiograph of the wrist and hand OR the patient has not completed prepubertal growth)
   - The patient has shown improvement (increased height or increased growth velocity)
   - Nutropin AQ will NOT be used concurrently with Increlex (mecasermin)

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #6.

6. Is the request for an adult patient with a diagnosis of growth hormone deficiency (GHD) (ICD-10 E23.0; Group E34.3), and does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist
   - Nutropin AQ will NOT be used concurrently with Increlex (mecasermin)

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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SOMATROPIN - NUTROPIN AQ (PART D)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOMATROPIN - NUTROPIN AQ (Nutropin AQ Nuspin)** requires the following rule(s) be met for renewal:

A. You meet ONE of the following:
   1. You are a pediatric patient with growth failure due to inadequate secretion (release) of endogenous (produced inside the body) growth hormone (GH)
   2. You have growth failure secondary to chronic (long-term) kidney disease
   3. You have idiopathic short stature (short height due to unknown cause)
   4. You have short stature associated with Turner syndrome (type of genetic disorder)
   5. You are an adult patient with growth hormone deficiency (GHD: type of hormone disorder with low growth hormone)

B. If you are a pediatric patient with growth failure due to inadequate secretion of endogenous growth hormone, renewal also requires:
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You have open epiphyses (end part of long bone) as confirmed by radiograph (type of imaging test) of the wrist and hand OR you have not completed prepubertal growth
   3. You have experienced improvement (increased height or increased growth velocity [rate]) on therapy
   4. You will NOT use Nutropin AQ concurrently (at the same time) with Increlex (mecasermin)

C. If you have growth failure secondary to chronic kidney disease, renewal also requires:
   1. You are a pediatric patient
   2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor) or a nephrologist (kidney doctor)
   3. You have not had a renal (kidney) transplant within the past year
   4. You have open epiphyses (end part of long bone) as confirmed by radiograph (type of imaging test) of the wrist and hand OR you have not completed prepubertal growth
   5. You have experienced improvement (increased height or increased growth velocity [rate]) on therapy
   6. You will NOT use Nutropin AQ concurrently (at the same time) with Increlex (mecasermin)

(Renewal denial text continued on next page)

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SOMATROPIN - NUTROPIN AQ (PART D)

RENEWAL CRITERIA (CONTINUED)

D. If you have idiopathic short stature, renewal also requires:
1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
2. You have open epiphyses (end part of long bone) as confirmed by radiograph (type of imaging test) of the wrist and hand
3. You have experienced improvement (increased height or increased growth velocity [rate]) on therapy

E. If you have short stature associated with Turner syndrome, renewal also requires:
1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
2. You have open epiphyses (end part of long bone) as confirmed by radiograph (type of imaging test) of the wrist and hand OR you have not completed prepubertal growth
3. You have experienced improvement (increased height or increased growth velocity [rate]) on therapy
4. You will NOT use Nutropin AQ concurrently (at the same time) with Increlex (mecasermin)

F. If you are an adult patient with growth hormone deficiency, renewal also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
3. You will NOT use Nutropin AQ concurrently (at the same time) with Increlex (mecasermin)

G. Request for Nutropin AQ Nuspin will NOT be approved for athletic enhancement (to perform better in sports) or anti-aging.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nutropin AQ Nuspin.

REFERENCES

Nutropin AQ Nuspin [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; July 2025.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOMATROPIN - NUTROPIN AQ (PART D)

For Part D use only:

SOMATROPIN - NUTROPIN AQ (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	INITIAL/RENEWAL: ATHLETIC ENHANCEMENT, ANTI-AGING PURPOSES.
Required Medical Information	INITIAL: PEDIATRIC GROWTH HORMONE DEFICIENCY (GHD), IDIOPATHIC SHORT STATURE (ISS): HEIGHT AT LEAST 2 STANDARD DEVIATIONS (SD) BELOW THE MEAN HEIGHT FOR CHILDREN OF THE SAME AGE AND GENDER. GROWTH FAILURE DUE TO CHRONIC KIDNEY DISEASE (CKD): PERSISTENT GROWTH FAILURE (HEIGHT BELOW THE TENTH PERCENTILE) AND PERSISTENT LOW HEIGHT VELOCITY (HEIGHT VELOCITY BELOW THE TWENTY-FIFTH PERCENTILE). TURNER SYNDROME (TS): CONFIRMED BY CHROMOSOMAL ANALYSIS (KARYOTYPING). ADULT GHD: 1) HAS A CONGENITAL, GENETIC, OR ORGANIC DISEASE (E.G., CRANIOPHARYNGIOMA, PITUITARY HYPOPLASIA, ECTOPIC POSTERIOR PITUITARY, PREVIOUS CRANIAL IRRADIATION), OR 2) GHD CONFIRMED BY ONE OF THE FOLLOWING GROWTH HORMONE (GH) STIMULATION TESTS: (A) INSULIN TOLERANCE TEST (PEAK GH OF 5 NG/ML OR LESS), (B) GLUCAGON-STIMULATION TEST (ONE OF THE FOLLOWING: (I) PEAK RESPONSE OF 3 NG/ML OR LESS AND BMI LESS THAN 25 KG/M2, (II) PEAK RESPONSE OF 3 NG/ML OR LESS AND BMI IS BETWEEN 25 - 30 KG/M2 WITH A PRE-TEST PROBABILITY, (III) PEAK RESPONSE OF 1 NG/ML OR LESS AND BMI IS BETWEEN 25 - 30 KG/M2 WITH LOW TEST PROBABILITY, OR (IV) PEAK RESPONSE OF 1 NG/ML OR LESS AND BMI IS GREATER THAN 30 KG/M2), OR (C) MACIMORELIN TEST (PEAK GH OF 2.8 NG/ML OR LESS).
Age Restrictions	N/A
Prescriber Restrictions	INITIAL/RENEWAL: PEDIATRIC GHD, ISS, TS, ADULT GHD: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST. GROWTH FAILURE DUE TO CKD: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST OR NEPHROLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT: NORDITROPIN, WHERE INDICATIONS ALIGN. PEDIATRIC GHD, ISS, TS: OPEN EPIPHYSES AS CONFIRMED BY RADIOGRAPH OF THE WRIST AND HAND. GROWTH FAILURE DUE TO CKD: NO RENAL TRANSPLANT OR AT LEAST ONE YEAR SINCE RENAL TRANSPLANT. INITIAL/RENEWAL: ADULT GHD, PEDIATRIC GHD, TS,

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	GROWTH FAILURE DUE TO CKD: NO CONCURRENT USE WITH INCRELEX. RENEWAL: ISS: 1) IMPROVEMENT WHILE ON THERAPY (INCREASED HEIGHT OR INCREASED GROWTH VELOCITY), AND 2) OPEN EPIPHYSES AS CONFIRMED BY RADIOGRAPH OF THE WRIST AND HAND. PEDIATRIC GHD, TS: 1) IMPROVEMENT WHILE ON THERAPY (INCREASED HEIGHT OR INCREASED GROWTH VELOCITY), AND 2) OPEN EPIPHYSES AS CONFIRMED BY RADIOGRAPH OF THE WRIST AND HAND OR HAS NOT COMPLETED PREPUBERTAL GROWTH. GROWTH FAILURE DUE TO CKD: 1) IMPROVEMENT WHILE ON THERAPY (INCREASED HEIGHT OR INCREASED GROWTH VELOCITY), 2) OPEN EPIPHYSES AS CONFIRMED BY RADIOGRAPH OF THE WRIST AND HAND OR HAS NOT COMPLETED PREPUBERTAL GROWTH, AND 3) NO RENAL TRANSPLANT WITHIN THE PAST YEAR.

Created: 07/22
Effective: 02/01/26 Client Approval: 01/26 P&T Approval: 04/25

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOMATROPIN - OMNITROPE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOMATROPIN	OMNITROPE	02824		GPI-10 (3010002000)	BRAND = OMNITROPE

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, continue to #2.

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SOMATROPIN - OMNITROPE (PART D)

INITIAL CRITERIA (CONTINUED)

2. Is the request for a pediatric patient with a diagnosis of growth failure due to inadequate secretion of endogenous growth hormone (GH) (ICD-10 Group E34.3), and does the patient meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   - The patient has open epiphyses (as confirmed by radiograph of the wrist and hand)
   - Omnitrope will NOT be used concurrently with Increlex (mecasermin)
   - The patient had a trial of or contraindication to the preferred agent: Norditropin

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Does the patient have a diagnosis of Prader-Willi syndrome (PWS) (ICD-10 Q87.11) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has a confirmed genetic diagnosis of PWS
   - Omnitrope will NOT be used concurrently with Increlex (mecasermin)
   - The patient had a trial of or contraindication to the preferred agent: Norditropin

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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SOMATROPIN - OMNITROPE (PART D)

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of growth failure born small for gestational age (SGA) (ICD-10 R62.52; Group P05.1) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   - The patient has open epiphyses (as confirmed by radiograph of the wrist and hand)
   - Omnitrope will NOT be used concurrently with Increlex (mecasermin)
   - The patient had a trial of or contraindication to the preferred agent: Norditropin

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Does the patient have a diagnosis of growth failure associated with Turner syndrome (ICD-10 Group Q96) and meet **ALL** of the following criteria?
   - The patient's diagnosis is confirmed by chromosomal analysis (karyotyping)
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has open epiphyses (as confirmed by radiograph of the wrist and hand)
   - Omnitrope will NOT be used concurrently with Increlex (mecasermin)
   - The patient had a trial of or contraindication to the preferred agent: Norditropin

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #6.

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SOMATROPIN - OMNITROPE (PART D)

INITIAL CRITERIA (CONTINUED)

6. Does the patient have a diagnosis of idiopathic short stature (ISS) (ICD-10 R62.52) and meet **ALL** of the following criteria?
- Therapy is prescribed by or in consultation with an endocrinologist
- The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
- The patient has open epiphyses (as confirmed by radiograph of the wrist and hand)
- The patient had a trial of or contraindication to the preferred agent: Norditropin

If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #7.

7. Is the request for an adult patient with a diagnosis of growth hormone deficiency (GHD) (ICD-10 E23.0; Group E34.3), and does the patient meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with an endocrinologist
- Omnitrope will NOT be used concurrently with Increlex (mecasermin)
- The patient had a trial of or contraindication to the preferred agent: Norditropin

If yes, continue to #8.
If no, do not approve.
DENIAL TEXT: See the initial denial text on the next page.

8. Does the patient have a congenital, genetic, or organic disease (e.g., craniopharyngioma [tumor], pituitary hypoplasia, ectopic posterior pituitary, previous cranial irradiation)?

If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #9.

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SOMATROPIN - OMNITROPE (PART D)

INITIAL CRITERIA (CONTINUED)

9. Is the patient's diagnosis confirmed by **ONE** of the following growth hormone stimulation tests?
   - Insulin tolerance test (peak growth hormone of 5 ng/mL or less)
   - Glucagon-stimulation test (peak response of 3 ng/mL or less AND the patient's BMI is less than 25 kg/m2; OR peak response of 3 ng/mL or less AND the patient's BMI is between 25 and 30 kg/m2 with a high pre-test probability; OR peak response of 1 ng/mL or less AND the patient's BMI is between 25 and 30 kg/m2 with a low test probability; OR peak response of 1 ng/mL or less AND the patient's BMI is greater than 30 kg/m2)
   - Macimorelin test (peak growth hormone of 2.8 ng/mL or less)

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOMATROPIN - OMNITROPE** requires the following rule(s) be met for approval:
   A. You meet ONE of the following:
      1. You are a pediatric patient with growth failure due to inadequate secretion (release) of endogenous (produced inside the body) growth hormone (GH)
      2. You have Prader-Willi syndrome (PWS: type of genetic disorder)
      3. You have growth failure born small for gestational age (SGA: birth weight is lower than expected for the number of weeks of pregnancy)
      4. You have growth failure associated with Turner syndrome (type of genetic disorder)
      5. You have idiopathic short stature (ISS: short height due to unknown cause)
      6. You are an adult patient with growth hormone deficiency (GHD: type of hormone disorder with low growth hormone)

   (Initial denial text continued on next page)

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SOMATROPIN - OMNITROPE (PART D)

INITIAL CRITERIA (CONTINUED)

B. If you are a pediatric patient with growth failure due to inadequate secretion of endogenous growth hormone, approval also requires:
1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
2. Your height is at least 2 standard deviations (SD: a measure of variation from the average) below the mean (average) height for children of the same age and gender
3. You have open epiphyses (end part of long bone) as confirmed by radiograph (a type of imaging test) of the wrist and hand
4. You will NOT use Omnitrope concurrently (at the same time) with Increlex (mecasermin)
5. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Norditropin

C. If you have Prader-Willi syndrome, approval also requires:
1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
2. You have a confirmed genetic diagnosis of Prader-Willi syndrome
3. You will NOT use Omnitrope concurrently (at the same time) with Increlex (mecasermin)
4. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Norditropin

D. If you have growth failure born small for gestational age, approval also requires:
1. You are 2 years of age or older
2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
3. Your height is at least 2 standard deviations (SD: a measure of variation from the average) below the mean (average) height for children of the same age and gender
4. You have open epiphyses (end part of long bone) as confirmed by radiograph (a type of imaging test) of the wrist and hand
5. You will NOT use Omnitrope concurrently (at the same time) with Increlex (mecasermin)
6. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Norditropin

E. If you have growth failure associated with Turner syndrome, approval also requires:
1. Your diagnosis is confirmed by chromosomal analysis (karyotyping: a lab test used to examine your genetic information)
2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
3. You have open epiphyses (end part of long bone) as confirmed by radiograph (a type of imaging test) of the wrist and hand
4. You will NOT use Omnitrope concurrently (at the same time) with Increlex (mecasermin)
5. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Norditropin

(Initial denial text continued on next page)

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SOMATROPIN - OMNITROPE (PART D)

INITIAL CRITERIA (CONTINUED)

F. If you have idiopathic short stature, approval also requires:
1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
2. Your height is at least 2 standard deviations (SD: a measure of variation from the average) below the mean (average) height for children of the same age and gender
3. You have open epiphyses (end part of long bone) as confirmed by radiograph (a type of imaging test) of the wrist and hand
4. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Norditropin

G. If you are an adult patient with growth hormone deficiency, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
3. You will NOT use Omnitrope concurrently (at the same time) with Increlex (mecasermin)
4. You meet ONE of the following:
   a. You have congenital (at birth), genetic, or organic disease (such as craniopharyngioma [tumor], pituitary hypoplasia [a type of brain condition], ectopic posterior pituitary [a type of brain condition], previous cranial irradiation [radiation to the brain])
   b. Your diagnosis is confirmed by ONE of the following growth hormone stimulation tests:
      i. Insulin tolerance test (peak growth hormone of 5 ng/mL or less)
      ii. Glucagon-stimulation test (peak response of 3 ng/mL or less AND your body mass index [BMI: a tool for evaluating body fat] is less than 25 kg/m2 OR peak response of 3 ng/mL or less AND your BMI is between 25 and 30 kg/m2 with a high pre-test probability OR peak response of 1 ng/mL or less AND your BMI is between 25 and 30 kg/m2 with a low test probability OR peak response of 1 ng/mL or less AND your BMI is greater than 30 kg/m2)
      iii. Macimorelin test (peak growth hormone of 2.8 ng/mL or less)
5. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Norditropin

G. Request for Omnitrope will NOT be approved for athletic enhancement (to perform better in sports) or anti-aging purposes.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOMATROPIN - OMNITROPE (PART D)

RENEWAL CRITERIA

1. Is the request for **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, continue to #2.

2. Is the request for a pediatric patient with a diagnosis of growth failure due to inadequate secretion of endogenous growth hormone (GH) (ICD-10 Group E34.3), and does the patient meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has open epiphyses (as confirmed by radiograph of the wrist and hand ORthe patient has not completed prepubertal growth)
   - The patient has shown improvement (increased height or increased growth velocity)
   - Omnitrope will NOT be used concurrently with Increlex (mecasermin)

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Does the patient have a diagnosis of Prader-Willi syndrome (PWS) (ICD-10 Q87.11) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has shown improvement in body composition
   - Omnitrope will NOT be used concurrently with Increlex (mecasermin)

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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SOMATROPIN - OMNITROPE (PART D)

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of idiopathic short stature (ISS) (ICD-10 R62.52) and meet **ALL** of the following criteria?
- Therapy is prescribed by or in consultation with an endocrinologist
- The patient has open epiphyses (as confirmed by radiograph of the wrist and hand)
- The patient has shown improvement (increased height or increased growth velocity)

If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #5.

5. Does the patient have **ONE** of the following diagnoses?
- Growth failure born small for gestational age (SGA) (ICD-10 R62.52; Group P05.1)
- Growth failure associated with Turner syndrome (ICD-10 Group Q96)

If yes, continue to #6.
If no, continue to #7.

6. Does the patient meet **ALL** of the following criteria?
- Therapy is prescribed by or in consultation with an endocrinologist
- The patient has open epiphyses (as confirmed by radiograph of the wrist and hand)
- The patient has shown improvement (increased height or increased growth velocity OR the patient has not completed prepubertal growth)
- Omnitrope will NOT be used concurrently with Increlex (mecasermin)

If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.
DENIAL TEXT: See the renewal denial text at the end of the guideline.

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RENEWAL CRITERIA (CONTINUED)

7. Is the request for an adult patient with a diagnosis of growth hormone deficiency (GHD) (ICD-10 E23.0; Group E34.3), and does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist
   - Omnitrope will NOT be used concurrently with Increlex (mecasermin)

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOMATROPIN - OMNITROPE** requires the following rule(s) be met for renewal:

   A. You meet ONE of the following:
      1. You are a pediatric patient with growth failure due to an inadequate secretion (release) of endogenous (produced inside the body) growth hormone (GH)
      2. You have Prader-Willi syndrome (PWS: type of genetic disorder)
      3. You have growth failure born small for gestational age (SGA: birth weight is lower than expected for the number of weeks of pregnancy)
      4. You have growth failure associated with Turner syndrome (type of genetic disorder)
      5. You have idiopathic short stature (ISS: short height due to unknown cause)
      6. You are an adult patient with growth hormone deficiency (GHD: type of hormone disorder with low growth hormone)

   B. If you are a pediatric patient with growth failure due to inadequate secretion of endogenous growth hormone, renewal also requires:
      1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
      2. You have open epiphyses (end part of long bone) as confirmed by radiograph (type of imaging test) of the wrist and hand OR you have not completed prepubertal growth
      3. You have experienced improvement (increased height or increased growth velocity [rate]) on therapy
      4. You will not use Omnitrope concurrently (at the same time) with Increlex (mecasermin)

   (Renewal denial text continued on next page)

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SOMATROPIN - OMNITROPE (PART D)

RENEWAL CRITERIA (CONTINUED)

C. If you have Prader-Willi syndrome, renewal also requires:
1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
2. You have experienced improvement in body composition
3. You will not use Omnitrope concurrently (at the same time) with Increlex (mecasermin)

D. If you have idiopathic short stature, renewal also requires:
1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
2. You have open epiphyses (end part of long bone) as confirmed by radiograph (type of imaging test) of the wrist and hand
3. You have experienced improvement (increased height or increased growth velocity [rate]) on therapy

E. If you have growth failure born small for gestational age or growth failure associated with Turner syndrome, renewal also requires:
1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
2. You have open epiphyses (end part of long bone) as confirmed by radiograph (type of imaging test) of the wrist and hand
3. You have experienced improvement (increased height or increased growth velocity [rate] OR you have not completed prepubertal growth) on therapy
4. You will not use Omnitrope concurrently (at the same time) with Increlex (mecasermin)

E. If you are an adult patient with growth hormone deficiency, renewal also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
3. You will not use Omnitrope concurrently (at the same time) with Increlex (mecasermin)

F. Request for Omnitrope will NOT be approved for athletic enhancement (to perform better in sports) or anti-aging purposes.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Omnitrope.

REFERENCES

Omnitrope [Prescribing Information]. Princeton, NJ: Sandoz Inc.; July 2025.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOMATROPIN - OMNITROPE (PART D)

For Part D use only:

SOMATROPIN - OMNITROPE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	INITIAL/RENEWAL: ATHLETIC ENHANCEMENT, ANTI-AGING PURPOSES.
Required Medical Information	INITIAL: PEDIATRIC GROWTH HORMONE DEFICIENCY (GHD), IDIOPATHIC SHORT STATURE (ISS), SMALL FOR GESTATIONAL AGE (SGA): HEIGHT AT LEAST 2 STANDARD DEVIATIONS BELOW THE MEAN HEIGHT FOR CHILDREN OF THE SAME AGE AND GENDER. TURNER SYNDROME (TS): CONFIRMED BY CHROMOSOMAL ANALYSIS (KARYOTYPING). PRADER WILLI SYNDROME (PWS): CONFIRMED GENETIC DIAGNOSIS OF PWS. ADULT GHD: 1) HAS A CONGENITAL, GENETIC, OR ORGANIC DISEASE (E.G., CRANIOPHARYNGIOMA, PITUITARY HYPOPLASIA, ECTOPIC POSTERIOR PITUITARY, PREVIOUS CRANIAL IRRADIATION), OR 2) GHD CONFIRMED BY ONE OF THE FOLLOWING GROWTH HORMONE (GH) STIMULATION TESTS: (A) INSULIN TOLERANCE TEST (PEAK GH OF 5 NG/ML OR LESS), (B) GLUCAGON-STIMULATION TEST (ONE OF THE FOLLOWING: (I) PEAK RESPONSE OF 3 NG/ML OR LESS AND BMI LESS THAN 25 KG/M2, (II) PEAK RESPONSE OF 3 NG/ML OR LESS AND BMI IS BETWEEN 25 - 30 KG/M2 WITH A PRE-TEST PROBABILITY, (III) PEAK RESPONSE OF 1 NG/ML OR LESS AND BMI IS BETWEEN 25 - 30 KG/M2 WITH LOW TEST PROBABILITY, OR (IV) PEAK RESPONSE OF 1 NG/ML OR LESS AND BMI IS GREATER THAN 30 KG/M2), OR (C) MACIMORELIN TEST (PEAK GH OF 2.8 NG/ML OR LESS).
Age Restrictions	SGA: 2 YEARS OF AGE OR OLDER.
Prescriber Restrictions	INITIAL/RENEWAL: ALL INDICATIONS: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT: NORDITROPIN. PEDIATRIC GHD, ISS, SGA, TS: 1) OPEN EPIPHYSES AS CONFIRMED BY RADIOGRAPH OF THE WRIST AND HAND. INITIAL/RENEWAL: ADULT GHD, PEDIATRIC GHD, SGA, TS, PWS: NO CONCURRENT USE WITH INCRELEX. RENEWAL: ISS: 1) IMPROVEMENT WHILE ON THERAPY (INCREASED HEIGHT OR INCREASED GROWTH VELOCITY), AND 2) OPEN EPIPHYSES AS CONFIRMED BY RADIOGRAPH OF THE WRIST AND HAND. PEDIATRIC GHD, SGA, TS: 1) IMPROVEMENT WHILE ON THERAPY (INCREASED HEIGHT OR INCREASED GROWTH VELOCITY), AND 2) OPEN

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	EPIPHYSES AS CONFIRMED BY RADIOGRAPH OF THE WRIST AND HAND OR HAS NOT COMPLETED PREPUBERTAL GROWTH. PWS: IMPROVEMENT IN BODY COMPOSITION.

Created: 07/22
Effective: 02/01/26 Client Approval: 01/26 P&T Approval: 04/25

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOMATROPIN - SAIZEN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOMATROPIN	SAIZEN, SAIZEN-SAIZENPREP	02824		GPI-10 (3010002010)	BRAND = SAIZEN, SAIZEN - SAIZENPREP

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, continue to #2.

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SOMATROPIN - SAIZEN (PART D)

INITIAL CRITERIA (CONTINUED)

2. Is the request for a pediatric patient with a diagnosis of growth failure due to inadequate secretion of endogenous growth hormone (GH) (ICD-10 Group E34.3), and does the patient meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   - The patient has open epiphyses (as confirmed by radiograph of the wrist and hand)
   - The requested medication will NOT be used concurrently with Increlex (mecasermin)
   - The patient had a trial of or contraindication to the preferred agent: Norditropin

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Is the request for an adult patient with a diagnosis of growth hormone deficiency (GHD) (ICD-10 E23.0; Group E34.3), and does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The requested medication will NOT be used concurrently with Increlex (mecasermin)
   - The patient had a trial of or contraindication to the preferred agent: Norditropin

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have a congenital, genetic, or organic disease (e.g., craniopharyngioma [tumor], pituitary hypoplasia, ectopic posterior pituitary, previous cranial irradiation)?

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

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SOMATROPIN - SAIZEN (PART D)

INITIAL CRITERIA (CONTINUED)

5. Is the patient's diagnosis confirmed by **ONE** of the following growth hormone stimulation tests?
   - Insulin tolerance test (peak growth hormone of 5 ng/mL or less)
   - Glucagon-stimulation test (peak response of 3 ng/mL or less AND the patient's BMI is less than 25 kg/m2; OR peak response of 3 ng/mL or less AND the patient's BMI is between 25 and 30 kg/m2 with a high pre-test probability; OR peak response of 1 ng/mL or less AND the patient's BMI is between 25 and 30 kg/m2 with a low test probability; OR peak response of 1 ng/mL or less AND the patient's BMI is greater than 30 kg/m2)
   - Macimorelin test (peak growth hormone of 2.8 ng/mL or less)

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOMATROPIN - SAIZEN** requires the following rule(s) be met for approval:

   A. You meet ONE of the following:
      1. You are a pediatric patient with growth failure due to inadequate secretion (release) of endogenous (produced inside the body) growth hormone (GH)
      2. You are an adult patient with growth hormone deficiency (GHD: type of hormone disorder with low growth hormone)

   B. If you are a pediatric patient with growth failure due to inadequate secretion of endogenous growth hormone, approval also requires:
      1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
      2. Your height is at least 2 standard deviations (SD: a measure of variation from the average) below the mean (average) height for children of the same age and gender
      3. You have open epiphyses (end part of long bone) as confirmed by radiograph (a type of imaging test) of the wrist and hand
      4. You will NOT use the requested medication concurrently (at the same time) with Increlex (mecasermin)
      5. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Norditropin

   (Initial denial text continued on next page)

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SOMATROPIN - SAIZEN (PART D)

INITIAL CRITERIA (CONTINUED)

C. If you are an adult patient with growth hormone deficiency, approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
3. You will NOT use the requested medication concurrently (at the same time) with Increlex (mecasermin)
4. You meet ONE of the following:
   a. You have congenital (at birth), genetic, or organic disease (such as craniopharyngioma [tumor], pituitary hypoplasia [a type of brain condition], ectopic posterior pituitary [a type of brain condition], previous cranial irradiation [radiation to the brain])
   b. Your diagnosis is confirmed by ONE of the following growth hormone stimulation tests:
      i. Insulin tolerance test (peak growth hormone of 5 ng/mL or less)
      ii. Glucagon-stimulation test (peak response of 3 ng/mL or less AND your body mass index [BMI: a tool for evaluating body fat] is less than 25 kg/m2 OR peak response of 3 ng/mL or less AND your BMI is between 25 and 30 kg/m2 with a high pre-test probability OR peak response of 1 ng/mL or less AND your BMI is between 25 and 30 kg/m2 with a low test probability OR peak response of 1 ng/mL or less AND your BMI is greater than 30 kg/m2)
      iii. Macimorelin test (peak growth hormone of 2.8 ng/mL or less)
5. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Norditropin

D. Request for Saizen will NOT be approved for athletic enhancement (to perform better in sports) or anti-aging purposes.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOMATROPIN - SAIZEN (PART D)

RENEWAL CRITERIA

1. Is the request for **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, continue to #2.

2. Is the request for a pediatric patient with a diagnosis of growth failure due to inadequate secretion of endogenous growth hormone (GH) (ICD-10 Group E34.3), and does the patient meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has open epiphyses (as confirmed by radiograph of the wrist and hand) ORthe patient has not completed prepubertal growth
   - The patient has shown improvement (i.e., increased height or increased growth velocity)
   - The requested medication will NOT be used concurrently with Increlex (mecasermin)

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Is the request for an adult patient with a diagnosis of growth hormone deficiency (GHD) (ICD-10 E23.0; Group E34.3), and does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The requested medication will NOT be used concurrently with Increlex (mecasermin)

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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SOMATROPIN - SAIZEN (PART D)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOMATROPIN - SAIZEN** requires the following rule(s) be met for renewal:

A. You meet ONE of the following:
   1. You are a pediatric patient with growth failure due to inadequate secretion (release) of endogenous (produced inside the body) growth hormone (GH)
   2. You are an adult patient with growth hormone deficiency (GHD: type of hormone disorder with low growth hormone)

B. If you are a pediatric patient with growth failure due to inadequate secretion of endogenous growth hormone, renewal also requires:
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You have open epiphyses (end part of long bone) as confirmed by radiograph (type of imaging test) of the wrist and hand OR you have not completed prepubertal growth
   3. You have experienced improvement (increased height or increased growth velocity [rate]) on therapy
   4. You will NOT use the requested medication concurrently (at the same time) with Increlex (mecasermin)

C. If you are an adult patient with growth hormone deficiency, renewal also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   3. You will NOT use the requested medication concurrently (at the same time) with Increlex (mecasermin)

D. Request for Saizen will NOT be approved for athletic enhancement (to perform better in sports) or anti-aging purposes.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Saizen.

REFERENCES

Saizen [Prescribing Information]. Rockland, MA: EMD Serono, Inc.; February 2020.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOMATROPIN - SAIZEN (PART D)

For Part D use only:

SOMATROPIN - SAIZEN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	INITIAL/RENEWAL: ATHLETIC ENHANCEMENT, ANTI-AGING PURPOSES.
Required Medical Information	INITIAL: PEDIATRIC GROWTH HORMONE DEFICIENCY (GHD): HEIGHT AT LEAST 2 STANDARD DEVIATIONS BELOW THE MEAN HEIGHT FOR CHILDREN OF THE SAME AGE AND GENDER. ADULT GHD: 1) HAS A CONGENITAL, GENETIC, OR ORGANIC DISEASE (E.G., CRANIOPHARYNGIOMA, PITUITARY HYPOPLASIA, ECTOPIC POSTERIOR PITUITARY, PREVIOUS CRANIAL IRRADIATION), OR 2) GHD CONFIRMED BY ONE OF THE FOLLOWING GROWTH HORMONE (GH) STIMULATION TESTS: (A) INSULIN TOLERANCE TEST (PEAK GH OF 5 NG/ML OR LESS), (B) GLUCAGON-STIMULATION TEST (ONE OF THE FOLLOWING: (I) PEAK RESPONSE OF 3 NG/ML OR LESS AND BMI LESS THAN 25 KG/M2, (II) PEAK RESPONSE OF 3 NG/ML OR LESS AND BMI IS BETWEEN 25 - 30 KG/M2 WITH A PRE-TEST PROBABILITY, (III) PEAK RESPONSE OF 1 NG/ML OR LESS AND BMI IS BETWEEN 25 - 30 KG/M2 WITH LOW TEST PROBABILITY, OR (IV) PEAK RESPONSE OF 1 NG/ML OR LESS AND BMI IS GREATER THAN 30 KG/M2), OR (C) MACIMORELIN TEST (PEAK GH OF 2.8 NG/ML OR LESS).
Age Restrictions	N/A
Prescriber Restrictions	INITIAL/RENEWAL: ALL INDICATIONS: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS
Other Criteria	INITIAL: TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT: NORDITROPIN. PEDIATRIC GHD: OPEN EPIPHYSES AS CONFIRMED BY RADIOGRAPH OF THE WRIST AND HAND. INITIAL/RENEWAL: ALL INDICATIONS: NO CONCURRENT USE WITH INCRELEX. RENEWAL: PEDIATRIC GHD: 1) IMPROVEMENT WHILE ON THERAPY (INCREASED HEIGHT OR INCREASED GROWTH VELOCITY), AND 2) OPEN EPIPHYSES AS CONFIRMED BY RADIOGRAPH OF THE WRIST AND HAND OR HAS NOT COMPLETED PREPUBERTAL GROWTH.

Created: 07/22
Effective: 02/01/26 Client Approval: 01/26 P&T Approval: 04/25

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOMATROPIN - SEROSTIM (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOMATROPIN	SEROSTIM	02824		GPI-10 (3010002010)	BRAND = SEROSTIM

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of HIV with wasting or cachexia (ICD-10 R64) and meet **ALL** of the following criteria?
   - Serostim is NOT prescribed for athletic enhancement or anti-aging purposes
   - Therapy is prescribed by or in consultation with a gastroenterologist, nutritional support specialist or infectious disease specialist
   - The patient is currently on HIV anti-retroviral therapy (e.g., Descovy [emtricitabine-tenofovir], Triumeq [abacavir-dolutegravir- lamivudine])

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SOMATROPIN - SEROSTIM (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient meet **ONE** of the following criteria for weight loss?
   - 10% unintentional weight loss over 12 months
   - 5% weight loss over 6 months
   - 5% body cell mass (BCM) loss within 6 months
   - Body cell mass (BCM) less than 35% (men) of total body weight AND a body mass index (BMI) less than 27 kg per meter squared
   - Body cell mass (BCM) less than 23% (women) of total body weight AND a body mass index (BMI) less than 27 kg per meter squared
   - Body mass index (BMI) less than 20 kg per meter squared

   If yes, **approve for 9 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOMATROPIN - SEROSTIM** requires the following rule(s) be met for approval:
   A. You have human immunodeficiency virus (HIV: an immune system disease caused by a virus) with wasting or cachexia (condition of severe weight and muscle loss)
   B. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions), nutritional support specialist, or infectious disease specialist (a doctor who specializes in the treatment of infections)
   C. You are currently on HIV anti-retroviral therapy (HIV treatment such as Descovy [emtricitabine-tenofovir], Triumeq [abacavir-dolutegravir- lamivudine])

   (Initial denial text continued on next page)

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SOMATROPIN - SEROSTIM (PART D)

INITIAL CRITERIA (CONTINUED)

D. You meet ONE of the following criteria for weight loss:
   1. You have 10% unintentional weight loss over 12 months
   2. You have 5% weight loss over 6 months
   3. You have 5% body cell mass (BCM: a tool for evaluating nutritional status) loss within 6 months
   4. If you are a male, your body cell mass (BCM) is less than 35% of your total body weight AND your body mass index (BMI: a tool for evaluating body fat) is less than 27 kg per meter squared
   5. If you are a female, your body cell mass (BCM) is less than 23% of your total body weight AND your body mass index (BMI) is less than 27 kg per meter squared
   6. Your body mass index (BMI) is less than 20 kg per meter squared

E. Request for Serostim will NOT be approved for athletic enhancement (to perform better in sports) or anti-aging purposes

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOMATROPIN - SEROSTIM (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of HIV with wasting or cachexia (ICD-10 R64) and meet **ALL** of the following criteria?
   - Serostim is NOT prescribed for athletic enhancement or anti-aging purposes
   - The patient is currently on HIV anti-retroviral therapy (e.g., Descovy [emtricitabine-tenofovir], Triumeq [abacavir-dolutegravir- lamivudine])
   - The patient has shown clinical benefit in muscle mass and weight

   If yes, **approve for 9 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOMATROPIN - SEROSTIM** requires the following rule(s) be met for renewal:
   A. You have human immunodeficiency virus (HIV: an immune system disease caused by a virus) with wasting or cachexia (condition of severe weight and muscle loss)
   B. You are currently on HIV anti-retroviral therapy (HIV treatment such as Descovy [emtricitabine-tenofovir], Triumeq [abacavir-dolutegravir- lamivudine])
   C. You have shown clinical benefit in muscle mass and weight
   D. Renewal request for Serostim will NOT be approved for athletic enhancement (to perform better in sports) or anti-aging purposes

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Serostim.

REFERENCES

Serostim [Prescribing Information] Rockland, MA: EMD Serono, Inc.; June 2019.

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SOMATROPIN - SEROSTIM (PART D)

For Part D use only:

SOMATROPIN - SEROSTIM (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	INITIAL/RENEWAL: ATHLETIC ENHANCEMENT, ANTI-AGING PURPOSES
Required Medical Information	INITIAL: HIV/WASTING: ONE OF THE FOLLOWING FOR WEIGHT LOSS: 1) 10% UNINTENTIONAL WEIGHT LOSS OVER 12 MONTHS OR 5% WEIGHT LOSS OVER 6 MONTHS, 2) 5% BODY CELL MASS (BCM) LOSS WITHIN 6 MONTHS, 3) BCM LESS THAN 35% (MEN) OF TOTAL BODY WEIGHT AND BODY MASS INDEX (BMI) LESS THAN 27 KG PER METER SQUARED, 4) BCM LESS THAN 23% (WOMEN) OF TOTAL BODY WEIGHT AND BMI LESS THAN 27 KG PER METER SQUARED, OR 5) BMI LESS THAN 20 KG PER METER SQUARED.
Age Restrictions	N/A
Prescriber Restrictions	HIV/WASTING: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST, NUTRITIONAL SUPPORT SPECIALIST, OR INFECTIOUS DISEASE SPECIALIST.
Coverage Duration	INITIAL/RENEWAL: 9 MONTHS.
Other Criteria	HIV/WASTING: RENEWAL: 1) CLINICAL BENEFIT IN MUSCLE MASS AND WEIGHT.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOMATROPIN - ZOMACTON (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOMATROPIN	ZOMACTON	02824		GPI-10 (3010002000)	BRAND = ZOMACTON

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, continue to #2.

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SOMATROPIN - ZOMACTON (PART D)

INITIAL CRITERIA (CONTINUED)

2. Is the request for a pediatric patient with a diagnosis of growth failure due to inadequate secretion of endogenous growth hormone (GH) (ICD-10 Group E34.3), and does the patient meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   - The patient has open epiphyses (as confirmed by radiograph of the wrist and hand)
   - Zomacton will NOT be used concurrently with Increlex (mecasermin)
   - The patient had a trial of or contraindication to the preferred agent: Norditropin

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Does the patient have a diagnosis of short stature associated with Turner syndrome (ICD-10 Group Q96) and meet **ALL** of the following criteria?
   - The patient's diagnosis is confirmed by chromosomal analysis (karyotyping)
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has open epiphyses (as confirmed by radiograph of the wrist and hand)
   - Zomacton will NOT be used concurrently with Increlex (mecasermin)
   - The patient had a trial of or contraindication to the preferred agent: Norditropin

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of idiopathic short stature (ISS) (ICD-10 R62.52) and meet **ALL** of the following criteria?
- Therapy is prescribed by or in consultation with an endocrinologist
- The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
- The patient has open epiphyses (as confirmed by radiograph of the wrist and hand)
- The patient had a trial of or contraindication to the preferred agent: Norditropin

If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #5.

5. Does the patient have a diagnosis of short stature or growth failure with short stature homeobox-containing gene (SHOX) (ICD-10 E34.328) deficiency and meet **ALL** of the following criteria?
- Therapy is prescribed by or in consultation with an endocrinologist
- The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
- The patient has open epiphyses (as confirmed by radiograph of the wrist and hand)
- Zomacton will NOT be used concurrently with Increlex (mecasermin)

If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #6.

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SOMATROPIN - ZOMACTON (PART D)

INITIAL CRITERIA (CONTINUED)

6. Does the patient have a diagnosis of short stature born small for gestational age (SGA) (ICD-10 R62.52; Group P05.1) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   - The patient has open epiphyses (as confirmed by radiograph of the wrist and hand)
   - Zomacton will NOT be used concurrently with Increlex (mecasermin)
   - The patient had a trial of or contraindication to the preferred agent: Norditropin

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #7.

7. Is the request for an adult patient with a diagnosis of growth hormone deficiency (GHD) (ICD-10 E23.0; Group E34.3), and does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist
   - Zomacton will NOT be used concurrently with Increlex (mecasermin)
   - The patient had a trial of or contraindication to the preferred agent: Norditropin

   If yes, continue to #8.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

8. Does the patient have a congenital, genetic, or organic disease (e.g., craniopharyngioma [tumor], pituitary hypoplasia, ectopic posterior pituitary, previous cranial irradiation)?

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #9.

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SOMATROPIN - ZOMACTON (PART D)

INITIAL CRITERIA (CONTINUED)

9. Is the patient's diagnosis confirmed by ONE of the following growth hormone stimulation tests?
   - Insulin tolerance test (peak growth hormone of 5 ng/mL or less)
   - Glucagon-stimulation test (peak response of 3 ng/mL or less AND the patient's BMI is less than 25 kg/m2; OR peak response of 3 ng/mL or less AND the patient's BMI is between 25 and 30 kg/m2 with a high pre-test probability; OR peak response of 1 ng/mL or less AND the patient's BMI is between 25 and 30 kg/m2 with a low test probability; OR peak response of 1 ng/mL or less AND the patient's BMI is greater than 30 kg/m2)
   - Macimorelin test (peak growth hormone of 2.8 ng/mL or less)

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOMATROPIN - ZOMACTON** requires the following rule(s) be met for approval:
   A. You meet ONE of the following:
      1. You are a pediatric patient with growth failure due to inadequate secretion (release) of endogenous (produced inside the body) growth hormone (GH)
      2. You have short stature associated with Turner syndrome (type of genetic disorder)
      3. You have idiopathic short stature (ISS: short height due to unknown cause)
      4. You have short stature or growth failure with short stature homeobox-containing gene (SHOX) deficiency (type of genetic disorder)
      5. You have short stature born small for gestational age (SGA: birth weight is lower than expected for the number of weeks of pregnancy)
      6. You are an adult patient with growth hormone deficiency (GHD: type of hormone disorder with low growth hormone)

   (Initial denial text continued on next page)

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SOMATROPIN - ZOMACTON (PART D)

INITIAL CRITERIA (CONTINUED)

B. If you are a pediatric patient with growth failure due to inadequate secretion of endogenous growth hormone, approval also requires:
1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
2. Your height is at least 2 standard deviations (SD: a measure of variation from the average) below the mean (average) height for children of the same age and gender
3. You have open epiphyses (end part of long bone) as confirmed by radiograph (a type of imaging test) of the wrist and hand
4. You will NOT use Zomacton concurrently (at the same time) with Increlex (mecasermin)
5. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Norditropin

C. If you have short stature associated with Turner syndrome, approval also requires:
1. Your diagnosis is confirmed by chromosomal analysis (karyotyping: a lab test used to examine your genetic information)
2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
3. You have open epiphyses (end part of long bone) as confirmed by radiograph (a type of imaging test) of the wrist and hand
4. You will NOT use Zomacton concurrently (at the same time) with Increlex (mecasermin)
5. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Norditropin

D. If you have idiopathic short stature, approval also requires:
1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
2. Your height is at least 2 standard deviations (SD: a measure of variation from the average) below the mean (average) height for children of the same age and gender
3. You have open epiphyses (end part of long bone) as confirmed by radiograph (a type of imaging test) of the wrist and hand
4. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Norditropin

E. If you have short stature or growth failure with SHOX deficiency, approval also requires:
1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
2. Your height is at least 2 standard deviations (SD: a measure of variation from the average) below the mean (average) height for children of the same age and gender
3. You have open epiphyses (end part of long bone) as confirmed by radiograph (a type of imaging test) of the wrist and hand
4. You will NOT use Zomacton concurrently (at the same time) with Increlex (mecasermin)

(Initial denial text continued on next page)

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SOMATROPIN - ZOMACTON (PART D)

INITIAL CRITERIA (CONTINUED)

F. If you have short stature born small for gestational age, approval also requires:
1. You are 2 years of age or older
2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
3. Your height is at least 2 standard deviations (SD: a measure of variation from the average) below the mean (average) height for children of the same age and gender
4. You have open epiphyses (end part of long bone) as confirmed by radiograph (a type of imaging test) of the wrist and hand
5. You will NOT use Zomacton concurrently (at the same time) with Increlex (mecasermin)
6. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Norditropin

G. If you are an adult patient with growth hormone deficiency, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
3. You will NOT use Zomacton concurrently (at the same time) with Increlex (mecasermin)
4. You meet ONE of the following:
   a. You have congenital (at birth), genetic, or organic disease (such as craniopharyngioma [tumor], pituitary hypoplasia [a type of brain condition], ectopic posterior pituitary [a type of brain condition], previous cranial irradiation [radiation to the brain])
   b. Your diagnosis is confirmed by ONE of the following growth hormone stimulation tests:
      i. Insulin tolerance test (peak growth hormone of 5 ng/mL or less)
      ii. Glucagon-stimulation test (peak response of 3 ng/mL or less AND your body mass index [BMI: a tool for evaluating body fat] is less than 25 kg/m2 OR peak response of 3 ng/mL or less AND your BMI is between 25 and 30 kg/m2 with a high pre-test probability OR peak response of 1 ng/mL or less AND your BMI is between 25 and 30 kg/m2 with a low test probability OR peak response of 1 ng/mL or less AND your BMI is greater than 30 kg/m2)
      iii. Macimorelin test (peak growth hormone of 2.8 ng/mL or less)
5. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Norditropin

G. Request for Zomacton will NOT be approved for athletic enhancement (to perform better in sports) or anti-aging purposes.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOMATROPIN - ZOMACTON (PART D)

RENEWAL CRITERIA

1. Is the request for **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, continue to #2.

2. Is the request for a pediatric patient with a diagnosis of growth failure due to inadequate secretion of endogenous growth hormone (GH) (ICD-10 Group E34.3), and does the patient meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has open epiphyses (as confirmed by radiograph of the wrist and hand) OR the patient has not completed prepubertal growth
   - The patient has shown improvement (increased height or increased growth velocity)
   - Zomacton will NOT be used concurrently with Increlex (mecasermin)

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Does the patient have a diagnosis of idiopathic short stature (ISS) (ICD-10 R62.52) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has open epiphyses (as confirmed by radiograph of the wrist and hand)
   - The patient has shown improvement (increased height or increased growth velocity)

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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SOMATROPIN - ZOMACTON (PART D)

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have **ONE** of the following diagnoses?
   - Short stature associated with Turner syndrome (ICD-10 Group Q96)
   - Short stature or growth failure with short stature homeobox-containing gene (SHOX) deficiency (ICD-10 E34.328)
   - Short stature born small for gestational age (SGA) (ICD-10 R62.52; Group P05.1)

   If yes, continue to #5.
   If no, continue to #6.

5. Does the patient meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has open epiphyses (as confirmed by radiograph of the wrist and hand OR the patient has not completed prepubertal growth)
   - The patient has shown improvement (increased height or increased growth velocity)
   - Zomacton will NOT be used concurrently with Increlex (mecasermin)

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

6. Is the request for an adult patient with a diagnosis of growth hormone deficiency (GHD) (ICD-10 E23.0; Group E34.3), and does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist
   - Zomacton will NOT be used concurrently with Increlex (mecasermin)

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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SOMATROPIN - ZOMACTON (PART D)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOMATROPIN - ZOMACTON** requires the following rule(s) be met for renewal:

A. You meet ONE of the following:
   1. You are a pediatric patient with growth failure due to inadequate secretion (release) of endogenous (produced inside the body) growth hormone (GH)
   2. You have short stature associated with Turner syndrome (type of genetic disorder)
   3. You have idiopathic short stature (ISS: short height due to unknown cause)
   4. You have short stature or growth failure with short stature homeobox-containing gene (SHOX) deficiency (type of genetic disorder)
   5. You have short stature born small for gestational age (SGA: birth weight is lower than expected for the number of weeks of pregnancy)
   6. You are an adult patient with growth hormone deficiency (GHD: type of hormone disorder with low growth hormone)

B. If you are a pediatric patient with growth failure due to inadequate secretion of endogenous growth hormone, renewal also requires:
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You have open epiphyses (end part of long bone) as confirmed by radiograph (type of imaging test) of the wrist and hand OR you have not completed prepubertal growth
   3. You have experienced improvement (increased height or increased growth velocity [rate]) on therapy
   4. You will NOT use Zomacton concurrently (at the same time) with Increlex (mecasermin

C. If you have idiopathic short stature, renewal also requires:
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You have open epiphyses (end part of long bone) as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. You have experienced improvement (increased height or increased growth velocity [rate]) on therapy

(Renewal denial text continued on next page)

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SOMATROPIN - ZOMACTON (PART D)

RENEWAL CRITERIA (CONTINUED)

D. If you have short stature associated with Turner syndrome, short stature or growth failure with SHOX deficiency, or short stature born small for gestational age, renewal also requires:
1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
2. You have open epiphyses (end part of long bone) as confirmed by radiograph (type of imaging test) of the wrist and hand OR you have not completed prepubertal growth
3. You have experienced improvement (increased height or increased growth velocity [rate]) on therapy
4. You will NOT use Zomacton concurrently (at the same time) with Increlex (mecasermin)

E. If you are an adult patient with growth hormone deficiency, renewal also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
3. You will NOT use Zomacton concurrently (at the same time) with Increlex (mecasermin)

F. Request for Zomacton will NOT be approved for athletic enhancement (to perform better in sports) or anti-aging purposes.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Zomacton.

REFERENCES
Zomacton [Prescribing Information]. Parsippany, NJ: Ferring Pharmaceuticals Inc.; April 2024.

For Part D use only:

SOMATROPIN - ZOMACTON (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	INITIAL/RENEWAL: ATHLETIC ENHANCEMENT, ANTI-AGING PURPOSES.
Required Medical Information	INITIAL: PEDIATRIC GROWTH HORMONE DEFICIENCY (GHD), IDIOPATHIC SHORT STATURE (ISS), SMALL FOR GESTATIONAL AGE (SGA), SHORT STATURE HOMEOBOX-CONTAINING GENE (SHOX) DEFICIENCY: HEIGHT AT LEAST 2 STANDARD DEVIATIONS BELOW THE MEAN HEIGHT FOR CHILDREN OF THE SAME AGE AND GENDER. TURNER SYNDROME (TS): CONFIRMED BY CHROMOSOMAL ANALYSIS (KARYOTYPING). ADULT GHD: 1) HAS A CONGENITAL, GENETIC, OR ORGANIC DISEASE (E.G., CRANIOPHARYNGIOMA, PITUITARY

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	HYPOPLASIA, ECTOPIC POSTERIOR PITUITARY, PREVIOUS CRANIAL IRRADIATION), OR 2) GHD CONFIRMED BY ONE OF THE FOLLOWING GROWTH HORMONE (GH) STIMULATION TESTS: (A) INSULIN TOLERANCE TEST (PEAK GH OF 5 NG/ML OR LESS), (B) GLUCAGON-STIMULATION TEST (ONE OF THE FOLLOWING: (I) PEAK RESPONSE OF 3 NG/ML OR LESS AND BMI LESS THAN 25 KG/M2, (II) PEAK RESPONSE OF 3 NG/ML OR LESS AND BMI IS BETWEEN 25 - 30 KG/M2 WITH A PRE-TEST PROBABILITY, (III) PEAK RESPONSE OF 1 NG/ML OR LESS AND BMI IS BETWEEN 25 - 30 KG/M2 WITH LOW TEST PROBABILITY, OR (IV) PEAK RESPONSE OF 1 NG/ML OR LESS AND BMI IS GREATER THAN 30 KG/M2), OR (C) MACIMORELIN TEST (PEAK GH OF 2.8 NG/ML OR LESS).
Age Restrictions	SGA: 2 YEARS OF AGE OR OLDER
Prescriber Restrictions	INITIAL/RENEWAL: ALL INDICATIONS: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT: NORDITROPIN, WHERE INDICATIONS ALIGN. PEDIATRIC GHD, ISS, SGA, TS, SHOX DEFICIENCY: OPEN EPIPHYSES AS CONFIRMED BY RADIOGRAPH OF THE WRIST AND HAND. INITIAL/RENEWAL: ADULT GHD, PEDIATRIC GHD, SGA, TS, SHOX DEFICIENCY: NO CONCURRENT USE WITH INCRELEX. RENEWAL: ISS: 1) IMPROVEMENT WHILE ON THERAPY (INCREASED HEIGHT OR INCREASED GROWTH VELOCITY), AND 2) OPEN EPIPHYSES AS CONFIRMED BY RADIOGRAPH OF THE WRIST AND HAND. PEDIATRIC GHD, SGA, TS, SHOX DEFICIENCY: 1) IMPROVEMENT WHILE ON THERAPY (INCREASED HEIGHT OR INCREASED GROWTH VELOCITY), AND 2) OPEN EPIPHYSES AS CONFIRMED BY RADIOGRAPH OF THE WRIST AND HAND OR HAS NOT COMPLETED PREPUBERTAL GROWTH.

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Effective: 02/01/26 Client Approval: 01/26 P&T Approval: 04/25

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SONIDEGIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SONIDEGIB PHOSPHATE	ODOMZO	42369		GPI-10 (2137006020)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced basal cell carcinoma (BCC) (ICD-10 C44.91, C44.01, C44.41, C44.81; Groups C44.11, C44.21, C44.31, C44.51, C44.61, C44.71) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - This is a recurrence of basal cell carcinoma (BCC) following surgery or radiation therapy OR the patient is not a candidate for surgery or radiation therapy
   - The patient's baseline serum creatine kinase (CK) and serum creatinine levels have been obtained prior to initiating therapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SONIDEGIB (Odomzo)** requires the following rule(s) be met for approval:
   A. You have locally advanced basal cell carcinoma (BCC: a type of skin cancer that has spread from where it started to nearby tissue or lymph nodes)
   B. You are 18 years of age or older
   C. This is a recurrence (disease returns) of basal cell carcinoma (BCC: a type of skin cancer) after surgery or radiation therapy OR you are not a candidate for surgery or radiation therapy
   D. Your baseline serum creatine kinase (CK: a type of protein) and serum creatinine levels (type of lab test to measure kidney function) have been obtained before starting therapy
   (Denial text continued on next page)

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SONIDEGIB (PART D)

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the prescribing information and/or drug monograph for Odomzo.

REFERENCE

Odomzo [Prescribing Information]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; May 2019.

For Part D use only:

SONIDEGIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	LOCALLY ADVANCED BASAL CELL CARCINOMA (BCC): BASELINE SERUM CREATINE KINASE (CK) AND SERUM CREATININE LEVELS
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

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Effective: 01/01/25 Client Approval: 08/24 P&T Approval: 11/15

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STANDARD PART D
PRIOR AUTHORIZATION GUIDELINES

SONROTOCLAX (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SONROTOCLAX	BEQALZI	51355		GPI-10 (2147006500)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory mantle cell lymphoma (MCL) (ICD-10 Group C83.1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received at least TWO lines of systemic therapy, including a Bruton's tyrosine kinase (BTK) inhibitor (e.g., Jaypirca [pirtobrutinib], Calquence [acalabrutinib], Velcade [bortezomib])

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: Our guideline named **SONROTOCLAX (Beqalzi)** requires the following rule(s) be met for approval:
   A. You have relapsed or refractory mantle cell lymphoma (MCL: a type of blood cancer that has returned or did not respond to treatment)
   B. You are 18 years of age or older
   C. You have received at least TWO lines of systemic therapy (treatment that targets the entire body), including a Bruton's tyrosine kinase (BTK) inhibitor (such as Jaypirca [pirtobrutinib], Calquence [acalabrutinib], Velcade [bortezomib])

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Beqalzi.

REFERENCES
Beqalzi [Prescribing Information]. Pennington, NJ: BeOne Medicines USA, Inc.; May 2026.

Created: 09/26
Effective: 09/19/26 DMC Approval: 09/15/26

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SORAFENIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SORAFENIB TOSYLATE	NEXAVAR, SORAFENIB TOSYLATE	33400		GPI-10 (2153306040)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC) (ICD-10 Groups C64, C65)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of unresectable hepatocellular carcinoma (ICD-10 C22.0)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Does the patient have a diagnosis of locally recurrent or metastatic, progressive, differentiated thyroid carcinoma (DTC) (ICD-10 C73) **AND** meet the following criterion?
   - The patient's cancer is refractory to radioactive iodine treatment

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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SORAFENIB (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SORAFENIB (Nexavar)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Advanced renal cell carcinoma (RCC: type of kidney cancer)
   2. Unresectable hepatocellular carcinoma (liver cancer that cannot be removed with surgery)
   3. Locally recurrent or metastatic, progressive, differentiated thyroid carcinoma (DTC) (a type of thyroid cancer that returns, spreads, or is getting worse that does not fully respond to a type of treatment)

B. If you have locally recurrent/metastatic, progressive, differentiated thyroid carcinoma, approval also requires:
   1. Your cancer is refractory to radioactive iodine treatment (does not respond to a type of treatment)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Review for Nexavar.

REFERENCES

Nexavar [Prescribing Information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; August 2023.

For Part D use only:

SORAFENIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SORAFENIB (PART D)

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 05/11
Client Approval: 08/24
P&T Approval: 11/14

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOTATERCEPT-CSRK (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOTATERCEPT-CSRK	WINREVAIR	49475		GPI-10 (4011007020)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0; Group I27.2) and meet **ALL** of the following criteria?
   - The patient is 18 years of age and older
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   - Pulmonary vascular resistance (PVR) greater than 2 Wood units (WU)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SOTATERCEPT-CSRK (PART D)

INITIAL CRITERIA (CONTINUED)

3. Has the patient been on background PAH therapy (for at least 3 months) with at least TWO of the following agents from different drug classes?
   - Oral endothelin receptor antagonist (e.g., Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
   - Oral phosphodiesterase-5 inhibitor (e.g., Revatio [sildenafil], Adcirca [tadalafil])
   - Oral cGMP stimulator (e.g., Adempas [riociguat])
   - IV/SQ prostacyclin (e.g., Flolan [epoprostenol], Remodulin [treprostinil])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

4. Is the patient on ONE agent from one of the following drug classes, **AND** has a contraindication or intolerance to ALL of the other drug classes?
   - Oral endothelin receptor antagonist (e.g., Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
   - Oral phosphodiesterase-5 inhibitor (e.g., Revatio [sildenafil], Adcirca [tadalafil])
   - Oral cGMP stimulator (e.g., Adempas [riociguat])
   - IV/SQ prostacyclin (e.g., Flolan [epoprostenol], Remodulin [treprostinil])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SOTATERCEPT-CSRK (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOTATERCEPT-CSRK (Winrevair)** requires the following rule(s) be met for approval:

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
B. You are 18 years of age and older
C. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
D. Your pulmonary arterial hypertension diagnosis is confirmed by right heart catheterization (a test used to measure how well the heart is pumping) with ALL of the following lab values:
    1. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
    2. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
    3. Pulmonary vascular resistance (PVR) greater than 2 Wood units
E. You meet ONE of the following:
    1. You have been on background PAH therapy (for at least 3 months) with at least TWO of the following medications from different drug classes:
        a. Oral endothelin receptor antagonist (such as Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
        b. Oral phosphodiesterase-5 inhibitor for PAH (such as Revatio [sildenafil], Adcirca [tadalafil])
        c. Oral cGMP stimulator (such as Adempas [riociguat])
        d. Intravenous or subcutaneous prostacyclin (such as Flolan [epoprostenol], Remodulin [treprostinil])
    2. You are on ONE medication from one of the following drug classes, AND you have a contraindication to (harmful for you to use) or intolerance (side effect) to ALL of the other drug classes:
        a. Oral endothelin receptor antagonist (such as Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
        b. Oral phosphodiesterase-5 inhibitor for PAH (such as Revatio [sildenafil], Adcirca [tadalafil])
        c. Oral cGMP stimulator (such as Adempas [riociguat])
        d. Intravenous or subcutaneous prostacyclin (such as Flolan [epoprostenol], Remodulin [treprostinil])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOTATERCEPT-CSRK (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0; Group I27.2)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOTATERCEPT-CSRK (Winrevair)** requires the following rule(s) be met for renewal:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Winrevair.

REFERENCES
Winrevair [Prescribing Information]. Rahway, NJ: Merck Sharp & Dohme LLC; March 2024.

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SOTATERCEPT-CSRK (PART D)

For Part D use only:

SOTATERCEPT-CSRK	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	PULMONARY ARTERIAL HYPERTENSION (PAH): INITIAL: DIAGNOSIS CONFIRMED BY RIGHT HEART CATHETERIZATION WITH THE FOLLOWING PARAMETERS: 1) MEAN PULMONARY ARTERY PRESSURE (PAP) GREATER THAN 20 MMHG, 2) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF 15 MMHG OR LESS, AND 3) PULMONARY VASCULAR RESISTANCE (PVR) GREATER THAN 2 WOOD UNITS.
Age Restrictions	N/A
Prescriber Restrictions	PAH: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	PAH: INITIAL: 1) ON BACKGROUND PAH THERAPY (FOR AT LEAST 3 MONTHS) WITH AT LEAST TWO OF THE FOLLOWING AGENTS FROM DIFFERENT DRUG CLASSES: A) ORAL ENDOTHELIN RECEPTOR ANTAGONIST, B) ORAL PHOSPHODIESTERASE TYPE-5 INHIBITOR FOR PAH, C) ORAL CGMP STIMULATOR, D) IV/SQ PROSTACYCLIN, OR 2) ON ONE AGENT FROM ONE OF THE ABOVE DRUG CLASSES, AND HAS A CONTRAINDICATION OR INTOLERANCE TO ALL OF THE OTHER DRUG CLASSES.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOTORASIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOTORASIB	LUMAKRAS	47400		GPI-10 (2153248000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer has a KRAS G12C-mutation, as determined by an FDA-approved test
   - The patient has received at least one prior systemic therapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of metastatic colorectal cancer (mCRC) (ICD-10 C19) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Lumakras will be used in combination with Vectibix (panitumumab)
   - The patient's cancer has a KRAS G12C-mutation, as determined by an FDA-approved test
   - The patient has received previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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SOTORASIB (PART D)

GUIDELINES FOR USE

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOTORASIB (Lumakras)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Locally advanced or metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread from where it started to nearby tissue or lymph nodes or has spread to other parts of the body)
   2. Metastatic colorectal cancer (mCRC: a type of digestive tract cancer that has spread to other parts of the body)

B. If you have locally advanced or metastatic non-small cell lung cancer, approval also requires:
   1. You are 18 years of age or older
   2. Your cancer has a KRAS G12C-mutation (type of gene mutation), as detected by a Food and Drug Administration (FDA)-approved test
   3. You have received at least one prior systemic therapy (treatment that spreads throughout the entire body)

C. If you have metastatic colorectal cancer, approval also requires:
   1. You are 18 years of age or older
   2. Lumakras will be used in combination with Vectibix (panitumumab)
   3. Your cancer has a KRAS G12C-mutation (abnormal change in a type of gene), as determined by a Food and Drug Administration (FDA)-approved test
   4. You have received previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy (types of cancer treatments)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOTORASIB (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Lumakras.

REFERENCES
Lumakras [Prescribing Information]. Thousand Oaks, CA: Amgen, Inc.; January 2025.

For Part D use only:

SOTORASIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SPARSENTAN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SPARSENTAN	FILSPARI	48721		GPI-10 (5648306500)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of primary immunoglobulin A nephropathy (IgAN) (ICD-10 Group N02.B) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is at risk for disease progression
   - Therapy is prescribed by or in consultation with a nephrologist
   - The patient's IgAN diagnosis is confirmed by a biopsy
   - The patient has proteinuria of at least 0.5 g/day
   - The patient has an eGFR of at least 30 mL/min/1.73 m(2)

   If yes, **approve for 9 months by HICL or GPI-10.**
   If no, continue to #2.

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SPARSENTAN (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of focal segmental glomerulosclerosis (FSGS) (ICD-10 Group N04.1) and meet **ALL** of the following criteria?
   - The patient is 8 years of age or older
   - The patient has proteinuria
   - Therapy is prescribed by or in consultation with a nephrologist
   - The patient's diagnosis is confirmed by a renal biopsy
   - The patient has a urine-protein creatinine ratio (UPCR) of at least 1.5 g/g
   - The patient has an eGFR of at least 30 mL/min/1.73 m(2)
   - The patient had a trial of or contraindication to at least 3 months of treatment with ONE of the following clinical standard of care agents: an ACE inhibitor (e.g., benazepril, lisinopril), an ARB (e.g., losartan, valsartan)
   - Filspari will NOT be used concurrently with an ACE inhibitor (e.g., benazepril, lisinopril) or an ARB (e.g., losartan, valsartan)
   - The patient does NOT have nephrotic syndrome as evidenced by nephrotic range proteinuria (i.e., UPCR of at least 3.0 g/g in adults [18 years of age or older]; UPCR of at least 2.0 g/g in children [less than 18 years of age])
   - The patient does NOT have nephrotic syndrome as evidenced by the presence of hypoalbuminemia, edema, or hyperlipidemia

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.

   INITIAL DENIAL TEXT: Our guideline named **SPARSENTAN (Filspari)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Primary immunoglobulin A nephropathy (IgAN: a type of kidney disease)
      2. Focal segmental glomerulosclerosis (FSGS: a type of kidney disease)

   B. If you have primary immunoglobulin A nephropathy, approval also requires:
      1. You are 18 years of age or older
      2. You are at risk for disease progression (worsening)
      3. Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor)
      4. Your diagnosis is confirmed by a biopsy (removal of cells or tissue for examination)
      5. You have proteinuria (high levels of protein in the urine) of at least 0.5 g/day
      6. You have an estimated glomerular filtration rate (eGFR: a tool for evaluating kidney function) of at least 30 mL/min/1.73 m(2)

   (Initial denial text continued on next page)

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SPARSENTAN

INITIAL CRITERIA (CONTINUED)

C. If you have focal segmental glomerulosclerosis, approval also requires:

1. You are 8 years of age or older
2. Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor)
3. Your diagnosis is confirmed by a renal biopsy (removal of cells or tissue from the kidney for examination)
4. You have a urine-protein creatinine ratio (UPCR: a test that measures the amount of protein in urine) of at least 1.5 g/g
5. You have an estimated glomerular filtration rate (eGFR: a tool for evaluating kidney function) of at least 30 mL/min/1.73 m(2)
6. You have tried or have a contraindication to (harmful for you to use) at least 3 months of treatment with ONE of the following clinical standard of care medications: an angiotensin converting enzyme inhibitor (ACE-I: a type of medication used to protect kidneys, such as benazepril, lisinopril), an angiotensin receptor blocker (ARB: a type of medication used to protect kidneys, such as losartan, valsartan)
7. You will NOT use Filspari concurrently (at the same time) with an angiotensin converting enzyme inhibitor (ACE-I: a type of medication used to protect kidneys, such as benazepril, lisinopril) or an angiotensin receptor blocker (ARB: a type of medication used to protect kidneys, such as losartan, valsartan)
8. You do NOT have nephrotic syndrome (a type of kidney disease) as shown by nephrotic range proteinuria (high levels of protein in the urine) [urine-protein creatinine ratio (UPCR: a test that measures the amount of protein in urine) of at least 3.0 g/g in adults (18 years of age or older); UPCR of at least 2.0 g/g in children (less than 18 years of age)]
9. You do NOT have nephrotic syndrome (a type of kidney disease) as shown by hypoalbuminemia (low levels of protein in the urine), edema (swelling caused by fluid build-up in the body), or hyperlipidemia (high level of fat in the blood)

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SPARSENTAN (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of primary immunoglobulin A nephropathy (IgAN) (ICD-10 Group N02.B) and meet **ONE** of the following criteria?
   - The patient has had a reduction in proteinuria
   - The patient has improved or stable kidney function compared to baseline

   If yes, **approve for 9 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of focal segmental glomerulosclerosis (FSGS) (ICD-10 Group N04.1) and meet **ALL** of the following criteria?
   - The patient has a reduction in proteinuria from baseline
   - The patient has a reduction in urine-protein creatinine ratio (UPCR)
   - Filspari will NOT be used concurrently with an ACE inhibitor (e.g., benazepril, lisinopril) or an ARB (e.g., losartan, valsartan)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SPARSENTAN (Filspari)** requires the following rule(s) be met for renewal:

   A. You have ONE of the following:
      1. Primary immunoglobulin A nephropathy (IgAN: a type of kidney disease)
      2. Focal segmental glomerulosclerosis (FSGS: a type of kidney disease)

   B. If you have primary immunoglobulin A nephropathy, renewal also requires you meet ONE of the following:
      1. You had a reduction in proteinuria (increased levels of protein in the urine)
      2. You have improvement or stable kidney function compared to baseline (before treatment)

   C. If you have focal segmental glomerulosclerosis, renewal also requires:
      1. You have had a reduction (decrease) in proteinuria (a condition with high levels of protein in the urine) compared to baseline (before starting Filspari)
      2. You have had a reduction (decrease) in urine-protein creatinine ratio (UPCR: a test that measures the amount of protein in urine)
      3. You will NOT use Filspari concurrently (at the same time) with an angiotensin converting enzyme inhibitor (ACE-I: a type of medication used to protect kidneys, such as benazepril, lisinopril) or an angiotensin receptor blocker (ARB: a type of medication used to protect kidneys, such as losartan, valsartan)

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SPARSENTAN (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Filspari.

REFERENCES

Filspari [Prescribing Information]. San Diego, CA: Travere Therapeutics, Inc.; April 2026.

For Part D use only:

SPARSENTAN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	INITIAL: PRIMARY IMMUNOGLOBULIN A NEPHROPATHY (IGAN): 1) DIAGNOSIS CONFIRMED BY BIOPSY, 2) PROTEINURIA OF AT LEAST 0.5 G/DAY, AND 3) EGFR OF AT LEAST 30ML/MIN/1.73M2. FOCAL SEGMENTAL GLOMERULOSCLEROSIS (FSGS): 1) DIAGNOSIS CONFIRMED BY RENAL BIOPSY, 2) URINE-PROTEIN CREATINE RATIO (UPCR) OF AT LEAST 1.5 G/G, 3) EGFR OF AT LEAST 30 ML/MIN/1.73 M2, AND 4) NO NEPHROTIC SYNDROME AS EVIDENCE BY: (A) NEPHROTIC RANGE PROTEINURIA (I.E., UPCR OF AT LEAST 3.0 G/G IN ADULTS, UPCR OF AT LEAST 2.0 G/G IN CHILDREN), AND (B) THE PRESENCE OF HYPOALBUMINEMIA, EDEMA, OR HYPERLIPIDEMIA.
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: PRIMARY IGAN, FSGS: PRESCRIBED BY OR IN CONSULTATION WITH A NEPHROLOGIST.
Coverage Duration	PRIMARY IGAN: INITIAL/RENEWAL: 9 MONTHS. FSGS: INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: FSGS: 1) TRIAL OF OR CONTRAINDICATION TO AT LEAST 3 MONTHS OF TREATMENT WITH ONE OF THE FOLLOWING CLINICAL STANDARD OF CARE AGENTS: AN ACE INHIBITOR OR AN ARB, AND 2) NO CONCURRENT USE WITH AN ACE INHIBITOR OR AN ARB. RENEWAL: PRIMARY IGAN: REDUCTION IN PROTEINURIA, OR IMPROVED OR STABLE KIDNEY FUNCTION COMPARED TO BASELINE. FSGS: 1) REDUCTION IN PROTEINURIA FROM BASELINE, 2) REDUCTION IN UPCR, AND 3) NO CONCURRENT USE WITH AN ACE INHIBITOR OR AN ARB.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SPESOLIMAB-SBZO IV BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SPESOLIMAB-SBZO	SPEVIGO		52851	GPI-14 (90250577702050)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	Yes	No	No	Yes	No	No	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit).**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #5.

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SPESOLIMAB-SBZO IV BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

If yes, **refer to plan. (The health plan makes the final payment determination decision)**

- **For CSR's: Refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override)**
- **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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SPESOLIMAB-SBZO IV BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the request for the treatment of a generalized pustular psoriasis (GPP) (ICD-10 L40.1) flare and the patient meets **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient weighs at least 40 kg (88 lbs.)
   - Therapy is prescribed by or in consultation with a dermatologist
   - The patient has sterile, macroscopically visible pustules on non-acral skin
   - The patient has not received more than one dose in the previous 30 days and that dose was not within the last 7 days
   - Spevigo will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of GPP

   If yes, **approve for 1 month by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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SPESOLIMAB-SBZO IV BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SPESOLIMAB-SBZO IV (Spevigo)** requires the following rule(s) be met for approval:

A. The request is for the treatment of a generalized pustular psoriasis (GPP: a type of skin condition) flare
B. You are 12 years of age or older
C. You weigh at least 40 kilograms (88 pounds)
D. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
E. You have sterile, macroscopically visible pustules (blisters with non-infectious pus that can be seen with the naked eye) on non-acral skin (skin in areas of the body such as arms and legs)
F. You have not received more than one dose in the previous 30 days and that dose was not within the last 7 days
G. You will NOT use Spevigo concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of generalized pustular psoriasis

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Spevigo. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Spevigo [Prescribing Information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc., March 2024.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed May 5, 2025].

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SPESOLIMAB-SBZO IV BvD (PART D)

For Part D use only:

SPESOLIMAB-SBZO IV (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	GENERALIZED PUSTULAR PSORIASIS (GPP) FLARE: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST.
Coverage Duration	1 MONTH
Other Criteria	GPP FLARE: 1) PRESENCE OF STERILE, MACROSCOPICALLY VISIBLE PUSTULES ON NON-ACRAL SKIN, 2) NOT RECEIVED MORE THAN ONE DOSE IN THE PREVIOUS 30 DAYS AND THAT DOSE WAS NOT WITHIN THE LAST 7 DAYS, AND 3) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SPESOLIMAB-SBZO SQ (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SPESOLIMAB-SBZO	SPEVIGO		55498 57703	GPI-14 (9025057770E530, 9025057770E540)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of generalized pustular psoriasis (GPP) (ICD-10 L40.1) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient weighs at least 40 kg (88 lbs)
   - Therapy is prescribed by or in consultation with a dermatologist
   - The patient has a history of GPP as defined by the presence of sterile, macroscopically visible pustules on non-acral skin
   - Spevigo will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of GPP

   If yes, **approve for 3 months by GPID or GPI-14 for all strengths.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SPESOLIMAB-SBZO SQ (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SPESOLIMAB-SBZO SQ (Spevigo)** requires the following rule(s) be met for approval:

A. You have generalized pustular psoriasis (GPP: a type of skin condition)
B. You are 12 years of age or older
C. You weigh at least 40 kilograms (88 pounds)
D. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
E. You have a history of GPP as defined by the presence of sterile, macroscopically visible pustules (blisters with non-infectious pus that can be seen with the naked eye) on non-acral skin (skin in areas of the body such as arms and legs)
F. You will NOT use Spevigo concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of GPP

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SPESOLIMAB-SBZO SQ (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of generalized pustular psoriasis (GPP) (ICD-10 L40.1) and meet **ALL** of the following criteria?
   - The patient has shown a clinical response
   - Spevigo will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of GPP

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SPESOLIMAB-SBZO SQ (Spevigo)** requires the following rule(s) be met for renewal:
   A. You have generalized pustular psoriasis (GPP: a type of skin condition)
   B. You have experienced a clinical response
   C. You will NOT use Spevigo concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of GPP

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Spevigo.

REFERENCES
Spevigo [Prescribing Information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; March 2024.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SPESOLIMAB-SBZO SQ (PART D)

For Part D use only:

SPESOLIMAB-SBZO SQ (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	GENERALIZED PUSTULAR PSORIASIS (GPP): PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST.
Coverage Duration	INITIAL: 3 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	GPP: INITIAL: 1) HISTORY OF GPP DEFINED BY PRESENCE OF STERILE, MACROSCOPICALLY VISIBLE PUSTULES ON NON-ACRAL SKIN, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION. RENEWAL: 1) HAS SHOWN A CLINICAL RESPONSE, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR THE SAME INDICATION.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

STIRIPENTOL (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
STIRIPENTOL	DIACOMIT	35461		GPI-10 (7260007000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of seizures associated with Dravet syndrome (ICD-10 Group G40.83) and meet **ALL** of the following criteria?
   - The patient is 6 months of age or older
   - The patient weighs at least 7 kg (15.4 lbs)
   - The patient is currently being treated with clobazam
   - Therapy is prescribed by or in consultation with a neurologist

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **STIRIPENTOL (Diacomit)** requires the following rule(s) be met for approval:
   A. You have seizures associated with Dravet syndrome (a rare type of seizure)
   B. You are 6 months of age or older
   C. You weigh at least 7 kilograms (15.4 pounds)
   D. You are currently being treated with clobazam (a type of seizure medication)
   E. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)

   (Initial denial text continued on next page)

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STIRIPENTOL (PART D)

INITIAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STIRIPENTOL (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of seizures associated with Dravet syndrome (ICD-10 Group G40.83) **AND** meet the following criterion?
   - The patient is currently being treated with clobazam

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **STIRIPENTOL (Diacomit)** requires the following rule(s) be met for renewal:
   A. You have seizures associated with Dravet syndrome (a rare type of seizure)
   B. You are currently being treated with clobazam (a type of seizure medication)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Diacomit.

REFERENCES
Diacomit [Prescribing Information]. Beauvais, France: Biocodex; July 2022.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

STIRIPENTOL (PART D)

For Part D use only:

STIRIPENTOL (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	DRAVET SYNDROME: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	N/A

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SULBACTAM-DURLOBACTAM BVD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SULBACTAM SOD/DURLOBACTAM SOD	XACDURO	48956		GPI-10 (1699250210)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	Yes	No	No	Yes	No	No	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is the drug administered via an implantable pump?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, continue to #2.

2. Is the drug administered via an external pump?

   If yes, continue to #3.
   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

3. Is the drug specifically infused through an external infusion pump covered by Medicare?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SULBACTAM-DURLOBACTAM BVD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of hospital-acquired bacterial pneumonia (HABP) or ventilator-associated bacterial pneumonia (VABP) (ICD-10 J95.851) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The infection is caused by susceptible isolates of *Acinetobacter baumannii-calcoaceticus* complex

   If yes, **approve for 30 days by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SULBACTAM-DURLOBACTAM (Xacduro)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Hospital-acquired bacterial pneumonia (HABP: a type of lung infection)
      2. Ventilator-associated bacterial pneumonia (VABP: a type of lung infection)
   B. You are 18 years of age or older
   C. Your infection is caused by susceptible isolates of *Acinetobacter baumannii-calcoaceticus* complex (a type of bacteria)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SULBACTAM-DURLOBACTAM BVD (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xacduro.

The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs administered by an implantable pump are covered under Part B. Drugs administered via an external pump are covered under Part B if they are included under the local coverage policy of the applicable Medicare coverage policies (National and/or Local Coverage Policies). Drugs administered via an external pump that are not included under the applicable Medicare coverage policies are covered under Part D. A CMS website to assist with National and Local Coverage Determination for B versus D review is http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx.

REFERENCES

Xacduro [Prescribing Information]. Waltham, MA: La Jolla Pharmaceutical Company; May 2023.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: http://www.cms.gov/PrescriptionDrugCovContra/12_PartDManuals.asp. [Accessed July 2, 2025]

For Part D use only:

SULBACTAM-DURLOBACTAM (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	30 DAYS
Other Criteria	N/A

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SULOPENEM ETZADROXIL-PROBENECID (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SULOPENEM ETZADROXIL-PROBENECID	ORLYNVAH	49961		GPI-10 (1616990275)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of uncomplicated urinary tract infection (uUTI) (ICD-10 N39.0) and meet **ALL** of the following criteria?
   - The patient is a female AND 18 years of age or older
   - The patient's infection is caused by *Escherichia coli*, *Klebsiella pneumoniae*, or *Proteus mirabilis*
   - The patient has limited or no alternative ORAL antibacterial treatment options

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - Therapy is prescribed by or in consultation with an infectious disease (ID) specialist
   - The patient has a documented culture demonstrating uUTI that is caused by a bacteria with sensitivity to sulopenem or ertapenem AND resistance or contraindication to all alternatives (e.g. Pivya [pivmecillinam], trimethoprim-sulfamethoxazole [TMP-SMX], nitrofurantoin, fosfomycin, penicillins [e.g., amoxicillin-clavulanate], cephalosporins [e.g., cephalexin], fluoroquinolones [e.g. ciprofloxacin])
   - The request is for continuation of Orlynvah from an inpatient setting

   If yes, **approve for 5 days by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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SULOPENEM ETZADROXIL-PROBENECID (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SULOPENEM ETZADROXIL-PROBENECID (Orlynvah)** requires the following rule(s) be met for approval:

A. You have uncomplicated urinary tract infection (uUTI: a type of bacterial infection)
B. You are a female AND 18 years of age or older
C. Your uncomplicated urinary tract infection (a type of bacterial infection) is caused by *Escherichia coli*, *Klebsiella pneumoniae*, or *Proteus mirabilis* (types of bacteria)
D. You have limited or no alternative ORAL antibacterial treatment options
E. You meet ONE of the following:
    1. Therapy is prescribed by or in consultation with an infectious disease specialist (a doctor who specializes in the treatment of infections)
    2. You have a documented culture demonstrating your uncomplicated urinary tract infection (a type of bacterial infection) is caused by a bacteria with sensitivity (lab test that shows what medications work on which bacteria) to sulopenem or ertapenem AND resistance (medication will not work for that bacteria) or contraindication (harmful for you to use) to all alternatives (such as Pivya [pivmecillinam], trimethoprim-sulfamethoxazole [TMP-SMX], nitrofurantoin, fosfomycin, penicillins [such as amoxicillin-clavulanate], cephalosporins [such as cephalexin], fluoroquinolones [such as ciprofloxacin])
    3. The request is for continuation of Orlynvah from an inpatient setting

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SULOPENEM ETZADROXIL-PROBENECID (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Orlynvah.

REFERENCES

Orlynvah [Prescribing Information]. Chicago, IL: Iterum Therapeutics U.S. Limited; March 2025.

For Part D use only:

SULOPENEM ETZADROXIL-PROBENECID (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	5 DAYS
Other Criteria	UNCOMPLICATED URINARY TRACT INFECTIONS (UUTI): 1) PRESCRIBED BY OR IN CONSULTATION WITH AN INFECTIOUS DISEASE SPECIALIST, 2) DOCUMENTED CULTURE DEMONSTRATES UUTI IS CAUSED BY A BACTERIA WITH SENSITIVITY TO SULOPENEM OR ERTAPENEM AND RESISTANCE OR CONTRAINDICATION TO ALL ALTERNATIVES (E.G., PIVMECILLINAM, TRIMETHOPRIM-SULFAMETHOXAZOLE, NITROFURANTOIN, FOSFOMYCIN, PENICILLINS, CEPHALOSPORINS, FLUOROQUINOLONES), OR 3) CONTINUATION OF ORLYNVAH FROM AN INPATIENT SETTING.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SUNITINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SUNITINIB MALATE	SUTENT, SUNITINIB MALATE	33445		GPI-10 (2153307030)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
Yes	No	No	Yes	Yes	No	Yes	No	No	Yes	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of renal cell carcinoma (RCC) (ICD-10 Groups C64, C65) **AND** meet the following criterion?
- The patient is 18 years of age or older

If yes, continue to #2.
If no, continue to #4.

2. Is the patient's cancer advanced?

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #3.

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SUNITINIB (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Is the patient at high risk of recurrent renal cell carcinoma (RCC) following nephrectomy **AND** meet the following criterion?
   - The requested drug will be used as adjuvant treatment

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See denial text at the end of the guideline.

4. Does the patient have a diagnosis of gastrointestinal stromal tumor (GIST) (ICD-10 Group C49.A) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to imatinib mesylate (Gleevec)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Does the patient have a diagnosis of unresectable locally advanced or metastatic pancreatic neuroendocrine tumor (pNET) (ICD-10 C25.4) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's tumor is progressive and well-differentiated

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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SUNITINIB (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SUNITINIB (Sutent)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Renal cell carcinoma (RCC: a type of kidney cancer)
   2. Gastrointestinal stromal tumor (GIST: a type of digestive tumor)
   3. Unresectable locally advanced or metastatic pancreatic neuroendocrine tumor (pNET) (a type of tumor in the pancreas that cannot be completely removed by surgery or has spread to other parts of the body)

B. If you have renal cell carcinoma, approval also requires:
   1. You are 18 years of age or older
   2. You meet ONE of the following:
      a. You have advanced disease
      b. You are at high risk of recurrent renal cell carcinoma (cancer returning) following nephrectomy (surgical removal of kidney) AND the requested drug will be used as adjuvant (add-on) treatment

C. If you have gastrointestinal stromal tumor, approval also requires:
   1. You are 18 years of age or older
   2. You have tried or have a contraindication to (harmful for you to use) imatinib mesylate (Gleevec)

D. If you have unresectable locally advanced or metastatic pancreatic neuroendocrine tumor, approval also requires:
   1. You are 18 years of age or older
   2. Your tumor is progressive (getting worse) and well-differentiated (looks like healthy cells)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the prescribing information and/or drug monograph for Sutent.

REFERENCES

Sutent [Prescribing Information]. New York, NY: Pfizer Labs; August 2021.

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SUNITINIB (PART D)

For Part D use only:

SUNITINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	GASTROINTESTINAL STROMAL TUMORS (GIST): TRIAL OF OR CONTRAINDICATION TO IMATINIB.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SUTIMLIMAB-JOME (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SUTIMLIMAB-JOME	ENJAYMO	47799		GPI-10 (8580308530)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of cold agglutinin disease (CAD) (ICD-10 D59.12) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SUTIMLIMAB-JOME (Enjaymo)** requires the following rule(s) be met for approval:
   A. You have cold agglutinin disease (CAD: a rare type of blood condition)
   B. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SUTIMLIMAB-JOME (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Enjaymo.

REFERENCES
Enjaymo [Prescribing Information]. Waltham, MA: Bioverativ USA, Inc.; February 2022.

For Part D use only:

SUTIMLIMAB-JOME (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
No	No	Yes

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SUZETRIGINE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SUZETRIGINE	JOURNAVX	50239		GPI-10 (6417507000)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of moderate to severe acute pain (ICD-10 R52, Group G89.1) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient previously received treatment with Journavx?

   If yes, continue to #3.
   If no, **approve for 30 days by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

3. Is the request for the treatment of a new episode of acute pain?

   If yes, **approve for 30 days by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SUZETRIGINE (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SUZETRIGINE (Journavx)** requires the following rule(s) be met for approval:

A. You have moderate to severe acute (short-term) pain
B. You are 18 years of age or older
C. If you have previously received treatment with Journavx, approval also requires:
   1. The request is for the treatment of a new episode of acute pain

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Journavx.

REFERENCES

Journavx [Prescribing Information]. Boston, MA: Vertex Pharmaceuticals, Inc.; January 2025.

For Part D use only:

SUZETRIGINE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	30 DAYS
Other Criteria	MODERATE TO SEVERE ACUTE PAIN: IF TREATMENT EXPERIENCED, REQUEST IS FOR THE TREATMENT OF A NEW EPISODE OF ACUTE PAIN.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TADALAFIL - ADCIRCA, ALYQ TIRF (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TADALAFIL	ADCIRCA, ALYQ, TADALAFIL		26587	GPI-14 (40143080000320)	

These are TIRF-Like drugs requiring a payment determination for "Part D" or "Non-Part D".

PAYMENT DETERMINATION CRITERIA

1. Is the request for **ONE** of the following?
   - Pulmonary arterial hypertension (PAH) (World Health Organization Group 1) (ICD-10 I27.0, Group I27.2)
   - Prophylaxis of high altitude pulmonary edema
   - Secondary Raynaud's phenomenon (ICD-10 Group I73.0)

   If yes, **set MCARE_DRUG_DETERM_OVR to 'Y' and approve for 12 months by GPID or GPI-14. Document in the PA comments: Part D Determination Override and diagnosis.**

   If no, **do not enter an MCARE override. Then, process as follows:**
   CSR Note:
   - If the caller is a physician, member, and/or AOR, please initiate a verbal PA intake request in MR3.
   - If the caller is a pharmacy, please advise the pharmacy to contact the provider or member to pursue a payment determination and document the diagnosis provided in MedAccess.

   Please follow the clinical authorization process within the HQ notes.

   RPH Note:
   - Review for both FDA and Part D compendial supported off-label indications.
   - If the provided diagnosis is not FDA approved or compendial supported off-label use, **set MCARE_DRUG_DETERM_OVR to 'N' and enter override within the denied PA for 12 months by GPID or GPI-14.**
   - If the diagnosis is UNKNOWN do not enter an MCARE override; follow the criteria for any additional UM and decision the case accordingly. Provide the following PAC instruction**:** '**PAC: do not enter an MCARE override**.'

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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TADALAFIL - ADCIRCA, ALYQ TIRF (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (World Health Organization Group 1) (ICD-10 I27.0, Group I27.2) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   - The patient is NOT concurrently or intermittently taking oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
   - The requested medication will NOT be used concurrently with guanylate cyclase (GC) stimulators (e.g., Adempas [riociguat])

   If yes, continue to #2.
   If no, continue to #3.

2. Is the PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of 15 mmHg or less
   - Pulmonary vascular resistance (PVR) greater than 2 Wood units

   If yes, **approve for 12 months by GPID or GPI-14. NOTE: If the claim rejects for payment determination after analyzing, then follow the above TIRF-Like determination criteria.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   - **If indication is Part D, but other criteria not met: Set MCARE_DRUG_DETERM_OVR to 'Y' and enter override within the partially denied PA for 12 months by GPID or GPI-14.**

   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TADALAFIL - ADCIRCA, ALYQ TIRF (PART D)

INITIAL CRITERIA (CONTINUED)

3. Is the request for **ONE** of the following?
   - Prophylaxis of high altitude pulmonary edema
   - Secondary Raynaud's phenomenon (ICD-10 Group I73.0)

   If yes, **approve for 12 months by GPID or GPI-14. NOTE: If the claim rejects for payment determination after analyzing, then follow the above TIRF-Like determination criteria.** **APPROVAL TEXT (IF APPLICABLE):** The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   If not a Part D indication: Set MCARE_DRUG_DETERM_OVR to 'N' and enter override within the denied PA for 12 months by GPID or GPI-14.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TADALAFIL - ADCIRCA, ALYQ** requires the following rule(s) be met for approval:

   A. The request is for ONE of the following:
      1. Pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization Group 1: a way to classify the severity of disease)
      2. Prophylaxis of high altitude pulmonary edema (prevention of a type of lung condition at high elevation)
      3. Secondary Raynaud's phenomenon (a type of blood vessel disorder caused by another condition)

   B. If you have pulmonary arterial hypertension (World Health Organization Group 1), approval also requires:
      1. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
      2. Your pulmonary arterial hypertension diagnosis is confirmed by right heart catheterization (a test used to measure how well the heart is pumping) with ALL of the following lab values:
         a. Mean pulmonary artery pressure (PAP: a type of measurement for pulmonary arterial hypertension) greater than 20 mmHg
         b. Pulmonary capillary wedge pressure (PCWP: a type of measurement for pulmonary arterial hypertension) of 15 mmHg or less
         c. Pulmonary vascular resistance (PVR: a type of measurement for pulmonary arterial hypertension) greater than 2 Wood units

   (Initial denial text continued on next page)

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TADALAFIL - ADCIRCA, ALYQ TIRF (PART D)

INITIAL CRITERIA (CONTINUED)

3. You are NOT concurrently (at the same time) or intermittently (off and on) taking oral erectile dysfunction agents (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
4. You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (drugs that also treat pulmonary hypertension such as Adempas [riociguat])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TADALAFIL - ADCIRCA, ALYQ TIRF (PART D)

RENEWAL CRITERIA

NOTE: For the request of prophylaxis of high altitude pulmonary edema, and secondary Raynaud's phenomenon, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (World Health Organization Group 1) (ICD-10 I27.0, Group I27.2) and meet **ALL** of the following criteria?
   - The patient is NOT concurrently or intermittently taking oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
   - The requested medication will NOT be used concurrently with guanylate cyclase (GC) stimulators (e.g., Adempas [riociguat])

   If yes, **approve for 12 months by GPID or GPI-14. NOTE: If the claim rejects for payment determination after analyzing, then follow the above TIRF-Like determination criteria. APPROVAL TEXT (IF APPLICABLE):** The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   - **If not a Part D indication: Set MCARE_DRUG_DETERM_OVR to 'N' and enter override within the denied PA for 12 months by GPID or GPI-14.**
   - **If indication is Part D, but other criteria not met: Set MCARE_DRUG_DETERM_OVR to 'Y' and enter override within the partially denied PA for 12 months by GPID or GPI-14.**

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TADALAFIL - ADCIRCA, ALYQ** requires the following rule(s) be met for renewal:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization Group 1)
   B. You are NOT concurrently (at the same time) or intermittently (off and on) taking oral erectile dysfunction agents (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
   C. You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (drugs that also treat pulmonary hypertension such as Adempas [riociguat])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TADALAFIL - ADCIRCA, ALYQ TIRF (PART D)

RATIONALE

Prior authorization on these drugs is required due to a high potential for non-Part D use. These drugs should NOT be used for non-medically accepted indications as defined in section 1860D-2(e)(4) of the Act. For further information, please refer to the Prescribing Information and/or Drug Monograph for Alyq, and Adcirca.

REFERENCES

Adcirca [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; September 2020.
Alyq [Prescribing Information]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; September 2021.
Announcement of Calendar Year (CY) 2015 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. April 7, 2014. Section III – Part D: Appropriate Utilization of Prior Authorization Requirements to Determine Part D Drug Status. Page 112 – 114.

For Part D use only:

TADALAFIL - ADCIRCA, ALYQ (PART D)	
Covered Uses	ALL MEDICALLY-ACCEPTED INDICATIONS.
Exclusion Criteria	N/A
Required Medical Information	PULMONARY ARTERIAL HYPERTENSION (PAH): INITIAL: DIAGNOSIS CONFIRMED BY RIGHT HEART CATHETERIZATION WITH THE FOLLOWING PARAMETERS: 1) MEAN PULMONARY ARTERY PRESSURE (PAP) GREATER THAN 20 MMHG, 2) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF 15 MMHG OR LESS, AND 3) PULMONARY VASCULAR RESISTANCE (PVR) GREATER THAN 2 WOOD UNITS.
Age Restrictions	N/A
Prescriber Restrictions	PAH: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	PAH: INITIAL/RENEWAL: 1) NOT CONCURRENTLY OR INTERMITTENTLY TAKING ORAL ERECTILE DYSFUNCTION AGENTS (E.G. CIALIS, VIAGRA) OR ANY ORGANIC NITRATES IN ANY FORM, AND 2) NO CONCURRENT USE WITH GUANYLATE CYCLASE STIMULATORS.

Core	Advantage	Plus
Yes	Yes	Yes

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TADALAFIL-CIALIS DvE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TADALAFIL	CIALIS, TADALAFIL		99409 20736	GPI-14 (40304080000302, 40304080000305)	

These are DvE drugs requiring a payment determination for "Part D" or "Non-Part D".

PAYMENT DETERMINATION CRITERIA

1. Does the patient have a diagnosis of benign prostatic hyperplasia (BPH) (ICD-10 Group N40)?

NOTE: Non-FDA approved indications (this includes off label uses [e.g., prophylaxis of high altitude pulmonary edema, secondary Raynaud's phenomenon] listed in any CMS approved compendia) should NOT be approved under Part D.

If yes, **set CMS_DVE_OVR to 'D', and approve for 12 months by GPID or GPI-14. Document in the PA comments: Part D Determination Override.**

If no, **set CMS_DVE_OVR to 'E', and approve for 12 months by GPID or GPI-14. Document in the PA comments: Payment Determination Override. This is not a Part D indication.**

NOTE: If the claim rejects after analyzing, then follow the clinical authorization process within HQ notes.

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TADALAFIL-CIALIS DvE (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the drug being used for a non-FDA approved indication (this includes off label uses [e.g., prophylaxis of high altitude pulmonary edema, secondary Raynaud's phenomenon (ICD-10 Group I73.0)] listed in any CMS approved compendia)?

   If yes, do not approve.
   Set CMS_DVE_OVR to 'E' and enter override within the denied PA for 12 months by GPID or GPI-14.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of erectile dysfunction (ICD-10 Group N52) without benign prostatic hyperplasia (BPH)?

   If yes, do not approve.
   Set CMS_DVE_OVR to 'E' and enter override within the denied PA for 12 months by GPID or GPI-14.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #3.

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TADALAFIL-CIALIS DvE (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of benign prostatic hyperplasia (BPH) (ICD-10 Group N40)?

   If yes, continue to #4.
   If no, do not approve.
   Set CMS_DVE_OVR to 'E' and enter override within the denied PA for 12 months by GPID or GPI-14.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient meet **ALL** of the following criteria?
   - The patient had a trial of one 5-alpha-reductase inhibitor (e.g., finasteride, dutasteride)
   - The patient had a trial of one alpha blocker (e.g., doxazosin, terazosin, tamsulosin, alfuzosin)

   If yes, **approve both 2.5 mg and 5 mg tablets for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: **Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TADALAFIL-CIALIS** requires the following rule(s) be met for approval:
   A. You have benign prostatic hyperplasia (BPH: a type of prostate condition)
   B. You have tried one 5-alpha-reductase inhibitor (such as finasteride, dutasteride)
   C. You have tried one alpha blocker (such as doxazosin, terazosin, tamsulosin, alfuzosin)
   D. This medication will not be approved for any of the following conditions:
      1. The request is for erectile dysfunction (ED: difficulty getting or keeping an erection) and you do NOT have benign prostatic hyperplasia
      2. The request is for a non-Food and Drug Administration (FDA) approved indication (this includes off label uses [such as prophylaxis of high altitude pulmonary edema (prevention of a type of lung condition at high elevation), secondary Raynaud's phenomenon (a type of blood vessel disorder that is caused by another condition)] listed in one of the Centers for Medicare & Medicaid Services (CMS) approved compendia)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TADALAFIL-CIALIS DvE (PART D)

RATIONALE

Pursuant to Chapter 6 of the Medicare Prescription Drug Benefit Manual, Section 20.1-Excluded Categories, erectile dysfunction (ED) "drugs will meet the definition of a Part D drug when prescribed for medically-accepted indications approved by the FDA other than sexual or erectile dysfunction (such as pulmonary hypertension). However, ED drugs will not meet the definition of a Part D drug when used off-label, even when the off-label use is listed in one of the compendia found in section 1927(g)(1)(B)(i) of the Act: American Hospital Formulary Service Drug Information, and DRUGDEX® Information System."

The goal of the Payment Determination section of this guideline is to limit the coverage of Cialis to the Medicare Part D covered indication of benign prostatic hyperplasia (BPH) and exclude coverage for erectile dysfunction (ED) or any other off label indication.

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cialis.

REFERENCES

Cialis [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; February 2018.

Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements. Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf. [Accessed July 2024].

For Part D use only:

TADALAFIL-CIALIS (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	ERECTILE DYSFUNCTION WITHOUT DIAGNOSIS OF BENIGN PROSTATIC HYPERPLASIA (BPH).
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	BPH: 1) TRIAL OF ONE ALPHA BLOCKER (E.G., DOXAZOSIN, TERAZOSIN, TAMSULOSIN, ALFUZOSIN), AND 2) TRIAL OF ONE 5-ALPHA-REDUCTASE INHIBITOR (E.G., FINASTERIDE, DUTASTERIDE). APPLIES TO 2.5MG AND 5MG STRENGTHS ONLY.

Core	Advantage	Plus
Yes	Yes	Yes

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TADALAFIL-TADLIQ TIRF (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TADALAFIL	TADLIQ		52585	GPI-14 (40143080001820)	

These are TIRF-Like drugs requiring a payment determination for "Part D" or "Non-Part D".

PAYMENT DETERMINATION CRITERIA

1. Is the request for **ONE** of the following?
   - Pulmonary arterial hypertension (PAH) (World Health Organization Group 1) (ICD-10 I27.0, Group I27.2)
   - Prophylaxis of high altitude pulmonary edema
   - Secondary Raynaud's phenomenon (ICD-10 Group I73.0)

   If yes, **set MCARE_DRUG_DETERM_OVR to 'Y' and approve for 12 months by GPID or GPI-14. Document in the PA comments: Part D Determination Override and diagnosis.**

   If no, **do not enter an MCARE override. Then, process as follows:**
   CSR Note:
   - If the caller is a physician, member, and/or AOR, please initiate a verbal PA intake request in MR3.
   - If the caller is a pharmacy, please advise the pharmacy to contact the provider or member to pursue a payment determination and document the diagnosis provided in MedAccess.

   Please follow the clinical authorization process within the HQ notes.

   RPH Note:
   - Review for both FDA and Part D compendial supported off-label indications.
   - If the provided diagnosis is not FDA approved or compendial supported off-label use, **set MCARE_DRUG_DETERM_OVR to 'N' and enter override within the denied PA for 12 months by GPID or GPI-14.**
   - If the diagnosis is UNKNOWN do not enter an MCARE override; follow the criteria for any additional UM and decision the case accordingly. Provide the following PAC instruction**:** '**PAC: do not enter an MCARE override**.'

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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TADALAFIL-TADLIQ TIRF (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (World Health Organization Group 1) (ICD-10 I27.0, Group I27.2) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   - The patient is NOT concurrently or intermittently taking oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
   - Tadliq will NOT be used concurrently with guanylate cyclase (GC) stimulators (e.g., Adempas [riociguat])
   - The patient is unable to swallow tablets

   If yes, continue to #2.
   If no, continue to #3.

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INITIAL CRITERIA (CONTINUED)

2. Is the PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of 15 mmHg or less
   - Pulmonary vascular resistance (PVR) greater than 2 Wood units

   If yes, **approve for 12 months by GPID or GPI-14. NOTE: If the claim rejects for payment determination after analyzing, then follow the above TIRF-Like determination criteria.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   - **If indication is Part D, but other criteria not met: Set MCARE_DRUG_DETERM_OVR to 'Y' and enter override within the partially denied PA for 12 months by GPID or GPI-14.**

   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Is the request for **ONE** of the following?
   - Prophylaxis of high altitude pulmonary edema
   - Secondary Raynaud's phenomenon (ICD-10 Group I73.0)

   If yes, **approve for 12 months by GPID or GPI-14. NOTE: If the claim rejects for payment determination after analyzing, then follow the above TIRF-Like determination criteria.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   If not a Part D indication: Set MCARE_DRUG_DETERM_OVR to 'N' and enter override within the denied PA for 12 months by GPID or GPI-14.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TADALAFIL-TADLIQ** requires the following rule(s) be met for approval:
   A. The request is for ONE of the following:
      1. Pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization Group 1: a way to classify the severity of disease)
      2. Prophylaxis of high altitude pulmonary edema (prevention of a type of lung condition at high elevation)
      3. Secondary Raynaud's phenomenon (a type of blood vessel disorder that is caused by another condition)

   (Initial denial text continued on next page)

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TADALAFIL-TADLIQ TIRF (PART D)

INITIAL CRITERIA (CONTINUED)

B. If you have pulmonary arterial hypertension (World Health Organization Group 1), approval also requires:

1. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
2. Your pulmonary arterial hypertension diagnosis is confirmed by right heart catheterization (a test used to measure how well the heart is pumping) with ALL of the following lab values:
   a. Mean pulmonary artery pressure (PAP: a type of measurement for pulmonary arterial hypertension) greater than 20 mmHg
   b. Pulmonary capillary wedge pressure (PCWP: a type of measurement for pulmonary arterial hypertension) of 15 mmHg or less
   c. Pulmonary vascular resistance (PVR: a type of measurement for pulmonary arterial hypertension) greater than 2 Wood units
3. You are NOT concurrently (at the same time) or intermittently (off and on) taking oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
4. You will NOT use Tadliq concurrently (at the same time) with guanylate cyclase (GC) stimulators (drugs that also treat pulmonary hypertension such as Adempas [riociguat])
5. You are unable to swallow tablets

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TADALAFIL-TADLIQ TIRF (PART D)

RENEWAL CRITERIA

NOTE: For the request of prophylaxis of high altitude pulmonary edema, and secondary Raynaud's phenomenon, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (World Health Organization Group 1) (ICD-10 I27.0, Group I27.2) and meet **ALL** of the following criteria?
   - The patient is NOT concurrently or intermittently taking oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
   - Tadliq will NOT be used concurrently with guanylate cyclase (GC) stimulators (e.g., Adempas [riociguat])

   If yes, **approve for 12 months by GPID or GPI-14. NOTE: If the claim rejects for payment determination after analyzing, then follow the above TIRF-Like determination criteria.** **APPROVAL TEXT (IF APPLICABLE):** The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   - **If not a Part D indication: Set MCARE_DRUG_DETERM_OVR to 'N' and enter override within the denied PA for 12 months by GPID or GPI-14.**
   - **If indication is Part D, but other criteria not met: Set MCARE_DRUG_DETERM_OVR to 'Y' and enter override within the partially denied PA for 12 months by GPID or GPI-14.**

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TADALAFIL-TADLIQ** requires the following rule(s) be met for renewal:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization Group 1: a way to classify the severity of disease)
   B. You are NOT concurrently (at the same time) or intermittently (off and on) taking oral erectile dysfunction agents (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
   C. You will NOT use Tadliq concurrently (at the same time) with guanylate cyclase stimulators (drugs that also treat pulmonary hypertension such as Adempas [riociguat])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TADALAFIL-TADLIQ TIRF (PART D)

RATIONALE

Prior authorization on these drugs is required due to a high potential for non-Part D use. These drugs should NOT be used for non-medically accepted indications as defined in section 1860D-2(e)(4) of the Act. For further information, please refer to the Prescribing Information and/or Drug Monograph for Tadliq.

REFERENCES

Tadliq [Prescribing Information]. Farmville, NC: CMP Pharma, Inc.; October 2022.
Announcement of Calendar Year (CY) 2015 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. April 7, 2014. Section III – Part D: Appropriate Utilization of Prior Authorization Requirements to Determine Part D Drug Status. Page 112 – 114.

For Part D use only:

TADALAFIL-TADLIQ (PART D)	
Covered Uses	ALL MEDICALLY-ACCEPTED INDICATIONS.
Exclusion Criteria	N/A
Required Medical Information	PULMONARY ARTERIAL HYPERTENSION (PAH): INITIAL: DIAGNOSIS CONFIRMED BY RIGHT HEART CATHETERIZATION WITH THE FOLLOWING PARAMETERS: 1) MEAN PULMONARY ARTERY PRESSURE (PAP) GREATER THAN 20 MMHG, 2) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF 15 MMHG OR LESS, AND 3) PULMONARY VASCULAR RESISTANCE (PVR) GREATER THAN 2 WOOD UNITS.
Age Restrictions	N/A
Prescriber Restrictions	PAH: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	PAH: INITIAL: 1) NOT CONCURRENTLY OR INTERMITTENTLY TAKING ORAL ERECTILE DYSFUNCTION AGENTS (E.G. CIALIS, VIAGRA) OR ANY ORGANIC NITRATES IN ANY FORM, 2) NO CONCURRENT USE WITH GUANYLATE CYCLASE STIMULATORS, AND 3) INABILITY TO SWALLOW TABLETS. RENEWAL: 1) NOT CONCURRENTLY OR INTERMITTENTLY TAKING ORAL ERECTILE DYSFUNCTION AGENTS (E.G. CIALIS, VIAGRA) OR ANY ORGANIC NITRATES IN ANY FORM, AND 2) NO CONCURRENT USE WITH GUANYLATE CYCLASE STIMULATORS.

Core	Advantage	Plus
Yes	Yes	Yes

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TAFAMIDIS (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TAFAMIDIS MEGLUMINE	VYNDAQEL	41631		GPI-10 (4055008020)	
TAFAMIDIS	VYNDAMAX	45729		GPI-10 (4055008000)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of cardiomyopathy associated with wild type transthyretin-mediated amyloidosis (ICD-10 E85.82) or hereditary transthyretin-mediated amyloidosis (ATTR-CM) (ICD-10 E85.4) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a cardiologist, transthyretin amyloidosis (ATTR) specialist, or medical geneticist
   - The patient has New York Heart Association (NYHA) Class I, II, or III heart failure
   - The requested medication will NOT be used concurrently with other ATTR-CM TTR (transthyretin) stabilizers (e.g., acoramidis [Attruby])

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TAFAMIDIS (PART D)

INITIAL CRITERIA (CONTINUED)

2. Is the patient's diagnosis confirmed by **ONE** of the following?
   - A bone scan (scintigraphy) strongly positive for myocardial uptake of TC-99m-PYP *(Note: Strongly positive defined as heart to contralateral lung [H/CL] ratio of at least 1.5 or Grade 2 or greater localization to the heart using the Perugini Grade 1-3 scoring system)*
   - A biopsy of tissue of affected organ(s) (cardiac and possibly non-cardiac sites) to confirm amyloid presence AND chemical typing to confirm presence of transthyretin (TTR) protein

   If yes, **approve both Vyndaqel and Vyndamax for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TAFAMIDIS (Vyndaqel, Vyndamax)** requires the following rule(s) be met for approval:
   A. You have cardiomyopathy associated with wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM: a type of heart condition)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor), transthyretin amyloidosis (ATTR) specialist, or medical geneticist (doctor who treats gene disorders)
   D. You have New York Heart Association (NYHA: classificationsystem for heart failure) Class I, II or III heart failure
   E. You will NOT use the requested medication concurrently (at the same time) with other ATTR-CM TTR (transthyretin) stabilizers (such as acoramidis [Attruby])
   F. Your diagnosis is confirmed by ONE of the following:
      1. A bone scan (scintigraphy) strongly positive for myocardial uptake of TC-99m-PYP (a type of imaging agent) *(Note: Strongly positive defined as heart to contralateral lung [H/CL] ratio of at least 1.5 or Grade 2 or greater localization to the heart using the Perugini Grade 1-3 scoring system)*
      2. A biopsy of tissue of affected organ(s) (can be heart or non-heart related organs) to confirm amyloid (a type of protein) presence AND chemical typing to confirm presence of transthyretin (TTR) protein

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TAFAMIDIS (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of cardiomyopathy associated with wild type transthyretin-mediated amyloidosis (ICD-10 E85.82) or hereditary transthyretin-mediated amyloidosis (ATTR-CM) (ICD-10 E85.4) **AND** meet the following criterion?
   - The requested medication will NOT be used concurrently with other ATTR-CM TTR (transthyretin) stabilizers (e.g., acoramidis [Attruby])

   If yes, **approve both Vyndaqel and Vyndamax for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TAFAMIDIS (Vyndaqel, Vyndamax)** requires the following rule(s) be met for renewal:
   A. You have cardiomyopathy associated with wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM: a type of heart condition)
   B. You will NOT use the requested medication concurrently (at the same time) with other ATTR-CM TTR (transthyretin) stabilizers (such as acoramidis [Attruby])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Vyndaqel and Vyndamax.

REFERENCES
Vyndaqel [Prescribing Information]. New York, NY: Pfizer Inc.; October 2023.
Vyndamax [Prescribing Information]. New York, NY: Pfizer Inc.; October 2023.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TAFAMIDIS (PART D)

For Part D use only:

TAFAMIDIS (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	CARDIOMYOPATHY ASSOCIATED WITH WILD TYPE OR HEREDITARY TRANSTHYRETIN-MEDIATED AMYLOIDOSIS (ATTR-CM): INITIAL: 1) NEW YORK HEART ASSOCIATION (NYHA) CLASS I, II, OR III HEART FAILURE, AND 2) DIAGNOSIS CONFIRMED BY (A) BONE SCAN (SCINTIGRAPHY) STRONGLY POSITIVE FOR MYOCARDIAL UPTAKE OF TC-99M-PYP, OR (B) BIOPSY OF TISSUE OF AFFECTED ORGAN(S) (CARDIAC AND POSSIBLY NON-CARDIAC SITES) TO CONFIRM AMYLOID PRESENCE AND CHEMICAL TYPING TO CONFIRM PRESENCE OF TRANSTHYRETIN (TTR) PROTEIN.
Age Restrictions	N/A
Prescriber Restrictions	ATTR-CM: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST, ATTR SPECIALIST, OR MEDICAL GENETICIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS
Other Criteria	ATTR-CM: INITIAL/RENEWAL: NO CONCURRENT USE WITH OTHER ATTR-CM TTR STABILIZERS (E.G., ACORAMIDIS)

Created: 05/19
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 01/25

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TAFASITAMAB-CXIX BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TAFASITAMAB-CXIX	MONJUVI	46758		GPI-10 (2135146720)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	Yes	No	No	Yes	No	No	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit).**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, continue to #6.
   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, continue to #6.
   If no, continue to #5.

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enterany override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

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TAFASITAMAB-CXIX BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

6. Is the drug administered via an implantable pump?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, continue to #7.

7. Is the drug administered via an external pump?

   If yes, continue to #8.
   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

8. Is the drug specifically infused through an external infusion pump covered by Medicare?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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TAFASITAMAB-CXIX BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of diffuse large B-cell lymphoma (DLBCL) (ICD-10 Group C83.3), not otherwise specified, and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The cancer has relapsed or is refractory
   - The patient is not eligible for autologous stem cell transplant (ASCT)
   - Monjuvi will be used in combination with Revlimid (lenalidomide)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of follicular lymphoma (FL) (ICD-10 Group C82) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The cancer has relapsed or is refractory
   - Monjuvi will be used in combination with Revlimid (lenalidomide) and rituximab

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See denial text at the end of the guideline.

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TAFASITAMAB-CXIX BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TAFASITAMAB-CXIX (Monjuvi)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Diffuse large B-cell lymphoma (DLBCL: a type of blood cancer)
   2. Follicular lymphoma (FL: a type of blood cancer)

B. If you have diffuse large B-cell lymphoma (not otherwise specified), approval also requires:
   1. You are 18 years of age or older
   2. Your cancer has relapsed or is refractory (cancer that has returned or does not fully respond to treatment)
   3. You are not eligible for autologous stem cell transplant (ASCT: stem cell transplant transferred from your own body)
   4. Monjuvi will be used in combination with Revlimid (lenalidomide)

C. If you have follicular lymphoma, approval also requires:
   1. You are 18 years of age or older
   2. Your cancer has relapsed or is refractory (cancer that has returned or does not fully respond to treatment)
   3. Monjuvi will be used in combination with Revlimid (lenalidomide) and rituximab

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TAFASITAMAB-CXIX BvD (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Monjuvi. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B. Drugs administered by an implantable pump are covered under Part B. Drugs administered via an external pump are covered under Part B if they are included under the local coverage policy of the applicable Medicare coverage policies (National and/or Local Coverage Policies). Drugs administered via an external pump that are not included under the applicable Medicare coverage policies are covered under Part D. A CMS website to assist with National and Local Coverage Determination for B versus D review is http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx.

REFERENCES

Monjuvi [Prescribing Information]. Wilmington, DE: Incyte Corporation; June 2025.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed July 2, 2025].

For Part D use only:

TAFASITAMAB-CXIX (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TALAZOPARIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TALAZOPARIB TOSYLATE	TALZENNA	45368		GPI-10 (2153558040)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced or metastatic breast cancer (ICD-10 Group C50) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer is HER2-negative
   - The patient patient's cancer has a deleterious or suspected deleterious germline BRCA mutation (*gBRCAm*), as confirmed by an FDA-approved companion diagnostic test for Talzenna
   - The patient has been treated with chemotherapy (e.g., doxorubicin, docetaxel) in the neoadjuvant, adjuvant, or metastatic setting

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient's cancer is NOT hormone receptor (HR)-positive
   - The patient's cancer is hormone receptor (HR)-positive AND the patient has received prior treatment with endocrine therapy (e.g., tamoxifen, Arimidex [anastrozole]) or endocrine therapy is considered to be inappropriate for the patient

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TALAZOPARIB (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of metastatic castration-resistant prostate cancer (mCRPC) (ICD-10 Z19.2, C61) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Talzenna will be used in combination with enzalutamide (Xtandi)
   - The patient's cancer has a homologous recombination repair (HRR) gene mutation

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient meet **ONE** of the following criteria?
   - The patient previously had a bilateral orchiectomy
   - The patient has a castrate level of testosterone (i.e., less than 50 ng/dL)
   - Talzenna will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog (e.g., Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TALAZOPARIB (Talzenna)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Locally advanced or metastatic breast cancer (breast cancer that has spread to nearby tissue or lymph nodes or has spread to other parts of the body)
      2. Metastatic castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and no longer responds to testosterone lowering treatment)

   (Denial text continued on next page)

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TALAZOPARIB (PART D)

GUIDELINES FOR USE (CONTINUED)

B. If you have locally advanced or metastatic breast cancer, approval also requires:
1. You are 18 years of age or older
2. Your cancer is HER2 (human epidermal growth factor receptor 2: a type of protein)-negative
3. You have a deleterious or suspected deleterious germline breast cancer susceptibility gene (BRCA) mutation (gBRCAm: a type of abnormal change in a gene), as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic test for Talzenna
4. You have been treated with chemotherapy (such as doxorubicin, docetaxel) in the neoadjuvant (given before main treatment), adjuvant (add-on to main treatment), or metastatic setting (to treat disease that has spread to other parts of the body)
5. You meet ONE of the following:
   a. You do not have hormone receptor (HR)-positive breast cancer
   b. You have hormone receptor (HR)-positive breast cancer, and you have been treated with prior endocrine (hormone) therapy (such as tamoxifen, Arimidex [anastrozole]), or endocrine therapy is considered to be inappropriate for you

C. If you have metastatic castration-resistant prostate cancer, approval also requires:
1. You are 18 years of age or older
2. Talzenna will be used in combination with enzalutamide (Xtandi)
3. Your cancer has a homologous recombination repair (HRR) gene mutation (a type of abnormal change in a gene)
4. You meet ONE of the following:
   a. You previously received a bilateral orchiectomy (both testicles have been surgically removed)
   b. You have a castrate level of testosterone (blood testosterone levels are less than 50 ng/dL)
   c. Talzenna will be used concurrently (at the same time) with a gonadotropin-releasing hormone (GnRH) analog (such as Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Talzenna.

REFERENCES

Talzenna [Prescribing Information]. New York, NY: Pfizer Labs; March 2024.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TALAZOPARIB (PART D)

For Part D use only:

TALAZOPARIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	ADVANCED OR METASTATIC BREAST CANCER: 1) HAS BEEN TREATED WITH CHEMOTHERAPY IN THE NEOADJUVANT, ADJUVANT, OR METASTATIC SETTING, AND 2) IF HORMONE RECEPTOR (HR)-POSITIVE BREAST CANCER, RECEIVED PRIOR TREATMENT WITH ENDOCRINE THERAPY OR IS CONSIDERED INAPPROPRIATE FOR ENDOCRINE THERAPY. METASTATIC CASTRATION-RESISTANT PROSTATE CANCER: 1) RECEIVED A BILATERAL ORCHIECTOMY, 2) CASTRATE LEVEL OF TESTOSTERONE (I.E., LESS THAN 50 NG/DL), OR 3) CONCURRENT USE WITH A GONADOTROPIN RELEASING HORMONE (GNRH) ANALOG.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TALETRECTINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TALETRECTINIB ADIPATE	IBTROZI	50637		GPI-10 (2153387505)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's tumor is ROS1-positive

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TALETRECTINIB (Ibtrozi)** requires the following rule(s) be met for approval:
   A. You have locally advanced or metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread from where it started to nearby tissue or lymph nodes or to other parts of the body)
   B. You are 18 years of age or older
   C. Your tumor is ROS1-positive (abnormal change in a type of gene)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TALETRECTINIB (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ibtrozi.

REFERENCES

Ibtrozi [Prescribing Information]. Burlington, MA: Nuvation Bio Inc.; June 2025.

For Part D use only:

TALETRECTINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TALIMOGENE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TALIMOGENE LAHERPAREPVEC	IMLYGIC	42741		GPI-10 (2157407040)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable melanoma (ICD-10 Group C43) and meet **ALL** of the following criteria?
   - The patient has a recurrence of melanoma lesions after initial surgery
   - The patient does not have a history of primary or acquired immunodeficient states, leukemia, lymphoma, or AIDS
   - Imlygic will NOT be used concurrently with immunosuppressive therapy
   - Imlygic will NOT be used concurrently with a medical therapy for the treatment of melanoma, including pembrolizumab (Keytruda), nivolumab (Opdivo), ipilimumab (Yervoy), dabrafenib (Tafinlar), trametinib (Mekinist), vemurafenib (Zelboraf), interleukin-2, interferon, dacarbazine, temozolomide (Temodar), paclitaxel, carboplatin, imatinib (Gleevec), melphalan (Alkeran), imiquimod, or radiation therapy

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Will Imlygic be injected into cutaneous, subcutaneous, and/or nodal lesions that are visible, palpable, or detectable by ultrasound guidance?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve
   DENIAL TEXT: See the denial text at the end of the guideline.

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TALIMOGENE (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TALIMOGENE (Imlygic)** requires the following rule(s) be met for approval:

A. You have unresectable melanoma (a type of skin cancer that cannot be removed with surgery)
B. You have a recurrence of melanoma lesions after initial surgery (cancer returns after surgery)
C. You do not have a history of primary or acquired immunodeficient states (conditions that weaken the immune system), leukemia (a type of blood cancer), lymphoma (a type of blood cancer), or acquired immunodeficiency syndrome (AIDS: a type of immune system disorder caused by virus infection)
D. You will NOT use Imlygic concurrently (at the same time) with immunosuppressive therapy (treatment that lowers immune system activity)
E. You will NOT use Imlygic concurrently (at the same time) with a medical therapy for the treatment of melanoma, including pembrolizumab (Keytruda), nivolumab (Opdivo), ipilimumab (Yervoy), dabrafenib (Tafinlar), trametinib (Mekinist), vemurafenib (Zelboraf), interleukin-2, interferon, dacarbazine, temozolomide (Temodar), paclitaxel, carboplatin, imatinib (Gleevec), melphalan (Alkeran), imiquimod, or radiation therapy
F. Imlygic will be injected into cutaneous (skin), subcutaneous (under the skin), and/or nodal (lymph gland) lesions that are visible, palpable (can be felt), or detectable by ultrasound guidance (a type of procedure)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Imlygic.

REFERENCES

Imlygic [Prescribing Information]. Thousand Oaks, CA: Amgen, Inc.; February 2023.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TALIMOGENE (PART D)

For Part D use only:

TALIMOGENE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	UNRESECTABLE MELANOMA: 1) IMLYGIC TO BE INJECTED INTO CUTANEOUS, SUBCUTANEOUS, AND/OR NODAL LESIONS THAT ARE VISIBLE, PALPABLE, OR DETECTABLE BY ULTRASOUND GUIDANCE, 2) NO HISTORY OF PRIMARY OR ACQUIRED IMMUNODEFICIENT STATES, LEUKEMIA, LYMPHOMA, OR AIDS, AND 3) NO CONCURRENT USE WITH IMMUNOSUPPRESSIVE THERAPY OR MEDICAL THERAPY FOR TREATMENT OF MELANOMA, INCLUDING PEMBROLIZUMAB, NIVOLUMAB, IPILIMUMAB, DABRAFENIB, TRAMETINIB, VEMURAFENIB, INTERLEUKIN-2, INTERFERON, DACARBAZINE, TEMOZOLOMIDE, PACLITAXEL, CARBOPLATIN, IMATINIB, MELPHALAN, IMIQUIMOD, OR RADIATION THERAPY.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TALQUETAMAB-TGVS BVD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TALQUETAMAB-TGVS	TALVEY	49135		GPI-10 (2135207680)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	Yes	No	Yes	Yes	No	Yes	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #5.

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TALQUETAMAB-TGVS BVD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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TALQUETAMAB-TGVS BVD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory multiple myeloma (ICD-10 Group C90.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received at least four prior lines of therapy, including a proteasome inhibitor (e.g., Velcade [bortezomib], Kyprolis [carfilzomib]), an immunomodulatory agent (e.g., Revlimid [lenalidomide], Pomalyst [pomalidomide]), and an anti-CD38 monoclonal antibody (e.g., Darzalex [daratumumab])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TALQUETAMAB-TGVS (TALVEY)** requires the following rule(s) be met for approval:
   A. You have relapsed or refractory multiple myeloma (a type of blood cancer that has returned or did not respond to treatment)
   B. You are 18 years of age or older
   C. You have received at least four prior lines of therapy, including a proteasome inhibitor (such as Velcade [bortezomib], Kyprolis [carfilzomib]), an immunomodulatory agent (such as Revlimid [lenalidomide], Pomalyst [pomalidomide]), and an anti-CD38 monoclonal antibody (such as Darzalex [daratumumab])
   (Denial text continued on the next page)

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TALQUETAMAB-TGVS BVD (PART D)

GUIDELINE FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Talvey. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Talvey [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; August 2023.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed June 28, 2024].

For Part D use only:

TALQUETAMAB-TGVS (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TAPINAROF (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TAPINAROF	VTAMA	48031		GPI-10 (9025007500)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of plaque psoriasis (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist
   - The patient has psoriasis covering 3% to 20% of body surface area (BSA) (excluding scalp, palms, fingernails, toenails, and soles)
   - Vtama will NOT be used concurrently with other systemic immunomodulating agents (e.g., Stelara [ustekinumab], Otezla [apremilast]), topical corticosteroids (e.g., betamethasone dipropionate, clobetasol propionate), or topical non-steroidals (e.g., calcitriol, tazarotene)

     If yes, continue to #2.
     If no, continue to #3.

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TAPINAROF (PART D)

INITIAL CRITERIA (CONTINUED)

2. Has the patient had a trial of or contraindication to **TWO** of the following (from different categories)?
   - High or super-high potency topical corticosteroid (e.g., triamcinolone acetonide, fluocinonide, clobetasol propionate, halobetasol propionate)
   - Topical vitamin D analog (e.g., calcipotriene cream, calcitriol ointment)
   - Topical calcineurin inhibitor (e.g., Protopic [tacrolimus], Elidel [pimecrolimus])
   - Topical retinoid (e.g., tazarotene cream/gel)

   If yes, **approve for 3 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient have a diagnosis of atopic dermatitis (ICD-10 Group L20) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - The patient had a trial of or contraindication to a topical corticosteroid (e.g., triamcinolone 0.1% cream or ointment, mometasone furoate 0.1% ointment, fluocinonide 0.05% cream, halobetasol propionate 0.05% ointment) OR a topical calcineurin inhibitor (e.g., Elidel [pimecrolimus], Protopic [tacrolimus])
   - The patient had a trial of or contraindication to Eucrisa (crisaborole)

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TAPINAROF (PART D)

INITIAL CRITERIA (CONTINUED)

4. Will Vtama be used concurrently with **ANY** of the following for the treatment of atopic dermatitis?
   - Other non-steroidal topicals (e.g., calcineurin inhibitors [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)], PDE-4 inhibitors [e.g., Eucrisa (crisaborole)], JAK inhibitors [e.g., Opzelura (ruxolitinib), delgocitinib, AhR agonists)
   - Systemic therapeutic biologics (e.g., Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
   - Other JAK inhibitors (e.g., Rinvoq [upadacitinib], Cibinqo [abrocitinib])
   - Potent immunosuppressants (e.g., azathioprine, cyclosporine)

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, **approve for 3 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TAPINAROF (Vtama)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Plaque psoriasis (a type of skin condition)
      2. Atopic dermatitis (a type of skin condition)
   B. If you have plaque psoriasis, approval also requires:
      1. You are 18 years of age or older
      2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
      3. You have psoriasis covering 3% to 20% of body surface area (BSA) (excluding scalp, palms, fingernails, toenails, and soles)
      4. You will NOT use Vtama concurrently (at the same time) with other systemic immunomodulating agents (such as Stelara [ustekinumab], Otezla [apremilast]), topical corticosteroids (such as betamethasone dipropionate, clobetasol propionate), or topical non-steroidals (such as calcitriol, tazarotene)
      5. You have tried or have a contraindication to (harmful for you to use) TWO of the following (from different categories):
         a. High or super-high potency topical corticosteroid (such as triamcinolone acetonide, fluocinonide, clobetasol propionate, halobetasol propionate)
         b. Topical vitamin D analog (such as calcipotriene cream, calcitriol ointment)
         c. Topical calcineurin inhibitor (such as Protopic [tacrolimus], Elidel [pimecrolimus])
         d. Topical retinoid (such as tazarotene cream/gel)

   (Initial denial text continued on next page)

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TAPINAROF (PART D)

INITIAL CRITERIA (CONTINUED)

C. If you have atopic dermatitis, approval also requires:

1. You are 2 years of age or older
2. You have tried or have a contraindication to (harmful for you to use) a topical corticosteroid (such as triamcinolone 0.1% cream or ointment, mometasone furoate 0.1% ointment, fluocinonide 0.05% cream, halobetasol propionate 0.05% ointment) OR a topical calcineurin inhibitor (such as Elidel [pimecrolimus], Protopic [tacrolimus])
3. You have tried or have a contraindication to Eucrisa (crisaborole)
4. You will NOT use Vtama concurrently (at the same time) with ANY of the following for the treatment of atopic dermatitis (a type of skin condition):
   a. Other non-steroidal topicals (such as calcineurin inhibitors [such as Elidel (pimecrolimus), Protopic (tacrolimus)], PDE-4 [phosphodiesterase-4] inhibitors [such as Eucrisa (crisaborole)], JAK [Janus kinase] inhibitors [such as Opzelura (ruxolitinib), delgocitinib], AhR [aryl hydrocarbon receptor] agonists [a type of medication])
   b. Systemic therapeutic biologics (such as Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
   c. Other JAK (Janus kinase) inhibitors (such as Rinvoq [upadacitinib], Cibinqo [abrocitinib])
   d. Potent immunosuppressants (such as azathioprine, cyclosporine)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TAPINAROF (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of plaque psoriasis (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient has achieved or maintained clear or minimal disease
   - Vtama will NOT be used concurrently with other systemic immunomodulating agents (e.g., Stelara [ustekinumab], Otezla [apremilast]), topical corticosteroids (e.g., betamethasone dipropionate, clobetasol propionate), or topical non-steroidals (e.g., calcitriol, tazarotene)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of atopic dermatitis (ICD-10 Group L20) **AND** meet the following criterion?
   - The patient has experienced or maintained improvement in pruritus, relapsing-remitting dermatitis, or facial/interdigital involvement

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

3. Will Vtama be used concurrently with **ANY** of the following for the treatment of atopic dermatitis?
   - Other non-steroidal topicals (e.g., calcineurin inhibitors [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)], PDE-4 inhibitors [e.g., Eucrisa (crisaborole)], JAK inhibitors [e.g., Opzelura (ruxolitinib), delgocitinib], AhR agonists)
   - Systemic therapeutic biologics (e.g., Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
   - Other JAK inhibitors (e.g., Rinvoq [upadacitinib], Cibinqo [abrocitinib])
   - Potent immunosuppressants (e.g., azathioprine, cyclosporine)

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

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TAPINAROF (PART D)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TAPINAROF (Vtama)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Plaque psoriasis (a type of skin condition)
   2. Atopic dermatitis (a type of skin condition)

B. If you have plaque psoriasis, renewal also requires:
   1. You have achieved or maintained clear or minimal disease
   2. You will NOT use Vtama concurrently (at the same time) with other systemic immunomodulating agents (such as Stelara [ustekinumab], Otezla [apremilast]), topical corticosteroids (such as betamethasone dipropionate, clobetasol propionate), or topical non-steroidals (such as calcitriol, tazarotene)

C. If you have atopic dermatitis, renewal also requires:
   1. You have experienced or maintained improvement in pruritus (itchiness), relapsing-remitting (disease returns and goes away) dermatitis, or facial/interdigital (between the fingers or toes) involvement
   2. You will NOT use Vtama concurrently (at the same time) with ANY of the following for the treatment of atopic dermatitis (a type of skin condition):
      a. Other non-steroidal topicals (such as calcineurin inhibitors [such as Elidel (pimecrolimus), Protopic (tacrolimus)], PDE-4 [phosphodiesterase-4] inhibitors [such as Eucrisa (crisaborole)], JAK [Janus kinase] inhibitors [such as Opzelura (ruxolitinib), delgocitinib], AhR [aryl hydrocarbon receptor] agonists [a type of medication])
      b. Systemic therapeutic biologics (such as Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
      c. Other JAK (Janus kinase) inhibitors (such as Rinvoq [upadacitinib], Cibinqo [abrocitinib])
      d. Potent immunosuppressants (such as azathioprine, cyclosporine)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vtama.

REFERENCES

Vtama [Prescribing Information]. Long Beach, CA: Dermavant Sciences, Inc.; December 2024.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TAPINAROF (PART D)

For Part D use only:

TAPINAROF (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	PLAQUE PSORIASIS (PSO): INITIAL: 1) PSORIASIS COVERING 3 TO 20 PERCENT OF BODY SURFACE AREA, (EXCLUDING SCALP, PALMS, FINGERNAILS, TOENAILS, AND SOLES).
Age Restrictions	N/A
Prescriber Restrictions	PSO: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST.
Coverage Duration	INITIAL: 3 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: PSO: 1) NO CONCURRENT USE WITH OTHER SYSTEMIC IMMUNOMODULATING AGENTS (E.G., STELARA, OTEZLA), TOPICAL CORTICOSTEROIDS, OR TOPICAL NON-STEROIDALS (E.G., CALCITRIOL, TAZAROTENE), AND 2) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING (FROM DIFFERENT CATEGORIES): (A) HIGH OR SUPER-HIGH POTENCY TOPICAL CORTICOSTEROID, (B) TOPICAL VITAMIN D ANALOG, (C) TOPICAL CALCINEURIN INHIBITOR, (D) TOPICAL RETINOID (E.G., TAZAROTENE CREAM/GEL). ATOPIC DERMATITIS (AD): 1) TRIAL OF OR CONTRAINDICATION TO: (A) A TOPICAL CORTICOSTEROID OR TOPICAL CALCINEURIN INHIBITOR, AND (B) EUCRISA, AND 2) NO CONCURRENT USE WITH ANY OF THE FOLLOWING FOR ATOPIC DERMATITIS: (A) NON-STEROIDAL TOPICALS (E.G., CALCINEURIN INHIBITORS, PDE-4 INHIBITORS, JAK INHIBITORS, AHR AGONISTS), (B) SYSTEMIC THERAPEUTIC BIOLOGICS, (C) OTHER JAK INHIBITORS, OR (D) POTENT IMMUNOSUPPRESSANTS (E.G., AZATHIOPRINE, CYCLOSPORINE). RENEWAL: PSO: 1) ACHIEVED OR MAINTAINED CLEAR OR MINIMAL DISEASE, AND 2) NO CONCURRENT USE WITH OTHER SYSTEMIC IMMUNOMODULATING AGENTS, TOPICAL CORTICOSTEROIDS, OR TOPICAL NON-STEROIDALS. AD: 1) EXPERIENCED OR MAINTAINED IMPROVEMENT IN PRURITUS, RELAPSING-REMITTING DERMATITIS, OR FACIAL/INTERDIGITAL INVOLVEMENT, AND 2) NO CONCURRENT USE WITH ANY OF THE FOLLOWING FOR ATOPIC DERMATITIS: (A) NON-STEROIDAL TOPICALS, (B) SYSTEMIC THERAPEUTIC BIOLOGICS, (C) OTHER JAK INHIBITORS, OR (D) POTENT IMMUNOSUPPRESSANTS.

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TAPINAROF (PART D)

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TARLATAMAB-DLLE BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TARLATAMAB-DLLE	IMDELLTRA	49625		GPI-10 (2135207820)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	Yes	No	Yes	Yes	No	Yes	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit).**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #5.

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TARLATAMAB-DLLE BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enterany override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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TARLATAMAB-DLLE BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of small cell lung cancer (SCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has extensive-stage (ES) cancer
   - The patient has disease progression during or after platinum-based chemotherapy (e.g., carboplatin, cisplatin)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TARLATAMAB-DLLE (Imdelltra)** requires the following rule(s) be met for approval:
   A. You have small cell lung cancer (a type of lung cancer)
   B. You are 18 years of age or older
   C. You have extensive-stage cancer (cancer that has spread widely throughout the lungs or other parts of the body)
   D. You have disease progression (worsening of disease) during or after platinum-based chemotherapy (a type of therapy to treat cancer such as carboplatin, cisplatin)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TARLATAMAB-DLLE BvD (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Imdelltra. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Imdelltra [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; May 2024.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed April 8, 2025].

For Part D use only:

TARLATAMAB-DLLE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TASIMELTEON (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TASIMELTEON	HETLIOZ, HETLIOZ LQ, TASIMELTEON	40927		GPI-10 (6025007000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of non-24-hour sleep-wake disorder (non-24, N24SWD) (ICD-10 G47.24, G47.9) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is light-insensitive or has total blindness
   - The requested medication is for Hetlioz (tasimelteon) capsules

   If yes, **approve capsules for a lifetime by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of nighttime sleep disturbances in Smith-Magenis syndrome (SMS) (ICD-10 Q93.88)?

   If yes, continue to #3.
   If no, do no approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Is the requested medication for brand Hetlioz capsules **AND** the patient meets the following criterion?
   - The patient is 16 years of age or older

   If yes, **approve brand Hetlioz capsules for a lifetime by GPID or GPI-14.**
   If no, continue to #4.

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TASIMELTEON (PART D)

GUIDELINES FOR USE (CONTINUED)

4. Is the requested medication for Hetlioz LQ oral suspension **AND** the patient meets the following criterion?
   - The patient is 3 to 15 years of age

   If yes, **approve Hetlioz LQ oral suspension for a lifetime by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TASIMELTEON (Hetlioz, Hetlioz LQ)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Non-24-hour sleep-wake disorder (non-24, N24SWD: a type of sleep condition)
      2. Nighttime sleep disturbances in Smith-Magenis syndrome (SMS: a type of developmental disorder that causes sleeping problems)

   B. If you have non-24-hour sleep-wake disorder, approval also requires:
      1. You are 18 years of age or older
      2. You are light-insensitive (not affected by light) or have total blindness
      3. You are requesting the capsules

   C. If you have nighttime sleep disturbances in Smith-Magenis syndrome, approval also requires:
      1. You are requesting brand Hetlioz capsules, AND you are 16 years of age or older
      2. You are requesting Hetlioz LQ oral suspension, AND you are 3 to 15 years old

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, refer to the prescribing information and/or drug monograph for Hetlioz.

REFERENCES
Hetlioz [Prescribing Information]. Washington, D.C.: Vanda Pharmaceuticals, Inc.; December 2020.
Tasimelteon [Prescribing Information]. Parsippany, NJ: Teva Pharmaceuticals; May 2022.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TASIMELTEON (PART D)

For Part D use only:

TASIMELTEON (PART D)	
Covered uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	LIFETIME
Other Criteria	NON-24 HOUR SLEEP-WAKE DISORDER: LIGHT-INSENSITIVE OR HAS TOTAL BLINDNESS.

Created: 03/14
Effective: 01/01/26 Client Approval: 01/26 P&T Approval: 01/21

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TAVABOROLE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TAVABOROLE	KERYDIN, TAVABOROLE	41353		GPI-10 (9015608000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of onychomycosis (fungal infection) (ICD-10 B35.1) of the toenails?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have onychomycosis due to *Trichophyton rubrum* and meet **ALL** of the following criteria?
   - The patient had a trial of or contraindication to ciclopirox topical solution
   - The patient had a trial of or contraindication to oral terbinafine OR oral itraconazole

   If yes, **approve for 48 weeks by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Does the patient have onychomycosis due to *Trichophyton mentagrophytes* **AND** meet the following criterion?
   - The patient had a trial of or contraindication to oral terbinafine OR oral itraconazole

   If yes, **approve for 48 weeks by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TAVABOROLE (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TAVABOROLE (Kerydin)** requires the following rule(s) be met for approval:

A. You have onychomycosis of the toenails (toenail fungus infection)

B. If you have onychomycosis due to *Trichophyton rubrum* (a type of fungus), approval also requires:

1. You have tried or have a contraindication to (harmful for you to use) ciclopirox topical solution
2. You have tried or have a contraindication to (harmful for you to use) oral terbinafine OR oral itraconazole

C. If you have onychomycosis due to *Trichophyton mentagrophytes* (a type of fungus), approval also requires:

1. You have tried or have a contraindication to (harmful for you to use) oral terbinafine OR oral itraconazole

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kerydin.

REFERENCES

Kerydin [Prescribing Information]. Palo Alto, CA: Anacor Pharmaceuticals; October 2020.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TAVABOROLE (PART D)

For Part D use only:

TAVABOROLE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	48 WEEKS
Other Criteria	ONYCHOMYCOSIS DUE TO TRICHOPHYTON RUBRUM: 1) TRIAL OF OR CONTRAINDICATION TO CICLOPIROX TOPICAL SOLUTION, AND 2) TRIAL OF OR CONTRAINDICATION TO ORAL TERBINAFINE OR ORAL ITRACONAZOLE. ONYCHOMYCOSIS DUE TO TRICHOPHYTON MENTAGROPHYTES: 1) TRIAL OF OR CONTRAINDICATION TO ORAL TERBINAFINE OR ORAL ITRACONAZOLE.

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 11/16
Client Approval: 06/24
P&T Approval: 07/18

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TBO-FILGRASTIM (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TBO-FILGRASTIM	GRANIX	40426		GPI-10 (8240152070)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

************Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the patient receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever and meet **ALL** of the following criteria?
   - The patient is 1 month of age or older
   - The patient has a non-myeloid malignancy
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred agent: Nivestym (filgrastim-aafi)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TBO-FILGRASTIM (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TBO-FILGRASTIM (Granix)** requires the following rule(s) be met for approval:

A. You are receiving myelosuppressive anti-cancer drugs (drugs that decrease bone marrow activity) associated with a significant incidence of severe neutropenia (a type of blood condition) with fever
B. You are 1 month of age or older
C. You have a non-myeloid malignancy (cancer not affecting bone marrow)
D. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
E. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Nivestym (filgrastim-aafi)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Granix.

REFERENCES

Granix [Prescribing Information]. North Wales, PA: Teva Pharmaceuticals; November 2023.

For Part D use only:

TBO-FILGRASTIM (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR ONCOLOGIST.
Coverage Duration	12 MONTHS
Other Criteria	TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT NIVESTYM, WHERE INDICATIONS ALIGN.

Created: 09/22
Effective: 01/01/26 Client Approval: 01/26 P&T Approval: 05/20

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TEBENTAFUSP-TEBN BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TEBENTAFUSP-TEBN	KIMMTRAK	47779		GPI-10 (2135208060)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	YES	No	Yes	YES	No	Yes	YES	No	Yes	YES

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #5.

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TEBENTAFUSP-TEBN BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override)**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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TEBENTAFUSP-TEBN BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic uveal melanoma (ICD-10 Groups C69.3, C69.4, C69.6, C69.9) **AND** meet the following criteria?
   - The patient is 18 years of age or older
   - The patient is HLA-A*02:01-positive

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TEBENTAFUSP-TEBN (Kimmtrak)** requires the following rule(s) be met for approval:
   A. You have unresectable or metastatic uveal melanoma (a type of eye cancer that is unable to be removed by surgery or has spread to other parts of the body)
   B. You are 18 years of age or older
   C. You are HLA-A*02:01-positive (a complex of genes)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TEBENTAFUSP-TEBN BvD (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kimmtrak.
The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Kimmtrak [Prescribing Information]. Conshohocken, PA: Immunocore Commercial LLC; June 2024.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed April 4, 2025].

For Part D use only:

TEBENTAFUSP-TEBN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 02/22
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 04/22

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TECLISTAMAB-CQYV (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TECLISTAMAB-CQYV	TECVAYLI	48416		GPI-10 (2135208420)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory multiple myeloma (ICD-10 Group C90.0) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has received at least one prior line of therapy, including a proteasome inhibitor (e.g., Velcade [bortezomib], Kyprolis [carfilzomib]) and an immunomodulatory agent (e.g., Revlimid [lenalidomide], Pomalyst [pomalidomide]), AND Tecvayli will be used in combination with Darzalex Faspro (daratumumab-hyaluronidase-fihj)
   - The patient has received at least four prior lines of therapy, including a proteasome inhibitor (e.g., Velcade [bortezomib], Kyprolis [carfilzomib]), an immunomodulatory agent (e.g., Revlimid [lenalidomide], Pomalyst [pomalidomide]), and an anti-CD38 monoclonal antibody (e.g., Darzalex [daratumumab])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TECLISTAMAB-CQYV (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TECLISTAMAB-CQYV (Tecvayli)** requires the following rule(s) be met for approval:

A. You have relapsed or refractory multiple myeloma (a type of blood cancer that has returned or did not respond to treatment)
B. You are 18 years of age or older
C. You meet ONE of the following:
   1. You have received at least one prior line of therapy, including a proteasome inhibitor (such as Velcade [bortezomib], Kyprolis [carfilzomib]) and an immunomodulatory agent (such as Revlimid [lenalidomide], Pomalyst [pomalidomide]), AND Tecvayli will be used in combination with Darzalex Faspro (daratumumab-hyaluronidase-fihj)
   2. You have received at least four prior lines of therapy, including a proteasome inhibitor (such as Velcade [bortezomib], Kyprolis [carfilzomib]), an immunomodulatory agent (such as Revlimid [lenalidomide], Pomalyst [pomalidomide]), and an anti-CD38 monoclonal antibody (such as Darzalex [daratumumab])

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tecvayli.

REFERENCES

Tecvayli [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc., March 2026.

For Part D use only:

TECLISTAMAB-CQYV (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 11/22
Effective: 03/18/26 Client Approval: 03/26 P&T Approval: 04/26

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TEDUGLUTIDE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TEDUGLUTIDE	GATTEX	39890		GPI-10 (5253307000)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of short bowel syndrome (SBS) (ICD-10 Group K90.82) and meet **ALL** of the following?
   - The patient is 1 year of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - The patient is dependent on intravenous parenteral nutrition

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TEDUGLUTIDE (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TEDUGLUTIDE (Gattex)** requires the following rule(s) be met for approval:

A. You have short bowel syndrome (SBS: the body cannot absorb fluids and nutrients due to a lack of a functional small intestine)
B. You are 1 year of age or older
C. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
D. You are dependent on intravenous parenteral nutrition (nutrition given through a vein)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TEDUGLUTIDE (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of short bowel syndrome (SBS) (ICD-10 Group K90.82) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - The patient has a reduction in parenteral support compared to baseline
   - The patient has NOT achieved enteral autonomy

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TEDUGLUTIDE (Gattex)** requires the following rule(s) be met for renewal:
   A. You have short bowel syndrome (SBS: the body cannot absorb fluids and nutrients due to a lack of a functional small intestine)
   B. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
   C. You have a reduction in parenteral support (administration of nutrition given through a vein) compared to baseline
   D. You have NOT achieved enteral autonomy (you still need nutrition through a tube)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Gattex.

REFERENCES

Gattex [Prescribing Information]. Lexington, MA: Takeda Pharmaceuticals America, Inc; February 2024.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TEDUGLUTIDE (PART D)

For Part D use only:

TEDUGLUTIDE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	SHORT BOWEL SYNDROME (SBS): INITIAL/RENEWAL: PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST
Coverage Duration	INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS
Other Criteria	SBS: INITIAL: DEPENDENT ON INTRAVENOUS PARENTERAL NUTRITION. RENEWAL: 1) REDUCTION IN PARENTERAL SUPPORT COMPARED TO BASELINE, AND 2) HAS NOT ACHIEVED ENTERAL AUTONOMY.

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Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 07/24

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TELISOTUZUMAB VEDOTIN-TLLV BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TELISOTUZUMAB VEDOTIN-TLLV	EMRELIS	50574		GPI-10 (2135558060)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	Yes	No	Yes	Yes	No	Yes	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #5.

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TELISOTUZUMAB VEDOTIN-TLLV BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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TELISOTUZUMAB VEDOTIN-TLLV BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced or metastatic, non-squamous non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's tumor has high c-Met protein overexpression (at least 50% of tumor cells with strong [3+] staining), as determined by an FDA-approved test
   - The patient has received a prior systemic therapy (e.g., platinum therapy)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TELISOTUZUMAB VEDOTIN-TLLV BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TELISOTUZUMAB VEDOTIN-TLLV (Emrelis)** requires the following rule(s) be met for approval:

A. You have locally advanced or metastatic, non-squamous non-small cell lung cancer (NSCLC: a type of lung cancer that has spread from where it started to nearby tissue, lymph nodes, or other parts of the body)
B. You are 18 years of age or older
C. Your tumor has high c-Met protein overexpression (at least 50 percent of tumor cells with strong [3+] staining) (too many proteins are made), as determined by a Food and Drug Administration (FDA)-approved test
D. You have received a prior systemic therapy (such as platinum therapy [a type of therapy to treat cancer])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Emrelis.

The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Emrelis [Prescribing Information]. North Chicago, IL: AbbVie Inc., Inc.; May 2025.
Medicare Prescription Drug Benefit Manual Chapter 6 – Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed May 28, 2025].

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TELISOTUZUMAB VEDOTIN-TLLV BvD (PART D)

For Part D use only:

TELISOTUZUMAB VEDOTIN-TLLV (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 05/25
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 07/25

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TELOTRISTAT (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TELOTRISTAT ETIPRATE	XERMELO	44132		GPI-10 (5257007510)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of carcinoid syndrome diarrhea (ICD-10 E34.0, R19.7) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an oncologist or gastroenterologist
   - Xermelo will be used in combination with a somatostatin analog (e.g., octreotide)
   - The patient has been inadequately controlled by a somatostatin analog therapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TELOTRISTAT (Xermelo)** requires the following rule(s) be met for approval:
   A. You have carcinoid syndrome diarrhea (loose stool caused by a type of tumor)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with an oncologist (a type of cancer doctor) or gastroenterologist (doctor who treats digestive conditions)
   D. Xermelo will be used in combination with a somatostatin analog (such as octreotide)
   E. You have been inadequately (drug did not work) controlled by a somatostatin analog therapy (type of treatment that controls tumors releasing of certain chemicals)

   (Denial text continued on next page)

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TELOTRISTAT (PART D)

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xermelo.

REFERENCES

Xermelo [Prescribing Information]. Deerfield, IL. TerSera Therapeutics, LLC.; October 2020.

For Part D use only:

TELOTRISTAT (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	CARCINOID SYNDROME DIARRHEA: PRESCRIBED BY OR IN CONSULTATION WITH AN ONCOLOGIST OR GASTROENTEROLOGIST
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TEMOZOLOMIDE - IV (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TEMOZOLOMIDE	TEMODAR		17724	GPI-14 (21104070002120)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have glioblastoma (ICD-10 C72.9; Group C71) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has newly diagnosed glioblastoma
   - Temodar will be used concomitantly with radiotherapy and then as maintenance treatment thereafter

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have anaplastic astrocytoma (ICD-10 C71.9) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has newly diagnosed anaplastic astrocytoma
   - Temodar will be used as adjuvant treatment

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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TEMOZOLOMIDE - IV (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of refractory anaplastic astrocytoma (ICD-10 C71.9) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TEMOZOLOMIDE - IV (Temodar)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Newly diagnosed glioblastoma (a type of brain cancer)
      2. Newly diagnosed anaplastic astrocytoma (a type of brain cancer)
      3. Refractory anaplastic astrocytoma (a type of brain cancer that has not responded to treatment)

   B. If you have glioblastoma, approval also requires:
      1. You are 18 years of age or older
      2. You have newly diagnosed glioblastoma
      3. Temodar will be used concomitantly (at the same time) with radiotherapy (a type of cancer treatment) and then as maintenance treatment thereafter

   C. If you have anaplastic astrocytoma, approval also requires:
      1. You are 18 years of age or older
      2. You have newly diagnosed anaplastic astrocytoma
      3. Temodar will be used as adjuvant (add-on) treatment

   D. If you have refractory anaplastic astrocytoma, approval also requires:
      1. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TEMOZOLOMIDE - IV (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Temodar.

REFERENCES

Temodar [Prescribing Information]. Rahway, NJ: Merck Sharp & Dohme LLC; September 2023.

For Part D use only:

TEMOZOLOMIDE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TENAPANOR (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TENAPANOR HCL	IBSRELA		46915	GPI-10 (5255858010)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of irritable bowel syndrome with constipation (IBS-C) (ICD-10 K58.1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of the preferred agents: lubiprostone AND Linzess

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TENAPANOR (Ibsrela)** requires the following rule(s) be met for approval:
   A. You have irritable bowel syndrome with constipation (IBS-C: a type of bowel disease)
   B. You are 18 years of age or older
   C. You have tried the preferred medications: lubiprostone AND Linzess

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TENAPANOR (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Ibsrela.

REFERENCES
Ibsrela [Prescribing Information]. Waltham, MA: Ardelyx, Inc.; April 2022.

For Part D use only:

TENAPANOR (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	IRRITABLE BOWEL SYNDROME-CONSTIPATION (IBS-C): TRIAL OF THE PREFERRED AGENTS: LUBIPROSTONE AND LINZESS

Core	Advantage	Plus
No	No	Yes

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TEPLIZUMAB-MZWV BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TEPLIZUMAB-MZWV	TZIELD	48464		GPI-10 (2752106520)	

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #5.

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TEPLIZUMAB-MZWV BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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TEPLIZUMAB-MZWV BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of stage 2 type 1 diabetes (ICD-10 Group E10) and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - The patient has at least two positive pancreatic islet autoantibodies (e.g., insulin autoantibody, glutamic acid decarboxylase 65 autoantibodies, insulinoma-associated antigen 2 autoantibody)
   - An oral glucose tolerance test (or an alternative method, if an oral glucose tolerance test is not available) confirms the patient has dysglycemia without overt hyperglycemia
   - The patient's clinical history does not suggest type 2 diabetes
   - The patient has NOT previously received a 14-dose treatment course of Tzield

   If yes, **approve for 30 days by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of stage 3 type 1 diabetes (ICD-10 Group E10) and meet **ALL** of the following criteria?
   - The patient is 8 to 17 years of age
   - The patient has been recently diagnosed (within the last 8 weeks)
   - The patient has at least one positive pancreatic islet cell autoantibody (e.g., insulin autoantibody, glutamic acid decarboxylase 65 autoantibodies, insulinoma-associated antigen 2 autoantibody)
   - The patient has a peak C-peptide of at least 0.2 pmol/mL on a mixed-meal tolerance test (or an alternative method, if a mixed-meal tolerance test is not available)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TEPLIZUMAB-MZWV BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: Our guideline named **TEPLIZUMAB-MZWV (Tzield)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Stage 2 type 1 diabetes (an immune disorder with high blood sugar)
   2. Stage 3 type 1 diabetes (an immune disorder with high blood sugar)

B. If you have stage 2 type 1 diabetes, approval also requires:
   1. You are 1 year of age or older
   2. You have at least two positive pancreatic islet autoantibodies (predictors of type 1 diabetes such as insulin autoantibody, glutamic acid decarboxylase 65 autoantibodies, insulinoma-associated antigen 2 autoantibody)
   3. An oral glucose tolerance test (or an alternative method, if oral glucose tolerance test is not available) confirms you have dysglycemia (abnormal blood sugar stability) without overt hyperglycemia (high blood sugar)
   4. Your clinical history does not suggest type 2 diabetes (a disorder with high blood sugar)
   5. You have NOT previously received a 14-dose treatment course of Tzield

C. If you have stage 3 type 1 diabetes, approval also requires:
   1. You are 8 to 17 years of age
   2. You have been recently diagnosed (within the last 8 weeks)
   3. You have at least one positive pancreatic islet cell autoantibody (a predictor of type 1 diabetes such as insulin autoantibody, glutamic acid decarboxylase 65 autoantibodies, insulinoma-associated antigen 2 autoantibody)
   4. You have a peak C-peptide (a type of protein) of at least 0.2 pmol/mL on a mixed-meal tolerance test (a type of test that measures how the body regulates sugar levels in response to food) (or an alternative method, if a mixed-meal tolerance test is not available)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tzield. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Tzield [Prescribing Information]. Red Bank, NJ: Provention Bio, Inc.; June 2026.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed May 11, 2026].

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TEPLIZUMAB-MZWV BvD (PART D)

For Part D use only:

TEPLIZUMAB-MZWV (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	STAGE 2 TYPE 1 DIABETES (T1D): 1) AT LEAST TWO POSITIVE PANCREATIC ISLET AUTOANTIBODIES, 2) ORAL GLUCOSE TOLERANCE TEST OR ALTERNATIVE METHOD CONFIRMING DYSGLYCEMIA WITHOUT OVERT HYPERGLYCEMIA, AND 3) CLINICAL HISTORY DOES NOT SUGGEST TYPE 2 DIABETES. STAGE 3 T1D: 1) AT LEAST ONE POSITIVE PANCREATIC ISLET AUTOANTIBODY, 2) PEAK C-PEPTIDE OF AT LEAST 0.2 PMOL/ML ON A MIXED-MEAL TOLERANCE TEST (OR AN ALTERNATIVE METHOD IF A MIXED-MEAL TOLERANCE TEST IS NOT AVAILABLE)
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	STAGE 2 T1D: 30 DAYS. STAGE 3 T1D: 12 MONTHS.
Other Criteria	STAGE 2 T1D: 1) HAS NOT PREVIOUSLY RECEIVED A 14 DOSE TREATMENT COURSE.

Created: 02/23
Effective: 09/01/26 Client Approval: 07/26 DMC Approval: 06/26

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TEPOTINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TEPOTINIB HCL	TEPMETKO	47095		GPI-10 (2153377310)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Mesenchymal-epithelial transition (MET) exon 14 skipping alterations are present

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TEPOTINIB (Tepmetko)** requires the following rule(s) be met for approval:
   A. You have metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of the body)
   B. You are 18 years of age or older
   C. Mesenchymal-epithelial transition (MET) exon 14 skipping alterations (abnormal change in a gene that makes MET protein) are present

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TEPOTINIB (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tepmetko.

REFERENCES

Tepmetko [Prescribing Information]. Rockland, MA: EMD Serono, Inc.; February 2023.

For Part D use only:

TEPOTINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Created: 02/21
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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TEPROTUMUMAB-TRBW (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TEPROTUMUMAB-TRBW	TEPEZZA	46305		GPI-10 (3019207040)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of thyroid eye disease (ICD-10 E07.9, E05.00)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TEPROTUMUMAB-TRBW (Tepezza)** requires the following rule(s) be met for approval:
   A. You have thyroid eye disease (a type of eye condition)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Tepezza.

REFERENCES
Tepezza [Prescribing Information]. Deerfield, IL: Horizon Therapeutics USA, Inc., July 2023.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TEPROTUMUMAB-TRBW (PART D)

For Part D use only:

TEPROTUMUMAB-TRBW (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TERAZOSIN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TERAZOSIN HCL	TEZRULY	00094		GPI-10 (3620204010)	BRAND = TEZRULY

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of benign prostatic hyperplasia (BPH) (ICD-10 Group N40) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is a male
   - The patient has a contraindication to or is unable to swallow generic terazosin capsules

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of hypertension (HTN) (ICD-10 I10) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a contraindication to or is unable to swallow generic terazosin capsules

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TERAZOSIN (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TERAZOSIN (Tezruly)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Benign prostatic hyperplasia (BPH: a type of prostate condition)
   2. Hypertension (HTN: high blood pressure)

B. If you have benign prostatic hyperplasia, approval also requires:
   1. You are 18 years of age or older
   2. You are a male
   3. You have a contraindication to (harmful for you to use) or are unable to swallow generic terazosin capsules

C. If you have hypertension, approval also requires:
   1. You are 18 years of age or older
   2. You have a contraindication to (harmful for you to use) or are unable to swallow generic terazosin capsules

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tezruly.

REFERENCES

Tezruly [Prescribing Information]. Baudette, MN: ANI Pharmaceuticals, Inc.; July 2024.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TERAZOSIN (PART D)

For Part D use only:

TERAZOSIN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	BENIGN PROSTATIC HYPERPLASIA (BPH), HYPERTENSION (HTN): CONTRAINDICATION TO OR UNABLE TO SWALLOW GENERIC TERAZOSIN CAPSULES.

Created: 04/25
Effective: 05/12/25 Client Approval: 04/25 P&T Approval: 07/25

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TERIFLUNOMIDE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TERIFLUNOMIDE	AUBAGIO, TERIFLUNOMIDE	39624		GPI-10 (6240407000)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	Yes	No	No	Yes	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), to include clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease, **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TERIFLUNOMIDE (Aubagio)** requires the following rule(s) be met for approval:
   A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease returns and goes away), or active secondary progressive disease (advanced disease)
   B. You are 18 years of age or older
   (Denial text continued on next page)

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TERIFLUNOMIDE (PART D)

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Review for Aubagio.

REFERENCES

Aubagio [Prescribing Information]. Cambridge, MA: Genzyme Corporation; April 2021.

For Part D use only:

TERIFLUNOMIDE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 11/07
Effective: 01/01/26 Client Approval: 01/26 P&T Approval: 11/16

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CORE, ADVANTAGE, AND PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TERIPARATIDE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TERIPARATIDE	FORTEO, TERIPARATIDE	24700		GPI-10 (3004407000)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
Yes	No	No	Yes	No	No	Yes	No	No	Yes	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have **ONE** of the following diagnoses?
   - Postmenopausal osteoporosis (ICD-10 M81.0, Group M80.0) in a female
   - Primary or hypogonadal osteoporosis (ICD-10 M81.0, Group M80.0) in a male
   - Glucocorticoid-induced osteoporosis (ICD-10 M81.8, Group M80.8)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient is at high risk for fractures (defined as history of osteoporotic fracture or multiple risk factors for fracture)
   - The patient has failed or is intolerant to other osteoporosis therapy (e.g., Fosamax [alendronate], Actonel [risedronate])

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TERIPARATIDE (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Has the patient received a total of 24 months cumulative treatment with any parathyroid hormone therapy (e.g., Forteo [teriparatide], Tymlos [abaloparatide])?

   If yes, continue to #4.
   If no, **approve for 24 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

4. Has the patient remained at high risk for fracture OR has returned to having a high risk for fracture?

   If yes, **approve for 24 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TERIPARATIDE (Forteo)** requires the following rule(s) be met for approval:
   A. The request is for ONE of the following:
      1. Postmenopausal osteoporosis (a type of bone condition in women after menopause)
      2. Primary or hypogonadal (low level of testosterone) osteoporosis (a type of bone condition) in a male
      3. Glucocorticoid-induced osteoporosis (a type of bone condition caused by a type of medication such as prednisone)
   B. You meet ONE of the following:
      1. You are at high risk for fractures (defined as history of osteoporotic fracture [a type of complete or partial break in a bone] or multiple risk factors for fracture)
      2. You have failed or could not tolerate other available osteoporosis therapy (such as Fosamax [alendronate], Actonel [risedronate])
   C. You meet ONE of the following:
      1. You have received less than 24 months of cumulative treatment with any parathyroid hormone therapy (such as Forteo [teriparatide], Tymlos [abaloparatide])
      2. You have received a total of 24 months of cumulative treatment with any parathyroid hormone therapy (such as Forteo [teriparatide], Tymlos [abaloparatide]) AND remain at high risk for fracture or have returned to having a high risk for fracture

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TERIPARATIDE (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Forteo.

REFERENCES
Forteo [Prescribing Information]. Indianapolis, IN.: Eli Lilly and Company; July 2024.

For Part D use only:

TERIPARATIDE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	24 MONTHS
Other Criteria	OSTEOPOROSIS: HAS NOT RECEIVED A TOTAL OF 24 MONTHS CUMULATIVE TREATMENT WITH ANY PARATHYROID HORMONE THERAPY, UNLESS REMAINS AT OR HAS RETURNED TO HAVING A HIGH RISK FOR FRACTURE.

Created: 06/24
Effective: 07/01/25 Client Approval: 05/25 P&T Approval: 10/19

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TESAMORELIN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TESAMORELIN ACETATE	EGRIFTA SV, EGRIFTA WR	37268		GPI-10 (3015008510)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of HIV (ICD-10 B20) with lipodystrophy (ICD-10 E88.1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The requested medication will be used for the reduction of excess abdominal fat

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TESAMORELIN (Egrifta SV, Egrifta WR)** requires the following rule(s) be met for approval:
   A. You have human immunodeficiency virus (HIV: an immune system disease caused by a virus) with lipodystrophy (abnormal distribution of fat in the body)
   B. You are 18 years of age or older
   C. The requested medication will be used for the reduction of excess abdominal fat

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TESAMORELIN (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Egrifta.

REFERENCES

Egrifta SV [Prescribing Information]. Montreal, Québec, Canada: Theratechnologies Inc.; February 2024.

Egrifta WR [Prescribing Information]. Montreal, Québec, Canada: Theratechnologies Inc.; March 2025.

TESAMORELIN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 11/19
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 02/11

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TESTOSTERONE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TESTOSTERONE	ANDRODERM, ANDROGEL, FORTESTA, NATESTO, TESTIM, VOGELXO, TESTOSTERONE	01403		GPI-10 (2310003000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for a male patient with a diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) (ICD-10 E29.1) **AND** the patient meets the following criterion?
   - The patient 18 years of age or older

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient have **ONE** of the following laboratory values confirming low testosterone levels?
   - At least TWO total serum testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
   - A free serum testosterone level of less than 5 ng/dL (0.17 nmol/L)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TESTOSTERONE (PART D)

INITIAL CRITERIA (CONTINUED)

3. Is the patient 40 years of age or older?

   If yes, continue to #4.
   If no, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

4. Has the patient's prostate specific antigen (PSA) been evaluated for prostate cancer screening?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TESTOSTERONE (Androderm, Androgel, Fortesta, Natesto, Testim, Vogelxo)** requires the following rule(s) be met for approval:
   A. You have primary or secondary male hypogonadism (hypotestosteronism or low level of testosterone)
   B. You are 18 years of age or older
   C. You have ONE of the following lab values showing you have low testosterone levels:
      1. At least two total serum (blood) testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
      2. Free serum (blood) testosterone level of less than 5 ng/dL (0.17 nmol/L)
   D. If you are 40 years of age or older, approval also requires:
      1. Your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated for prostate cancer screening

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TESTOSTERONE (PART D)

RENEWAL CRITERIA

1. Is the request for a male patient with a diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) (ICD-10 E29.1) **AND** the patient meets the following criterion?
   - The patient has improved symptoms compared to baseline and has tolerated treatment

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the patient 40 years of age or older?

   If yes, continue to #3.
   If no**, approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

3. Has the patient's prostate specific antigen (PSA) been evaluated for prostate cancer screening?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TESTOSTERONE (Androderm, Androgel, Fortesta, Natesto, Testim, Vogelxo)** requires that the following rule(s) be met for renewal:
   A. You have primary or secondary male hypogonadism (hypotestosteronism or low level of testosterone)
   B. Your symptoms have improved compared to baseline and you have tolerated treatment
   C. If you are 40 years of age or older, renewal also requires:
      1. Your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated for prostate cancer screening

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TESTOSTERONE (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for the related testosterone formulation.

REFERENCES

Androderm [Prescribing Information]. Madison, NJ: Allegan, Inc.; May 2020.
Androgel 1% [Prescribing Information]. North Chicago, IL: AbbVie Inc.; May 2019.
Androgel 1.62% [Prescribing Information]. North Chicago, IL: AbbVie Inc.; November 2020.
Fortesta [Prescribing Information]. Malvern, PA: Endo Pharmaceuticals, Inc.; January 2022.
Natesto [Prescribing Information]. Englewood, CO: Aytu Biosciences, Inc.; October 2017.
Testim [Prescribing Information]. Malvern, PA: Endo Pharmaceuticals, Inc.; August 2021.
Testosterone 10mg (2%) [Prescribing Information]. Chestnut Ridge, NY: Par Pharmaceutical; January 2022.
Vogelxo [Prescribing Information]. Maple Grove, MN: Upsher-Smith Laboratories, Inc.; April 2020.

For Part D use only:

TESTOSTERONE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	MALE HYPOGONADISM: INITIAL: CONFIRMED BY: 1) AT LEAST TWO TOTAL SERUM TESTOSTERONE LEVELS OF LESS THAN 300 NG/DL TAKEN ON SEPARATE OCCASIONS, OR 2) FREE SERUM TESTOSTERONE LEVEL OF LESS THAN 5 NG/DL.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS
Other Criteria	MALE HYPOGONADISM: INITIAL: 1) 40 YEARS OR OLDER: PROSTATE SPECIFIC ANTIGEN (PSA) HAS BEEN EVALUATED FOR PROSTATE CANCER SCREENING. RENEWAL: 1) 40 YEARS OR OLDER: PSA HAS BEEN EVALUATED FOR PROSTATE CANCER SCREENING, AND 2) IMPROVED SYMPTOMS COMPARED TO BASELINE AND TOLERANCE TO TREATMENT.

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25 Created: 02/01
Commercial Effective: N/A Client Approval: 06/24 P&T Approval: 10/22

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TESTOSTERONE CYPIONATE - AZMIRO BVD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TESTOSTERONE CYPIONATE	AZMIRO		56456	GPI-14 (2310003010E530)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	Yes	No	No	Yes	No	No	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **refer to plan. (This should be processed under the member's medical benefit).**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #5.

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TESTOSTERONE CYPIONATE - AZMIRO BVD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

If yes, **refer to plan. (The health plan makes the final payment determination decision).**

- **For CSR's: Refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enterany override).**
- **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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TESTOSTERONE CYPIONATE - AZMIRO BVD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for a male patient with a diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) (ICD-10 E29.1) and the patient meets **ONE** of the following criteria confirming low testosterone levels?
   - The patient has at least TWO total serum testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
   - The patient has a free serum testosterone level of less than 5 ng/dL (0.17 nmol/L)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Has the patient had a trial of or contraindication to generic testosterone cypionate?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Is the patient 40 years of age or older?

   If yes, continue to #4.
   If no, **approve for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

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TESTOSTERONE CYPIONATE - AZMIRO BVD (PART D)

INITIAL CRITERIA (CONTINUED)

4. Has the patient's prostate specific antigen (PSA) been evaluated for prostate cancer screening?

   If yes, **approve for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TESTOSTERONE CYPIONATE - AZMIRO** requires the following rule(s) be met for approval:

   A. You have primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
   B. You meet ONE of the following criteria showing you have low testosterone levels:
      1. You have at least TWO total serum (blood) testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
      2. You have a free serum (blood) testosterone level of less than 5 ng/dL (0.17 nmol/L)
   C. You have tried or have a contraindication to (harmful for you to use) generic testosterone cypionate
   D. If you are 40 years of age or older, approval also requires:
      1. Your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated for prostate cancer screening

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TESTOSTERONE CYPIONATE - AZMIRO BVD (PART D)

RENEWAL CRITERIA

1. Is the request for a male patient with a diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) (ICD-10 E29.1) **AND** the patient meets the following criterion?
   - The patient has had improved symptoms compared to baseline and has tolerated treatment

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the patient 40 years of age or older?

   If yes, continue to #3.
   If no, **approve for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

3. Has the patient's prostate specific antigen (PSA) been evaluated for prostate cancer screening?

   If yes, **approve for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TESTOSTERONE CYPIONATE - AZMIRO** requires the following rule(s) be met for renewal:
   A. You have primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
   B. Your symptoms have improved compared to baseline (before treatment) and you have tolerated treatment
   C. If you are 40 years of age or older, renewal also requires:
      1. Your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated for prostate cancer screening

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TESTOSTERONE CYPIONATE - AZMIRO BVD (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Azmiro.

REFERENCES

Azmiro [Prescribing Information]. Princeton, NJ: Slayback Pharma LLC; May 2024.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/medicare/coverage/prescription-drug-coverage-contracting/prescription-drug-benefit-manual. [Accessed April 4, 2025].

For Part D use only:

TESTOSTERONE CYPIONATE - AZMIRO (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	MALE HYPOGONADISM: INITIAL: CONFIRMED BY: 1) AT LEAST TWO TOTAL SERUM TESTOSTERONE LEVELS OF LESS THAN 300 NG/DL TAKEN ON SEPARATE OCCASIONS, OR 2) FREE SERUM TESTOSTERONE LEVEL OF LESS THAN 5 NG/DL.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	MALE HYPOGONADISM: INITIAL: 1) TRIAL OF OR CONTRAINDICATION TO GENERIC TESTOSTERONE CYPIONATE, AND 2) 40 YEARS OR OLDER: PROSTATE SPECIFIC ANTIGEN (PSA) HAS BEEN EVALUATED FOR PROSTATE CANCER SCREENING. RENEWAL: 1) 40 YEARS OR OLDER: PSA HAS BEEN EVALUATED FOR PROSTATE CANCER SCREENING, AND 2) IMPROVED SYMPTOMS COMPARED TO BASELINE AND TOLERANCE TO TREATMENT.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TESTOSTERONE CYPIONATE - DEPO (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TESTOSTERONE CYPIONATE	DEPO-TESTOSTERONE, TESTOSTERONE CYPIONATE		10191 10194	GPI-14 (23100030102010, 23100030102015, 23100030102070)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
Yes	No	No	Yes	No	No	Yes	No	No	Yes	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for a male patient with a diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) (ICD-10 E29.1) and the patient has **ONE** of the following laboratory values confirming low testosterone levels?
   - At least TWO total serum testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
   - A free serum testosterone level of less than 5 ng/dL (0.17 nmol/L)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient 40 years of age or older?

   If yes, continue to #3.
   If no, **approve all strengths for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

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TESTOSTERONE CYPIONATE - DEPO (PART D)

INITIAL CRITERIA (CONTINUED)

3. Has the patient's prostate specific antigen (PSA) been evaluated for prostate cancer screening?

If yes, **approve all strengths for 12 months by GPID or GPI-14.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TESTOSTERONE CYPIONATE - DEPO (Depo-Testosterone)** requires the following rule(s) be met for approval:

A. You have primary or secondary male hypogonadism (hypotestosteronism or low level of testosterone)
B. You have ONE of the following lab values showing you have low testosterone levels:
   1. At least two total serum (blood) testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
   2. Free serum (blood) testosterone level of less than 5 ng/dL (0.17 nmol/L)
C. If you are 40 years of age or older, approval also requires:
   1. Your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated for prostate cancer screening

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TESTOSTERONE CYPIONATE - DEPO (PART D)

RENEWAL CRITERIA

1. Is the request for a male patient with a diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) (ICD-10 E29.1) **AND** the patient meets the following criterion?
   - The patient has improved symptoms compared to baseline and has tolerated treatment

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the patient 40 years of age or older?

   If yes, continue to #3.
   If no, **approve all strengths for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

3. Has the patient's prostate specific antigen (PSA) been evaluated for prostate cancer screening?

   If yes, **approve all strengths for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TESTOSTERONE CYPIONATE - DEPO (Depo-Testosterone)** requires the following rule(s) be met for renewal:
   A. You have primary or secondary male hypogonadism (hypotestosteronism or low level of testosterone)
   B. Your symptoms have improved compared to baseline and you have tolerated treatment
   C. If you are 40 years of age or older, renewal also requires:
      1. Your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated for prostate cancer screening

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TESTOSTERONE CYPIONATE - DEPO (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Depo-Testosterone.

REFERENCES

Depo-Testosterone [Prescribing Information]. Pharmacia & Upjohn Company; August 2020.
Testosterone Cypionate [Prescribing Information]. Parsippany, NJ: Actavis Pharma, Inc.; November 2018.

For Part D use only:

TESTOSTERONE CYPIONATE - DEPO (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	MALE HYPOGONADISM: INITIAL: CONFIRMED BY: 1) AT LEAST TWO TOTAL SERUM TESTOSTERONE LEVELS OF LESS THAN 300 NG/DL TAKEN ON SEPARATE OCCASIONS, OR 2) FREE SERUM TESTOSTERONE LEVEL OF LESS THAN 5 NG/DL.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS
Other Criteria	MALE HYPOGONADISM: INITIAL: 1) 40 YEARS OR OLDER: PROSTATE SPECIFIC ANTIGEN (PSA) HAS BEEN EVALUATED FOR PROSTATE CANCER SCREENING. RENEWAL: 1) 40 YEARS OR OLDER: PSA HAS BEEN EVALUATED FOR PROSTATE CANCER SCREENING, AND 2) IMPROVED SYMPTOMS COMPARED TO BASELINE AND TOLERANCE TO TREATMENT.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TESTOSTERONE ENANTHATE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TESTOSTERONE ENANTHATE	XYOSTED, TESTOSTERONE ENANTHATE	01401		GPI-10 (2310003020)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for a male patient with a diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) (ICD-10 E29.1) and the patient has **ONE** of the following laboratory values confirming low testosterone levels?
   - At least TWO total serum testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
   - A free serum testosterone level of less than 5 ng/dL (0.17 nmol/L)

   If yes, continue to #2.
   If no, continue to #6.

2. Is the patient 40 years of age or older?

   If yes, continue to #3.
   If no, continue to #4.

3. Has the patient's prostate specific antigen (PSA) been evaluated for prostate cancer screening?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TESTOSTERONE ENANTHATE (PART D)

INITIAL CRITERIA (CONTINUED)

4. Is the request for generic intramuscular testosterone enanthate 200 mg/mL?

   If yes, **approve for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Is the request for Xyosted **AND** the patient 18 years of age or older?

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

6. Is the request for a male patient with a diagnosis of delayed puberty (ICD-10 E30.0) not secondary to a pathological disorder who meets the following criterion?
   - The request is for generic intramuscular testosterone enanthate 200 mg/mL

   If yes, **approve for 6 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #7.

7. Is the request for a female patient with a diagnosis of metastatic breast cancer (ICD-10 Group C50) who meets the following criterion?
   - The request is for generic intramuscular testosterone enanthate 200 mg/mL

   If yes, continue to #8.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

8. Is the patient postmenopausal?

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, continue to #9.

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TESTOSTERONE ENANTHATE (PART D)

INITIAL CRITERIA (CONTINUED)

9. Is the patient premenopausal and meets **ALL** of the following criteria?
   - The patient has benefited from an oophorectomy
   - The patient is considered to have a hormone-responsive tumor

   If yes, **approve for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TESTOSTERONE ENANTHATE (Xyosted)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Primary or secondary male hypogonadism (hypotestosteronism or low level of testosterone)
      2. Delayed puberty not secondary to a pathological disorder (not due to disease) in a male
      3. Metastatic breast cancer (cancer that has spread to other areas of the body) in a female

   B. If you are a male with primary or secondary hypogonadism, approval also requires:
      1. You have ONE of the following lab values showing you have low testosterone levels:
         a. At least two total serum (blood) testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
         b. Free serum (blood) testosterone level of less than 5 ng/dL (0.17 nmol/L)
      2. If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated for prostate cancer screening
      3. If the request is for Xyosted, you are 18 years of age or older

   C. If you are a male with delayed puberty not secondary to a pathological disorder, approval also requires:
      1. Your request is for generic intramuscular (injected into muscle) testosterone enanthate 200 mg/mL

   (Initial denial text continued on next page)

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TESTOSTERONE ENANTHATE (PART D)

INITIAL CRITERIA (CONTINUED)

D. If you are a female with metastatic breast cancer, approval also requires:

1. You meet ONE of the following:
   a. You are postmenopausal (after menopause)
   b. You are premenopausal (before menopause), you have benefited from an oophorectomy (surgical removal of the ovaries), and your tumor is hormone-responsive
2. Your request is for generic intramuscular (injected into muscle) testosterone enanthate 200 mg/mL

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TESTOSTERONE ENANTHATE (PART D)

RENEWAL CRITERIA

NOTE: For the diagnosis of metastatic breast cancer, please refer to the Initial Criteria section.

1. Is the request for a male patient with a diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) (ICD-10 E29.1) **AND** the patient meets the following criterion?
   - The patient has had improved symptoms compared to baseline and has tolerated treatment

   If yes, continue to #2.
   If no, continue to #4.

2. Is the patient 40 years of age or older?

   If yes, continue to #3.

   If no, **approve the requested drug for 12 months as follows:**
   - **Intramuscular testosterone enanthate 200 mg/mL: Approve by GPID or GPI-14.**
   - **Xyosted: Approve for all strengths by GPID or GPI-14.**

   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

3. Has the patient's prostate specific antigen (PSA) been evaluated for prostate cancer screening?

   If yes, **approve the requested drug for 12 months as follows:**
   - **Intramuscular testosterone enanthate 200 mg/mL: Approve by GPID or GPI-14.**
   - **Xyosted: Approve for all strengths by GPID or GPI-14.**

   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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TESTOSTERONE ENANTHATE (PART D)

RENEWAL CRITERIA (CONTINUED)

4. Is the request for a male patient with a diagnosis of delayed puberty (ICD-10 E30.0) not secondary to a pathological disorder who meets **ALL** of the following criteria?
   - The patient has not received more than two 6-month courses of testosterone replacement therapy
   - The request is for generic intramuscular testosterone enanthate 200 mg/mL

   If yes, **approve for 6 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TESTOSTERONE ENANTHATE (Xyosted)** requires that the following rule(s) be met for renewal:

   A. You have ONE of the following:
      1. Primary or secondary male hypogonadism (hypotestosteronism or low level of testosterone)
      2. Delayed puberty not secondary to a pathological disorder (not due to disease) in a male

   B. If you are a male with primary or secondary hypogonadism, renewal also requires:
      1. Your symptoms have improved compared to baseline and you have tolerated treatment
      2. If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated for prostate cancer screening

   C. If you are a male with delayed puberty not secondary to a pathological disorder, renewal also requires:
      1. You have not received more than two 6-month courses of testosterone replacement therapy
      2. Your request is for generic intramuscular (injected into muscle) testosterone enanthate 200 mg/mL

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TESTOSTERONE ENANTHATE (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for testosterone enanthate and Xyosted.

REFERENCES

Testosterone Enanthate [Prescribing Information]. Berkeley Heights, NJ: Hikma Pharmaceuticals, Inc.; November 2021.
Xyosted [Prescribing Information]. Ewing, NJ: Antares Pharma, Inc.; April 2023.

For Part D use only:

TESTOSTERONE ENANTHATE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	MALE HYPOGONADISM: INITIAL: CONFIRMED BY: 1) AT LEAST TWO TOTAL SERUM TESTOSTERONE LEVELS OF LESS THAN 300 NG/DL TAKEN ON SEPARATE OCCASIONS, OR 2) FREE SERUM TESTOSTERONE LEVEL OF LESS THAN 5 NG/DL.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	INITIAL/RENEWAL: MALE DELAYED PUBERTY: 6MO, MALE HYPOGONADISM: 12 MO. OTHER INDICATIONS: 12 MO.
Other Criteria	INITIAL: MALE HYPOGONADISM: 1) 40 YEARS OR OLDER: PROSTATE SPECIFIC ANTIGEN (PSA) HAS BEEN EVALUATED FOR PROSTATE CANCER SCREENING. RENEWAL: MALE HYPOGONADISM: 1) 40 YEARS OR OLDER: PSA HAS BEEN EVALUATED FOR PROSTATE CANCER SCREENING, AND 2) IMPROVED SYMPTOMS COMPARED TO BASELINE AND TOLERANCE TO TREATMENT. MALE DELAYED PUBERTY: HAS NOT RECEIVED MORE THAN TWO 6-MONTH COURSES OF TESTOSTERONE REPLACEMENT THERAPY

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TESTOSTERONE UNDECANOATE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TESTOSTERONE UNDECANOATE	AVEED, JATENZO, KYZATREX, TLANDO, UNDECATREX	07304		GPI-10 (2310003080)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for a male patient with a diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) (ICD-10 E29.1) **AND** the patient meets the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient have **ONE** of the following laboratory values confirming low testosterone levels?
   - At least TWO total serum testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
   - A free serum testosterone level of less than 5 ng/dL (0.17 nmol/L)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Is the patient 40 years of age or older?

   If yes, continue to #4.
   If no, continue to #5.

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TESTOSTERONE UNDECANOATE (PART D)

INITIAL CRITERIA (CONTINUED)

4. Has the patient's prostate specific antigen (PSA) been evaluated for prostate cancer screening?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

5. Has the patient had a trial of or contraindication to **TWO** of the following preferred agents: testosterone 12.5/1.25g, testosterone 20.25/1.25, testosterone 50 mg (1%)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   INITIAL DENIAL TEXT: Our guideline named **TESTOSTERONE UNDECANOATE (Aveed, Jatenzo, Kyzatrex, Tlando, Undecatrex)** requires the following rule(s) be met for approval:
   A. You have primary or secondary male hypogonadism (hypotestosteronism or low level of testosterone)
   B. You are 18 years of age or older
   C. You have ONE of the following lab values showing you have low testosterone levels:
      1. At least two total serum (blood) testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
      2. A free serum (blood) testosterone level of less than 5 ng/dL (0.17 nmol/L)
   D. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: testosterone 12.5/1.25g, testosterone 20.25/1.25, testosterone 50 mg (1%)
   E. If you are 40 years of age or older, approval also requires:
      1. Your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated for prostate cancer screening

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TESTOSTERONE UNDECANOATE (PART D)

RENEWAL CRITERIA

1. Is the request for a male patient with a diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) (ICD-10 E29.1) **AND** the patient meets the following criterion?
   - The patient has had improved symptoms compared to baseline and has tolerated treatment

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the patient 40 years of age or older?

   If yes, continue to #3.
   If no, **approve for 12 months by HICL or GPI-10.**

3. Has the patient's prostate specific antigen (PSA) been evaluated for prostate cancer screening?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: Our guideline named **TESTOSTERONE UNDECANOATE (Aveed, Jatenzo, Kyzatrex, Tlando, Undecatrex)** requires the following rule(s) be met for renewal:
   A. You have primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
   B. Your symptoms have improved compared to baseline and you have tolerated treatment
   C. If you are 40 years of age or older, renewal also requires:
      1. Your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated for prostate cancer screening

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TESTOSTERONE UNDECANOATE (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Aveed, Jatenzo, Tlando, Kyatrex, or Undecatrex.

REFERENCES

Aveed [Prescribing Information]. Malvern, PA: Endo Pharmaceuticals Solutions, Inc.; August 2021.
Jatenzo [Prescribing Information]. Northbrook, IL: Clarus Therapeutics, Inc.; March 2019.
Tlando [Prescribing Information]. Ewing, NJ: Antares Pharma, Inc.; March 2022.
Undecatrex [Prescribing Information]. San Antonio, TX: Trifluent Pharma, Inc.; September 2022.
Kyzatrex [Prescribing Information]. Raleigh, NC: Marius Pharmaceuticals; July 2025.

For Part D use only:

TESTOSTERONE UNDECANOATE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	MALE HYPOGONADISM: INITIAL: CONFIRMED BY: 1) AT LEAST TWO TOTAL SERUM TESTOSTERONE LEVELS OF LESS THAN 300 NG/DL TAKEN ON SEPARATE OCCASIONS, OR 2) FREE SERUM TESTOSTERONE LEVEL OF LESS THAN 5 NG/DL.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS
Other Criteria	MALE HYPOGONADISM: INITIAL: 1) 40 YEARS OR OLDER: PROSTATE SPECIFIC ANTIGEN (PSA) HAS BEEN EVALUATED FOR PROSTATE CANCER SCREENING, AND 2) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: TESTOSTERONE 12.5/1.25G, TESTOSTERONE 20.25/1.25, TESTOSTERONE 50 MG (1%). RENEWAL: 1) 40 YEARS OR OLDER: PSA HAS BEEN EVALUATED FOR PROSTATE CANCER SCREENING, AND 2) IMPROVED SYMPTOMS COMPARED TO BASELINE AND TOLERANCE TO TREATMENT.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TETRABENAZINE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TETRABENAZINE	XENAZINE, TETRABENAZINE	07350		GPI-10 (6238007000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chorea associated with Huntington's disease (ICD-10 G10) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with a neurologist or movement disorder specialist

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TETRABENAZINE (Xenazine)** requires the following rule(s) be met for approval:
   A. You have chorea (involuntary muscle movements) associated with Huntington's disease (a type of brain disorder)
   B. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor) or movement disorder specialist

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TETRABENAZINE (PART D)

RATIONALE

For further information, please refer to the Prescribing Information, and/or Drug Monograph for Xenazine.

REFERENCES

Xenazine [Prescribing Information]. Deerfield, IL: Lundbeck Pharmaceuticals LLC; November 2019.

For Part D use only:

TETRABENAZINE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	HUNTINGTONS DISEASE: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST OR MOVEMENT DISORDER SPECIALIST
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25 Created: 02/09
Commercial Effective: N/A Client Approval: 06/24 P&T Approval: 05/18

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TEZACAFTOR/IVACAFTOR (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TEZACAFTOR/ IVACAFTOR	SYMDEKO	44771		GPI-10 (4530990280)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of cystic fibrosis (CF) (ICD-10 Group E84) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a pulmonologist or cystic fibrosis (CF) expert
   - Symdeko will NOT be used concurrently with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (e.g., medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)
   - The patient is homozygous for the F508del mutation OR has a responsive mutation in the CFTR gene

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TEZACAFTOR/IVACAFTOR (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TEZACAFTOR/IVACAFTOR (Symdeko)** requires the following rule(s) be met for approval:

A. You have cystic fibrosis (CF: a type of lung disorder)
B. You are 6 years of age or older
C. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or cystic fibrosis expert
D. You will NOT use Symdeko concurrently (at the same time) with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (such as medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)
E. You are homozygous (have two copies of the same gene) for the *F508del* mutation (abnormal change) in the CFTR gene OR you have a responsive mutation in the CFTR gene (abnormal change in a type of gene that can be treated with Symdeko)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TEZACAFTOR/IVACAFTOR (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of cystic fibrosis (CF) (ICD-10 Group E84) and meet **ALL** of the following criteria?
   - The patient has experienced an improvement in clinical status
   - Symdeko will NOT be used concurrently with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (e.g., medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)

   If yes, **approve for lifetime by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TEZACAFTOR/IVACAFTOR (Symdeko)** requires the following rule(s) be met for renewal:
   A. You have cystic fibrosis (CF: a type of lung disorder)
   B. You have experienced an improvement in your clinical status
   C. You will NOT use Symdeko concurrently (at the same time) with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (such as medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the prescribing information and/or drug monograph for Symdeko.

REFERENCES

Symdeko [Prescribing Information]. Boston, MA: Vertex Pharmaceuticals Incorporated; January 2025.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TEZACAFTOR/IVACAFTOR (PART D)

For Part D use only:

TEZACAFTOR/IVACAFTOR (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	CYSTIC FIBROSIS (CF): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A PULMONOLOGIST OR CYSTIC FIBROSIS EXPERT
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: LIFETIME
Other Criteria	CF: INITIAL: NO CONCURRENT USE WITH ANOTHER CYSTIC FIBROSIS TRANSMEMBRANE CONDUCTANCE REGULATOR (CFTR) MODULATOR. RENEWAL: 1) IMPROVEMENT IN CLINICAL STATUS, AND 2) NO CONCURRENT USE WITH ANOTHER CFTR MODULATOR.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TEZEPELUMAB-EKKO BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TEZEPELUMAB-EKKO	TEZSPIRE	47740		GPI-10 (4460807525)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	Yes	No	No	Yes	No	No	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #5.

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TEZEPELUMAB-EKKO BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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TEZEPELUMAB-EKKO BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of severe asthma (ICD-10 Groups J45.5) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Therapy is prescribed by or in consultation with a physician specializing in allergy or pulmonary medicine
   - Tezspire will be used in combination with a medium, high-dose, or maximally tolerated inhaled corticosteroid (e.g., beclomethasone, mometasone, budesonide) AND at least one other maintenance medication (e.g., long-acting inhaled beta2-agonist [e.g., salmeterol, formoterol], long-acting muscarinic antagonist [e.g., Tudorza (aclidinium), ipratropium, Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [e.g., montelukast, zafirlukast, zileuton], theophylline)
   - Tezspire will NOT be used concurrently with another systemic biologic (e.g., Xolair [omalizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of asthma

   If yes, continue to #2.
   If no, continue to #7.

2. Does the patient meet **ONE** of the following criteria?
   - The patient experienced at least ONE asthma exacerbation requiring systemic corticosteroid (e.g. prednisone) burst lasting at least 3 days within the past 12 months
   - The patient experienced at least ONE serious exacerbation requiring hospitalization or emergency room visit within the past 12 months

   If yes, continue to #4.
   If no, continue to #3.

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TEZEPELUMAB-EKKO BvD (PART D)

INITIAL CRITERIA (CONTINUED)

3. Does the patient have poor symptom control despite current therapy as evidenced by at least **THREE** of the following within the past 4 weeks?
   - Daytime asthma symptoms more than twice per week
   - Any night waking due to asthma
   - Use of a short-acting inhaled beta2-agonist (SABA) reliever (e.g., albuterol) for symptoms more than twice per week
   - Any activity limitation due to asthma

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have a diagnosis of severe asthma with an eosinophilic phenotype (ICD-10 J82.83) and meet **ALL** of the following criteria?
   - The patient has a blood eosinophil level of at least 150 cells/mcL within the last 12 months
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Fasenra (benralizumab), Nucala (mepolizumab), Dupixent (dupilumab)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Does the patient have a diagnosis of severe oral corticosteroid-dependent asthma (ICD-10 J45.909) **AND** meet the following criterion?
   - The patient had a trial of or contraindication to the preferred agent: Dupixent (dupilumab)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #6.

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TEZEPELUMAB-EKKO BvD (PART D)

INITIAL CRITERIA (CONTINUED)

6. Does the patient have a diagnosis of severe allergic asthma (ICD-10 Group J45.5)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

7. Does the patient have a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) (ICD-10 Groups J32 and J33) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Tezspire will be used as add-on maintenance treatment
   - Therapy is prescribed by or in consultation with an otolaryngologist, allergist, or immunologist
   - There is evidence of nasal polyps by direct examination, endoscopy, or sinus CT scan
   - The patient has inadequately controlled disease
   - The patient had a 56-day trial of ONE topical nasal corticosteroid (e.g., mometasone, fluticasone)
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Nucala (mepolizumab), Dupixent (dupilumab)
   - Tezspire will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CRSwNP

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TEZEPELUMAB-EKKO (Tezspire)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Severe asthma (a type of lung condition)
      2. Chronic rhinosinusitis with nasal polyps (CRSwNP: inflammation of nasal and sinus ways with small growths in the nose)

   (Initial denial text continued on next page)

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TEZEPELUMAB-EKKO BvD (PART D)

INITIAL CRITERIA (CONTINUED)

B. If you have severe asthma, approval also requires:
1. You are 12 years of age or older
2. Therapy is prescribed by or in consultation with a doctor specializing in allergy or pulmonary (lung/breathing) medicine
3. Tezspire will be used in combination with a medium, high-dose, or maximally tolerated inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least one other maintenance medication (taken on a regular basis), such as a long-acting inhaled beta2-agonist (such as salmeterol, formoterol), long-acting muscarinic antagonist (such as Tudorza [aclidinium], Incruse Ellipta [umeclidinium], Spiriva [tiotropium]), leukotriene receptor antagonist (such as montelukast, zafirlukast, zileuton), theophylline
4. You will NOT use Tezspire concurrently (at the same time) with another systemic biologic (such as Xolair [omalizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of asthma
5. You meet ONE of the following:
   a. You have experienced at least ONE asthma exacerbation (worsening of symptoms) requiring systemic corticosteroid (such as prednisone) burst lasting at least 3 days within the past 12 months
   b. You have experienced at least ONE serious asthma exacerbation requiring hospitalization or emergency room visit within the past 12 months
   c. You have poor symptom control despite current therapy as evidenced by at least THREE of the following within the past 4 weeks:
      i. Daytime asthma symptoms more than twice per week
      ii. Any night waking due to asthma
      iii. Use of a short-acting inhaled beta2-agonist reliever (such as albuterol) for symptoms more than twice per week
      iv. Any activity limitation due to asthma

C. If you have severe asthma with an eosinophilic phenotype (type of inflammatory asthma), approval also requires:
1. You have a blood eosinophil level (type of white blood cell) of at least 150 cells/mcL within the last 12 months
2. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Fasenra (benralizumab), Nucala (mepolizumab), Dupixent (dupilumab)

D. If you have severe oral corticosteroid-dependent asthma, approval also requires:
1. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Dupixent (dupilumab)

(Initial denial text continued on next page)

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TEZEPELUMAB-EKKO BvD (PART D)

INITIAL CRITERIA (CONTINUED)

E. If you have severe allergic asthma, no additional criteria are required

F. If you have chronic rhinosinusitis with nasal polyps, approval also requires:

1. You are 12 years of age or older
2. Tezspire will be used as add-on maintenance treatment
3. Therapy is prescribed by or in consultation with an otolaryngologist (ear, nose, and throat doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
4. There is evidence of nasal polyps (non-cancerous growths) by direct examination, endoscopy (using a small camera), or sinus computed tomography (CT) scan (a type of imaging test)
5. You have inadequately controlled disease
6. You had a 56-day trial of ONE intranasal corticosteroid (such as mometasone nasal spray)
7. You had a trial of or contraindication to (harmful for) ONE of the following preferred medications: Nucala (mepolizumab), Dupixent (dupilumab)
8. You will NOT use Tezspire concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic rhinosinusitis with nasal polyps

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TEZEPELUMAB-EKKO BvD (PART D)

RENEWAL CRITERIA

1. Does the patient have severe asthma (ICD-10 Group J45.5) and meet **ALL** of the following criteria?
   - The patient continues to use an inhaled corticosteroid (e.g., beclomethasone, mometasone, budesonide) AND at least one other maintenance medication (e.g., long-acting inhaled beta2-agonist [e.g., salmeterol, formoterol], a long-acting muscarinic antagonist [e.g., Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [e.g., montelukast, zafirlukast, zileuton], theophylline)
   - Tezspire will NOT be used concurrently with another systemic biologic (e.g., Xolair [omalizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of asthma

   If yes, continue to #2.
   If no, continue to #3.

2. Has the patient shown a clinical response as evidenced by **ONE** of the following?
   - Reduction in asthma exacerbations from baseline
   - Decreased utilization of rescue medications (e.g., albuterol)
   - Increase in percent predicted FEV1 from pretreatment baseline
   - Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

3. Does the patient have a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) (ICD-10 Groups J32 and Group J33) and meet **ALL** of the following criteria?
   - The patient has shown a clinical benefit compared to baseline (e.g., improvements in nasal congestion, sense of smell, size of polyps)
   - Tezspire will NOT be used concurrently with another systemic biologic e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CRSwNP

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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TEZEPELUMAB-EKKO BvD (PART D)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TEZEPELUMAB-EKKO (Tezspire)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Severe asthma (a type of lung condition)
   2. Chronic rhinosinusitis with nasal polyps (CRSwNP: inflammation of nasal and sinus ways with small growths in the nose)

B. If you have severe asthma, renewal also requires:
   1. You will continue to use an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least one other maintenance medication (taken on a regular basis) such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast, zileuton), theophylline
   2. You have shown a clinical response as evidenced by ONE of the following:
      a. You have experienced a reduction in asthma exacerbations (worsening of symptoms) from baseline
      b. You have decreased your use of rescue medications (such as albuterol)
      c. Your percent predicted FEV1 (amount of air exhaled in one second) has increased from pretreatment baseline (before starting Tezspire)
      d. You have experienced a reduction in severity or frequency of asthma-related symptoms (such as wheezing, shortness of breath, coughing)
   3. You will NOT use Tezspire concurrently (at the same time) with another systemic biologic (such as Xolair [omalizumab]) or targeted small molecules (such as JAK[Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of asthma

C. If you have chronic rhinosinusitis with nasal polyps, renewal also requires:
   1. You have shown a clinical benefit compared to baseline (before starting Tezspire) (such as improvements in nasal congestion, sense of smell, size of polyps)
   2. You will NOT use Tezspire concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic rhinosinusitis with nasal polyps

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TEZEPELUMAB-EKKO BvD (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tezspire. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Tezspire [Prescribing Information]. Thousand Oaks, CA: Amgen, Inc.; October 2025.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed June 27, 2024].

For Part D use only:

TEZEPELUMAB-EKKO (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	ASTHMA WITH AN EOSINOPHILIC PHENOTYPE: INITIAL: BLOOD EOSINOPHIL LEVEL OF AT LEAST 150 CELLS/MCL WITHIN THE LAST 12 MONTHS.
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: ASTHMA: PRESCRIBED BY OR IN CONSULTATION WITH A PHYSICIAN SPECIALIZING IN ALLERGY OR PULMONARY MEDICINE. CHRONIC RHINOSINUSITIS WITH NASAL POLYPS (CRSWNP): PRESCRIBED BY OR IN CONSULTATION WITH AN OTOLARYNGOLOGIST, ALLERGIST OR IMMUNOLOGIST.
Coverage Duration	INITIAL: ASTHMA: 12 MO., CRSWNP: 6 MO. RENEWAL: ASTHMA, CRSWNP: 12 MOS.
Other Criteria	INITIAL: ASTHMA: 1) CONCURRENT THERAPY WITH A MEDIUM, HIGH-DOSE, OR MAXIMALLY TOLERATED INHALED CORTICOSTEROID (ICS) AND ONE OTHER MAINTENANCE MEDICATION, 2) ONE ASTHMA EXACERBATION REQUIRING SYSTEMIC CORTICOSTEROID BURST LASTING AT LEAST 3 DAYS WITHIN THE PAST 12 MONTHS, OR ONE SERIOUS EXACERBATION REQUIRING HOSPITALIZATION OR ER VISIT WITHIN THE PAST 12 MONTHS, OR POOR SYMPTOM CONTROL DESPITE CURRENT THERAPY AS EVIDENCED BY AT LEAST THREE OF THE FOLLOWING WITHIN THE PAST 4 WEEKS: (A) DAYTIME ASTHMA SYMPTOMS MORE THAN TWICE PER WEEK, (B) ANY NIGHT WAKING DUE TO ASTHMA, (C) SABA RELIEVER FOR SYMPTOMS MORE THAN TWICE PER WEEK, (D) ANY ACTIVITY LIMITATION DUE TO ASTHMA, AND 3) ONE

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	OF THE FOLLOWING: (A) ASTHMA WITH AN EOSINOPHILIC PHENOTYPE: TRIAL OF OR CONTRAINDICATION TO TWO OF THE PREFERRED AGENTS: FASENRA, NUCALA, DUPIXENT, (B) ORAL CORTICOSTEROID-DEPENDENT ASTHMA: TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT: DUPIXENT, OR (C) ALLERGIC ASTHMA: TRIAL OF OR CONTRAINDICATION TO PREFERRED AGENT NOT REQUIRED. CRSWNP: 1) A 56 DAY TRIAL OF ONE TOPICAL NASAL CORTICOSTEROID, 2) TRIAL OF OR CONTRAINDICATION TO ONE OF THE FOLLOWING PREFERRED AGENTS: NUCALA, DUPIXENT, 3) EVIDENCE OF NASAL POLYPS BY DIRECT EXAMINATION, ENDOSCOPY, OR SINUS CT SCAN, AND 4) INADEQUATELY CONTROLLED DISEASE. INITIAL/RENEWAL: ALL INDICATIONS: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION. RENEWAL: ASTHMA: 1) CONTINUED USE OF AN ICS AND ONE OTHER MAINTENANCE MEDICATION, AND 2) CLINICAL RESPONSE AS EVIDENCED BY: (A) REDUCTION IN ASTHMA EXACERBATIONS FROM BASELINE, (B) DECREASED UTILIZATION OF RESCUE MEDICATIONS, (C) INCREASE IN PERCENT PREDICTED FEV1 FROM PRETREATMENT BASELINE, OR (D) REDUCTION IN SEVERITY OR FREQUENCY OF ASTHMA-RELATED SYMPTOMS. CRSWNP: CLINICAL BENEFIT COMPARED TO BASELINE.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

THALIDOMIDE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
THALIDOMIDE	THALOMID	11465		GPI-10 (9939207000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of multiple myeloma (ICD-10 Group C90.0) **AND** meet the following criterion?
   - Thalomid will be used in combination with dexamethasone

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.
   If no, continue to #2.

2. Does the patient have a diagnosis of erythema nodosum leprosum (ENL) (ICD-10 L52)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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THALIDOMIDE (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **THALIDOMIDE (Thalomid)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Multiple myeloma (a type of blood cancer)
   2. Erythema nodosum leprosum (a type of immune condition)

B. If you have multiple myeloma, approval also requires:
   1. Thalomid will be used in combination with dexamethasone

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Thalomid.

REFERENCES

Thalomid [Prescribing Information]. Summit, NJ: Celgene Corporation; February 2021.

For Part D use only:

THALIDOMIDE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TILDRAKIZUMAB-ASMN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TILDRAKIZUMAB-ASMN	ILUMYA	44823		GPI-10 (9025058010)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is a candidate for phototherapy or systemic therapy
   - Therapy is prescribed by or in consultation with a dermatologist
   - The patient has psoriasis covering 3% or more of body surface area (BSA) OR psoriatic lesions affecting the hands, feet, genital area, scalp, or face
   - Ilumya will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Cosentyx (secukinumab), Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima, Selarsdi/Yesintek /ustekinumab-aauz, Skyrizi (risankizumab-rzaa), Tremfya (guselkumab), Otezla (apremilast)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TILDRAKIZUMAB-ASMN (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TILDRAKIZUMAB-ASMN (Ilumya)** requires the following rule(s) be met for approval:

A. You have moderate to severe plaque psoriasis (PsO: a type of skin condition)
B. You are 18 years of age or older
C. You are a candidate for phototherapy (light therapy) or systemic therapy (therapy that travels through the entire body)
D. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
E. You have psoriasis covering 3% or more of body surface area (BSA) OR psoriatic lesions (rashes) affecting your hands, feet, genital area, scalp, or face
F. You will NOT use Ilumya concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis
G. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Cosentyx (secukinumab), Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima, Selarsdi /Yesintek /ustekinumab-aauz, Skyrizi (risankizumab-rzaa), Tremfya (guselkumab), Otezla (apremilast)

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TILDRAKIZUMAB-ASMN (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Ilumya will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TILDRAKIZUMAB-ASMN (Ilumya)** requires the following rule(s) be met for renewal:
   A. You have moderate to severe plaque psoriasis (PsO: a type of skin condition)
   B. You continue to benefit from the medication
   C. You will NOT use Ilumya concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Ilumya.

REFERENCES
Ilumya [Prescribing Information]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; December 2025.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TILDRAKIZUMAB-ASMN (PART D)

For Part D use only:

TILDRAKIZUMAB-ASMN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	PLAQUE PSORIASIS (PSO): INITIAL: PSORIASIS COVERING 3 PERCENT OR MORE OF BODY SURFACE AREA OR PSORIATIC LESIONS AFFECTING THE HANDS, FEET, GENITAL AREA, SCALP, OR FACE.
Age Restrictions	N/A
Prescriber Restrictions	PSO: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	PSO: INITIAL: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: COSENTYX, HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, SELARSDI/YESINTEK/USTEKINUMAB-AAUZ, SKYRIZI, TREMFYA, OTEZLA. INITIAL/RENEWAL: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION. RENEWAL: CONTINUES TO BENEFIT FROM THE MEDICATION.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TIOPRONIN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TIOPRONIN	THIOLA EC, TIOPRONIN, VENXXIVA		46629, 46633	GPI-14 (56600050000620, 56600050000630)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	Yes	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of cystinuria (ICD-10 E72.01) and meet **ALL** of the following criteria?
   - The patient weighs at least 20 kg (44 lbs)
   - Therapy is prescribed by or in consultation with a nephrologist

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient have nephrolithiasis and meet **ONE** of the following criteria?
   - The patient's kidney stone analysis shows the presence of cystine
   - The patient's urinalysis shows pathognomonic hexagonal cystine crystals
   - The patient has a family history of cystinuria AND a positive cyanide-nitroprusside screening

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TIOPRONIN (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: **Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TIOPRONIN (Thiola EC, Venxxiva)** requires the following rule(s) be met for approval:

A. You have cystinuria (a type of genetic disorder)
B. You weigh at least 20 kilograms (44 pounds)
C. Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor)
D. You have nephrolithiasis (kidney stones) and also meet ONE of the following:
    1. Your kidney stone analysis shows there is cystine (an amino acid)
    2. Your urine analysis shows there are hexagonal cystine crystals that are pathognomonic (signs relating to the disease)
    3. You have a family history of cystinuria AND you tested positive for the cyanide-nitroprusside screening (a test to determine the amount of cystine in your body)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TIOPRONIN (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of cystinuria (ICD-10 E72.01) **AND** meet the following criterion?
   - The patient continues to benefit from the medication

   If yes, **approve for lifetime by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TIOPRONIN (Thiola EC, Venxxiva)** requires the following rule(s) be met for renewal:
   A. You have cystinuria (a type of genetic disorder)
   B. You continue to benefit from the medication

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Thiola EC, Venxxiva.

REFERENCES

Thiola EC (tiopronin delayed-release tablets) [Prescribing Information]. Basking Ridge, NJ: Torrent Pharma Inc.; February 2024.
Venxxiva [Prescribing Information]. Cambridge, UK: Cycle Pharmaceuticals Ltd; December 2024.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TIOPRONIN (PART D)

For Part D use only:

TIOPRONIN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	CYSTINURIA: INITIAL: HAS NEPHROLITHIASIS AND ONE OF THE FOLLOWING: 1) STONE ANALYSIS SHOWING PRESENCE OF CYSTINE, 2) PRESENCE OF PATHOGNOMONIC HEXAGONAL CYSTINE CRYSTALS ON URINALYSIS, OR 3) FAMILY HISTORY OF CYSTINURIA AND POSITIVE CYANIDE-NITROPRUSSIDE SCREENING.
Age Restrictions	N/A
Prescriber Restrictions	CYSTINURIA: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEPHROLOGIST.
Coverage Duration	INITIAL: 12 MONTHS, RENEWAL: LIFETIME.
Other Criteria	CYSTINURIA: RENEWAL: CONTINUES TO BENEFIT FROM THE MEDICATION.

Created: 07/23
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 05/23

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TIRZEPATIDE - ZEPBOUND DVE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TIRZEPATIDE	ZEPBOUND, ZEPBOUND KWIKPEN	48014		GPI-10 (6125258000)	BRAND = ZEPBOUND, ZEPBOUND KWIKPEN

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	Yes	No	No	Yes	No	No	Yes	No	No	Yes

This is a DvE drug requiring a payment determination for "Part D" or "Non-Part D."

PAYMENT DETERMINATION CRITERIA

1. Does the patient have a diagnosis of obstructive sleep apnea (OSA) (ICD-10 G47.33) and meet **ALL** of the following criteria?
   - The patient has moderate to severe OSA (defined as an Apnea Hypopnea Index [AHI] of at least 15 events per hour on polysomnogram at baseline)
   - The patient is 18 years of age or older
   - Zepbound will be used in combination with a reduced-calorie diet and increased physical activity
   - The patient is obese (BMI of at least 30 kg/m[2] or the patient is Asian and has a BMI of at least 27.5 kg/m[2]) at baseline

   If yes, **set CMS_DVE_OVR to 'D' and approve for 12 months by GPID for all strengths and formulations or by GPI-10. Document in the PA comments: Part D Determination Override.**

   If no, **set CMS_DVE_OVR to 'E' and approve for 12 months by GPID or GPI-10. Document in the PA comments: Payment Determination Override. This is not a Part D indication.**

   NOTE: If the claim rejects after analyzing, then follow the clinical authorization process within the HQ notes.

   RPH Review
   Review for Part D compendial supported off-label indications. If yes for a Part D indication, **set CMS_DVE_OVR to 'D' and approve for 12 months by GPID for all strengths and formulations or by GPI-10. Document in the PA comments: Part D Determination Override.**

   If not a Part D indication, and you are denying other UM **Set CMS_DVE_OVR to 'E' within the denied PA for 12 months by GPID or by GPI-10.**

   If the diagnosis is UNKNOWN do not enter a DVE override; follow the criteria for any additional UM and decision the case accordingly. Provide the following PAC instruction: '**PAC: do not enter a DVE override**.'

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TIRZEPATIDE - ZEPBOUND DVE (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TIRZEPATIDE - ZEPBOUND** requires the following rule(s) be met for approval:

A. You have moderate to severe obstructive sleep apnea (OSA: a disorder where airflow is blocked during sleep) (defined as an Apnea Hypopnea Index [AHI: a tool used to evaluate disease severity] of at least 15 events per hour on polysomnogram [a type of sleep test] at baseline [before treatment])
B. You are 18 years of age or older
C. Zepbound will be used in combination with a reduced-calorie diet and increased physical activity
D. You are obese (body mass index [BMI: a tool for evaluating body fat] of at least 30 kg/m[2], or you are Asian and have a BMI of at least 27.5 kg/m[2]) at baseline (before treatment)

RATIONALE

To limit the coverage of Zepbound to the Medicare Part D covered indication of moderate to severe obstructive sleep apnea and exclude coverage for the treatment of obesity. For further information, please refer to the Prescribing Information and/or Drug Monograph for Zepbound.

REFERENCES

Zepbound [Prescribing Information]. Indianapolis, IN: Lilly USA, LLC; February 2026.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements. Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf. [Accessed March 2026].

For Part D use only:

TIRZEPATIDE - ZEPBOUND (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	PART D DOES NOT COVER THIS DRUG WHEN USED FOR TREATMENT OF OBESITY.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 01/25
Effective: 06/13/26 Client Approval: 06/26 P&T Approval: 04/26

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TISLELIZUMAB-JSGR (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TISLELIZUMAB-JSGR	TEVIMBRA	49457		GPI-10 (2135796700)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic esophageal squamous cell carcinoma (ESCC) (ICD-10 Group C15) **AND** meets the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, continue to #4.

2. Will Tevimbra be used in combination with platinum (e.g., cisplatin, oxaliplatin)-containing chemotherapy **AND** the patient meets the following criterion?
   - The patient's tumor programmed death-ligand 1 (PD-L1) expression is at least 1

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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TISLELIZUMAB-JSGR (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Will Tevimbra be used as a single agent **AND** the patient meets the following criterion?
   - Tevimbra will be used after a prior systemic chemotherapy (e.g., paclitaxel, docetaxel, irinotecan) that did NOT include a PD-(L)1 inhibitor (e.g., Opdivo [nivolumab])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient have a diagnosis of unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma (G/GEJ) (ICD-10 Group C16) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer is HER2-negative
   - Tevimbra will be used in combination with platinum (e.g., cisplatin, oxaliplatin) and fluoropyrimidine-based chemotherapy (e.g., fluorouracil [5-FU], capecitabine)
   - The patient's tumors programmed death-ligand 1 (PD-L1) expression is at least 1

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TISLELIZUMAB-JSGR (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TISLELIZUMAB-JSGR (Tevimbra)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Unresectable or metastatic esophageal squamous cell carcinoma (ESCC: a type of digestive system cancer that cannot be removed by surgery or has spread to other parts of the body)
   2. Unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma (G/GEJ: a type of digestive system cancer that cannot be removed by surgery or has spread to other parts of the body)

B. If you have unresectable or metastatic esophageal squamous cell carcinoma, approval also requires:
   1. You are 18 years of age or older
   2. You meet ONE of the following:
      a. Tevimbra will be used in combination with platinum (such as cisplatin, oxaliplatin)-containing chemotherapy (medications used to treat cancer) AND your tumor programmed death-ligand 1 (PD-L1: a type of protein) expression is at least 1
      b. Tevimbra will be used as a single agent (given alone) after a prior systemic chemotherapy (cancer treatment that targets the entire body such as paclitaxel, docetaxel, irinotecan) that did NOT include a PD-(L)1 inhibitor (a type of medication such as Opdivo [nivolumab])

C. If you have unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:
   1. You are 18 years of age or older
   2. Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-negative
   3. Tevimbra will be used in combination with platinum (such as cisplatin, oxaliplatin) and fluoropyrimidine-based chemotherapy (such as fluorouracil [5-FU], capecitabine)
   4. Your tumor programmed death-ligand 1 (PD-L1: a type of protein) expression is at least 1

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TISLELIZUMAB-JSGR (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tevimbra.

REFERENCES

Tevimbra [Prescribing Information]. San Mateo, CA: BeiGene; April 2025.

For Part D use only:

TISLELIZUMAB-JSGR (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 09/24
Effective: 05/17/25 Client Approval: 05/25 P&T Approval: 07/25

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TISOTUMAB VEDOTIN-TFTV (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TISOTUMAB VEDOTIN-TFTV	TIVDAK	47582		GPI-10 (2135928080)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of recurrent or metastatic cervical cancer (ICD-10 Group C53) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had disease progression on or after chemotherapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TISOTUMAB VEDOTIN-TFTV (Tivdak)** requires the following rule(s) be met for approval:
   A. You have recurrent or metastatic cervical cancer (cancer has returned or spread to other parts of the body)
   B. You are 18 years of age or older
   C. You had disease progression on or after chemotherapy (drugs used to treat cancer)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TISOTUMAB VEDOTIN-TFTV (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tivdak.

REFERENCES

Tivdak [Prescribing Information]. Bothell, WA: Seagen, Inc.; March 2022.

For Part D use only:

TISOTUMAB VEDOTIN-TFTV (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Created: 09/21
Effective: 01/01/25 Client Approval: 08/24 P&T Approval: 10/21

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TIVOZANIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TIVOZANIB HCL	FOTIVDA	45740		GPI-10 (2153307625)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory advanced renal cell carcinoma (RCC) (ICD-10 Groups C64, C65) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received two or more prior systemic therapies (e.g., Cabometyx [cabozantinib], Keytruda [pembrolizumab], Opdivo [nivolumab])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TIVOZANIB (Fotivda)** requires the following rule(s) be met for approval:
   A. You have relapsed or refractory advanced renal cell carcinoma (RCC) (a type of kidney cancer that has returned or does not respond to treatment)
   B. You are 18 years of age or older
   C. You have received two or more prior systemic therapies (such as Cabometyx [cabozantinib], Keytruda [pembrolizumab], Opdivo [nivolumab])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TIVOZANIB (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Fotivda.

REFERENCES
Fotivda [Prescribing Information]. Boston, MA: AVEO Pharmaceuticals, Inc.; March 2021.

For Part D use only:

TIVOZANIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25 Created: 04/21
Commercial Effective: N/A Client Approval: 06/24 P&T Approval: 04/21

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TOCILIZUMAB IV (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TOCILIZUMAB	ACTEMRA		27366 27367 27368	GPI-14 (66500070002030, 66500070002035, 66500070002040)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

NOTE: For requests for the SQ dosage form of Actemra, please see the TOCILIZUMAB SQ PA guideline.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for the treatment of coronavirus disease 2019 (COVID-19) in a hospitalized patient?

   If yes, **do not approve**. [NOTE: This indication is for hospital use only.]
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, continue to #2.

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TOCILIZUMAB IV (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Actemra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Orencia (abatacept)

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths of the IV formulation.** **APPROVAL TEXT (IF APPLICABLE):** The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Does the patient have a diagnosis of giant cell arteritis (GCA) (ICD-10 M31.5, M31.6) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has completed, started, or will soon start a tapering course of glucocorticoids (e.g., prednisone)
   - Actemra will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of GCA
   - The patient had a trial of or contraindication to the preferred agent: Rinvoq (upadacitinib)

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths of the IV formulation.** **APPROVAL TEXT (IF APPLICABLE):** The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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TOCILIZUMAB IV (PART D)

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (PJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Actemra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of PJIA
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
     - Xeljanz IR (tofacitinib IR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Orencia (abatacept)

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths of the IV formulation.** **APPROVAL TEXT (IF APPLICABLE):** The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Does the patient have a diagnosis of systemic juvenile idiopathic arthritis (SJIA) (ICD-10 Group M08.2) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist, dermatologist, or immunologist
   - Actemra will NOT be used concurrently with another systemic biologic (e.g., Ilaris [canakinumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) forthe treatment of SJIA
   - The patient had a trial of or contraindication to the preferred agent: Tyenne (tocilizumab-aazg)

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths of the IV formulation.** **APPROVAL TEXT (IF APPLICABLE):** The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #6.

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TOCILIZUMAB IV (PART D)

INITIAL CRITERIA (CONTINUED)

6. Is the request for the treatment of chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome (CRS) (ICD-10 Z92.850; Group D89.83) and the patient meets **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Actemra will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CRS
   - The patient had a trial of or contraindication to the preferred agent: Tyenne IV (tocilizumab-aazg)

   If yes, **approve for 1 month by GPID or GPI-14 for all strengths of the IV formulation.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TOCILIZUMAB IV (Actemra)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
      2. Giant cell arteritis (GCA: a type of inflammatory condition)
      3. Polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
      4. Systemic juvenile idiopathic arthritis (SJIA: a type of joint condition)
      5. Chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome (CRS: inflammatory response that can be triggered by a variety of factors such as infections and certain drugs)

   (Initial denial text continued on next page)

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TOCILIZUMAB IV (PART D)

INITIAL CRITERIA (CONTINUED)

B. If you have moderate to severe rheumatoid arthritis, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You will NOT use Actemra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
   b. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
   c. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
   d. Orencia (abatacept)

C. If you have giant cell arteritis, approval also requires:
1. You are 18 years of age or older
2. You have completed, started, or will soon start a tapering course (slowly lowering the dose to stop use) of glucocorticoids (such as prednisone)
3. You will NOT use Actemra concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of giant cell arteritis
4. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Rinvoq (upadacitinib)

(Initial denial text continued on next page)

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TOCILIZUMAB IV (PART D)

INITIAL CRITERIA (CONTINUED)

D. If you have polyarticular juvenile idiopathic arthritis, approval also requires:
1. You are 2 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You will NOT use Actemra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis
4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
   b. Xeljanz IR (tofacitinib immediate-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
   c. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
   d. Orencia (abatacept)

E. If you have systemic juvenile idiopathic arthritis, approval also requires:
1. You are 2 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
3. You will NOT use Actemra concurrently (at the same time) with another systemic biologic (such as Ilaris [canakinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic juvenile idiopathic arthritis
4. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Tyenne (tocilizumab-aazg)

F. If you have chimeric antigen receptor T cell-induced severe or life-threatening cytokine release syndrome, approval also requires:
1. You are 2 years of age or older
2. You will NOT use Actemra concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of cytokine release syndrome
3. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Tyenne IV (tocilizumab-aazg intravenous)

G. NOTE: Actemra will NOT be approved for the treatment of coronavirus disease 2019 (COVID-19) in hospitalized patients

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TOCILIZUMAB IV (PART D)

RENEWAL CRITERIA

NOTE: For the diagnosis of cytokine release syndrome (CRS), please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Actemra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths of the IV formulation.** **APPROVAL TEXT (IF APPLICABLE):** The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of giant cell arteritis (GCA) (ICD-10 M31.5, M31.6) **AND** meet the following criterion?
   - Actemra will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of GCA

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths of the IV formulation.** **APPROVAL TEXT (IF APPLICABLE):** The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (PJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Actemra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of PJIA

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths of the IV formulation.** **APPROVAL TEXT (IF APPLICABLE):** The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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TOCILIZUMAB IV (PART D)

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of systemic juvenile idiopathic arthritis (SJIA) (ICD-10 Group M08.2) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - The patient had a trial of or contraindication to the preferred agent: Tyenne (tocilizumab-aazg)
   - Actemra will NOT be used concurrently with another systemic biologic (e.g., Ilaris [canakinumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) forthe treatment of SJIA

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths of the IV formulation.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TOCILIZUMAB IV (Actemra)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
      2. Giant cell arteritis (GCA: a type of inflammatory condition)
      3. Polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
      4. Systemic juvenile idiopathic arthritis (SJIA: a type of joint condition)

   B. If you have moderate to severe rheumatoid arthritis, renewal also requires:
      1. You continue to benefit from the medication
      2. You will NOT use Actemra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis

   C. If you have giant cell arteritis, renewal also requires:
      1. You will NOT use Actemra concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of giant cell arteritis

   (Renewal denial text continued on next page)

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RENEWAL CRITERIA (CONTINUED)

D. If you have polyarticular juvenile idiopathic arthritis, renewal also requires:
1. You continue to benefit from the medication
2. You will NOT use Actemra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis

E. If you have systemic juvenile idiopathic arthritis, renewal also requires:
1. You continue to benefit from the medication
2. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Tyenne (tocilizumab-aazg)
3. You will NOT use Actemra concurrently (at the same time) with another systemic biologic (such as Ilaris [canakinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic juvenile idiopathic arthritis

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RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Actemra.

REFERENCE
Actemra [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; December 2025.

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TOCILIZUMAB IV (PART D)

For Part D use only:

TOCILIZUMAB IV (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	CORONAVIRUS DISEASE 2019 (COVID-19) IN HOSPITALIZED PATIENTS
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: RHEUMATOID ARTHRITIS (RA), POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS (SJIA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST, DERMATOLOGIST, OR IMMUNOLOGIST.
Coverage Duration	INITIAL: RA, PJIA, SJIA, GCA: 6 MONTHS. CRS: 1 MONTH. RENEWAL: RA, PJIA, SJIA, GCA: 12 MONTHS.
Other Criteria	INITIAL: ALL INDICATIONS: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION. RA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, XELJANZ, RINVOQ, ORENCIA. GIANT CELL ARTERITIS (GCA): 1) HAS COMPLETED, STARTED, OR WILL SOON START A TAPERING COURSE OF GLUCOCORTICOIDS, AND 2) TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT: RINVOQ. PJIA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, XELJANZ IR, RINVOQ, ORENCIA. SJIA: TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT: TYENNE. CYTOKINE RELEASE SYNDROME (CRS): TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT: TYENNE IV. RENEWAL: RA, PJIA: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR THE SAME INDICATION. GCA: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR THE SAME INDICATION. SJIA: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, 2) TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT: TYENNE, AND 3) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR THE SAME INDICATION.

Created: 02/10
Effective: 08/01/26 Client Approval: 07/26 DMC Approval: 06/16/26

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TOCILIZUMAB SQ (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TOCILIZUMAB	ACTEMRA, ACTEMRA ACTPEN		35486 45082	GPI-14 (6650007000E520, (6650007000D520)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

NOTE: For requests for the IV dosage form of Actemra, please see the TOCILIZUMAB IV PA guideline.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Actemra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Orencia (abatacept)

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TOCILIZUMAB SQ (PART D)

INITIAL CRITERIA (CONTINUED)

If yes, **approve for 6 months by GPID or GPI-14 for all strengths of the subcutaneous formulations (syringe and pen injector).**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.
If no, continue to #2.

2. Does the patient have a diagnosis of giant cell arteritis (GCA) (ICD-10 M31.5, M31.6) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has completed, started, or will soon start a tapering course of glucocorticoids (e.g., prednisone)
   - Actemra will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of GCA
   - The patient had a trial of or contraindication to the preferred agent: Rinvoq (upadacitinib)

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths of the subcutaneous formulations (syringe and pen injector).**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Does the patient have a diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) (ICD-10 M34.81) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a pulmonologist or rheumatologist
   - The patient does NOT have other etiologies of interstitial lung disease (ILD) [e.g., heart failure/fluid overload, drug-induced lung toxicity (cyclophosphamide, methotrexate, ACE-inhibitors), recurrent aspiration (such as from GERD), pulmonary vascular disease, pulmonary edema, pneumonia, chronic pulmonary thromboembolism, alveolar hemorrhage or ILD caused by another rheumatic disease, such as mixed connective tissue disease (MCTD)]
   - Actemra will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of SSc-ILD

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths of the subcutaneous formulations (syringe and pen injector).**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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TOCILIZUMAB SQ (PART D)

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (PJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Actemra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of PJIA
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
     - Xeljanz IR (tofacitinib IR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Orencia (abatacept)

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths of the subcutaneous formulations (syringe and pen injector).**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Does the patient have a diagnosis of systemic juvenile idiopathic arthritis (SJIA) (ICD-10 Group M08.2) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist, dermatologist, or immunologist
   - Actemra will NOT be used concurrently with another systemic biologic (e.g., Ilaris [canakinumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of SJIA
   - The patient had a trial of or contraindication to the preferred agent: Tyenne (tocilizumab-aazg)

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths of the subcutaneous formulations (syringe and pen injector).**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TOCILIZUMAB SQ (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TOCILIZUMAB SQ (Actemra)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Giant cell arteritis (GCA: a type of inflammatory condition)
   3. Systemic sclerosis-associated interstitial lung disease (SSc-ILD: a type of lung condition)
   4. Polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
   5. Systemic juvenile idiopathic arthritis (SJIA: a type of joint condition)

B. If you have moderate to severe rheumatoid arthritis, approval also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Actemra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
   4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      a. Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
      b. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
      c. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
      d. Orencia (abatacept)

(Initial denial text continued on next page)

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TOCILIZUMAB SQ (PART D)

INITIAL CRITERIA (CONTINUED)

C. If you have giant cell arteritis, approval also requires:
1. You are 18 years of age or older
2. You have completed, started, or will soon start a tapering course (slowly lowering the dose to stop use) of glucocorticoids (such as prednisone)
3. You will NOT use Actemra concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of giant cell arteritis
4. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Rinvoq (upadacitinib)

D. If you have systemic sclerosis-associated interstitial lung disease, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or rheumatologist (a type of immune system doctor)
3. You do not have other causes of interstitial lung disease (such as heart failure/fluid overload, drug-induced lung toxicity [cyclophosphamide, methotrexate, angiotensin-converting enzyme [ACE]-inhibitors [class of blood pressure medications], recurrent aspiration [inhaling] such as from gastroesophageal reflux disease [GERD, acid reflux], pulmonary vascular disease [affecting blood vessels in lungs], pulmonary edema [excess fluid in the lungs], pneumonia [type of lung infection], chronic pulmonary thromboembolism [blood clot in lungs], alveolar hemorrhage [bleeding of a part of the lungs], interstitial lung disease caused by another rheumatic [inflammatory] disease such as mixed connective tissue disease [MCTD: a type of autoimmune disorder])
4. You will NOT use Actemra concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic sclerosis-associated interstitial lung disease

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TOCILIZUMAB SQ (PART D)

INITIAL CRITERIA (CONTINUED)

E. If you have polyarticular juvenile idiopathic arthritis, approval also requires:
1. You are 2 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You will NOT use Actemra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis
4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
   b. Xeljanz IR (tofacitinib immediate-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
   c. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
   d. Orencia (abatacept)

F. If you have systemic juvenile idiopathic arthritis, approval also requires:
1. You are 2 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
3. You will NOT use Actemra concurrently (at the same time) with another systemic biologic (such as Ilaris [canakinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic juvenile idiopathic arthritis
4. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Tyenne (tocilizumab-aazg)

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TOCILIZUMAB SQ (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of giant cell arteritis (GCA) (ICD-10 M31.5, M31.6) **AND** meet the following criterion?
   - Actemra will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of GCA

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths of the subcutaneous formulations (syringe and pen injector).**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) (ICD-10 M34.81) and meet **ALL** of the following criteria?
   - The patient has experienced a clinical meaningful improvement or maintenance in annual rate of decline
   - Actemra will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of SSc-ILD

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths of the subcutaneous formulations (syringe and pen injector).**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Actemra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths of the subcutaneous formulations (syringe and pen injector).**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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TOCILIZUMAB SQ (PART D)

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (PJIA) (ICD-10 M08.3; Group M08.0) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Actemra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of PJIA

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths of the subcutaneous formulations (syringe and pen injector).**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Does the patient have a diagnosis of systemic juvenile idiopathic arthritis (SJIA) (ICD-10 Group M08.2) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - The patient had a trial of or contraindication to the preferred agent: Tyenne (tocilizumab-aazg)
   - Actemra will NOT be used concurrently with another systemic biologic (e.g., Ilaris [canakinumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) forthe treatment of SJIA

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths of the subcutaneous formulations (syringe and pen injector).**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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TOCILIZUMAB SQ (PART D)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TOCILIZUMAB SQ (Actemra)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Giant cell arteritis (GCA: a type of inflammatory condition)
   2. Systemic sclerosis-associated interstitial lung disease (SSc-ILD: a type of lung condition)
   3. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   4. Polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
   5. Systemic juvenile idiopathic arthritis (SJIA: a type of joint condition)

B. If you have giant cell arteritis, renewal also requires:
   1. You will NOT use Actemra concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of giant cell arteritis

C. If you have systemic sclerosis-associated interstitial lung disease, renewal also requires:
   1. You have experienced a clinically meaningful improvement or maintenance in annual rate of decline
   2. You will NOT use Actemra concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic sclerosis-associated interstitial lung disease

D. If you have moderate to severe rheumatoid arthritis, renewal also requires:
   1. You continue to benefit from the medication
   2. You will NOT use Actemra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis

E. If you have polyarticular juvenile idiopathic arthritis, renewal also requires:
   1. You continue to benefit from the medication
   2. You will NOT use Actemra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis

(Renewal denial text continued on next page)

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TOCILIZUMAB SQ (PART D)

RENEWAL CRITERIA (CONTINUED)

F. If you have systemic juvenile idiopathic arthritis, renewal also requires:
1. You continue to benefit from the medication
2. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Tyenne (tocilizumab-aazg)
3. You will NOT use Actemra concurrently (at the same time) with another systemic biologic (such as Ilaris [canakinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic juvenile idiopathic arthritis

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Actemra.

REFERENCE
Actemra [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; September 2024.

For Part D use only:

TOCILIZUMAB SQ (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: RHEUMATOID ARTHRITIS (RA), POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS (SJIA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST, DERMATOLOGIST, OR IMMUNOLOGIST. SYSTEMIC SCLEROSIS-ASSOCIATED INTERSTITIAL LUNG DISEASE (SSC-ILD): PRESCRIBED BY OR IN CONSULTATION WITH A PULMONOLOGIST OR RHEUMATOLOGIST.
Coverage Duration	INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: RA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, XELJANZ, RINVOQ, ORENCIA. GIANT CELL ARTERITIS (GCA): 1) HAS COMPLETED, STARTED, OR WILL SOON START A TAPERING COURSE OF GLUCOCORTICOIDS, AND 2) TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT: RINVOQ. SSC-ILD: DOES NOT HAVE OTHER KNOWN CAUSES OF INTERSTITIAL LUNG DISEASE (E.G., CONNECTIVE TISSUE DISEASE, DRUG TOXICITY, ASBESTOS OR BERYLLIUM EXPOSURE,

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	HYPERSENSITIVITY PNEUMONITIS). PJIA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, XELJANZ IR, RINVOQ, ORENCIA. SJIA: TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT: TYENNE. INITIAL/RENEWAL: ALL INDICATIONS: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION. RENEWAL: RA, PJIA: CONTINUES TO BENEFIT FROM THE MEDICATION. SSC-ILD: CLINICAL MEANINGFUL IMPROVEMENT OR MAINTENANCE IN ANNUAL RATE OF DECLINE. SJIA: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT: TYENNE.

Created: 11/13
Effective: 05/01/26 Client Approval: 04/26 P&T Approval: 04/25

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TOCILIZUMAB-AAZG IV (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TOCILIZUMAB-AAZG	TYENNE		55366 55368 55372	GPI-14 (66500070172030, 66500070172040, 66500070172035)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

NOTE: For requests for the SQ dosage form of Tyenne, please see the TOCILIZUMAB-AAZG SQ PA guideline.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for the treatment of coronavirus disease 2019 (COVID-19) in a hospitalized adult?

    If yes, do not approve. [NOTE: This indication is for hospital use only.]
    DENIAL TEXT: See the initial denial text at the end of the guideline.

    If no, continue to #2.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TOCILIZUMAB-AAZG IV (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TOCILIZUMAB-AAZG	TYENNE		55366 55368 55372	GPI-14 (66500070172030, 66500070172040, 66500070172035)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

NOTE: For requests for the SQ dosage form of Tyenne, please see the TOCILIZUMAB-AAZG SQ PA guideline.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for the treatment of coronavirus disease 2019 (COVID-19) in a hospitalized patient?

   If yes, do not approve. [NOTE: This indication is for hospital use only.]
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, continue to #2.

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TOCILIZUMAB-AAZG IV (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Tyenne will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
     - Orencia (abatacept)
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths of the IV formulation.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Does the patient have a diagnosis of giant cell arteritis (GCA) (ICD-10 M31.5, M31.6) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has completed, started, or will soon start a tapering course of glucocorticoids (e.g., prednisone)
   - Tyenne will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of GCA
   - The patient had a trial of or contraindication to the preferred agent: Rinvoq (upadacitinib)

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths of the IV formulation.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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TOCILIZUMAB-AAZG IV (PART D)

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (PJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Tyenne will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of PJIA
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
     - Orencia (abatacept)
     - Xeljanz IR (tofacitinib IR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths of the IV formulation.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Does the patient have a diagnosis of systemic juvenile idiopathic arthritis (SJIA) (ICD-10 Group M08.2) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist, dermatologist, or immunologist
   - Tyenne will NOT be used concurrently with another systemic biologic (e.g., Ilaris [canakinumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of SJIA

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths of the IV formulation.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #6.

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TOCILIZUMAB-AAZG IV (PART D)

INITIAL CRITERIA (CONTINUED)

6. Is the request for the treatment of chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome (CRS) (ICD-10 Z92.850; Group D89.83) and the patient meets **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Tyenne will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CRS

   If yes, **approve for 1 month by GPID or GPI-14 for all strengths of the IV formulation.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TOCILIZUMAB-AAZG IV (Tyenne)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
      2. Giant cell arteritis (GCA: a type of inflammatory condition)
      3. Polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
      4. Systemic juvenile idiopathic arthritis (SJIA: a type of joint condition)
      5. Chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome (CRS: inflammatory response that can be triggered by a variety of factors such as infections and certain drugs)

   (Initial denial text continued on next page)

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TOCILIZUMAB-AAZG IV (PART D)

INITIAL CRITERIA (CONTINUED)

B. If you have moderate to severe rheumatoid arthritis, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
   b. Orencia (abatacept)
   c. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
   d. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])

C. If you have giant cell arteritis, approval also requires:
1. You are 18 years of age or older
2. You have completed, started, or will soon start a tapering course (slowly lowering the dose to stop use) of glucocorticoids (such as prednisone)
3. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of giant cell arteritis
4. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Rinvoq (upadacitinib)

(Initial denial text continued on next page)

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TOCILIZUMAB-AAZG IV (PART D)

INITIAL CRITERIA (CONTINUED)

D. If you have polyarticular juvenile idiopathic arthritis, approval also requires:
1. You are 2 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis
4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
   b. Orencia (abatacept)
   c. Xeljanz IR (tofacitinib immediate-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
   d. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])

E. If you have systemic juvenile idiopathic arthritis, approval also requires:
1. You are 2 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
3. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic (such as Ilaris [canakinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic juvenile idiopathic arthritis

F. If you have chimeric antigen receptor T cell-induced severe or life-threatening cytokine release syndrome, approval also requires:
1. You are 2 years of age or older
2. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of cytokine release syndrome

G. **NOTE:** Tyenne will NOT be approved for the treatment of coronavirus disease 2019 (COVID-19) in hospitalized patients.

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TOCILIZUMAB-AAZG IV (PART D)

RENEWAL CRITERIA

NOTE: For the diagnosis of cytokine release syndrome (CRS), please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Tyenne will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths of the IV formulation.** **APPROVAL TEXT (IF APPLICABLE):** The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of giant cell arteritis (GCA) (ICD-10 M31.5, M31.6) **AND** meet the following criterion?
   - Tyenne will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of GCA

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths of the IV formulation.** **APPROVAL TEXT (IF APPLICABLE):** The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (PJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Tyenne will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of PJIA

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths of the IV formulation.** **APPROVAL TEXT (IF APPLICABLE):** The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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TOCILIZUMAB-AAZG IV (PART D)

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of systemic juvenile idiopathic arthritis (SJIA) (ICD-10 Group M08.2) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Tyenne will NOT be used concurrently with another systemic biologic (e.g., Ilaris [canakinumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) forthe treatment of SJIA

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths of the IV formulation.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TOCILIZUMAB-AAZG IV (Tyenne)** requires the following rule(s) be met for renewal:

   A. You have ONE of the following:
      1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
      2. Giant cell arteritis (GCA: a type of inflammatory condition)
      3. Polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
      4. Systemic juvenile idiopathic arthritis (SJIA: a type of joint condition)

   B. If you have moderate to severe rheumatoid arthritis, renewal also requires:
      1. You continue to benefit from the medication
      2. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis

   C. If you have giant cell arteritis, renewal also requires:
      1. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of giant cell arteritis

   (Renewal denial text continued on next page)

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TOCILIZUMAB-AAZG IV (PART D)

RENEWAL CRITERIA (CONTINUED)

D. If you have polyarticular juvenile idiopathic arthritis, renewal also requires:
1. You continue to benefit from the medication
2. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis

E. If you have systemic juvenile idiopathic arthritis, renewal also requires:
1. You continue to benefit from the medication
2. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic (such as Ilaris [canakinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic juvenile idiopathic arthritis

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Tyenne.

REFERENCES
Tyenne [Prescribing Information]. Lake Zurich, IL: Fresenius Kabi USA, LLC; May 2025.

For Part D use only:

TOCILIZUMAB-AAZG IV (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	CORONAVIRUS DISEASE 2019 (COVID-19) IN HOSPITALIZED PATIENTS
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: RHEUMATOID ARTHRITIS (RA), POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS (SJIA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST, DERMATOLOGIST, OR IMMUNOLOGIST.
Coverage Duration	INITIAL: RA, PJIA, SJIA, GCA: 6 MONTHS. CRS: 1 MONTH. RENEWAL: RA, PJIA, SJIA, GCA: 12 MONTHS.
Other Criteria	INITIAL: ALL INDICATIONS: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION. RA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, XELJANZ, RINVOQ, ORENCIA. GIANT CELL ARTERITIS (GCA): 1) HAS COMPLETED,

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	STARTED, OR WILL SOON START A TAPERING COURSE OF GLUCOCORTICOIDS, AND 2) TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT: RINVOQ. PJIA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, XELJANZ IR, ORENCIA, RINVOQ. RENEWAL: RA, PJIA, SJIA: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR THE SAME INDICATION. GCA: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR THE SAME INDICATION.

Created: 04/25
Effective: 08/01/26 Client Approval: 07/26 DMC Approval: 06/16/26

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TOCILIZUMAB-AAZG IV (PART D)

RENEWAL CRITERIA (CONTINUED)

D. If you have polyarticular juvenile idiopathic arthritis, renewal also requires:
1. You continue to benefit from the medication
2. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis

E. If you have systemic juvenile idiopathic arthritis, renewal also requires:
1. You continue to benefit from the medication
2. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic (such as Ilaris [canakinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic juvenile idiopathic arthritis

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tyenne.

REFERENCES

Tyenne [Prescribing Information]. Lake Zurich, IL: Fresenius Kabi USA, LLC; May 2025.

For Part D use only:

TOCILIZUMAB-AAZG IV (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	CORONAVIRUS DISEASE 2019 (COVID-19) IN HOSPITALIZED ADULTS
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: RHEUMATOID ARTHRITIS (RA), POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS (SJIA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST, DERMATOLOGIST, OR IMMUNOLOGIST.
Coverage Duration	INITIAL: RA, PJIA, SJIA, GCA: 6 MONTHS. CRS: 1 MONTH. RENEWAL: RA, PJIA, SJIA, GCA: 12 MONTHS.
Other Criteria	INITIAL: ALL INDICATIONS: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION. RA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, XELJANZ, RINVOQ, ORENCIA. GIANT CELL ARTERITIS (GCA): 1) HAS COMPLETED,

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TOCILIZUMAB-AAZG SQ (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TOCILIZUMAB-AAZG	TYENNE		55373 55374	GPI-14 (6650007017D520, 6650007017E520)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

NOTE: For requests for the IV dosage form of Tyenne, please see the TOCILIZUMAB-AAZG-IV PA guideline.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Tyenne will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
     - Orencia (abatacept)
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])

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TOCILIZUMAB-AAZG SQ (PART D)

INITIAL CRITERIA (CONTINUED)

If yes, **approve for 6 months by GPID or GPI-14 for all strengths of the SQ formulations (syringe and autoinjector).**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #2.

2. Does the patient have a diagnosis of giant cell arteritis (GCA) (ICD-10 M31.5, M31.6) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has completed, started, or will soon start a tapering course of glucocorticoids (e.g., prednisone)
   - Tyenne will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of GCA
   - The patient had a trial of or contraindication to the preferred agent: Rinvoq (upadacitinib)

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths of the SQ formulations (syringe and autoinjector).**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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TOCILIZUMAB-AAZG SQ (PART D)

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (pJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Tyenne will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of pJIA
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
     - Orencia (abatacept)
     - Xeljanz IR (tofacitinib IR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths of the SQ formulations (syringe and autoinjector).**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

4. Does the patient have a diagnosis of systemic juvenile idiopathic arthritis (SJIA) (ICD-10 Group M08.2) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist, dermatologist, or immunologist
   - Tyenne will NOT be used concurrently with another systemic biologic (e.g., Ilaris [canakinumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of SJIA

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths of the SQ formulations (syringe and autoinjector).**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TOCILIZUMAB-AAZG SQ (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TOCILIZUMAB-AAZG SQ (Tyenne)** requires the following rule(s) be met for approval:

A. You have ONE of the following
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Giant cell arteritis (GCA: a type of inflammatory condition)
   3. Polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition)
   4. Systemic juvenile idiopathic arthritis (SJIA: a type of joint condition)

B. If you have moderate to severe rheumatoid arthritis, approval also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
   4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      a. Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
      b. Orencia (abatacept)
      c. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
      d. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])

C. If you have giant cell arteritis, approval also requires:
   1. You are 18 years of age or older
   2. You have completed, started, or will soon start a tapering course (slowly lowering the dose to stop use) of glucocorticoids (such as prednisone)
   3. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of giant cell arteritis
   4. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Rinvoq (upadacitinib)

(Initial denial text continued on next page)

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TOCILIZUMAB-AAZG SQ (PART D)

INITIAL CRITERIA (CONTINUED)

D. If you have polyarticular juvenile idiopathic arthritis, approval also requires:
1. You are 2 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis
4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima
   b. Orencia (abatacept)
   c. Xeljanz IR (tofacitinib immediate-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])
   d. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima])

E. If you have systemic juvenile idiopathic arthritis, approval also requires:
1. You are 2 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
3. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic (such as Ilaris [canakinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4 inhibitor) for the treatment of systemic juvenile idiopathic arthritis

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TOCILIZUMAB-AAZG SQ (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Tyenne will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths of the SQ formulations (syringe and autoinjector).**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of giant cell arteritis (GCA) (ICD-10 M31.5, M31.6) **AND** meet the following criterion?
   - Tyenne will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of GCA

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths of the SQ formulations (syringe and autoinjector).**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (pJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Tyenne will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of pJIA

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths of the SQ formulations (syringe and autoinjector).**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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TOCILIZUMAB-AAZG SQ (PART D)

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of systemic juvenile idiopathic arthritis (SJIA) (ICD-10 Group M08.2) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Tyenne will NOT be used concurrently with another systemic biologic (e.g., Ilaris [canakinumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) forthe treatment of SJIA

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths of the SQ formulations (syringe and autoinjector).**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TOCILIZUMAB-AAZG SQ (Tyenne)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
      2. Giant cell arteritis (GCA: a type of inflammatory condition)
      3. Polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition)
      4. Systemic juvenile idiopathic arthritis (SJIA: a type of joint condition)

   B. If you have moderate to severe rheumatoid arthritis, renewal also requires:
      1. You continue to benefit from the medication
      2. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis

   C. If you have giant cell arteritis, renewal also requires:
      1. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of giant cell arteritis

   (Renewal denial text continued on next page)

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TOCILIZUMAB-AAZG SQ (PART D)

RENEWAL CRITERIA (CONTINUED)

D. If you have polyarticular juvenile idiopathic arthritis, renewal also requires:
1. You continue to benefit from the medication
2. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis

E. If you have systemic juvenile idiopathic arthritis, renewal also requires:
1. You continue to benefit from the medication
2. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic (such as Ilaris [canakinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic juvenile idiopathic arthritis

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tyenne.

REFERENCES

Tyenne [Prescribing Information]. Lake Zurich, IL: Fresenius Kabi USA, LLC; May 2025.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TOCILIZUMAB-AAZG SQ (PART D)

For Part D use only:

TOCILIZUMAB-AAZG SQ (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: RHEUMATOID ARTHRITIS (RA), POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS (SJIA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST, DERMATOLOGIST, OR IMMUNOLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: RA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, XELJANZ, RINVOQ, ORENCIA. GIANT CELL ARTERITIS (GCA): 1) HAS COMPLETED, STARTED, OR WILL SOON START A TAPERING COURSE OF GLUCOCORTICOIDS, AND 2) TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT: RINVOQ. PJIA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, XELJANZ IR, ORENCIA, RINVOQ. INITIAL/RENEWAL: ALL INDICATIONS: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION. RENEWAL: RA, PJIA, SJIA: CONTINUES TO BENEFIT FROM THE MEDICATION.

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Effective: 05/01/26 Client Approval: 04/26 P&T Approval: 04/25

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TOFACITINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TOFACITINIB CITRATE	XELJANZ, XELJANZ XR, TOFACITINIB CITRATE, TOFACITINIB CITRATE ER	39768		GPI-10 (6660306510)	FDB: ROUTE ≠ MISCELL.

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M06.9; Groups M05.7, M05.8, M05.9, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers (e.g., Humira [adalimumab]/Cyltezo/Yuflyma)
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient had a trial of or contraindication to 3 months of treatment with ONE conventional synthetic DMARD (disease-modifying antirheumatic drug) (e.g., methotrexate at a dose of at least 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, sulfasalazine)
   - The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

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TOFACITINIB (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
- The patient is 2 years of age or older
- The patient had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers (e.g., Humira [adalimumab]/Cyltezo/Yuflyma)
- Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
- The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #3.

3. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- The patient had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers (e.g., Humira [adalimumab]/Cyltezo/Yuflyma)
- Therapy is prescribed by or in consultation with a rheumatologist
- The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS
- The patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam)

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #4.

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TOFACITINIB (PART D)

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers (e.g., Humira [adalimumab]/Cyltezo/Yuflyma)
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Does the patient have a diagnosis of polyarticular course juvenile idiopathic arthritis (pcJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - The patient had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers (e.g., Humira [adalimumab]/Cyltezo/Yuflyma)
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of pcJIA

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TOFACITINIB (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TOFACITINIB (Xeljanz, Xeljanz XR)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Ankylosing spondylitis (AS: a type of joint condition)
   4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   5. Polyarticular course juvenile idiopathic arthritis (pcJIA: a type of joint condition)

B. If you have moderate to severe rheumatoid arthritis, approval also requires:
   1. You are 18 years of age or older
   2. You had an inadequate response (drug did not work) or intolerance (side effect) to one or more tumor necrosis factor (TNF) blockers (such as Humira [adalimumab]/Cyltezo/Yuflyma)
   3. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   4. You have tried or have a contraindication to (harmful for you to use) 3 months of treatment with ONE conventional synthetic DMARD (disease-modifying antirheumatic drug, such as methotrexate at a dose of at least 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, sulfasalazine)
   5. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)

C. If you have psoriatic arthritis, approval also requires:
   1. You are 2 years of age or older
   2. You had an inadequate response (drug did not work) or intolerance (side effect) to one or more tumor necrosis factor (TNF) blockers (such as Humira [adalimumab]/Cyltezo/Yuflyma)
   3. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   4. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)

(Initial denial text continued on next page)

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TOFACITINIB (PART D)

INITIAL CRITERIA (CONTINUED)

D. If you have ankylosing spondylitis, approval also requires:
1. You are 18 years of age or older
2. You had an inadequate response (drug did not work) or intolerance (side effect) to one or more tumor necrosis factor (TNF) blockers (such as Humira [adalimumab]/Cyltezo/Yuflyma)
3. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
4. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis (a type of joint condition)
5. You have tried or have a contraindication to (harmful for you to use) an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)

E. If you have moderate to severe ulcerative colitis, approval also requires:
1. You are 18 years of age or older
2. You had an inadequate response (drug did not work) or intolerance (side effect) to one or more tumor necrosis factor (TNF) blockers (such as Humira [adalimumab]/Cyltezo/Yuflyma)
3. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
4. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)

F. If you have polyarticular course juvenile idiopathic arthritis, approval also requires:
1. You are 2 years of age or older
2. You had an inadequate response (drug did not work) or intolerance (side effect) to one or more tumor necrosis factor (TNF) blockers (such as Humira [adalimumab]/Cyltezo/Yuflyma)
3. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
4. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular course juvenile idiopathic arthritis (a type of joint condition)

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TOFACITINIB (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M06.9; Groups M05.7, M05.8, M05.9, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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TOFACITINIB (PART D)

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of polyarticular course juvenile idiopathic arthritis (pcJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of pcJIA

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) **AND** meet the following criterion?
   - The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TOFACITINIB (Xeljanz, Xeljanz XR)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
      2. Psoriatic arthritis (PsA: a type of skin and joint condition)
      3. Ankylosing spondylitis (AS: a type of joint condition)
      4. Polyarticular course juvenile idiopathic arthritis (pcJIA: a type of joint condition)
      5. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

   (Renewal denial text continued on next page)

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TOFACITINIB (PART D)

RENEWAL CRITERIA (CONTINUED)

B. If you have moderate to severe rheumatoid arthritis, renewal also requires:
1. You continue to benefit from the medication
2. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)

C. If you have psoriatic arthritis, renewal also requires:
1. You continue to benefit from the medication
2. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)

D. If you have ankylosing spondylitis, renewal also requires:
1. You continue to benefit from the medication
2. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis (a type of joint condition)

E. If you have polyarticular course juvenile idiopathic arthritis, renewal also requires:
1. You continue to benefit from the medication
2. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular course juvenile idiopathic arthritis (a type of joint condition)

F. If you have moderate to severe ulcerative colitis, renewal also requires:
1. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)

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TOFACITINIB (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xeljanz.

REFERENCES

Xeljanz, Xeljanz XR [Prescribing Information]. New York, NY: Pfizer Laboratories Div PfizerInc.; October 2025.

For Part D use only:

TOFACITINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: RHEUMATOID ARTHRITIS (RA), ANKYLOSING SPONDYLITIS (AS), POLYARTICULAR COURSE JUVENILE IDIOPATHIC ARTHRITIS (PCJIA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST OR DERMATOLOGIST. ULCERATIVE COLITIS (UC): PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: RA: TRIAL OF OR CONTRAINDICATION TO 3 MONTHS OF TREATMENT WITH ONE CONVENTIONAL SYNTHETIC DMARD (DISEASE-MODIFYING ANTIRHEUMATIC DRUG) - IF A PATIENT TRIED METHOTREXATE, THEN TRIAL AT A DOSE OF AT LEAST 20 MG PER WEEK OR MAXIMALLY TOLERATED DOSE IS REQUIRED. AS: TRIAL OF OR CONTRAINDICATION TO AN NSAID. INITIAL/RENEWAL: ALL INDICATIONS: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION. RENEWAL: RA, PSA, AS, PCJIA: CONTINUES TO BENEFIT FROM THE MEDICATION.

Created: 11/12
Effective: 06/13/26 Client Approval: 06/26 DMC Approval: 06/09/26

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TOFERSEN BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TOFERSEN	QALSODY	48878		GPI-10 (7450408000)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	Yes	No	No	Yes	No	No	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #5.

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TOFERSEN BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TOFERSEN BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of amyotrophic lateral sclerosis (ALS) (ICD-10 G12.21) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient has a superoxide dismutase 1 (SOD1) gene mutation

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TOFERSEN (QALSODY)** requires the following rule(s) be met for approval:
   A. You have amyotrophic lateral sclerosis (ALS: a type of brain and nerve condition)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor)
   D. You have a superoxide dismutase 1 (SOD1: an enzyme) gene mutation (an abnormal change in your gene)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TOFERSEN BvD (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Qalsody. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Qalsody [Prescribing Information]. Cambridge, MA: Biogen MA Inc.; April 2023.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed June 28, 2024].

For Part D use only:

TOFERSEN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	AMYOTROPHIC LATERAL SCLEROSIS (ALS): PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST.
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 05/23
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 04/23

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TOLVAPTAN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TOLVAPTAN	JYNARQUE, TOLVAPTAN	36348		GPI-10 (3045406000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of autosomal dominant polycystic kidney disease (ADPKD) (ICD-10 Q61.2, Q61.3) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is at risk of rapidly progressing ADPKD (e.g., genetic factors, hypertension, increased kidney size)
   - Therapy is prescribed by or in consultation with a nephrologist
   - The patient has confirmed polycystic kidney disease via CT, MRI, or ultrasound
   - The patient does not have end stage renal disease [ESRD] (i.e., receiving dialysis)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TOLVAPTAN (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TOLVAPTAN (Jynarque)** requires the following rule(s) be met for approval:

A. You have autosomal dominant polycystic kidney disease (ADPKD: a type of kidney condition)
B. You are 18 years of age or older
C. You are at risk of rapidly progressing ADPKD (such as having genetic factors, hypertension [high blood pressure], increased kidney size)
D. Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor)
E. You have confirmed polycystic kidney disease by CT (computerized tomography), MRI (magnetic resonance imaging), or ultrasound imaging (types of lab imaging tests)
F. You do not have end stage renal disease (ESRD: advanced kidney disease) (You are not receiving dialysis [process of removing excess water, toxins from the blood])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TOLVAPTAN (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of autosomal dominant polycystic kidney disease (ADPKD) (ICD-10 Q61.2, Q61.3) **AND** meet the following criterion?
   - The patient has NOT progressed to end stage renal disease (ESRD)/dialysis

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TOLVAPTAN (Jynarque)** requires the following rule(s) be met for renewal:
   A. You have autosomal dominant polycystic kidney disease (ADPKD: a type of kidney condition)
   B. You have NOT progressed to end stage renal disease (ESRD: advanced kidney disease) or dialysis [process of removing excess water, toxins from the blood]

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Jynarque.

REFERENCES

Jynarque [Prescribing Information]. Rockville, MD: Otsuka America Pharmaceutical, Inc.; October 2020.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TOLVAPTAN (PART D)

For Part D use only:

TOLVAPTAN (PART D)	
Covered uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	AUTOSOMAL DOMINANT POLYCYSTIC KIDNEY DISEASE (ADPKD): INITIAL: CONFIRMED POLYCYSTIC KIDNEY DISEASE VIA CT, MRI, OR ULTRASOUND.
Age Restrictions	N/A
Prescriber Restrictions	ADPKD: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEPHROLOGIST.
Coverage Duration	INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS
Other Criteria	ADPKD: INITIAL: DOES NOT HAVE ESRD (I.E., RECEIVING DIALYSIS). RENEWAL: HAS NOT PROGRESSED TO ESRD/DIALYSIS.

Created: 05/18
Effective: 10/31/25 Client Approval: 10/25 P&T Approval: 07/18

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TOPICAL TRETINOIN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRETINOIN	ALTRENO, ATRALIN, AVITA, RETIN-A, TRETINOIN	02468		GPI-10 (9005003000)	FDB: ROUTE = TOPICAL
TRETINOIN MICROSPHERES	RETIN-A MICRO, RETIN-A MICRO PUMP, TRETINOIN MICROSPHERE	32888		GPI-10 (9005003020)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the request for the treatment of acne vulgaris (ICD-10 L70.0)?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the request for a cosmetic indication (e.g., melasma, photoaging, or wrinkles) (ICD-10 L98.8, Group L81)? (Note: Actinic keratosis is not considered a cosmetic indication)

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, defer to the clinical pharmacist for further review.

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TOPICAL TRETINOIN (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Is the request for a generic formulation of topical tretinoin or tretinoin microsphere?

   If yes, **approve generic only for both tretinoin and tretinoin microsphere for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

4. Is the request for brand Atralin, Avita, Retin-A, or Retin-A Micro **AND** the patient meets the following criterion?
   - The patient had a trial of or contraindication to a generic topical tretinoin product

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Is the request for Altreno and the patient meets **ALL** of the following criteria?
   - The patient is 9 years of age or older
   - The patient had a trial of or contraindication to a generic topical tretinoin product

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TOPICAL TRETINOIN (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TOPICAL TRETINOIN (Atralin, Altreno, Avita, Retin-A, Retin-A Micro)** requires the following rule(s) be met for approval:

A. You have acne vulgaris (a type of skin infection usually called pimples)

B. If the request is for brand Atralin, Avita, Retin-A, Retin-A Micro, approval also requires:

1. You have tried or have a contraindication to (harmful for you to use) a generic topical tretinoin product

C. If the request is for Altreno, approval also requires:

2. You are 9 years of age or older
3. You have tried or have a contraindication to (harmful for you to use) a generic topical tretinoin product

D. Your request is NOT for a cosmetic (not for appearance) diagnosis (such as melasma [freckle-like spots on the skin], photoaging [skin damage from the sun], wrinkles). For other non-cosmetic indications, further review is required.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Topical Tretinoin products.

REFERENCES

Altreno [Prescribing Information]. Bridgewater, NJ: Bausch Health US, LLC; March 2020.
Atralin [Prescribing Information]. Bridgewater, NJ: Bausch Health US, LLC; February 2024.
Avita cream [Prescribing Information]. Morgantown, WV: Mylan Pharmaceuticals Inc.; July 2018.
Avita gel [Prescribing Information]. Morgantown, WV: Mylan Pharmaceuticals Inc.; January 2018.
Retin-A Micro [Prescribing Information]. Bridgewater, NJ: Bausch Health US, LLC; October 2023.
Retin-A [Prescribing Information]. Bridgewater, NJ: Bausch Health US, LLC; March 2024.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TOPICAL TRETINOIN (PART D)

For Part D use only:

TOPICAL TRETINOIN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	COSMETIC INDICATIONS SUCH AS WRINKLES, PHOTOAGING, MELASMA.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	ACNE VULGARIS: BRAND TOPICAL TRETINOIN REQUIRES TRIAL OF OR CONTRAINDICATION TO A GENERIC TOPICAL TRETINOIN PRODUCT.

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25 Created: 02/02
Commercial Effective: N/A Client Approval: 10/24 P&T Approval: 10/23

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CORE, ADVANTAGE, PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TORIPALIMAB-TPZI BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TORIPALIMAB-TPZI	LOQTORZI	49284		GPI-10 (2135797072)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	Yes	No	Yes	Yes	No	Yes	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit).**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, continue to #6.
   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, continue to #6.
   If no, continue to #5.

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TORIPALIMAB-TPZI BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision).**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

6. Is the drug administered via an implantable pump?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, continue to #7.

7. Is the drug administered via an external pump?

   If yes, continue to #8.
   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

8. Is the drug specifically infused through an external infusion pump covered by Medicare?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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TORIPALIMAB-TPZI BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic or recurrent locally advanced nasopharyngeal carcinoma (NPC) (ICD-10 Group C11) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Loqtorzi will be used for first-line treatment
   - Loqtorzi will be used in combination with cisplatin and gemcitabine

   If yes, **approve for 24 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of recurrent unresectable or metastatic nasopharyngeal carcinoma (NPC) (ICD-10 Group C11) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Loqtorzi will be used as a single agent
   - The patient experienced disease progression on or after a platinum-containing chemotherapy (e.g., cisplatin)

   If yes, **approve for lifetime by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TORIPALIMAB-TPZI BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TORIPALIMAB-TPZI (Loqtorzi)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Metastatic or recurrent locally advanced nasopharyngeal carcinoma (a type of neck cancer that has spread to other parts of the body or was previously treated and has spread to nearby tissue or lymph nodes)
   2. Recurrent unresectable or metastatic nasopharyngeal carcinoma (a type of neck cancer that was previously treated and unable to be removed by surgery or that has spread to other parts of the body)

B. If you have metastatic or recurrent locally advanced nasopharyngeal carcinoma, approval also requires:
   1. You are 18 years of age or older
   2. Loqtorzi will be used as first-line (initial) treatment
   3. Loqtorzi will be used in combination with cisplatin and gemcitabine

C. If you have recurrent unresectable or metastatic nasopharyngeal carcinoma, approval also requires:
   1. You are 18 years of age or older
   2. Loqtorzi will be used as a single agent (used alone)
   3. You have experienced disease progression (worsening of disease) on or after a platinum-containing chemotherapy (a type of cancer treatment, such as cisplatin)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TORIPALIMAB-TPZI BvD (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Loqtorzi.

The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B. Drugs administered by an implantable pump are covered under Part B. Drugs administered via an external pump are covered under Part B if they are included under the local coverage policy of the applicable Medicare coverage policies (National and/or Local Coverage Policies). Drugs administered via an external pump that are not included under the applicable Medicare coverage policies are covered under Part D. A CMS website to assist with National and Local Coverage Determination for B versus D review is http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx.

REFERENCES

Loqtorzi [Prescribing Information]. Redwood City, CA: Coheres Biosciences, Inc.; October 2024.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed June 28, 2024].

For Part D use only:

TORIPALIMAB-TPZI (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	NASOPHARYNGEAL CARCINOMA (NPC): FIRST LINE TREATMENT: 24 MOS, PREVIOUSLY TREATED: LIFETIME.
Other Criteria	N/A

Created: 12/23
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 01/24

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TOTAL PARENTERAL NUTRITION AGENT BVD DETERMINATION (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AMINO ACIDS	CLINIMIX, CLINIMIX E, PROSOL, OTHERS			GPI-8 (80302010, 80302020)	STC 0181 & C318 AND ROUTE = INTRAVEN.
FAT EMULSIONS	INTRALIPID, OTHERS			GPI-8 (80200010, 80451010)	STC 0330 AND ROUTE = INTRAVEN.
DEXTROSE IN WATER				GPI-8 (80100020)	STC = 0188 EXCEPT HICL 00915

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	Yes	No	Yes	Yes	No	Yes	Yes	Yes	Yes	YES

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

NOTE: This PA is for administrative purposes to determine Medicare Part B versus Medicare Part D funding and applies to all TPN products.

GUIDELINES FOR USE

1. Is the patient receiving total parenteral nutrition (TPN) because of a non-functioning digestive tract?

   If yes, **approve as requested for 12 months by HICL or GPI-8 under Part B. (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field)**

   If no, **approve as requested for 12 months by HICL or GPI-8 under Part D. (Populate B vs. D field with a 'D' in the PA override field)**

RATIONALE

TPN for patients due to a non-functioning digestive tract is covered under Part B.

REFERENCE

Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Appendix C- Summary of Coverage Policy Medicare Part B Versus Part D Coverage Issues. Rev 18, 01-15-16. Available at: http://www.cms.gov/PrescriptionDrugCovContra/12_PartDManuals.asp. [Accessed July 11, 2024].

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TOTAL PARENTERAL NUTRITION AGENT BVD DETERMINATION (PART D)

For Part D use only:

TOTAL PARENTERAL NUTRITION AGENT BVD DETERMINATION (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	PART D DOES NOT COVER THIS DRUG FOR PATIENTS RECEIVING TOTAL PARENTERAL NUTRITION FOR A NONFUNCTIONING DIGESTIVE TRACT
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A
Quantity Limit (from Formulary ASCII file)	N/A

Created: 11/07
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 11/16

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CORE, ADVANTAGE, PLUS OPEN, AND PLUS CLOSED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TOVORAFENIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TOVORAFENIB	OJEMDA	49542		GPI-10 (2153207500)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory low-grade glioma (LGG) (ICD-10 D33.2) **AND** meet the following criterion?
   - The patient's cancer has a BRAF fusion, BRAF rearrangement, or BRAF V600 mutation

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TOVORAFENIB (Ojemda)** requires the following rule(s) be met for approval:
   A. You have relapsed or refractory low-grade glioma (LGG) (a type of brain cancer that has returned or did not respond to treatment)
   B. Your cancer has a BRAF fusion, BRAF rearrangement, or BRAF V600 mutation (types of abnormal changes in genes)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CORE, ADVANTAGE, PLUS OPEN, AND PLUS CLOSED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TOVORAFENIB (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Ojemda.

REFERENCES
Ojemda [Prescribing Information]. Brisbane, CA: Day One Biopharmaceuticals, Inc.; April 2024.

For Part D use only:

TOVORAFENIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Part D Effective: 06/10/24 Created: 05/24
Commercial Effective: N/A Client Approval: 05/24 P&T Approval: 07/24

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRABECTEDIN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRABECTEDIN	YONDELIS	35367		GPI-10 (2110707500)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic liposarcoma or leiomyosarcoma (ICD-10 Groups C49, C48) **AND** meets the following criterion?
   - The patient has received previous therapy with an anthracycline-containing regimen (e.g., doxorubicin)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline for **TRABECTEDIN (Yondelis)** requires the following rule(s) be met for approval:
   A. You have unresectable or metastatic liposarcoma or leiomyosarcoma (types of cancer that begin in the fat cells or muscle tissue and cannot be removed with surgery or has spread to other parts of the body)
   B. You have received previous therapy with an anthracycline-containing regimen (such as doxorubicin)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRABECTEDIN (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Yondelis.

REFERENCES
Yondelis [Prescribing Information]. Horsham, PA: Janssen Products, LP, June 2020.

Part D use only:

TRABECTEDIN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 11/15
Effective: 01/01/26 Client Approval: 01/26 P&T Approval: 11/15

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRALOKINUMAB-LDRM (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRALOKINUMAB-LDRM	ADBRY	47741		GPI-10 (9027308045)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe atopic dermatitis (AD) (ICD-10 Group L20) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist, allergist, or immunologist
   - Adbry will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Eucrisa (crisaborole)]) for the treatment of atopic dermatitis
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Dupixent (dupilumab), Rinvoq (upadacitinib)

     If yes, continue to #2.
     If no, do not approve.
     DENIAL TEXT: See the initial denial text at the end of the guideline.

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TRALOKINUMAB-LDRM (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a trial of or contraindication to **ONE** of the following?
   - High potency topical corticosteroid (e.g., halobetasol propionate 0.01% lotion, triamcinolone acetonide 0.5% cream or ointment) or a super-high potency topical corticosteroid (e.g., fluocinonide 0.1% cream, clobetasol propionate 0.05% cream or ointment)
   - Topical calcineurin inhibitor (e.g., tacrolimus, pimecrolimus)
   - Topical PDE-4 inhibitor (e.g., crisaborole [Eucrisa], Adquey [difamilast], Zoryve [roflumilast])
   - Topical AhR agonist (e.g., Vtama [tapinarof])
   - Topical JAK inhibitor (e.g., ruxolitinib [Opzelura])

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.

   INITIAL DENIAL TEXT: Our guideline named **TRALOKINUMAB-LDRM (Adbry)** requires the following rule(s) be met for approval:
   A. You have moderate to severe atopic dermatitis (AD: a type of skin condition)
   B. You are 12 years of age or older
   C. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
   D. You will NOT use Adbry concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Eucrisa (crisaborole)]) for the treatment of atopic dermatitis
   E. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Dupixent (dupilumab), Rinvoq (upadacitinib)
   F. You have tried or have a contraindication to (harmful for you to use) ONE of the following:
      1. High potency topical corticosteroid (such as halobetasol propionate 0.01% lotion, triamcinolone acetonide 0.5% cream or ointment) or a super-high potency topical corticosteroid (such as fluocinonide 0.1% cream, clobetasol propionate 0.05% cream or ointment)
      2. Topical calcineurin inhibitor (such as tacrolimus, pimecrolimus)
      3. Topical PDE-4 inhibitor (such as Eucrisa [crisaborole], Adquey [difamilast], Zoryve [roflumilast])
      4. Topical aryl hydrocarbon receptor (AhR) agonist (such as Vtama [tapinarof])
      5. Topical JAK inhibitor (such as Opzelura [ruxolitinib])

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRALOKINUMAB-LDRM (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe atopic dermatitis (AD) (ICD-10 Group L20) and meet **ALL** of the following criteria?
   - The patient has shown improvement while on Adbry
   - Adbry will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Eucrisa (crisaborole)]) for the treatment of atopic dermatitis

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: Our guideline named **TRALOKINUMAB-LDRM (Adbry)** requires the following rule(s) be met for renewal:
   A. You have moderate to severe atopic dermatitis (AD: a type of skin condition)
   B. You have shown improvement while on Adbry
   C. You will NOT use Adbry concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Eucrisa (crisaborole)]) for the treatment of atopic dermatitis

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Adbry.

REFERENCES

Adbry [Prescribing Information]. Madison, NJ: LEO Pharma Inc; December 2025.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRALOKINUMAB-LDRM (PART D)

For Part D use only:

TRALOKINUMAB-LDRM (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	AD: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST, ALLERGIST, OR IMMUNOLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	AD: INITIAL: 1) TRIAL OF OR CONTRAINDICATION TO ONE OF THE FOLLOWING: (A) HIGH OR SUPER-HIGH POTENCY TOPICAL CORTICOSTEROID, (B) TOPICAL CALCINEURIN INHIBITOR, (C) TOPICAL PDE4 INHIBITOR, (D) TOPICAL AHR AGONIST OR (E) TOPICAL JAK INHIBITOR, 2) TRIAL OF OR CONTRAINDICATION TO ONE OF THE FOLLOWING PREFERRED AGENTS: DUPIXENT, RINVOQ, AND 3) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION. RENEWAL: 1) IMPROVEMENT WHILE ON THERAPY, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR THE SAME INDICATION.

Created: 01/22
Effective: 08/01/26 Client Approval: 07/26 DMC Approval: 06/30/26

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRAMADOL (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRAMADOL HCL	QDOLO, TRAMADOL HCL		48598	GPI-14 (65100095102005)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	Yes	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the request for the management of pain (ICD-10 R52) and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's pain is severe enough to require an opioid analgesic
   - Alternative treatments for the patient's pain are inadequate
   - The patient had a trial of or contraindication to generic tramadol IR tablet or generic tramadol/acetaminophen combination product
   - The patient is unable to take oral solid formulations of tramadol or tramadol/acetaminophen combination product (e.g., difficulty swallowing)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TRAMADOL (Qdolo)** requires the following rule(s) be met for approval:
   A. The request is for pain management
   B. You are 18 years of age or older
   C. Your pain is severe enough to require an opioid analgesic (a type of pain medication)
   (Denial text continued on the next page)

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TRAMADOL (PART D)

GUIDELINES FOR USE (CONTINUED)

D. Alternative (other) treatments for your pain are inadequate (did not work)
E. You have tried or have a contraindication to (harmful for you to use) generic tramadol immediate-release (IR) tablet or a generic tramadol/acetaminophen combination product
F. You are unable to take oral solid formulations (such as a tablet) of tramadol or tramadol/acetaminophen combination product (such as difficulty swallowing)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Qdolo.

REFERENCES

Qdolo [Prescribing Information]. Athens, GA: Athena Bioscience, LLC; December 2023.

For Part D use only:

TRAMADOL (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 MONTHS
Other Criteria	PAIN: 1) TRIAL OF OR CONTRAINDICATION TO GENERIC TRAMADOL IMMEDIATE RELEASE TABLET OR GENERIC TRAMADOL/ACETAMINOPHEN COMBINATION PRODUCT, AND 2) UNABLE TO TAKE ORAL SOLID FORMULATIONS OF TRAMADOL OR TRAMADOL/ACETAMINOPHEN COMBINATION PRODUCT (E.G., DIFFICULTY SWALLOWING).

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 06/24
Client Approval: 06/24
P&T Approval: 01/21

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRAMETINIB SOLUTION (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRAMETINIB DIMETHYL SULFOXIDE	MEKINIST		53859	GPI-14 (21533570102120)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic melanoma (ICD-10 Group C43) and meet **ALL** of the following criteria?
   - The patient has a BRAF V600E or V600K mutation as detected by an FDA-approved test
   - Mekinist will be used as a single agent in a BRAF-inhibitor treatment-naive patient OR in combination with Tafinlar (dabrafenib)

   If yes, continue to #7.
   If no, continue to #2.

2. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient has a BRAF V600E mutation as detected by an FDA-approved test
   - Mekinist will be used in combination with Tafinlar (dabrafenib)

   If yes, continue to #7.
   If no, continue to #3.

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TRAMETINIB SOLUTION (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of melanoma (ICD-10 Group C43) and meet **ALL** of the following criteria?
   - The patient has a BRAF V600E or V600K mutation as detected by an FDA-approved test
   - Mekinist will be used as an adjuvant therapy in combination with Tafinlar (dabrafenib)
   - There is involvement of lymph node(s), following complete resection

   If yes, continue to #7.
   If no, continue to #4.

4. Does the patient have a diagnosis of locally advanced or metastatic anaplastic thyroid cancer (ATC) (ICD-10 C73) and meet **ALL** of the following criteria?
   - The patient has a BRAF V600E mutation
   - Mekinist will be used in combination with Tafinlar (dabrafenib)
   - The patient has no satisfactory locoregional treatment options available

   If yes, continue to #7.
   If no, continue to #5.

5. Does the patient have a diagnosis of unresectable or metastatic solid tumor and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - The patient has a BRAF V600E mutation
   - Mekinist will be used in combination with Tafinlar (dabrafenib)
   - The patient's disease has progressed following prior treatment and has no satisfactory alternative treatment options

   If yes, continue to #7.
   If no, continue to #6.

6. Does the patient have a diagnosis of low-grade glioma (LGG) (ICD-10 D33.2) and meet **ALL** of the following criteria?
   - The patient is 1 to 17 years of age
   - The patient has a BRAF V600E mutation
   - Mekinist will be used in combination with Tafinlar (dabrafenib)
   - The patient requires systemic therapy

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TRAMETINIB SOLUTION (PART D)

GUIDELINES FOR USE (CONTINUED)

7. Is the patient unable to swallow Mekinist (trametinib) tablets?

If yes, **approve for 12 months by GPID or GPI-14.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TRAMETINIB SOLUTION (Mekinist)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Unresectable or metastatic melanoma (a type of skin cancer that cannot be removed by surgery or has spread to other parts of the body)
   2. Metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of the body)
   3. Melanoma (a type of skin cancer)
   4. Locally advanced or metastatic anaplastic thyroid cancer (ATC: a type of thyroid cancer that has spread to nearby tissue or lymph nodes or has spread to other parts of the body)
   5. Unresectable or metastatic solid tumor (tumor that cannot be removed by surgery or has spread to other parts of the body)
   6. Low-grade glioma (LGG: a type of brain cancer)

B. You are unable to swallow Mekinist (trametinib) tablets

C. If you have unresectable or metastatic melanoma, approval also requires:
   1. You have a BRAF V600E or V600K mutation (abnormal change in gene) as detected by a Food and Drug Administration (FDA)-approved test
   2. Mekinist will be used as a single agent in a BRAF-inhibitor treatment-naïve patient (you have not been previously treated for this cancer) OR in combination with Tafinlar (dabrafenib)

D. If you have metastatic non-small cell lung cancer, approval also requires:
   1. You have a BRAF V600E mutation (abnormal change in gene) as detected by a Food and Drug Administration (FDA)-approved test
   2. Mekinist will be used in combination with Tafinlar (dabrafenib)

(Denial text continued on next page)

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TRAMETINIB SOLUTION (PART D)

GUIDELINES FOR USE (CONTINUED)

E. If you have melanoma, approval also requires:
1. You have a BRAF V600E or V600K mutation (abnormal change in gene) as detected by a Food and Drug Administration (FDA)-approved test
2. Mekinist will be used as adjuvant (add-on) therapy in combination with Tafinlar (dabrafenib)
3. There is involvement of lymph node(s), following complete resection (surgical removal)

F. If you have locally advanced or metastatic anaplastic thyroid cancer, approval also requires:
1. You have a BRAF V600E mutation (abnormal change in gene)
2. Mekinist will be used in combination with Tafinlar (dabrafenib)
3. You do not have any satisfactory locoregional treatment options available (treatments that are focused on the affected area)

G. If you have an unresectable or metastatic solid tumor, approval also requires:
1. You are 1 year of age or older
2. You have a BRAF V600E mutation (abnormal change in gene)
3. Mekinist will be used in combination with Tafinlar (dabrafenib)
4. Your disease has progressed following prior treatment and has no satisfactory alternative treatment options

H. If you have low-grade glioma, approval also requires:
1. You are 1 to 17 years of age
2. You have a BRAF V600E mutation (abnormal change in gene)
3. Mekinist will be used in combination with Tafinlar (dabrafenib)
4. You require systemic therapy (treatment that targets the entire body)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Mekinist.

REFERENCES
Mekinist [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2024.

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TRAMETINIB SOLUTION (PART D)

For Part D use only:

TRAMETINIB SOLUTION (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	UNRESECTABLE OR METASTATIC MELANOMA, MELANOMA, METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC), LOCALLY ADVANCED OR METASTATIC ANAPLASTIC THYROID CANCER (ATC), UNRESECTABLE OR METASTATIC SOLID TUMOR, LOW-GRADE GLIOMA (LGG): UNABLE TO SWALLOW MEKINIST TABLETS.

Part D Effective: 01/01/25 Created: 05/23
Commercial Effective: N/A Client Approval: 06/24 P&T Approval: 10/23

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRAMETINIB TABLET (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRAMETINIB DIMETHYL SULFOXIDE	MEKINIST		34726 34727	GPI-14 (21533570100310, 21533570100330)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic melanoma (ICD-10 Group C43) and meet **ALL** of the following criteria?
   - The patient has a BRAF V600E or V600K mutation as detected by an FDA-approved test
   - Mekinist will be used as a single agent in a BRAF-inhibitor treatment-naive patient OR in combination with Tafinlar (dabrafenib)

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of melanoma (ICD-10 Group C43) and meet **ALL** of the following criteria?
   - The patient has a BRAF V600E or V600K mutation as detected by an FDA-approved test
   - Mekinist will be used as an adjuvant therapy in combination with Tafinlar (dabrafenib)
   - There is involvement of lymph node(s), following complete resection

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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TRAMETINIB TABLET (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient has a BRAF V600E mutation as detected by an FDA-approved test
   - Mekinist will be used in combination with Tafinlar (dabrafenib)

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

4. Does the patient have a diagnosis of locally advanced or metastatic anaplastic thyroid cancer (ATC) (ICD-10 C73) and meet **ALL** of the following criteria?
   - The patient has a BRAF V600E mutation
   - Mekinist will be used in combination with Tafinlar (dabrafenib)
   - The patient has no satisfactory locoregional treatment options available

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Does the patient have a diagnosis of unresectable or metastatic solid tumor and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - The patient has a BRAF V600E mutation
   - Mekinist will be used in combination with Tafinlar (dabrafenib)
   - The patient's disease has progressed following prior treatment and has no satisfactory alternative treatment options

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #6.

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TRAMETINIB TABLET (PART D)

GUIDELINES FOR USE (CONTINUED)

6. Does the patient have a diagnosis of low-grade glioma (LGG) (ICD-10 D33.2) and meet **ALL** of the following criteria?
   - The patient is 1 to 17 years of age
   - The patient has a BRAF V600E mutation
   - Mekinist will be used in combination with Tafinlar (dabrafenib)
   - The patient requires systemic therapy

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TRAMETINIB TABLET (Mekinist)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Unresectable or metastatic melanoma (a type of skin cancer that cannot be removed by surgery or has spread to other parts of the body)
      2. Melanoma (a type of skin cancer)
      3. Metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of the body)
      4. Locally advanced or metastatic anaplastic thyroid cancer (ATC: a type of thyroid cancer that has spread to nearby tissue or lymph nodes or has spread to other parts of the body)
      5. Unresectable or metastatic solid tumor (tumor that cannot be removed by surgery or has spread to other parts of the body)
      6. Low-grade glioma (LGG: a type of brain cancer)

   B. If you have unresectable or metastatic melanoma, approval also requires:
      1. You have a BRAF V600E or V600K mutation (abnormal change in gene) as detected by a Food and Drug Administration (FDA)-approved test
      2. Mekinist will be used as a single agent in a BRAF-inhibitor treatment-naive patient (you have not been previously treated for this cancer) OR in combination with Tafinlar (dabrafenib)

   (Denial text continued on next page)

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TRAMETINIB TABLET (PART D)

GUIDELINES FOR USE (CONTINUED)

C. If you have melanoma, approval also requires:
1. You have a BRAF V600E or V600K mutation (abnormal change in gene) as detected by a Food and Drug Administration (FDA)-approved test
2. Mekinist will be used as adjuvant (add-on) therapy in combination with Tafinlar (dabrafenib)
3. There is involvement of lymph node(s), following complete resection (surgical removal)

D. If you have metastatic non-small cell lung cancer, approval also requires:
1. You have a BRAF V600E mutation (abnormal change in gene) as detected by a Food and Drug Administration (FDA)-approved test
2. Mekinist will be used in combination with Tafinlar (dabrafenib)

E. If you have locally advanced or metastatic anaplastic thyroid cancer, approval also requires:
1. You have a BRAF V600E mutation (abnormal change in gene)
2. Mekinist will be used in combination with Tafinlar (dabrafenib)
3. You do not have any satisfactory locoregional treatment options available (treatments that are focused on the affected area)

F. If you have an unresectable or metastatic solid tumor, approval also requires:
1. You are 1 year of age or older
2. You have a BRAF V600E mutation (abnormal change in gene)
3. Mekinist will be used in combination with Tafinlar (dabrafenib)
4. Your disease has progressed following prior treatment and has no satisfactory alternative treatment options

G. If you have low-grade glioma, approval also requires:
1. You are 1 to 17 years of age
2. You have a BRAF V600E mutation (abnormal change in gene)
3. Mekinist will be used in combination with Tafinlar (dabrafenib)
4. You require systemic therapy (treatment that targets the entire body)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Mekinist.

REFERENCES
Mekinist [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; August 2023.

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TRAMETINIB TABLET (PART D)

For Part D use only:

TRAMETINIB TABLET (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25 Created: 07/13
Commercial Effective: N/A Client Approval: 06/24 P&T Approval: 10/23

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRASTUZUMAB BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRASTUZUMAB	HERCEPTIN	18801		GPI-10 (2117007000)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	Yes	No	No	Yes	No	No	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, continue to #6.
   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, continue to #6.
   If no, continue to #5.

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enterany override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

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TRASTUZUMAB BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

6. Is the drug administered via an implantable pump?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, continue to #7.

7. Is the drug administered via an external pump?

   If yes, continue to #8.
   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

8. Is the drug specifically infused through an external infusion pump covered by Medicare?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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TRASTUZUMAB BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of breast cancer (ICD-10 Group C50) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has HER2-overexpressing (HER2-positive) cancer, as detected by an FDA-approved companion diagnostic test for Herceptin
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Herzuma (trastuzumab-pkrb), Ogivri (trastuzumab-dkst), Ontruzant (trastuzumab-dttb), Trazimera (trastuzumab-qyyp)

   If yes, continue to #2.
   If no, continue to #4.

2. Will Herceptin be used as adjuvant treatment and the patient meets **ONE** of the following criteria?
   - Herceptin will be used as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
   - Herceptin will be used as part of a treatment regimen with docetaxel and carboplatin
   - Herceptin will be used as a single agent following multi-modality anthracycline based therapy (e.g., daunorubicin, doxorubicin, Idamycin [idarubicin], Ellence [epirubicin], Valstar [valrubicin])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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TRASTUZUMAB BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Is the patient's cancer metastatic and does the patient meet **ONE** of the following criteria?
   - Herceptin will be used in combination with paclitaxel
   - Herceptin will be used as a single agent in a patient who has received one or more chemotherapy regimens for metastatic disease

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient have a diagnosis of metastatic gastric or gastroesophageal junction adenocarcinoma (ICD-10 Group C16) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has HER2-overexpressing (HER2-positive) cancer, as detected by an FDA-approved companion diagnostic test for Herceptin
   - Herceptin will be used in combination with cisplatin and Xeloda (capecitabine) or 5-fluorouracil
   - The patient has not received prior treatment for metastatic disease

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TRASTUZUMAB BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TRASTUZUMAB (Herceptin)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Breast cancer
   2. Metastatic gastric or gastroesophageal junction adenocarcinoma (a type of digestive system cancer that has spread to other parts of the body)

B. If you have breast cancer, approval also requires:
   1. You are 18 years of age or older
   2. Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive, as detected by a Food and Drug Administration (FDA)-approved companion diagnostic test for Herceptin
   3. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Herzuma (trastuzumab-pkrb), Ogivri (trastuzumab-dkst), Ontruzant (trastuzumab-dttb), Trazimera (trastuzumab-qyyp)
   4. You meet ONE of the following:
      a. Herceptin will be used as adjuvant (additional) treatment, and you meet ONE of the following:
         i. Herceptin will be used as part of a treatment plan that includes doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
         ii. Herceptin will be used as part of a treatment plan with docetaxel and carboplatin
         iii. Herceptin will be used as a single medication following multi-modality anthracycline based therapy (therapy using a class of cancer medication that combines more than one method of treatment), such as daunorubicin, doxorubicin, Idamycin (idarubicin), Ellence (epirubicin), Valstar (valrubicin)
      b. Your breast cancer is metastatic (cancer that has spread to other parts of the body), and you meet ONE of the following:
         i. Herceptin will be used in combination with paclitaxel
         ii. Herceptin will be used as a single medication if you have received one or more chemotherapy regimens for metastatic disease (disease that has spread to other parts of the body)

(Denial text continued on next page)

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TRASTUZUMAB BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

C. If you have metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:

1. You are 18 years of age or older
2. Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive, as detected by a Food and Drug Administration (FDA)-approved companion diagnostic test for Herceptin
3. Herceptin will be used in combination with cisplatin and Xeloda (capecitabine) or 5-fluorouracil
4. You have not received prior treatment for metastatic disease (disease that has spread to other parts of the body)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Herceptin.
The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B. Drugs administered by an implantable pump are covered under Part B. Drugs administered via an external pump are covered under Part B if they are included under the local coverage policy of the applicable Medicare coverage policies (National and/or Local Coverage Policies). Drugs administered via an external pump that are not included under the applicable Medicare coverage policies are covered under Part D. A CMS website to assist with National and Local Coverage Determination for B versus D review is http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx.

REFERENCES

Herceptin [Package Information]. South San Francisco, CA: Genentech, Inc.; June 2024.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed April 10, 2025].

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRASTUZUMAB BvD (PART D)

For Part D use only:

TRASTUZUMAB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	ADJUVANT BREAST CANCER, METASTATIC BREAST CANCER: TRIAL OF OR CONTRAINDICATION TO ONE OF THE FOLLOWING PREFERRED AGENTS: HERZUMA, OGIVRI, ONTRUZANT, TRAZIMERA.

Created: 08/12
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 05/15

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRASTUZUMAB-ANNS BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRASTUZUMAB-ANNS	KANJINTI	45796		GPI-10 (2117007014)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	Yes	No	No	Yes	No	No	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, continue to #6.
   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, continue to #6.
   If no, continue to #5.

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

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TRASTUZUMAB-ANNS BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

6. Is the drug administered via an implantable pump?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, continue to #7.

7. Is the drug administered via an external pump?

   If yes, continue to #8.
   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

8. Is the drug specifically infused through an external infusion pump covered by Medicare?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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TRASTUZUMAB-ANNS BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of breast cancer (ICD-10 Group C50) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has HER2-overexpressing (HER2-positive) cancer, as detected by an FDA-approved companion diagnostic test for a trastuzumab product
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Herzuma (trastuzumab-pkrb), Ogivri (trastuzumab-dkst), Ontruzant (trastuzumab-dttb), Trazimera (trastuzumab-qyyp)

   If yes, continue to #2.
   If no, continue to #4.

2. Will Kanjinti be used as adjuvant treatment and the patient meets **ONE** of the following criteria?
   - Kanjinti will be used as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
   - Kanjinti will be used as part of a treatment regimen with docetaxel and carboplatin
   - Kanjinti will be used as a single agent following multi-modality anthracycline based therapy (e.g., daunorubicin, doxorubicin, Idamycin [idarubicin], Ellence [epirubicin], Valstar [valrubicin])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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TRASTUZUMAB-ANNS BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Is the patient's cancer metastatic and does the patient meet **ONE** of the following criteria?
   - Kanjinti will be used in combination with paclitaxel
   - Kanjinti will be used as a single agent in a patient who has received one or more chemotherapy regimens for metastatic disease

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient have a diagnosis of metastatic gastric or gastroesophageal junction adenocarcinoma (ICD-10 Group C16) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has HER2-overexpressing (HER2-positive) cancer, as detected by an FDA-approved companion diagnostic test for a trastuzumab product
   - Kanjinti will be used in combination with cisplatin and Xeloda (capecitabine) or 5-fluorouracil
   - The patient has not received prior treatment for metastatic disease

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TRASTUZUMAB-ANNS BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TRASTUZUMAB-ANNS (Kanjinti)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Breast cancer
   2. Metastatic gastric or gastroesophageal junction adenocarcinoma (a type of digestive system cancer that has spread to other parts of the body)

B. If you have breast cancer, approval also requires:
   1. You are 18 years of age or older
   2. Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive, as detected by a Food and Drug Administration (FDA)-approved companion diagnostic test for a trastuzumab product
   3. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Herzuma (trastuzumab-pkrb), Ogivri (trastuzumab-dkst), Ontruzant (trastuzumab-dttb), Trazimera (trastuzumab-qyyp)
   4. You meet ONE of the following:
      a. Kanjinti will be used as adjuvant (additional) treatment, and you meet ONE of the following:
         i. Kanjinti will be used as part of a treatment plan that includes doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
         ii. Kanjinti will be used as part of a treatment plan with docetaxel and carboplatin
         iii. Kanjinti will be used as a single medication following multi-modality anthracycline based therapy (therapy using a class of cancer medication that combines more than one method of treatment), such as daunorubicin, doxorubicin, Idamycin (idarubicin), Ellence (epirubicin), Valstar (valrubicin)
      b. Your breast cancer is metastatic (cancer that has spread to other parts of the body), and you meet ONE of the following:
         i. Kanjinti will be used in combination with paclitaxel
         ii. Kanjinti will be used as a single medication if you have received one or more chemotherapy regimens for metastatic disease (disease that has spread to other parts of the body)

(Denial text continued on next page)

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TRASTUZUMAB-ANNS BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

C. If you have metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:

1. You are 18 years of age or older
2. Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive, as detected by a Food and Drug Administration (FDA)-approved companion diagnostic test for a trastuzumab product
3. Kanjinti will be used in combination with cisplatin and Xeloda (capecitabine) or 5-fluorouracil
4. You have not received prior treatment for metastatic disease (disease that has spread to other parts of the body)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kanjinti.

The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B. Drugs administered by an implantable pump are covered under Part B. Drugs administered via an external pump are covered under Part B if they are included under the local coverage policy of the applicable Medicare coverage policies (National and/or Local Coverage Policies). Drugs administered via an external pump that are not included under the applicable Medicare coverage policies are covered under Part D. A CMS website to assist with National and Local Coverage Determination for B versus D review is http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx.

REFERENCES

Kanjinti [Prescribing Information]. Thousand Oaks, CA: Amgen, Inc.; December 2024.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/medicare/coverage/prescription-drug-coverage-contracting/prescription-drug-benefit-manual [Accessed April 10, 2025].

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRASTUZUMAB-ANNS BvD (PART D)

For Part D use only:

TRASTUZUMAB-ANNS (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	ADJUVANT BREAST CANCER, METASTATIC BREAST CANCER: TRIAL OF OR CONTRAINDICATION TO ONE OF THE FOLLOWING PREFERRED AGENTS: HERZUMA, OGIVRI, ONTRUZANT, TRAZIMERA.

Created: 07/19
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 07/19

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRASTUZUMAB-DKST BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRASTUZUMAB-DKST	OGIVRI	44673		GPI-10 (2117007030)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	Yes	No	Yes	Yes	No	Yes	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, continue to #6.
   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, continue to #6.
   If no, continue to #5.

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enterany override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

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TRASTUZUMAB-DKST BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

6. Is the drug administered via an implantable pump?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, continue to #7.

7. Is the drug administered via an external pump?

   If yes, continue to #8.
   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

8. Is the drug specifically infused through an external infusion pump covered by Medicare?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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TRASTUZUMAB-DKST BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of breast cancer (ICD-10 Group C50) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has HER2-overexpressing (HER2-positive) cancer, as detected by an FDA-approved companion diagnostic test for a trastuzumab product

   If yes, continue to #2.
   If no, continue to #4.

2. Will Ogivri be used as adjuvant treatment and the patient meets **ONE** of the following criteria?
   - Ogivri will be used as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
   - Ogivri will be used as part of a treatment regimen with docetaxel and carboplatin
   - Ogivri will be used as a single agent following multi-modality anthracycline based therapy (e.g., daunorubicin, doxorubicin, Idamycin [idarubicin], Ellence [epirubicin], Valstar [valrubicin])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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TRASTUZUMAB-DKST BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Is the patient's cancer metastatic and does the patient meet **ONE** of the following criteria?
   - Ogivri will be used in combination with paclitaxel
   - Ogivri will be used as a single agent in a patient who has received one or more chemotherapy regimens for metastatic disease

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient have a diagnosis of metastatic gastric or gastroesophageal junction adenocarcinoma (ICD-10 Group C16) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has HER2-overexpressing (HER2-positive) cancer, as detected by an FDA-approved companion diagnostic test for a trastuzumab product
   - Ogivri will be used in combination with cisplatin and Xeloda (capecitabine) or 5-fluorouracil
   - The patient has not received prior treatment for metastatic disease

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TRASTUZUMAB-DKST BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TRASTUZUMAB-DKST (Ogivri)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Breast cancer
   2. Metastatic gastric or gastroesophageal junction adenocarcinoma (a type of digestive system cancer that has spread to other parts of the body)

B. If you have breast cancer, approval also requires:
   1. You are 18 years of age or older
   2. Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive, as detected by a Food and Drug Administration (FDA)-approved companion diagnostic test for a trastuzumab product
   3. You meet ONE of the following:
      a. Ogivri will be used as adjuvant (additional) treatment, and you meet ONE of the following:
         i. Ogivri will be used as part of a treatment plan that includes doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
         ii. Ogivri will be used as part of a treatment plan with docetaxel and carboplatin
         iii. Ogivri will be used as a single medication following multi-modality anthracycline based therapy (therapy using a class of cancer medications that combines more than one method of treatment), such as daunorubicin, doxorubicin, Idamycin (idarubicin), Ellence (epirubicin), Valstar (valrubicin)
      b. Your breast cancer is metastatic (cancer that has spread to other parts of the body), and you meet ONE of the following:
         i. Ogivri will be used in combination with paclitaxel
         ii. Ogivri will be used as a single medication if you have received one or more chemotherapy regimens (type of cancer treatment) for metastatic disease (disease that has spread to other parts of the body)

(Denial text continued on next page)

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TRASTUZUMAB-DKST BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

C. If you have metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:

1. You are 18 years of age or older
2. Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive, as detected by a Food and Drug Administration-approved companion diagnostic test for a trastuzumab product
3. Ogivri will be used in combination with cisplatin and Xeloda (capecitabine) or 5-fluorouracil
4. You have not received prior treatment for metastatic disease (disease that has spread to other parts of the body)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ogivri.

The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B. Drugs administered by an implantable pump are covered under Part B. Drugs administered via an external pump are covered under Part B if they are included under the local coverage policy of the applicable Medicare coverage policies (National and/or Local Coverage Policies). Drugs administered via an external pump that are not included under the applicable Medicare coverage policies are covered under Part D. A CMS website to assist with National and Local Coverage Determination for B versus D review is http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx.

REFERENCES

Ogivri [Prescribing Information]. Cambridge, MA: Biocon Biologics Inc.; November 2024.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/medicare/coverage/prescription-drug-coverage-contracting/prescription-drug-benefit-manual. [Accessed April 3, 2025].

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TRASTUZUMAB-DKST BvD (PART D)

For Part D use only:

TRASTUZUMAB-DKST (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 11/19
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 01/18

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRASTUZUMAB-DTTB BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRASTUZUMAB-DTTB	ONTRUZANT	45571		GPI-10 (2117007034)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	Yes	No	No	Yes	No	No	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, continue to #6.
   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, continue to #6.
   If no, continue to #5.

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enterany override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

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TRASTUZUMAB-DTTB BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

6. Is the drug administered via an implantable pump?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, continue to #7.

7. Is the drug administered via an external pump?

   If yes, continue to #8.
   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

8. Is the drug specifically infused through an external infusion pump covered by Medicare?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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TRASTUZUMAB-DTTB BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of breast cancer (ICD-10 Group C50) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has HER2-overexpressing (HER2-positive) cancer, as detected by an FDA-approved companion diagnostic test for a trastuzumab product

   If yes, continue to #2.
   If no, continue to #4.

2. Will Ontruzant be used as adjuvant treatment and the patient meets **ONE** of the following criteria?
   - Ontruzant will be used as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
   - Ontruzant will be used as part of a treatment regimen with docetaxel and carboplatin
   - Ontruzant will be used as a single agent following multi-modality anthracycline based therapy (e.g., daunorubicin, doxorubicin, Idamycin [idarubicin], Ellence [epirubicin], Valstar [valrubicin])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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TRASTUZUMAB-DTTB BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Is the patient's breast cancer metastatic and does the patient meet **ONE** of the following criteria?
   - Ontruzant will be used in combination with paclitaxel
   - Ontruzant will be used as a single agent in a patient who has received one or more chemotherapy regimens for metastatic disease

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient have a diagnosis of metastatic gastric or gastroesophageal junction adenocarcinoma (ICD-10 Group C16) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has HER2-overexpressing (HER2-positive) cancer, as detected by an FDA-approved companion diagnostic test for a trastuzumab product
   - Ontruzant will be used in combination with cisplatin and Xeloda (capecitabine) or 5-fluorouracil
   - The patient has not received prior treatment for metastatic disease

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TRASTUZUMAB-DTTB BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TRASTUZUMAB- DTTB (Ontruzant)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Breast cancer
   2. Metastatic gastric or gastroesophageal junction adenocarcinoma (a type of digestive system cancer that has spread to other parts of the body)

B. If you have breast cancer, approval also requires:
   1. You are 18 years of age or older
   2. Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive, as detected by a Food and Drug Administration (FDA)-approved companion diagnostic test for a trastuzumab product
   3. You meet ONE of the following:
      a. Ontruzant will be used as adjuvant (additional) treatment, and you meet ONE of the following:
         i. Ontruzant will be used as part of a treatment plan that includes doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
         ii. Ontruzant will be used as part of a treatment plan with docetaxel and carboplatin
         iii. Ontruzant will be used as a single medication following multi-modality anthracycline based therapy (therapy using a class of cancer medications that combines more than one method of treatment), such as daunorubicin, doxorubicin, Idamycin (idarubicin), Ellence (epirubicin), Valstar (valrubicin)
      b. Your breast cancer is metastatic (cancer that has spread to other parts of the body), and you meet ONE of the following:
         i. Ontruzant will be used in combination with paclitaxel
         ii. Ontruzant will be used as a single medication if you have received one or more chemotherapy regimens (type of cancer treatment) for metastatic disease (disease that has spread to other parts of the body)

(Denial text continued on the next page)

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GUIDELINES FOR USE (CONTINUED)

C. If you have metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:

1. You are 18 years of age or older
2. Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive, as detected by a Food and Drug Administration (FDA)-approved companion diagnostic test for a trastuzumab product
2. Ontruzant will be used in combination with cisplatin and Xeloda (capecitabine) or 5-fluorouracil
3. You have not received prior treatment for metastatic disease (disease that has spread to other parts of the body)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ontruzant.

The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B. Drugs administered by an implantable pump are covered under Part B. Drugs administered via an external pump are covered under Part B if they are included under the local coverage policy of the applicable Medicare coverage policies (National and/or Local Coverage Policies). Drugs administered via an external pump that are not included under the applicable Medicare coverage policies are covered under Part D. A CMS website to assist with National and Local Coverage Determination for B versus D review is http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx.

REFERENCES

Ontruzant [Prescribing Information]. Jersey City, NJ: Organon LLC.; February 2025.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed April 3, 2025].

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRASTUZUMAB-DTTB BvD (PART D)

For Part D use only:

TRASTUZUMAB-DTTB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 04/20
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 07/20

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRASTUZUMAB-HYALURONIDASE-OYSK (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRASTUZUMAB-HYALURONIDASE-OYSK	HERCEPTIN HYLECTA	45653		GPI-10 (2199000272)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of breast cancer (ICD-10 Group C50) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer is HER2-overexpressing (HER2-positive), as detected by an FDA-approved companion diagnostic for trastuzumab
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Herzuma (trastuzumab-pkrb), Ogivri (trastuzumab-dkst), Ontruzant (trastuzumab-dttb), Trazimera (trastuzumab-qyyp)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Will the medication be used as adjuvant therapy and the patient meets **ONE** of the following criteria?
   - Herceptin Hylecta will be used as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
   - Herceptin Hylecta will be used as part of a treatment regimen with docetaxel and carboplatin
   - Herceptin Hylecta will be used as a single agent following multi-modality anthracycline based therapy (e.g., daunorubicin, doxorubicin, Idamycin [idarubicin], Ellence [epirubicin], Valstar [valrubicin])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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TRASTUZUMAB-HYALURONIDASE-OYSK (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Is the patient's cancer metastatic and does the patient meet **ONE** of the following criteria?
   - Herceptin Hylecta will be used in combination with paclitaxel
   - Herceptin Hylecta will be used as a single agent in a patient who has received at least one chemotherapy regimen for metastatic disease

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TRASTUZUMAB-HYALURONIDASE-OYSK (Herceptin Hylecta)** requires the following rule(s) be met for approval:
   A. You have breast cancer
   B. You are 18 years of age or older
   C. Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive tumor, as detected by a Food and Drug Administration (FDA)-approved companion diagnostic for trastuzumab
   D. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Herzuma (trastuzumab-pkrb), Ogivri (trastuzumab-dkst), Ontruzant (trastuzumab-dttb), Trazimera (trastuzumab-qyyp)
   E. You meet ONE of the following:
      1. The requested medication will be used as adjuvant (additional) treatment, and you meet ONE of the following:
         a. Herceptin Hylecta will be used as part of a treatment plan that includes doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
         b. Herceptin Hylecta will be used as part of a treatment plan with docetaxel and carboplatin
         c. Herceptin Hylecta will be used as a single agent following multi-modality anthracycline based therapy (therapy using a class of cancer drugs that combines more than one method of treatment), such as daunorubicin, doxorubicin, Idamycin (idarubicin), Ellence (epirubicin), Valstar (valrubicin)
      2. Your cancer is metastatic (has spread to other parts of the body), and you meet ONE of the following:
         a. Herceptin Hylecta will be used in combination with paclitaxel
         b. Herceptin Hylecta will be used as a single agent if you have received at least one chemotherapy regimen (type of cancer treatment) for metastatic disease

   (Denial text continued on next page)

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TRASTUZUMAB-HYALURONIDASE-OYSK (PART D)

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Herceptin Hylecta.

REFERENCES

Herceptin Hylecta [Prescribing Information]. San Francisco, CA: Genentech, Inc., June 2024.

For Part D use only:

TRASTUZUMAB-HYALURONIDASE-OYSK (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	ADJUVANT BREAST CANCER, METASTATIC BREAST CANCER: TRIAL OF OR CONTRAINDICATION TO ONE OF THE FOLLOWING PREFERRED AGENTS: HERZUMA, OGIVRI, ONTRUZANT, TRAZIMERA.

Created: 04/19
Effective: 07/01/25 Client Approval: 06/25 P&T Approval: 04/19

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRASTUZUMAB-PKRB BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRASTUZUMAB-PKRB	HERZUMA	45541		GPI-10 (2117007060)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	Yes	No	No	Yes	No	No	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, continue to #6.
   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, continue to #6.
   If no, continue to #5.

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enterany override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field.).**

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TRASTUZUMAB-PKRB BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

6. Is the drug administered via an implantable pump?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field.).**

   If no, continue to #7.

7. Is the drug administered via an external pump?

   If yes, continue to #8.
   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

8. Is the drug specifically infused through an external infusion pump covered by Medicare?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field.).**

   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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TRASTUZUMAB-PKRB BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of breast cancer (ICD-10 Group C50) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has HER2-overexpressing (HER2-positive) cancer, as detected by an FDA-approved companion diagnostic test for a trastuzumab product

   If yes, continue to #2.
   If no, continue to #4.

2. Will Herzuma be used as adjuvant therapy and the patient meets **ONE** of the following criteria?
   - Herzuma will be used as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
   - Herzuma will be used as part of a treatment regimen with docetaxel and carboplatin
   - Herzuma will be used as a single agent following multi-modality anthracycline based therapy (e.g., daunorubicin, doxorubicin, Idamycin [idarubicin], Ellence [epirubicin], Valstar [valrubicin])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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TRASTUZUMAB-PKRB BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Is the patient's breast cancer metastatic and does the patient meet **ONE** of the following criteria?
   - Herzuma will be used in combination with paclitaxel
   - Herzuma will be used as a single agent in a patient who has received one or more chemotherapy regimens for metastatic disease

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient have a diagnosis of metastatic gastric or gastroesophageal junction adenocarcinoma (ICD-10 Group C16) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has HER2-overexpressing (HER2-positive) cancer, as detected by an FDA-approved companion diagnostic test for a trastuzumab product
   - Herzuma will be used in combination with cisplatin and Xeloda (capecitabine) or 5-fluorouracil
   - The patient has not received prior treatment for metastatic disease

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TRASTUZUMAB-PKRB BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TRASTUZUMAB-PKRB (Herzuma)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Breast cancer
   2. Metastatic gastric or gastroesophageal junction adenocarcinoma (a type of digestive cancer that has spread to other parts of the body)

B. If you have breast cancer, approval also requires:
   1. You are 18 years of age or older
   2. Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive, as detected by a Food and Drug Administration (FDA)-approved companion diagnostic test for a trastuzumab product
   3. You meet ONE of the following:
      a. Herzuma will be used as adjuvant (additional) treatment, and you meet ONE of the following:
         i. Herzuma will be used as part of a treatment plan that includes doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
         ii. Herzuma will be used as part of a treatment plan with docetaxel and carboplatin
         iii. Herzuma will be used as a single medication following multi-modality anthracycline based therapy (therapy using a class of cancer medications that combines more than one method of treatment), such as daunorubicin, doxorubicin, Idamycin (idarubicin), Ellence (epirubicin), Valstar (valrubicin)
      b. Your breast cancer is metastatic (cancer that has spread to other parts of the body), and you meet ONE of the following:
         i. Herzuma will be used in combination with paclitaxel
         ii. Herzuma will be used as a single medication if you have received one or more chemotherapy regimens (type of cancer treatment) for metastatic disease (disease that has spread to other parts of the body)

(Denial text continued on next page)

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GUIDELINES FOR USE (CONTINUED)

C. If you have metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:

1. You are 18 years of age or older
2. Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive, as detected by a Food and Drug Administration (FDA)-approved companion diagnostic test for a trastuzumab product
3. Herzuma will be used in combination with cisplatin and Xeloda (capecitabine) or 5-fluorouracil
4. You have not received prior treatment for metastatic disease (disease that has spread to other parts of the body)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Herzuma.

The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B. Drugs administered by an implantable pump are covered under Part B. Drugs administered via an external pump are covered under Part B if they are included under the local coverage policy of the applicable Medicare coverage policies (National and/or Local Coverage Policies). Drugs administered via an external pump that are not included under the applicable Medicare coverage policies are covered under Part D. A CMS website to assist with National and Local Coverage Determination for B versus D review is http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx.

REFERENCES

Herzuma [Prescribing Information]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; December 2024.

Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed April 3, 2025].

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRASTUZUMAB-PKRB BvD (PART D)

For Part D use only:

TRASTUZUMAB-PKRB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 03/20
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 01/19

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRASTUZUMAB-QYYP BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRASTUZUMAB-QYYP	TRAZIMERA	45657		GPI-10 (2117007065)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	Yes	No	No	Yes	No	No	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, continue to #6.
   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, continue to #6.
   If no, continue to #5.

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enterany override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

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TRASTUZUMAB-QYYP BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

6. Is the drug administered via an implantable pump?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, continue to #7.

7. Is the drug administered via an external pump?

   If yes, continue to #8.
   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

8. Is the drug specifically infused through an external infusion pump covered by Medicare?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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TRASTUZUMAB-QYYP BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of breast cancer (ICD-10 Group C50) **AND** meet the following criterion?
   - The patient has HER2-overexpressing (HER2-positive) cancer, as detected by an FDA-approved companion diagnostic test for a trastuzumab product

   If yes, continue to #2.
   If no, continue to #4.

2. Will Trazimera be used as adjuvant therapy and the patient meets **ONE** of the following criteria?
   - Trazimera will be used as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
   - Trazimera will be used as part of a treatment regimen with docetaxel and carboplatin
   - Trazimera will be used as a single agent following multi-modality anthracycline based therapy (e.g., daunorubicin, doxorubicin, Idamycin [idarubicin], Ellence [epirubicin], Valstar [valrubicin])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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TRASTUZUMAB-QYYP BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Is the patient's breast cancer metastatic and does the patient meet **ONE** of the following criteria?
   - Trazimera will be used in combination with paclitaxel
   - Trazimera will be used as a single agent in a patient who has received one or more chemotherapy regimens for metastatic disease

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient have a diagnosis of metastatic gastric or gastroesophageal junction adenocarcinoma (ICD-10 Group C16) and meet **ALL** of the following criteria?
   - The patient has HER2-overexpressing (HER2-positive) cancer, as detected by an FDA-approved companion diagnostic test for a trastuzumab product
   - Trazimera will be used in combination with cisplatin and Xeloda (capecitabine) or 5-fluorouracil
   - The patient has not received prior treatment for metastatic disease

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TRASTUZUMAB-QYYP BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TRASTUZUMAB-QYYP (Trazimera)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Breast cancer
   2. Metastatic gastric or gastroesophageal junction adenocarcinoma (a type of digestive system cancer that has spread to other parts of the body)

B. If you have breast cancer, approval also requires:
   1. Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive, as detected by a Food and Drug Administration (FDA)-approved companion diagnostic test for a trastuzumab product
   2. You meet ONE of the following:
      a. Trazimera will be used as adjuvant (additional) treatment, and you meet ONE of the following:
         i. Trazimera will be used as part of a treatment plan that includes doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
         ii. Trazimera will be used as part of a treatment plan with docetaxel and carboplatin
         iii. Trazimera will be used as a single medication following multi-modality anthracycline based therapy (therapy using a class of cancer medications that combines more than one method of treatment) such as daunorubicin, doxorubicin, Idamycin (idarubicin), Ellence (epirubicin), Valstar (valrubicin)
      b. Your breast cancer is metastatic (cancer that has spread to other parts of the body), and you meet ONE of the following:
         i. Trazimera will be used in combination with paclitaxel
         ii. Trazimera will be used as a single medication if you have received one or more chemotherapy regimens (type of cancer treatment) for metastatic disease (disease that has spread to other parts of the body)

(Denial text continued on next page)

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TRASTUZUMAB-QYYP BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

C. If you have metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:

1. Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive, as detected by a Food and Drug Administration (FDA)-approved companion diagnostic test for a trastuzumab product
2. Trazimera will be used in combination with cisplatin and Xeloda (capecitabine) or 5-fluorouracil
3. You have not received prior treatment for metastatic disease (disease that has spread to other parts of the body)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Trazimera.

The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B. Drugs administered by an implantable pump are covered under Part B. Drugs administered via an external pump are covered under Part B if they are included under the local coverage policy of the applicable Medicare coverage policies (National and/or Local Coverage Policies). Drugs administered via an external pump that are not included under the applicable Medicare coverage policies are covered under Part D. A CMS website to assist with National and Local Coverage Determination for B versus D review is http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx.

REFERENCES

Trazimera [Prescribing Information]. New York, NY: Pfizer Ireland Pharmaceuticals; November 2020.

Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed April 3, 2025].

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRASTUZUMAB-QYYP BvD (PART D)

For Part D use only:

TRASTUZUMAB-QYYP (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 02/20
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 04/19

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRASTUZUMAB-STRF BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRASTUZUMAB-STRF	HERCESSI	49554		GPI-10 (2117007040)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	Yes	No	No	Yes	No	No	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, continue to #6.
   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, continue to #6.
   If no, continue to #5.

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TRASTUZUMAB-STRF BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

6. Is the drug administered via an implantable pump?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field)**

   If no, continue to #7.

7. Is the drug administered via an external pump?

   If yes, continue to #8.
   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field)**

8. Is the drug specifically infused through an external infusion pump covered by Medicare?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field.**

   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field)**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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TRASTUZUMAB-STRF BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of breast cancer (ICD-10 Group C50) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer is HER2-overexpressing (HER2-positive), as detected by an FDA-approved companion diagnostic test for a trastuzumab product
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Herzuma (trastuzumab-pkrb), Ogivri (trastuzumab-dkst), Ontruzant (trastuzumab-dttb), Trazimera (trastuzumab-qyyp)

   If yes, continue to #2.
   If no, continue to #4.

2. Will Hercessi be used as adjuvant therapy and the patient meets **ONE** of the following criteria?
   - Hercessi will be used as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
   - Hercessi will be used as part of a treatment regimen with docetaxel and carboplatin
   - Hercessi will be used as a single agent following multi-modality anthracycline based therapy (e.g., daunorubicin, doxorubicin, Idamycin [idarubicin], Ellence [epirubicin], Valstar [valrubicin])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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TRASTUZUMAB-STRF BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Is the patient's cancer metastatic and does the patient meet **ONE** of the following criteria?
   - Hercessi will be used in combination with paclitaxel
   - Hercessi will be used as a single agent in a patient who has received at least one chemotherapy regimen for metastatic disease

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient have a diagnosis of metastatic gastric or gastroesophageal junction adenocarcinoma (ICD-10 Group C16) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer is HER2-overexpressing (HER2-positive), as detected by an FDA-approved companion diagnostic for a trastuzumab product
   - Hercessi will be used in combination with cisplatin AND either Xeloda (capecitabine) or 5-fluorouracil
   - The patient has NOT received prior treatment for metastatic disease

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TRASTUZUMAB-STRF BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TRASTUZUMAB-STRF (Hercessi)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Breast cancer
   2. Metastatic gastric or gastroesophageal junction adenocarcinoma (a type of digestive cancer that has spread to other parts of the body)

B. If you have breast cancer, approval also requires:
   1. You are 18 years of age or older
   2. Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive, as detected by a Food and Drug Administration (FDA)-approved companion diagnostic test for a trastuzumab product
   3. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Herzuma (trastuzumab-pkrb), Ogivri (trastuzumab-dkst), Ontruzant (trastuzumab-dttb), Trazimera (trastuzumab-qyyp)
   4. You meet ONE of the following:
      a. Hercessi will be used as adjuvant (additional) treatment, and you meet ONE of the following:
         i. Hercessi will be used as part of a treatment plan that includes doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
         ii. Hercessi will be used as part of a treatment plan with docetaxel and carboplatin
         iii. Hercessi will be used as a single medication following multi-modality anthracycline based therapy (therapy using a class of cancer medications that combines more than one method of treatment) such as daunorubicin, doxorubicin, Idamycin (idarubicin), Ellence (epirubicin), Valstar (valrubicin)
      b. Your cancer is metastatic (has spread to other parts of the body), and you meet ONE of the following:
         i. Hercessi will be used in combination with paclitaxel
         ii. Hercessi will be used as a single medication if you have received at least one chemotherapy regimen (type of cancer treatment) for metastatic disease (disease that has spread to other parts of the body)

(Denial text continued on next page)

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TRASTUZUMAB-STRF BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

C. If you have metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:

1. You are 18 years of age or older
2. Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive, as detected by a Food and Drug Administration (FDA)-approved companion diagnostic test for a trastuzumab product
3. Hercessi will be used in combination with cisplatin AND either Xeloda (capecitabine) or 5-fluorouracil
4. You have NOT received prior treatment for metastatic disease (disease that has spread to other parts of the body)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Hercessi.

The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B. Drugs administered by an implantable pump are covered under Part B. Drugs administered via an external pump are covered under Part B if they are included under the local coverage policy of the applicable Medicare coverage policies (National and/or Local Coverage Policies). Drugs administered via an external pump that are not included under the applicable Medicare coverage policies are covered under Part D. A CMS website to assist with National and Local Coverage Determination for B versus D review is http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx.

REFERENCES

Hercessi [Prescribing Information]. Raleigh, NC: Accord BioPharma Inc.; September 2024.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed November 5, 2025].

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRASTUZUMAB-STRF BvD (PART D)

For Part D use only:

TRASTUZUMAB-STRF (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	ADJUVANT BREAST CANCER, METASTATIC BREAST CANCER: TRIAL OF OR CONTRAINDICATION TO ONE OF THE FOLLOWING PREFERRED AGENTS: HERZUMA, OGIVRI, ONTRUZANT, TRAZIMERA.

Created: 11/25
Effective: 01/01/26 Client Approval: 11/25 P&T Approval: 01/25

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRAZODONE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRAZODONE HCL	RALDESY	01652		GPI-10 (5812008010)	BRAND = RALDESY

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of major depressive disorder (MDD) (ICD-10 Groups F32, F33) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a contraindication to OR is unable to swallow trazodone tablets

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TRAZODONE (Raldesy)** requires the following rule(s) be met for approval:
   A. You have major depressive disorder (a type of mental illness)
   B. You are 18 years of age or older
   C. You have a contraindication to (harmful for you to use) OR are unable to swallow trazodone tablets

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TRAZODONE (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Raldesy.

REFERENCES

Raldesy [Prescribing Information]. Parsippany, NJ: Validus Pharmaceuticals LLC; February 2025.

For Part D use only:

TRAZODONE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	MAJOR DEPRESSIVE DISORDER (MDD): CONTRAINDICATION TO OR UNABLE TO SWALLOW TRAZODONE TABLETS.

Created: 03/25
Effective: 04/01/25 Client Approval: 03/25 P&T Approval: 04/25

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TREMELIMUMAB-ACTL (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TREMELIMUMAB-ACTL	IMJUDO	48415		GPI-10 (2135528010)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable hepatocellular carcinoma (uHCC) (ICD-10 C22.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Imjudo will be used in combination with Imfinzi (durvalumab)
   - The patient has not received previous treatment with Imjudo

   If yes, **approve for 30 days by HICL or GPI-10 for #1 fill.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient does not have sensitizing epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) genomic tumor aberrations
   - Imjudo will be used in combination with Imfinzi (durvalumab) and platinum-based chemotherapy (e.g., cisplatin, carboplatin)
   - The patient has not received a total of 5 doses of Imjudo

   If yes, **approve for 5 months by HICL or GPI-10 for #5 fills.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TREMELIMUMAB-ACTL (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TREMELIMUMAB-ACTL (Imjudo)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Unresectable hepatocellular carcinoma (uHCC: a type of liver cancer that cannot be removed by surgery)
   2. Metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of the body)

B. If you have unresectable hepatocellular carcinoma, approval also requires:
   1. You are 18 years of age or older
   2. Imjudo will be used in combination with Imfinzi (durvalumab)
   3. You have not received previous treatment with Imjudo

C. If you have metastatic non-small cell lung cancer, approval also requires:
   1. You are 18 years of age or older
   2. You do not have sensitizing epidermal growth factor receptor (EGFR: a type of protein) mutations or anaplastic lymphoma kinase (ALK) genomic tumor aberrations (a type of abnormal gene)
   3. Imjudo will be used in combination with Imfinzi (durvalumab) and platinum-based chemotherapy (a type of cancer treatment, such as cisplatin, carboplatin)
   4. You have not received a total of 5 doses of Imjudo

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Imjudo.

REFERENCES

Imjudo [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; June 2023.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TREMELIMUMAB-ACTL (PART D)

For Part D use only:

TREMELIMUMAB-ACTL (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	UHCC: 30 DAYS. METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC): 5 MONTHS.
Other Criteria	UNRESECTABLE HEPATOCELLULAR CARCINOMA (UHCC): HAS NOT RECEIVED PRIOR TREATMENT WITH IMJUDO. NSCLC: HAS NOT RECEIVED A TOTAL OF 5 DOSES OF IMJUDO.

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 11/22
Client Approval: 06/24
P&T Approval: 01/23

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TREPROSTINIL DPI (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TREPROSTINIL	TYVASO DPI	36541		GPI-10 (4017008000)	FDB & Medi-Span: BRAND = TYVASO DPI%

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1)(ICD-10 I27.0, Group I27.2) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist

   If yes, continue to #2.
   If no, continue to #4.

2. Is the PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of 15 mmHg or less
   - Pulmonary vascular resistance (PVR) greater than 2 Wood units

   If yes, continue to #3.
   If no, do no approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TREPROSTINIL DPI (PART D)

INITIAL CRITERIA (CONTINUED)

3. Has the patient had a trial of or contraindication to **TWO** of the following agents from different drug classes?
   - Oral endothelin receptor antagonist (e.g., Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
   - Oral phosphodiesterase-5 inhibitor indicated for PAH (e.g., Revatio [sildenafil], Adcirca [tadalafil], Alyq [tadalafil], Tadliq [tadalafil])
   - Oral cGMP stimulator (e.g., Adempas [riociguat])
   - IV/SQ prostacyclin (e.g., Flolan [epoprostenol], Veletri [epoprostenol], Remodulin [treprostinil])

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have a diagnosis of pulmonary hypertension associated with interstitial lung disease (PH-ILD) (WHO Group 3) (ICD-10 I27.23) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist

   If yes, continue to #5.
   If no, do no approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

5. Is the PH-ILD diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of 15 mmHg or less
   - Pulmonary vascular resistance (PVR) greater than 2 Wood units

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TREPROSTINIL DPI (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TREPROSTINIL DPI (Tyvaso DPI)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1: a way to classify the severity of disease)
   2. Pulmonary hypertension associated with interstitial lung disease (PH-ILD: a type of heart and lung condition) (WHO Group 3: a way to classify the severity of disease)

B. If you have pulmonary arterial hypertension (WHO Group 1), approval also requires:
   1. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   2. Your pulmonary arterial hypertension diagnosis is confirmed by right heart catheterization (a test used to measure how well the heart is pumping) with ALL of the following lab values:
      a. Mean pulmonary artery pressure (PAP: a type of measurement for pulmonary arterial hypertension) greater than 20 mmHg
      b. Pulmonary capillary wedge pressure (PCWP: a type of measurement for pulmonary arterial hypertension) of 15 mmHg or less
      c. Pulmonary vascular resistance (PVR: a type of measurement for pulmonary arterial hypertension) greater than 2 Wood units
   3. You have tried or have a contraindication to (harmful for you to use) TWO of the following medications from different drug classes:
      a. Oral endothelin receptor antagonist (such as Tracleer [bosentan], Letairis [ambrisentan], Opsumit [macitentan])
      b. Oral phosphodiesterase-5 inhibitor indicated for PAH (such as Adcirca [tadalafil], Alyq [tadalafil], Tadliq [tadalafil], Revatio [sildenafil])
      c. Oral cGMP stimulator (such as Adempas [riociguat])
      d. Intravenous or subcutaneous prostacyclin (such as Flolan [epoprostenol], Veletri [epoprostenol], Remodulin [treprostinil])

(Initial denial text continued on next page)

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TREPROSTINIL DPI (PART D)

INITIAL CRITERIA (CONTINUED)

C. If you have pulmonary hypertension associated with interstitial lung disease (WHO Group 3), approval also requires:

1. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
2. Your pulmonary hypertension diagnosis is confirmed by right heart catheterization (a test used to measure how well the heart is pumping) with ALL of the following lab values:
   a. Mean pulmonary artery pressure (PAP: a type of measurement for pulmonary hypertension) greater than 20 mmHg
   b. Pulmonary capillary wedge pressure (PCWP: a type of measurement for pulmonary hypertension) of 15 mmHg or less
   c. Pulmonary vascular resistance (PVR: a type of measurement for pulmonary hypertension) greater than 2 Wood units

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TREPROSTINIL DPI (PART D)

RENEWAL CRITERIA

1. Does the patient have **ONE** of the following diagnoses?
   - Pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2)
   - Pulmonary hypertension associated with interstitial lung disease (PH-ILD) (WHO Group 3) (ICD-10 I27.23)

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TREPROSTINIL DPI (Tyvaso DPI)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1: a way to classify the severity of disease)
      2. Pulmonary hypertension associated with interstitial lung disease (PH-ILD: a type of heart and lung condition) (WHO Group 3: a way to classify the severity of disease)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Tyvaso DPI.

REFERENCES
Tyvaso DPI [Prescribing Information]. Research Triangle Park, NC: United Therapeutics Corp.; November 2025.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TREPROSTINIL DPI (PART D)

For Part D use only:

TREPROSTINIL DPI (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	INITIAL: PULMONARY ARTERIAL HYPERTENSION (PAH), PULMONARY HYPERTENSION-INTERSTITIAL LUNG DISEASE (PH-ILD): DIAGNOSIS CONFIRMED BY RIGHT HEART CATHETERIZATION WITH THE FOLLOWING PARAMETERS: 1) MEAN PULMONARY ARTERY PRESSURE (PAP) GREATER THAN 20 MMHG, 2) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF 15 MMHG OR LESS, AND 3) PULMONARY VASCULAR RESISTANCE (PVR) GREATER THAN 2 WOOD UNITS.
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: PAH, PH-ILD: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: PAH: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING AGENTS FROM DIFFERENT DRUG CLASSES: 1) ORAL ENDOTHELIN RECEPTOR ANTAGONIST, 2) ORAL PHOSPHODIESTERASE TYPE-5 INHIBITOR FOR PAH, 3) ORAL CGMP STIMULATOR, 4) IV/SQ PROSTACYCLIN.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TREPROSTINIL INHALED (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TREPROSTINIL	TYVASO		27492	GPI-14 (40170080002020)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

This is an inhalation drug that normally requires a nebulizer. If Payment Determination has not been assessed and/or is being contested, please reanalyze or refer to the NEBULIZER BVD DETERMINATION guideline in the library.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1)(ICD-10 I27.0, Group I27.2) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist

   If yes, continue to #2.
   If no, continue to #4.

2. Is the PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of 15 mmHg or less
   - Pulmonary vascular resistance (PVR) greater than 2 Wood units

   If yes, continue to #3.
   If no, do no approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TREPROSTINIL INHALED (PART D)

INITIAL CRITERIA (CONTINUED)

3. Has the patient had a trial of or contraindication to **TWO** of the following agents from different drug classes?
   - Formulary version of an Oral endothelin receptor antagonist (e.g., Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
   - Formulary version of an Oral phosphodiesterase-5 inhibitor indicated for PAH (e.g., Revatio [sildenafil], Adcirca [tadalafil], Alyq [tadalafil], Tadliq [tadalafil])
   - Formulary version of an Oral cGMP stimulator (e.g., Adempas [riociguat])
   - Formulary version of an IV/SQ prostacyclin (e.g., Flolan [epoprostenol], Veletri [epoprostenol], Remodulin [treprostinil])

   If yes, **approve for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have a diagnosis of pulmonary hypertension associated with interstitial lung disease (PH-ILD) (WHO Group 3) (ICD-10 I27.23) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist

   If yes, continue to #5.
   If no, do no approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

5. Is the PH-ILD diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of 15 mmHg or less
   - Pulmonary vascular resistance (PVR) greater than 2 Wood units

   If yes, **approve for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TREPROSTINIL INHALED (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TREPROSTINIL INHALED (Tyvaso)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1: a way to classify the severity of disease)
   2. Pulmonary hypertension associated with interstitial lung disease (PH-ILD: a type of heart and lung condition) (WHO Group 3: a way to classify the severity of disease)

B. If you have pulmonary arterial hypertension (WHO Group 1), approval also requires:
   1. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   2. Your pulmonary arterial hypertension diagnosis is confirmed by right heart catheterization (a test used to measure how well the heart is pumping) with ALL of the following lab values:
      a. Mean pulmonary artery pressure (PAP: a type of measurement for pulmonary arterial hypertension) greater than 20 mmHg
      b. Pulmonary capillary wedge pressure (PCWP: a type of measurement for pulmonary arterial hypertension) of 15 mmHg or less
      c. Pulmonary vascular resistance (PVR: a type of measurement for pulmonary arterial hypertension) greater than 2 Wood units
   3. You have tried or have a contraindication to (harmful for you to use) TWO of the following medications from different drug classes:
      a. Formulary version of an oral endothelin receptor antagonist (such as Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
      b. Formulary version of an oral phosphodiesterase-5 inhibitor indicated for PAH (such as Revatio [sildenafil], Adcirca [tadalafil], Alyq [tadalafil], Tadliq [tadalafil])
      c. Formulary version of an oral cGMP stimulator (such as Adempas [riociguat])
      d. Formulary version of an intravenous or subcutaneous prostacyclin (such as Flolan [epoprostenol], Veletri [epoprostenol], Remodulin [treprostinil])

(Initial denial text continued on next page)

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TREPROSTINIL INHALED (PART D)

INITIAL CRITERIA (CONTINUED)

C. If you have pulmonary hypertension associated with interstitial lung disease (WHO Group 3), approval also requires:

1. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
2. Your pulmonary hypertension diagnosis is confirmed by right heart catheterization (a test used to measure how well the heart is pumping) with ALL of the following lab values:
   a. Mean pulmonary artery pressure (PAP: a type of measurement for pulmonary hypertension) greater than 20 mmHg
   b. Pulmonary capillary wedge pressure (PCWP: a type of measurement for pulmonary hypertension) of 15 mmHg or less
   c. Pulmonary vascular resistance (PVR: a type of measurement for pulmonary hypertension) greater than 2 Wood units

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TREPROSTINIL INHALED (PART D)

RENEWAL CRITERIA

1. Does the patient have **ONE** of the following diagnoses?
   - Pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2)
   - Pulmonary hypertension associated with interstitial lung disease (PH-ILD) (WHO Group 3) (ICD-10 I27.23)

   If yes, **approve for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TREPROSTINIL INHALED (Tyvaso)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1: a way to classify the severity of disease)
      2. Pulmonary hypertension associated with interstitial lung disease (PH-ILD: a type of heart and lung condition) (WHO Group 3: a way to classify the severity of disease)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TREPROSTINIL INHALED (PART D)

RATIONALE

This drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination.

50.16.2 – Inhalation Durable Medical Equipment (DME) Supply Drugs (Rev. 18, 09-17-18)

Medicare Part B covers certain inhalation drugs, such as Albuterol and Levalbuterol nebulizer solutions, as supplies under the DME benefit. The DME benefit, however, is not available to beneficiaries residing in long-term care facilities (i.e. Nursing Facilities and Intermediate Care Facilities for Individuals with Intellectual Disabilities). Consequently, if the beneficiary is not on a Part A stay in one of these facilities, these inhalation drugs can be covered under Medicare Part D. CMS permits Part D sponsors to rely on a patient residence code of "3" or "9" on a pharmacy claim for determining when such inhalation drugs may be covered under Part D. Moreover, we expect that sponsors will only pay claims for these products when the pharmacy claim includes these specified patient residence codes regardless of any prior coverage determination based upon a prescriber statement indicating that the beneficiary resides in a long-term care facility (i.e. the prescriber statement and patient residence code must be aligned). For further information, please refer to the Prescribing Information and/or Drug Monograph for Tyvaso.

REFERENCES

Tyvaso [Prescribing Information]. Research Triangle Park, NC: United Therapeutics Corp.; November 2023.

Medicare Prescription Drug Benefit Manual Chapter 6 – Part D Drugs and Formulary Requirements, Appendix C- Summary of Coverage Policy Medicare Part B Versus Part D Coverage Issues. Rev 10, 02-19-10. Available at: http://www.cms.gov/PrescriptionDrugCovContra/12_PartDManuals.asp. [Accessed February 2, 2026].

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TREPROSTINIL INHALED (PART D)

For Part D use only:

TREPROSTINIL INHALED (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	INITIAL: PULMONARY ARTERIAL HYPERTENSION (PAH), PULMONARY HYPERTENSION-INTERSTITIAL LUNG DISEASE (PH-ILD): DIAGNOSIS CONFIRMED BY RIGHT HEART CATHETERIZATION WITH THE FOLLOWING PARAMETERS: 1) MEAN PULMONARY ARTERY PRESSURE (PAP) GREATER THAN 20 MMHG, 2) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF 15 MMHG OR LESS, AND 3) PULMONARY VASCULAR RESISTANCE (PVR) GREATER THAN 2 WOOD UNITS.
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: PAH, PH-ILD: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: PAH: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING AGENTS FROM DIFFERENT DRUG CLASSES: 1) FORMULARY VERSION OF AN ORAL ENDOTHELIN RECEPTOR ANTAGONIST, 2) FORMULARY VERSION OF AN ORAL PHOSPHODIESTERASE TYPE-5 INHIBITOR FOR PAH, 3) FORMULARY VERSION OF AN ORAL CGMP STIMULATOR, 4) FORMULARY VERSION OF AN IV/SQ PROSTACYCLIN. THIS DRUG MAY BE COVERED UNDER MEDICARE PART B OR D DEPENDING UPON THE CIRCUMSTANCES.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TREPROSTINIL INJECTABLE BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TREPROSTINIL SODIUM	REMODULIN, TREPROSTINIL		17433 17436 17434 17435 58175	GPI-14 (40170080002040, 40170080002050, 40170080002060, 40170080002070, 40170080002080)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	Yes	No	No	Yes	Yes	No	Yes	Yes	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, continue to #6.
   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, continue to #6.
   If no, continue to #5.

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TREPROSTINIL INJECTABLE BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override)**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by GPID or GPI-14 for all strengths under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

6. Is the drug administered via an implantable pump?

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**
   If no, continue to #7.

7. Is the drug administered using an external pump?

   If yes, continue to #8.
   If no, **approve for 12 months by GPID or GPI-14 for all strengths under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

8. Is the drug specifically infused through an external infusion pump covered by Medicare?

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, **approve for 12 months by GPID or GPI-14 for all strengths under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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TREPROSTINIL INJECTABLE BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient's PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of 15 mmHg or less
   - Pulmonary vascular resistance (PVR) greater than 2 Wood units (WU)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Is the request for continuation of Remodulin (treprostinil) therapy from hospital discharge?

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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TREPROSTINIL INJECTABLE BvD (PART D)

INITIAL CRITERIA (CONTINUED)

4. Is the request for a new start of Remodulin (treprostinil) therapy **AND** the patient meets the following criterion?
   - The physician has indicated the patient is intermediate or high risk

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Is the request for a new start of Remodulin (treprostinil) therapy and the patient had a trial of or contraindication to **TWO** of the following agents from different drug classes?
   - Formulary version of an oral endothelin receptor antagonist (e.g., Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
   - Formulary version of an oral phosphodiesterase-5 inhibitor indicated for PAH (e.g., Revatio [sildenafil], Adcirca [tadalafil], Alyq [tadalafil], Tadliq [tadalafil])
   - Formulary version of an oral cGMP stimulator (e.g., Adempas [riociguat])

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TREPROSTINIL INJECTABLE (Remodulin)** requires the following rule(s) be met for approval:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1: a way to classify the severity of disease)
   B. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)

   (Initial denial text continued on next page)

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TREPROSTINIL INJECTABLE BvD (PART D)

INITIAL CRITERIA (CONTINUED)

C. Your pulmonary arterial hypertension diagnosis is confirmed by right heart catheterization (a test used to measure how well the heart is pumping) with ALL of the following lab values:
   1. Mean pulmonary artery pressure (PAP: a type of measurement for pulmonary arterial hypertension) greater than 20 mmHg
   2. Pulmonary capillary wedge pressure (PCWP: a type of measurement for pulmonary arterial hypertension) of 15 mmHg or less
   3. Pulmonary vascular resistance (PVR: a type of measurement for pulmonary arterial hypertension) greater than 2 Wood units

D. You meet ONE of the following:
   1. The request is for continuation of Remodulin (treprostinil) therapy from hospital discharge
   2. The request is for a new start of Remodulin (treprostinil) AND your doctor has indicated you are intermediate or high risk
   3. The request is for a new start of Remodulin (treprostinil) AND you have tried or have a contraindication to (harmful for you to use) TWO of the following medications from different medication classes:
      a. Formulary version of an oral endothelin receptor antagonist (such as Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
      b. Formulary version of an oral phosphodiesterase-5 inhibitor indicated for PAH (such as Revatio [sildenafil], Adcirca [tadalafil], Alyq [tadalafil], Tadliq [tadalafil])
      c. Formulary version of an oral cGMP stimulator (such as Adempas [riociguat])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TREPROSTINIL INJECTABLE BvD (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1)(ICD-10 I27.0; Group I27.2)?

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TREPROSTINIL INJECTABLE (Remodulin)** requires the following rule(s) be met for renewal:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1: a way to classify the severity of disease)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or drug monograph for Remodulin.

The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B. Drugs administered by an implantable pump are covered under Part B. Drugs administered via an external pump are covered under Part B if they are included under the local coverage policy of the applicable Medicare coverage policies (National and/or Local Coverage Policies). Drugs administered via an external pump that are not included under the applicable Medicare coverage policies are covered under Part D. A CMS website to assist with National and Local Coverage Determination for B versus D review is http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx

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TREPROSTINIL INJECTABLE BvD (PART D)

REFERENCES

Remodulin [Prescribing Information]. Research Triangle Park, NC: United Therapeutics Corp.; October 2023.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed April 8, 2025].

For Part D use only:

TREPROSTINIL INJECTABLE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	PULMONARY ARTERIAL HYPERTENSION (PAH): INITIAL: DIAGNOSIS CONFIRMED BY RIGHT HEART CATHETERIZATION WITH THE FOLLOWING PARAMETERS: 1) MEAN PULMONARY ARTERY PRESSURE (PAP) GREATER THAN 20 MMHG, 2) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF 15 MMHG OR LESS, AND 3) PULMONARY VASCULAR RESISTANCE (PVR) GREATER THAN 2 WOOD UNITS.
Age Restrictions	N/A
Prescriber Restrictions	PAH: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS
Other Criteria	PAH: INITIAL: 1) CONTINUATION OF THERAPY FROM HOSPITAL DISCHARGE, 2) NEW START AND PHYSICIAN INDICATED PATIENT IS INTERMEDIATE OR HIGH RISK, OR 3) NEW START AND TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING AGENTS FROM DIFFERENT DRUG CLASSES: (A) FORMULARY VERSION OF AN ORAL ENDOTHELIN RECEPTOR ANTAGONIST, (B) FORMULARY VERSION OF AN ORAL PHOSPHODIESTERASE TYPE-5 INHIBITOR FOR PAH, (C) FORMULARY VERSION OF AN ORAL CGMP STIMULATOR.

Created: 10/16
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 01/24

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TREPROSTINIL ORAL (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TREPROSTINIL DIOLAMINE	ORENITRAM ER	40827		GPI-10 (4017008005)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   - The patient does NOT have severe hepatic impairment

   If yes, continue to #2.
   If no, do no approve.
   DENIAL TEXT: See initial denial text at the end of the guideline.

2. Is the PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of 15 mmHg or less
   - Pulmonary vascular resistance (PVR) greater than 2 Wood units

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Is the request for continuation of Orenitram therapy from hospital discharge?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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TREPROSTINIL ORAL (PART D)

INITIAL CRITERIA (CONTINUED)

4. Is the request for a new start of Orenitram and the patient had a trial of or contraindication to **TWO** of the following agents from different drug classes?

- Oral endothelin receptor antagonist (e.g., Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
- Oral phosphodiesterase-5 inhibitor for PAH (e.g., Revatio [sildenafil], Adcirca [tadalafil], Alyq [tadalafil], Tadliq [tadalafil])
- Oral cGMP stimulator (e.g., Adempas [riociguat])
- Oral prostanoid (e.g., Uptravi [selexipag])
- IV/SQ prostacyclin (e.g., Flolan [epoprostenol], Veletri [epoprostenol], Remodulin [treprostinil])

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TREPROSTINIL ORAL (Orenitram)** requires the following rules be met for approval:

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1: a way to classify the severity of disease)
B. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
C. You do NOT have severe hepatic (liver) impairment
D. Your pulmonary arterial hypertension diagnosis is confirmed by right heart catheterization (a test used to measure how well the heart is pumping) with ALL of the following lab values:
    1. Mean pulmonary artery pressure (PAP: a type of measurement for pulmonary arterial hypertension) greater than 20 mmHg
    2. Pulmonary capillary wedge pressure (PCWP: a type of measurement for pulmonary arterial hypertension) of 15 mmHg or less
    3. Pulmonary vascular resistance (PVR: a type of measurement for pulmonary arterial hypertension) greater than 2 Wood units

(Initial denial text continued on next page)

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TREPROSTINIL ORAL (PART D)

INITIAL CRITERIA (CONTINUED)

E. You meet ONE of the following:
   1. The request is for continuation of Orenitram therapy from hospital discharge
   2. The request is for a new start for Orenitram AND you have tried or have a contraindication to (harmful for you to use) TWO of the following medications from different drug classes:
      a. Oral endothelin receptor antagonist (such as Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
      b. Oral phosphodiesterase-5 inhibitor indicated for PAH (such as Revatio [sildenafil], Adcirca [tadalafil], Alyq [tadalafil], Tadliq [tadalafil])
      c. Oral cGMP stimulator (such as Adempas [riociguat])
      d. Oral prostanoid (such as Uptravi [selexipag])
      e. Intravenous or subcutaneous prostacyclin (such as Flolan [epoprostenol], Veletri [epoprostenol], Remodulin [treprostinil])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TREPROSTINIL ORAL (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH; WHO Group 1) (ICD-10 I27.0, Group I27.2)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TREPROSTINIL ORAL (Orenitram)** requires the following rule(s) be met for renewal:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1: a way to classify the severity of disease)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Orenitram.

REFERENCES

Orenitram [Prescribing Information]. Research Triangle Park, NC: United Therapeutics; February 2023.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TREPROSTINIL ORAL (PART D)

For Part D use only:

TREPROSTINIL ORAL (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	PULMONARY ARTERIAL HYPERTENSION (PAH): INITIAL: DIAGNOSIS CONFIRMED BY RIGHT HEART CATHETERIZATION WITH THE FOLLOWING PARAMETERS: 1) MEAN PULMONARY ARTERY PRESSURE (PAP) GREATER THAN 20 MMHG, 2) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF 15 MMHG OR LESS, AND 3) PULMONARY VASCULAR RESISTANCE (PVR) GREATER THAN 2 WOOD UNITS.
Age Restrictions	N/A
Prescriber Restrictions	PAH: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS
Other Criteria	PAH: INITIAL: 1) NO SEVERE HEPATIC IMPAIRMENT, AND 2) FOR NEW STARTS: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING AGENTS FROM DIFFERENT DRUG CLASSES: (A) ORAL ENDOTHELIN RECEPTOR ANTAGONIST, (B) PHOSPHODIESTERASE TYPE-5 INHIBITOR FOR PAH, (C) ORAL CGMP STIMULATOR, (D) ORAL PROSTANOID, (E) IV/SQ PROSTACYCLIN. FOR CONTINUATION FROM HOSPITAL DISCHARGE: NO STEP THERAPY REQUIRED.

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 02/14
Client Approval: 06/24
P&T Approval: 01/24

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ADVANTAGE AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TREPROSTINIL-YUTREPIA (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TREPROSTINIL SODIUM	YUTREPIA		57781 57782 57783 57784	GPI-10 (4017008010)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist

   If yes, continue to #2.
   If no, continue to #4.

2. Is the patient's PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of 15 mmHg or less
   - Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TREPROSTINIL-YUTREPIA (PART D)

INITIAL CRITERIA (CONTINUED)

3. Has the patient had a trial of or contraindication to **TWO** of the following agents from different drug classes?
   - Oral endothelin receptor antagonist (e.g., Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
   - Oral phosphodiesterase-5 inhibitor indicated for PAH (e.g., Revatio [sildenafil], Adcirca [tadalafil])
   - Oral cGMP stimulator (e.g., Adempas [riociguat])
   - IV/SQ prostacyclin (e.g., Flolan [epoprostenol], Remodulin [treprostinil])

   If yes, **approve all strengths for 12 months by GPID or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have a diagnosis of pulmonary hypertension associated with interstitial lung disease (PH-ILD) (WHO Group 3) (ICD-10 I27.23) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

5. Is the patient's PH-ILD diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of 15 mmHg or less
   - Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

   If yes, **approve all strengths for 12 months by GPID or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TREPROSTINIL-YUTREPIA (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TREPROSTINIL-YUTREPIA** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1: a way to classify the severity of disease)
   2. Pulmonary hypertension associated with interstitial lung disease (PH-ILD: a type of heart and lung condition) (World Health Organization [WHO] Group 3: a way to classify the severity of disease)

B. If you have pulmonary arterial hypertension (WHO Group 1), approval also requires:
   1. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   2. Your pulmonary arterial hypertension diagnosis is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
      a. Mean pulmonary artery pressure (PAP: a type of measurement for pulmonary hypertension) greater than 20 mmHg
      b. Pulmonary capillary wedge pressure (PCWP: a type of measurement for pulmonary hypertension) 15 mmHg or less
      c. Pulmonary vascular resistance (PVR: a type of measurement for pulmonary hypertension) greater than 2 Wood units
   3. You have tried or have a contraindication to (harmful for you to use) TWO of the following medications from different medication classes:
      a. Oral endothelin receptor antagonist (such as Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
      b. Oral phosphodiesterase-5 inhibitor for PAH (such as Revatio [sildenafil], Adcirca [tadalafil])
      c. Oral cGMP stimulator (such as Adempas [riociguat])
      d. Intravenous or subcutaneous prostacyclin (such as Flolan [epoprostenol], Remodulin [treprostinil])

(Initial denial text continued on next page)

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TREPROSTINIL-YUTREPIA (PART D)

INITIAL CRITERIA (CONTINUED)

C. If you have pulmonary hypertension associated with interstitial lung disease (WHO Group 3), approval also requires:

1. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
2. Your pulmonary hypertension diagnosis is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
   a. Mean pulmonary artery pressure (PAP: a type of measurement for pulmonary hypertension) greater than 20 mmHg
   b. Pulmonary capillary wedge pressure (PCWP: a type of measurement for pulmonary hypertension) 15 mmHg or less
   c. Pulmonary vascular resistance (PVR: a type of measurement for pulmonary hypertension) greater than 2 Wood units

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TREPROSTINIL-YUTREPIA (PART D)

RENEWAL CRITERIA

1. Does the patient have **ONE** of the following diagnoses?
   - Pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2)
   - Pulmonary hypertension associated with interstitial lung disease (PH-ILD) (WHO Group 3) (ICD-10 I27.23)

   If yes, **approve all strengths for 12 months by GPID or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TREPROSTINIL-YUTREPIA** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1: a way to classify the severity of disease)
      2. Pulmonary hypertension associated with interstitial lung disease (PH-ILD: a type of heart and lung condition) (World Health Organization [WHO] Group 3: a way to classify the severity of disease)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Yutrepia.

REFERENCES
Yutrepia [Prescribing Information]. Morrisville, NC: Liquidia Technologies, Inc.; May 2025.

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TREPROSTINIL-YUTREPIA (PART D)

For Part D use only:

TREPROSTINIL-YUTREPIA (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	INITIAL: PULMONARY ARTERIAL HYPERTENSION (PAH), PULMONARY HYPERTENSION-INTERSTITIAL LUNG DISEASE (PH-ILD): DIAGNOSIS CONFIRMED BY RIGHT HEART CATHETERIZATION WITH THE FOLLOWING PARAMETERS: 1) MEAN PULMONARY ARTERY PRESSURE (PAP) GREATER THAN 20 MMHG, 2) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF 15 MMHG OR LESS, AND 3) PULMONARY VASCULAR RESISTANCE (PVR) GREATER THAN 2 WOOD UNITS.
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: PAH, PH-ILD: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: PAH: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING AGENTS FROM DIFFERENT DRUG CLASSES: 1) ORAL ENDOTHELIN RECEPTOR ANTAGONIST, 2) ORAL PHOSPHODIESTERASE TYPE-5 INHIBITOR FOR PAH, 3) ORAL CGMP STIMULATOR, 4) IV/SQ PROSTACYCLIN.

Created: 06/25
Effective: 04/04/26 Client Approval: 04/26 P&T Approval: 04/24

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRIENTINE CAPSULE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRIENTINE HCL (CAPSULE)	SYPRINE, TRIENTINE HCL	01109		GPI-10 (9920002010)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
Yes	No	No	Yes	No	No	Yes	No	No	Yes	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Wilson's disease (ICD-10 E83.01) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hepatologist or gastroenterologist
   - The patient has a Leipzig score of 4 or greater
   - The patient had a trial of or contraindication to formulary version of penicillamine tablet

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TRIENTINE CAPSULE (Syprine)** requires the following rule(s) be met for approval:
   A. You have Wilson's disease (a type of genetic disorder)
   B. Therapy is prescribed by or in consultation with a hepatologist (a type of liver doctor) or gastroenterologist (doctor who treats digestive conditions)

   (Initial denial text continued on the next page)

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TRIENTINE CAPSULE (PART D)

INITIAL CRITERIA (CONTINUED)

C. You have a Leipzig score of 4 or greater (a type of diagnostic score)
D. You have tried or have a contraindication to (harmful for you to use) formulary version of penicillamine tablet

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TRIENTINE CAPSULE (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Wilson's disease (ICD-10 E83.01) **AND** meet the following criterion?
   - The patient continues to benefit from the medication

   If yes, **approve for lifetime by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TRIENTINE CAPSULE (Syprine)** requires the following rule(s) be met for renewal:
   A. You have Wilson's disease (a type of genetic disorder)
   B. You continue to benefit from the medication

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Syprine.

REFERENCES
Syprine [Prescribing Information]. Bridgewater, NJ: Bausch Health US, LLC; September 2020.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRIENTINE CAPSULE (PART D)

For Part D use only:

TRIENTINE CAPSULE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	WILSONS DISEASE: INITIAL: LEIPZIG SCORE OF 4 OR GREATER.
Age Restrictions	N/A
Prescriber Restrictions	WILSONS DISEASE: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A HEPATOLOGIST OR GASTROENTEROLOGIST.
Coverage Duration	INITIAL: 12 MONTHS, RENEWAL: LIFETIME.
Other Criteria	WILSONS DISEASE: INITIAL: TRIAL OF OR CONTRAINDICATION TO FORMULARY VERSION OF PENICILLAMINE TABLET. RENEWAL: CONTINUES TO BENEFIT FROM THE MEDICATION.

Created: 11/17
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 10/19

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRIENTINE TABLET (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRIENTINE TETRAHYDROCHLORIDE	CUVRIOR	45888		GPI-10 (9920002020)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Wilson's disease (ICD-10 E83.01) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a hepatologist or gastroenterologist
   - The patient has a prior or current Leipzig score of 4 or greater
   - The patient has a non-ceruloplasmin copper (NCC) level between 50 to 150 mcg/L or a 24-hour urinary copper excretion (UCE) between 100 to 500 mcg/24 hours
   - The patient had a trial of penicillamine for at least one year prior to starting Cuvrior

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TRIENTINE TABLET (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TRIENTINE TABLET (CUVRIOR)** requires the following rule(s) be met for approval:

A. You have Wilson's disease (a type of genetic disorder)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a hepatologist (a type of liver doctor) or gastroenterologist (doctor who treats digestive conditions)
D. You have a prior or current Leipzig score (a type of diagnostic score) of 4 or higher
E. You have a non-ceruloplasmin copper (NCC: a type of laboratory test) level between 50 mcg/L to 150 mcg/L or a 24-hour urinary copper excretion (UCE: a type of laboratory test) between 100 mcg to 500 mcg per 24 hours
F. You have tried penicillamine for at least one year prior to starting Cuvrior

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TRIENTINE TABLET (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Wilson's disease (ICD-10 E83.01) **AND** meet the following criterion?
   - The patient's copper levels are monitored via non-ceruloplasmin copper (NCC) or 24-hour urinary copper excretion (UCE) laboratory test

   If yes, **approve for lifetime by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TRIENTINE TABLET (CUVRIOR)** requires the following rules be met for renewal:
   A. You have Wilson's disease (a type of genetic disorder)
   B. Your body's copper levels are monitored through a non-ceruloplasmin copper (NCC: a type of laboratory test) test or 24-hour urinary copper excretion (UCE: a type of laboratory test) test

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Cuvrior.

REFERENCES
Cuvrior [Prescribing Information]. Chicago, IL: Orphalan SA; April 2022.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRIENTINE TABLET (PART D)

For Part D use only:

TRIENTINE TABLET (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	WILSONS DISEASE: INITIAL: 1) LEIPZIG SCORE OF 4 OR GREATER, AND 2) NONCERULOPLASMIN COPPER (NCC) LEVEL BETWEEN 50 TO 150 MCG/L OR A 24-HOUR URINARY COPPER EXCRETION (UCE) OF BETWEEN 100 TO 500 MCG/24 HOURS.
Age Restrictions	N/A
Prescriber Restrictions	WILSONS DISEASE: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A HEPATOLOGIST OR GASTROENTEROLOGIST.
Coverage Duration	INITIAL: 12 MONTHS. RENEWAL: LIFETIME.
Other Criteria	WILSONS DISEASE: INITIAL: TRIAL OF PENICILLAMINE FOR AT LEAST ONE YEAR PRIOR TO STARTING CUVRIOR. RENEWAL: COPPER LEVELS ARE MONITORED VIA NON-CERULOPLASMIN COPPER (NCC) OR 24-HOUR URINARY COPPER EXCRETION (UCE) TEST.

Part D Effective: 01/01/25 Created: 04/23
Commercial Effective: N/A Client Approval: 06/24 P&T Approval: 10/22

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRIFLURIDINE/TIPIRACIL (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRIFLURIDINE/ TIPIRACIL HCL	LONSURF	42544		GPI-10 (2199000275)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic colorectal cancer (ICD-10 C19) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Lonsurf will be used as a single agent OR in combination with bevacizumab
   - The patient has received treatment with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, and an anti-VEGF biological therapy (e.g., Zaltrap [ziv-aflibercept], Cyramza [ramucirumab])

   If yes, continue to #2.
   If no, continue to #4.

2. Is the patient's metastatic colorectal cancer RAS wild-type?

   If yes, continue to #3.
   If no, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

3. Has the patient had treatment with an anti-EGFR agent (e.g., Erbitux [cetuximab], Vectibix [panitumumab])?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TRIFLURIDINE/TIPIRACIL (PART D)

GUIDELINES FOR USE (CONTINUED)

4. Does the patient have a diagnosis of metastatic gastric or gastroesophageal junction adenocarcinoma (ICD-10 C16.0; Group C16) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received treatment with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/neu-targeted therapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TRIFLURIDINE/TIPIRACIL (Lonsurf)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Metastatic colorectal cancer (a type of digestive system cancer that has spread to other parts of the body)
      2. Metastatic gastric or gastroesophageal junction adenocarcinoma (a type of digestive system cancer that has spread to other parts of the body)

   B. If you have metastatic colorectal cancer, approval also requires:
      1. You are 18 years of age or older
      2. Lonsurf will be used as a single agent OR in combination with bevacizumab
      3. You had treatment with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy (drugs used to treat cancer), and an anti-VEGF biological therapy (such as Zaltrap [ziv-aflibercept], Cyramza [ramucirumab])
      4. If your metastatic colorectal cancer is RAS wild-type (a type of gene), you also had treatment with an anti-EGFR agent (such as Erbitux [cetuximab], Vectibix [panitumumab])

   C. If you have metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:
      1. You are 18 years of age or older
      2. You had treatment with at least two prior lines of chemotherapy (drugs used to treat cancer) that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2 (type of gene)/neu-targeted therapy

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TRIFLURIDINE/TIPIRACIL (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lonsurf.

REFERENCES

Lonsurf [Prescribing Information]; Princeton, NJ: Taiho Oncology, Inc; August 2023.

For Part D use only:

TRIFLURIDINE/TIPIRACIL (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Created: 10/15
Effective: 01/01/25 Client Approval: 08/24 P&T Approval: 10/23

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRIHEPTANOIN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRIHEPTANOIN	DOJOLVI	46676		GPI-10 (8020008000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of a long-chain fatty acid oxidation disorder (LC-FAOD) (ICD-10 Group E71.31) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a gastroenterologist or physician specialist in medical genetics/inherited metabolic disorders
   - The patient is symptomatic (e.g., rhabdomyolysis, cardiomyopathy) for LC-FAOD

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the LC-FAOD diagnosis confirmed by **TWO** of the following criteria?
   - The patient has disease-specific elevations of acylcarnitines on a newborn blood spot or in plasma
   - The patient has low enzyme activity in cultured fibroblasts
   - The patient has one or more known pathogenic mutations in *CPT2, ACADVL, HADHA, or HADHB*

   If yes, **approve for 4 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TRIHEPTANOIN (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TRIHEPTANOIN (Dojolvi)** requires the following rule(s) be met for approval:

A. You have a long-chain fatty acid oxidation disorder (LC-FAOD: a type of rare genetic disorder)
B. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions) or physician specialist in medical genetics/inherited metabolic disorders
C. You are symptomatic for LC-FAOD (such as having rhabdomyolysis [break down of muscle tissue] or cardiomyopathy [disease of the heart muscle])
D. Your LC-FAOD diagnosis is confirmed by TWO of the following:
    1. You have disease-specific elevations of acylcarnitines (a type of carrier for fatty acids) on a newborn blood spot (a type of laboratory test) or in plasma (blood)
    2. You have low enzyme activity in cultured fibroblasts (a type of cell found in the body)
    3. You have one or more known pathogenic mutations in CPT2, ACADVL, HADHA, or HADHB (types of gene mutations)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TRIHEPTANOIN (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of a long-chain fatty acid oxidation disorder (LC-FAOD) (ICD-10 Group E71.31) **AND** meet the following criterion?
   - The patient has had a positive clinical response (e.g., improved exercise tolerance) or stabilization of clinical status compared to baseline

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TRIHEPTANOIN (Dojolvi)** requires the following rule(s) be met for renewal:
   A. You have a long-chain fatty acid oxidation disorder (LC-FAOD: a type of rare genetic disorder)
   B. You have had a positive clinical response (such as improved exercise tolerance), or stabilization of clinical status compared to baseline

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Dojolvi.

REFERENCES

Dojolvi [Prescribing Information]. Novato, CA: Ultragenyx Pharmaceutical Inc.; October 2023.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRIHEPTANOIN (PART D)

For Part D use only:

TRIHEPTANOIN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	LONG-CHAIN FATTY ACID OXIDATION DISORDERS (LC-FAOD): INITIAL: DIAGNOSIS CONFIRMED BY TWO OF THE FOLLOWING: 1) DISEASE-SPECIFIC ELEVATIONS OF ACYLCARNITINES ON A NEWBORN BLOOD SPOT OR IN PLASMA, 2) LOW ENZYME ACTIVITY IN CULTURED FIBROBLASTS, OR 3) ONE OR MORE KNOWN PATHOGENIC MUTATIONS IN CPT2, ACADVL, HADHA, OR HADHB.
Age Restrictions	N/A
Prescriber Restrictions	LC-FAOD: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST OR PHYSICIAN SPECIALIST IN MEDICAL GENETICS/INHERITED METABOLIC DISORDERS.
Coverage Duration	INITIAL: 4 MONTHS, RENEWAL: 12 MONTHS.
Other Criteria	LC-FAOD: INITIAL: SYMPTOMATIC FOR LC-FAOD (E.G., RHABDOMYOLYSIS, CARDIOMYOPATHY). RENEWAL: POSITIVE CLINICAL RESPONSE (E.G., IMPROVED EXERCISE TOLERANCE) OR STABILIZATION OF CLINICAL STATUS COMPARED TO BASELINE.

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25 Created: 07/20
Commercial Effective: N/A Client Approval: 06/24 P&T Approval: 10/20

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRILACICLIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRILACICLIB DIHYDROCHLORIDE	COSELA	47121		GPI-10 (2175657020)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of extensive-stage small cell lung cancer (ES-SCLC) and meet **ALL** of the following?
   - The patient is 18 years of age or older
   - Cosela is being used to decrease the incidence of chemotherapy-induced myelosuppression
   - Cosela will be administered prior to a platinum/etoposide-containing regimen or topotecan-containing regimen

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TRILACICLIB (Cosela)** requires the following rule(s) be met for approval:
   A. You have extensive-stage small cell lung cancer (a type of lung cancer)
   B. You are 18 years of age or older
   C. Cosela is being used to decrease the incidence of chemotherapy-induced myelosuppression (decreased bone marrow activity causing fewer red blood cells, white blood cells, and platelets)
   D. Cosela will be given prior to a platinum/etoposide-containing regimen or topotecan-containing regimen (types of cancer treatment)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TRILACICLIB (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Cosela.

REFERENCES
Cosela [Prescribing Information]. Durham, NC: G1 Therapeutics, Inc.; August 2023.

For Part D use only:

TRILACICLIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 01/22
Client Approval: 06/24
P&T Approval: 04/21

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRIPTORELIN-TRELSTAR BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRIPTORELIN PAMOATE	TRELSTAR		15338 15344 28507	GPI-10 (2140505020)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	Yes	No	Yes	Yes	No	Yes	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #5.

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TRIPTORELIN-TRELSTAR BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override)**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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TRIPTORELIN-TRELSTAR BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced prostate cancer (ICD-10 C61)?

   If yes, **approve for 12 months for all strengths by GPID or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TRIPTORELIN (Trelstar)** requires the following rule(s) be met for approval:
   A. You have advanced prostate cancer (prostate cancer that has spread to nearby tissue or organs)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TRIPTORELIN-TRELSTAR BvD (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Trelstar. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Trelstar [Prescribing Information]. Ewing, NJ: Verity Pharmaceuticals, Inc; March 2023.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed July 1, 2024].

For Part D use only:

TRIPTORELIN-TRELSTAR (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS.
Other Criteria	N/A

Created: 09/22
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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRIPTORELIN-TRIPTODUR BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRIPTORELIN PAMOATE	TRIPTODUR		43603	GPI-10 (3008007040)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	Yes	No	No	Yes	No	No	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #5.

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TRIPTORELIN-TRIPTODUR BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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TRIPTORELIN-TRIPTODUR BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of central precocious puberty (CPP) (ICD-10 E30.1) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See initial denial text at the end of the guideline.

2. Is the request for a female patient who meets **ALL** of the following criteria?
   - The patient has an elevated level of luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
   - The patient is younger than 8 years of age at the onset of CPP
   - The patient is at Tanner stage 2 or above for breast development and pubic hair growth

   If yes, **approve for 12 months by GPID or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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TRIPTORELIN-TRIPTODUR BvD (PART D)

INITIAL CRITERIA (CONTINUED)

3. Is the request for a male patient who meets **ALL** of the following criteria?
   - The patient has an elevated level of luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
   - The patient is younger than 9 years of age at the onset of CPP
   - The patient is at Tanner stage 2 or above for genital development and pubic hair growth

   If yes, **approve for 12 months by GPID or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TRIPTORELIN-TRIPTODUR** requires the following rule(s) be met for approval:
   A. You have central precocious puberty (CPP: early sexual development in children)
   B. You are 2 years of age or older
   C. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
   D. If you are a female, approval also requires:
      1. You have a high level of luteinizing hormone (LH: a type of hormone) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
      2. You are/were younger than 8 years of age when your condition started
      3. You are at Tanner stage 2 or above (scale of physical measurements of development based on external sex characteristics) for breast development and pubic hair growth
   E. If you are a male, approval also requires:
      1. You have a high level of luteinizing hormone (LH: a type of hormone) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
      2. You are/were younger than 9 years of age when your condition started
      3. You are at Tanner stage 2 or above (scale of physical measurements of development based on external sex characteristics) for genital development and pubic hair growth

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRIPTORELIN-TRIPTODUR BvD (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of central precocious puberty (CPP) (ICD-10 E30.1) and meet **ALL** of the following criteria?
   - The patient's Tanner staging at initial diagnosis has stabilized or regressed during three separate medical visits in the previous year
   - The patient has not reached the actual age which corresponds to current pubertal age

   If yes, **approve for 12 months by GPID or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TRIPTORELIN-TRIPTODUR** requires the following rule(s) be met for renewal:
   A. You have central precocious puberty (CPP: early sexual development in children)
   B. Your Tanner staging (scale of physical measurements of development based on external sex characteristics) at initial diagnosis has stabilized or regressed (lowered) during three separate medical visits in the previous year
   C. You have not reached the actual age which corresponds to your current pubertal age

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Triptodur.
The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Triptodur [Prescribing Information]. Woburn, MA: Azurity Pharmaceuticals, Inc.; September 2025.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed February 3, 2026].

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRIPTORELIN-TRIPTODUR BvD (PART D)

For Part D use only:

TRIPTORELIN-TRIPTODUR (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	CENTRAL PRECOCIOUS PUBERTY (CPP): INITIAL: FEMALES: 1) ELEVATED LUTEINIZING HORMONE (LH) LEVEL GREATER THAN 0.2 TO 0.3 MIU/ML AT DIAGNOSIS, AND 2) AT TANNER STAGE 2 OR ABOVE FOR BREAST DEVELOPMENT AND PUBIC HAIR GROWTH. MALES: 1) ELEVATED LH LEVEL GREATER THAN 0.2 TO 0.3 MIU/ML AT DIAGNOSIS, AND 2) AT TANNER STAGE 2 OR ABOVE FOR GENITAL DEVELOPMENT AND PUBIC HAIR GROWTH.
Age Restrictions	N/A
Prescriber Restrictions	CPP: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	CPP: INITIAL: FEMALES: YOUNGER THAN 8 YEARS OF AGE AT ONSET OF CPP. MALES: YOUNGER THAN 9 YEARS OF AGE AT ONSET OF CPP. RENEWAL: 1) TANNER STAGING AT INITIAL DIAGNOSIS HAS STABILIZED OR REGRESSED DURING THREE SEPARATE MEDICAL VISITS IN THE PREVIOUS YEAR, AND 2) HAS NOT REACHED ACTUAL AGE WHICH CORRESPONDS TO CURRENT PUBERTAL AGE.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TROFINETIDE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TROFINETIDE	DAYBUE, DAYBUE STIX	48773		GPI-10 (7465307500)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Rett syndrome (ICD-10 F84.2) **AND** meet the following criterion?
   - The patient is 2 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TROFINETIDE (Daybue, Daybue Stix)** requires the following rule(s) be met for approval:
   A. You have Rett syndrome (a type of nervous system disorder)
   B. You are 2 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TROFINETIDE (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Daybue and Daybue Stix.

REFERENCES

Daybue [Prescribing Information]. San Diego, CA: Acadia Pharmaceuticals Inc.; December 2025.

Daybue Stix [Prescribing Information]. San Diego, CA: Acadia Pharmaceuticals Inc.; December 2025.

For Part D use only:

TROFINETIDE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TUCATINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TUCATINIB	TUKYSA	46459		GPI-10 (2117008000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced unresectable or metastatic breast cancer (ICD-10 Group C50) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's breast cancer is human epidermal growth factor receptor 2 (HER2)-positive
   - The patient has received at least one anti-HER2-based regimen (e.g., trastuzumab, trastuzumab with pertuzumab) in the metastatic setting
   - Tukysa will be used in combination with trastuzumab and capecitabine

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of unresectable or metastatic colorectal cancer (ICD-10 C19) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's colorectal cancer is RAS wild-type, human epidermal growth factor receptor 2 (HER2)-positive
   - The patient's cancer has progressed following treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy
   - Tukysa will be used in combination with trastuzumab

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TUCATINIB (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TUCATINIB (Tukysa)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Advanced unresectable or metastatic breast cancer (cancer that cannot be removed by surgery or has spread to other parts of the body)
   2. Unresectable or metastatic colorectal cancer (a type of digestive cancer that cannot be removed by surgery or has spread to other parts of the body)

B. If you have advanced unresectable or metastatic breast cancer, approval also requires:
   1. You are 18 years of age or older
   2. Your breast cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive
   3. You have received at least one anti-HER2-based treatment (such as trastuzumab, trastuzumab with pertuzumab) for metastatic (has spread to other parts of the body) disease
   4. Tukysa will be used in combination with trastuzumab and capecitabine

C. If you have unresectable or metastatic colorectal cancer, approval also requires:
   1. You are 18 years of age or older
   2. Your colorectal cancer is RAS-wild type (a type of gene), human epidermal growth factor receptor 2 (HER2: a type of protein)-positive
   3. Your cancer has progressed (worsened) following treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy (medications used to treat cancer)
   4. Tukysa will be used in combination with trastuzumab

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TUCATINIB (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Tukysa.

REFERENCES
Tukysa [Prescribing Information]. Bothell, WA: Seagen, Inc., January 2023.

For Part D use only:

TUCATINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

UBLITUXIMAB-XIIY BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
UBLITUXIMAB-XIIY	BRIUMVI	48560		GPI-10 (6240508505)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	Yes	No	No	Yes	No	No	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #5.

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UBLITUXIMAB-XIIY BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

If yes, **Refer to plan. (The health plan makes the final payment determination decision)**

- **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
- **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

UBLITUXIMAB-XIIY BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), to include clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease, and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial and failure of or contraindication to TWO agents indicated for relapsing forms of MS (e.g., Tecfidera [dimethyl fumarate], Vumerity [diroximel fumarate])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: **Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **UBLITUXIMAB-XIIY (Briumvi)** requires the following rules be met for approval:
   A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease returns and goes away), and active secondary progressive disease (advanced disease)
   B. You are 18 years of age or older
   C. You have tried and failed (drug did not work) or have a contraindication to (harmful foryou to use) TWO medications indicated for relapsing forms of MS (such as Tecfidera [dimethyl fumarate], Vumerity [diroximel fumarate])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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UBLITUXIMAB-XIIY BvD (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Review for Briumvi. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Briumvi [Prescribing Information]. Morrisville, NC: TG Therapeutics, Inc; December 2022.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed March 1, 2024].

For Part D use only:

UBLITUXIMAB-XIIY (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	RELAPSING FORM OF MULTIPLE SCLEROSIS (MS): TRIAL AND FAILURE OF OR CONTRAINDICATION TO TWO AGENTS INDICATED FOR RELAPSING FORMS OF MS.

Created: 02/23
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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

UBROGEPANT (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
UBROGEPANT	UBRELVY	46273		GPI-10 (6770108000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for the acute treatment of migraines (ICD-10 Group G43 except G43.7 and G43.E) and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Ubrelvy will NOT be used concurrently with other cGRP inhibitors (e.g., Zavzpret [zavegepant]) for acute treatment of migraines
   - The patient had a trial of or contraindication to ONE triptan (e.g., Maxalt [rizatriptan], Imitrex [sumatriptan], almotriptan)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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UBROGEPANT (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **UBROGEPANT (Ubrelvy)** requires the following rule(s) be met for approval:

A. The request is for the acute (quick onset) treatment of migraines (a type of headache)
B. You are 18 years of age or older
C. You will NOT use Ubrelvy concurrently (at the same time) with other calcitonin gene-related peptide (cGRP) inhibitors (such as Zavzpret [zavegepant]) for acute treatment of migraines
D. You have tried or have a contraindication to (harmful for you to use) ONE triptan (such as Maxalt [rizatriptan], Imitrex [sumatriptan], almotriptan)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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UBROGEPANT (PART D)

RENEWAL CRITERIA

1. Is the request for the acute treatment of migraines (ICD-10 Group G43 except G43.7 and G43.E) **AND** the patient meets the following criterion?
   - Ubrelvy will NOT be used concurrently with other cGRP inhibitors (e.g., Zavzpret [zavegepant]) for acute treatment of migraines

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has experienced an improvement from baseline in a validated acute treatment patient-reported outcome questionnaire (e.g., Migraine Assessment of Current Therapy [Migraine-ACT])
   - Therapy works consistently in the majority of migraine attacks

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **UBROGEPANT (Ubrelvy)** requires the following rule(s) be met for renewal:
   A. The request is for the acute (quick onset) treatment of migraines (a type of headache)
   B. You will not use Ubrelvy concurrently (at the same time) with other calcitonin gene-related peptide (cGRP) inhibitors (such as Zavzpret [zavegepant]) for acute treatment of migraines
   C. You meet ONE of the following:
      1. You have experienced an improvement from baseline in a validated acute treatment patient-reported outcome questionnaire (assessment tool used to help guide treatment such as Migraine Assessment of Current Therapy [MIGRAINE-ACT])
      2. Treatment works consistently in the majority of migraine attacks

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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UBROGEPANT (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Ubrelvy.

REFERENCES
Ubrelvy [Prescribing Information]. Madison, NJ: Allergan; June 2023.

For Part D use only:

UBROGEPANT (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	ACUTE MIGRAINE TREATMENT: INITIAL: 1) TRIAL OF OR CONTRAINDICATION TO ONE TRIPTAN (E.G., SUMATRIPTAN, RIZATRIPTAN), AND 2) NO CONCURRENT USE WITH OTHER CGRP INHIBITORS FOR ACUTE MIGRAINE TREATMENT. RENEWAL: 1) NO CONCURRENT USE WITH OTHER CGRP INHIBITORS FOR ACUTE MIGRAINE TREATMENT, AND 2) ONE OF THE FOLLOWING: (A) IMPROVEMENT FROM BASELINE IN A VALIDATED ACUTE TREATMENT PATIENT-REPORTED OUTCOME QUESTIONNAIRE, OR (B) THERAPY WORKS CONSISTENTLY IN MAJORITY OF MIGRAINE ATTACKS.

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25 Created: 04/20
Commercial Effective: N/A Client Approval: 06/24 P&T Approval: 10/23

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

UPADACITINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
UPADACITINIB	RINVOQ	45955		GPI-10 (6660307200)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had an inadequate response or intolerance to at least one tumor necrosis factor (TNF) blocker (e.g., Humira [adalimumab]/Cyltezo/Yuflyma)
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient had a trial of or contraindication to 3 months of treatment with ONE conventional synthetic DMARD (disease-modifying antirheumatic drug) (e.g., methotrexate at a dose of at least 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, sulfasalazine)
   - Rinvoq will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Xeljanz (tofacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, continue to #2.

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UPADACITINIB (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
- The patient is 2 years of age or older
- The patient had an inadequate response or intolerance to at least one tumor necrosis factor (TNF) blocker (e.g., Enbrel [etanercept])
- Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
- Rinvoq will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Xeljanz (tofacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

If yes, **approve for 6 months by HICL or GPI-10.**
If no, continue to #3.

3. Does the patient have a diagnosis of moderate to severe atopic dermatitis (AD) (ICD-10 Group L20) and meet **ALL** of the following criteria?
- The patient is 12 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist, allergist, or immunologist
- Rinvoq will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Opzelura (ruxolitinib)], PDE-4 inhibitor [e.g., Eucrisa (crisaborole)]) for the treatment of AD

If yes, continue to #4.
If no, continue to #5.

4. Did the patient have a trial of or contraindication to **ONE** of the following?
- Topical corticosteroid (e.g., hydrocortisone, clobetasol propionate, halobetasol propionate)
- Topical calcineurin inhibitor (e.g., Elidel [pimecrolimus], Protopic [tacrolimus])
- Topical PDE-4 inhibitor (e.g., Eucrisa [crisaborole], Adquey [difamilast], Zoryve [roflumilast])
- Topical AhR agonist (e.g., Vtama [tapinarof])
- Topical JAK inhibitor (e.g., Opzelura [ruxolitinib])

If yes, **approve for 6 months by HICL or GPI-10.**
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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UPADACITINIB (PART D)

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had an inadequate response or intolerance to at least one tumor necrosis factor (TNF) blocker (e.g., Humira [adalimumab]/Cyltezo/Yuflyma), OR has received at least one approved systemic therapy (e.g., Skyrizi [risankizumab-rzaa]) if TNF blockers are clinically inadvisable
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Rinvoq will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Xeljanz (tofacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, continue to #6.

6. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had an inadequate response or intolerance to at least one tumor necrosis factor (TNF) blocker (e.g., Humira [adalimumab]/Cyltezo/Yuflyma), OR has received at least one approved systemic therapy (e.g., Skyrizi [risankizumab-rzaa]) if TNF blockers are clinically inadvisable
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Rinvoq will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CD

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, continue to #7.

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UPADACITINIB (PART D)

INITIAL CRITERIA (CONTINUED)

7. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had an inadequate response or intolerance to at least one tumor necrosis factor (TNF) blocker (e.g., Humira [adalimumab]/Cyltezo/Yuflyma)
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Rinvoq will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Xeljanz (tofacitinib)], PDE-4 inhibitor) for the treatment of AS
   - The patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam)

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, continue to #8.

8. Does the patient have a diagnosis of non-radiographic axial spondyloarthritis (nr-axSpA) (ICD-10 Group M45.A) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had an inadequate response or intolerance to at least one tumor necrosis factor (TNF) blocker (e.g., Cimzia [certolizumab pegol])
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient has C-reactive protein (CRP) levels above the upper limit of normal, OR has sacroiliitis on magnetic resonance imaging (MRI)
   - Rinvoq will NOT be used concurrently with another systemic biologic (e.g., Taltz [ixekizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of nr-axSpA
   - The patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam)

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, continue to #9.

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UPADACITINIB (PART D)

INITIAL CRITERIA (CONTINUED)

9. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (pJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - The patient had an inadequate response or intolerance to at least one tumor necrosis factor (TNF) blocker (e.g., Humira [adalimumab]/Cyltezo/Yuflyma)
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Rinvoq will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Xeljanz (tofacitinib)], PDE-4 inhibitor) for the treatment of pJIA

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, continue to #10.

10. Does the patient have a diagnosis of giant cell arteritis (GCA) (ICD-10 M31.5, M31.6) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - The patient has completed, started, or will soon start a tapering course of glucocorticoids (e.g., prednisone)
    - Rinvoq will NOT be used concurrently with another systemic biologic (e.g., Actemra [tocilizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of GCA

    If yes, **approve for 6 months by HICL or GPI-10.**
    If no, do not approve.
    DENIAL TEXT: See the initial denial text at the end of the guideline.

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UPADACITINIB (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: Our guideline named **UPADACITINIB (Rinvoq)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Moderate to severe atopic dermatitis (AD: a type of skin condition)
   4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   5. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   6. Ankylosing spondylitis (AS: a type of joint condition)
   7. Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)
   8. Polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition in children)
   9. Giant cell arteritis (GCA: a type of inflammatory condition)

B. If you have moderate to severe rheumatoid arthritis, approval also requires:
   1. You are 18 years of age or older
   2. You had an inadequate response (drug did not work) or intolerance (side effect) to at least one tumor necrosis factor (TNF) blocker (such as Humira [adalimumab]/Cyltezo/Yuflyma)
   3. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   4. You have tried or have a contraindication to (harmful for you to use) 3 months of treatment with ONE conventional synthetic DMARD (disease-modifying antirheumatic drug, such as methotrexate at a dose of at least 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, sulfasalazine
   5. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis

C. If you have psoriatic arthritis, approval also requires:
   1. You are 2 years of age or older
   2. You had an inadequate response (drug did not work) or intolerance (side effect) to at least one tumor necrosis factor (TNF) blocker (such as Enbrel [etanercept])
   3. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (skin doctor)
   4. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

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UPADACITINIB (PART D)

INITIAL CRITERIA (CONTINUED)

D. If you have moderate to severe atopic dermatitis, approval also requires:
1. You are 12 years of age or older
2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
3. You will NOT use Rinvoq concurrently (at the same time) with other systemic biologics (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Opzelura (ruxolitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Eucrisa (crisaborole)] for the treatment of atopic dermatitis
4. You have tried or have a contraindication to (harmful for you to use) ONE of the following:
   a. Topical corticosteroid (such as hydrocortisone, clobetasol propionate, halobetasol propionate)
   b. Topical calcineurin inhibitor (such as Elidel [pimecrolimus], Protopic [tacrolimus])
   c. Topical PDE-4 inhibitor (such as Eucrisa [crisaborole], Adquey [difamilast], Zoryve [roflumilast])
   d. Topical aryl hydrocarbon receptor (AhR) agonist (such as Vtama [tapinarof])
   e. Topical JAK inhibitor (such as Opzelura [ruxolitinib])

E. If you have moderate to severe ulcerative colitis, approval also requires:
1. You are 18 years of age or older
2. You had an inadequate response (medication did not work) or intolerance (side effect) to at least one tumor necrosis factor (TNF) blocker (such as Humira [adalimumab]/Cyltezo/Yuflyma), OR you have received at least one approved systemic therapy (treatment that targets the entire body such as Skyrizi [risankizumab-rzaa]) if TNF blockers are clinically inadvisable (not recommended)
3. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
4. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

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UPADACITINIB (PART D)

INITIAL CRITERIA (CONTINUED)

F. If you have moderate to severe Crohn's disease, approval also requires:
1. You are 18 years of age or older
2. You had an inadequate response (medication did not work) or intolerance (side effect) to at least one tumor necrosis factor (TNF) blocker (such as Humira [adalimumab]/Cyltezo/Yuflyma), OR you have received at least one approved systemic therapy (treatment that targets the entire body such as Skyrizi [risankizumab-rzaa]) if TNF blockers are clinically inadvisable (not recommended)
3. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
4. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease

G. If you have ankylosing spondylitis, approval also requires:
1. You are 18 years of age or older
2. You had an inadequate response (drug did not work) or intolerance (side effect) to at least one tumor necrosis factor (TNF) blocker (such as Humira [adalimumab]/Cyltezo/Yuflyma)
3. Therapy is prescribed by or in consultation with a rheumatologist (type of immune system doctor)
4. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis
5. You have tried or have a contraindication to (harmful for you to use) an NSAID (nonsteroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)

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UPADACITINIB (PART D)

INITIAL CRITERIA (CONTINUED)

H. If you have non-radiographic axial spondyloarthritis, approval also requires:
1. You are 18 years of age or older
2. You had an inadequate response (drug did not work) or intolerance (side effect) to at least one tumor necrosis factor (TNF) blocker (such as Cimzia [certolizumab pegol])
3. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
4. Your C-reactive protein (CRP: a measure of how much inflammation is in the body) levels are above the upper limit of normal, OR you have sacroiliitis (inflammation where lower spine and pelvis connect) on magnetic resonance imaging (MRI: type of imaging lab)
5. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Taltz [ixekizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-radiographic axial spondyloarthritis
6. You have tried or have a contraindication to (harmful for you to use) an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)

I. If you have polyarticular juvenile idiopathic arthritis, approval also requires:
1. You are 2 years of age or older
2. You had an inadequate response (drug did not work) or intolerance (side effect) to at least one tumor necrosis factor (TNF) blocker (such as Humira [adalimumab]/Cyltezo/Yuflyma)
3. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
4. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis

J. If you have giant cell arteritis, approval also requires:
1. You are 18 years of age or older
2. You have completed, started, or will soon start a tapering course (slowly lowering the dose to stop use) of glucocorticoids (such as prednisone)
3. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Actemra [tocilizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment giant cell arteritis

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UPADACITINIB (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Rinvoq will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Xeljanz (tofacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Rinvoq will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Xeljanz (tofacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

3. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Rinvoq will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Xeljanz (tofacitinib)], PDE-4 inhibitor) for the treatment of AS

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #4.

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UPADACITINIB (PART D)

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of non-radiographic axial spondyloarthritis (nr-axSpA) (ICD-10 Group M45.A) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Rinvoq will NOT be used concurrently with another systemic biologic (e.g., Taltz [ixekizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of nr-axSpA

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #5.

5. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (pJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Rinvoq will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Xeljanz (tofacitinib)], PDE-4 inhibitor) for the treatment of pJIA

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #6.

6. Does the patient have a diagnosis of moderate to severe atopic dermatitis (AD) (ICD-10 Group L20) and meet **ALL** of the following criteria?
   - The patient has shown improvement while on therapy
   - Rinvoq will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Opzelura (ruxolitinib)], PDE-4 inhibitor [e.g., Eucrisa (crisaborole)]) for the treatment of AD

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #7.

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UPADACITINIB (PART D)

RENEWAL CRITERIA (CONTINUED)

7. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) **AND** meet the following criterion?
   - Rinvoq will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Xeljanz (tofacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #8.

8. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) **AND** meet the following criterion?
   - Rinvoq will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CD

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #9.

9. Does the patient have a diagnosis of giant cell arteritis (GCA) (ICD-10 M31.5, M31.6) **AND** meet the following criterion?
   - Rinvoq will NOT be used concurrently with another systemic biologic (e.g., Actemra [tocilizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of GCA

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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UPADACITINIB (PART D)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: Our guideline named **UPADACITINIB (Rinvoq)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Ankylosing spondylitis (AS: a type of joint condition)
   4. Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)
   5. Polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition in children)
   6. Moderate to severe atopic dermatitis (AD: a type of skin condition)
   7. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   8. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   9. Giant cell arteritis (GCA: a type of inflammatory condition)

B. If you have moderate to severe rheumatoid arthritis, renewal also requires:
   1. You continue to benefit from the medication
   2. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis

C. If you have psoriatic arthritis, renewal also requires:
   1. You continue to benefit from the medication
   2. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

D. If you have ankylosing spondylitis, renewal also requires:
   1. You continue to benefit from the medication
   2. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis

E. If you have non-radiographic axial spondyloarthritis, renewal also requires:
   1. You continue to benefit from the medication
   2. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Taltz [ixekizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-radiographic axial spondyloarthritis

(Renewal denial text continued on next page)

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UPADACITINIB (PART D)

RENEWAL CRITERIA (CONTINUED)

F. If you have polyarticular juvenile idiopathic arthritis, renewal also requires:
1. You continue to benefit from the medication
2. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis

G. If you have moderate to severe atopic dermatitis, renewal also requires:
1. You have shown improvement while on therapy
2. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Opzelura (ruxolitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Eucrisa (crisaborole)]) for the treatment of atopic dermatitis

H. If you have moderate to severe ulcerative colitis, renewal also requires:
1. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

I. If you have moderate to severe Crohn's disease, renewal also requires:
1. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease

J. If you have giant cell arteritis, renewal also requires:
1. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Actemra [tocilizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment giant cell arteritis

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Rinvoq.

REFERENCES
Rinvoq [Prescribing Information]. North Chicago, IL: AbbVie Inc.; October 2025.

For Part D use only:

UPADACITINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	INITIAL: NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS (NR-AXSPA): 1) C-REACTIVE PROTEIN LEVELS ABOVE THE

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	UPPER LIMIT OF NORMAL, OR 2) SACROILIITIS ON MAGNETIC RESONANCE IMAGING (MRI).
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: RHEUMATOID ARTHRITIS (RA), ANKYLOSING SPONDYLITIS (AS), NR-AXSPA, POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST OR DERMATOLOGIST. AD: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST, ALLERGIST, OR IMMUNOLOGIST. ULCERATIVE COLITIS (UC), CROHNS DISEASE (CD): PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: RA: TRIAL OF OR CONTRAINDICATION TO 3 MONTHS OF TREATMENT WITH ONE CONVENTIONAL SYNTHETIC DMARD (DISEASE-MODIFYING ANTIRHEUMATIC DRUG) - IF A PATIENT TRIED METHOTREXATE, THEN TRIAL AT A DOSE OF AT LEAST 20 MG PER WEEK OR MAXIMALLY TOLERATED DOSE IS REQUIRED. AD: TRIAL OF OR CONTRAINDICATION TO A TOPICAL CORTICOSTEROID, TOPICAL CALCINEURIN INHIBITOR, TOPICAL PDE4 INHIBITOR, TOPICAL AHR AGONIST OR TOPICAL JAK INHIBITOR. AS, NR-AXSPA: TRIAL OF OR CONTRAINDICATION TO AN NSAID (NON-STEROIDAL ANTI-INFLAMMATORY DRUG). GIANT CELL ARTERITIS (GCA): HAS COMPLETED, STARTED, OR WILL SOON START A TAPERING COURSE OF GLUCOCORTICOIDS. INITIAL/RENEWAL: ALL INDICATIONS: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION. RENEWAL: RA, PSA, AS, NR-AXSPA, PJIA: CONTINUES TO BENEFIT FROM THE MEDICATION. AD: IMPROVEMENT WHILE ON THERAPY.

Created: 08/19
Effective: 08/01/26 Client Approval: 07/26 DMC Approval: 06/30/26

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

URIDINE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
URIDINE TRIACETATE	XURIDEN		39481	GPI-10 (3090387520)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hereditary orotic aciduria (HOA) (ICD-10 E79.89) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with a prescriber specializing in inherited metabolic diseases

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the HOA diagnosis confirmed by **ALL** of the following criteria?
   - The patient has a genetic mutation in the uridine monophosphate synthase (UMPS) gene
   - The patient has an elevated urine orotic acid level according to an age-specific reference range

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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URIDINE (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **URIDINE (Xuriden)** requires the following rule(s) be met for approval:

A. You have hereditary orotic aciduria (HOA: a type of rare genetic disorder)
B. Therapy is prescribed by or in consultation with a prescriber specializing in inherited metabolic diseases
C. Your HOA diagnosis is confirmed by ALL of the following:
    1. You have a genetic mutation in the uridine monophosphate synthase (UMPS) gene (a type of gene)
    2. You have elevated urine orotic acid levels (high levels of a type of substance in the urine) according to an age-specific reference range

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

URIDINE (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary orotic aciduria (HOA) (ICD-10 E79.89) **AND** meet the following criterion?
   - The patient has had improvement from baseline or stabilization of age dependent hematologic parameters (e.g., neutrophil count, neutrophil percent, white blood cell count, mean corpuscular volume)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **URIDINE (Xuriden)** requires the following rule(s) be met for renewal:
   A. You have hereditary orotic aciduria (HOA: a type of rare genetic disorder)
   B. You have had improvement from baseline or stabilization of your age dependent hematologic parameters (blood lab tests such as neutrophil count, neutrophil percent, white blood cell count, mean corpuscular volume)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Xuriden.

REFERENCES
Xuriden [Prescribing Information]. Rockville, MD: Wellstat Therapeutics Corporation; December 2019.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

URIDINE (PART D)

For Part D use only:

URIDINE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	HEREDITARY OROTIC ACIDURIA (HOA): INITIAL: DIAGNOSIS CONFIRMED BY 1) GENETIC MUTATION OF URIDINE MONOPHOSPHATE SYNTHASE (UMPS) GENE, AND 2) ELEVATED URINE OROTIC ACID PER AGE-SPECIFIC REFERENCE RANGE.
Age Restrictions	N/A
Prescriber Restrictions	HOA: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A PRESCRIBER SPECIALIZING IN INHERITED METABOLIC DISEASES
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS
Other Criteria	HOA: RENEWAL: IMPROVEMENT FROM BASELINE OR STABILIZATION OF AGE DEPENDENT HEMATOLOGIC PARAMETERS (E.G., NEUTROPHIL COUNT, NEUTROPHIL PERCENT, WBC COUNT, MEAN CORPUSCULAR VOLUME)

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25 Created: 10/17
Commercial Effective: N/A Client Approval: 06/24 P&T Approval: 05/16

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

USTEKINUMAB-AAUZ SQ (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
USTEKINUMAB-AAUZ	USTEKINUMAB-AAUZ	49894		GPI-10 (9025058579)	GENERIC ONLY

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
Yes	No	No	Yes	No	No	Yes	No	No	Yes	No	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
- The patient is 6 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
- The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #2.

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USTEKINUMAB-AAUZ SQ (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist
   - The patient has psoriasis covering 3% or more of body surface area (BSA) OR psoriatic lesions affecting the hands, feet, genital area, scalp, or face
   - The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet **ONE** of the following criteria?
   - The patient has had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy)
   - The patient has a contraindication or intolerance to both immunosuppressant and PUVA (phototherapy)
   - The patient is switching from a different biologic (e.g., Humira [adalimumab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, **approve for 6 months by HICL or GPI-10**.
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

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USTEKINUMAB-AAUZ SQ (PART D)

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, **approve for 6 months by HICL or GPI-10**.
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **USTEKINUMAB-AAUZ SQ** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Psoriatic arthritis (PsA: a type of skin or joint condition)
      2. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
      3. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
      4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

   B. If you have psoriatic arthritis, approval also requires:
      1. You are 6 years of age or older
      2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (skin doctor)
      3. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

   (Initial denial text continued on next page)

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USTEKINUMAB-AAUZ SQ (PART D)

INITIAL CRITERIA (CONTINUED)

C. If you have moderate to severe plaque psoriasis, approval also requires:
1. You are 6 years of age or older
2. Therapy is prescribed by or in consultation with a dermatologist (skin doctor)
3. You have psoriasis covering 3% or more of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, genital area, scalp, or face
4. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis
5. You meet ONE of the following:
   a. You have had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy)
   b. You have a contraindication (harmful for you to use) or intolerance (side effect) to both immunosuppressant (a type of drug that decreases the body's immune response) and PUVA (phototherapy)
   c. You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication

D. If you have moderate to severe Crohn's disease, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
3. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease

E. If you have moderate to severe ulcerative colitis, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
3. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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USTEKINUMAB-AAUZ SQ (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) **AND** meet the following criterion?
   - The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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USTEKINUMAB-AAUZ SQ (PART D)

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) **AND** meet the following criterion?
   - The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **USTEKINUMAB-AAUZ SQ** requires the following rule(s) be met for renewal:

   A. You have ONE of the following:
      1. Psoriatic arthritis (PsA: a type of skin or joint condition)
      2. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
      3. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
      4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

   B. If you have psoriatic arthritis, renewal also requires:
      1. You continue to benefit from the medication
      2. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

   C. If you have moderate to severe plaque psoriasis, renewal also requires:
      1. You continue to benefit from the medication
      2. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis

   (Renewal denial text continued on next page)

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USTEKINUMAB-AAUZ SQ (PART D)

RENEWAL CRITERIA (CONTINUED)

D. If you have moderate to severe Crohn's disease, renewal also requires:
1. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease

E. If you have moderate to severe ulcerative colitis, renewal also requires:
1. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Otulfi (ustekinumab-aauz).

REFERENCES

Otulfi (ustekinumab-aauz) [Prescribing Information]. Lake Zurich, IL: Fresenius Kabi USA, LLC; January 2026.

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USTEKINUMAB-AAUZ SQ (PART D)

For Part D use only:

USTEKINUMAB-AAUZ SQ (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	INITIAL: PLAQUE PSORIASIS (PSO): PSORIASIS COVERING 3 PERCENT OR MORE OF BODY SURFACE AREA OR PSORIATIC LESIONS AFFECTING THE HANDS, FEET, GENITAL AREA, SCALP OR FACE.
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST. PSO: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST. CROHNS DISEASE (CD), ULCERATIVE COLITIS (UC): PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: PSO: 1) AT LEAST A 3 MONTH TRIAL OF ONE ORAL IMMUNOSUPPRESSANT (CYCLOSPORINE, METHOTREXATE, TACROLIMUS) OR PUVA (PHOTOTHERAPY), 2) CONTRAINDICATION OR INTOLERANCE TO BOTH IMMUNOSUPPRESSANT AND PUVA, OR 3) PATIENT IS SWITCHING FROM A DIFFERENT BIOLOGIC, PDE-4 INHIBITOR, OR JAK INHIBITOR FOR THE SAME INDICATION. INITIAL/RENEWAL: ALL INDICATIONS: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION. RENEWAL: PSA, PSO: CONTINUES TO BENEFIT FROM THE MEDICATION.

Created: 01/26
Effective: 03/01/26 Client Approval: 02/26 P&T Approval: 01/25

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

USTEKINUMAB-AEKN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
USTEKINUMAB-AEKN	SELARSDI	49526		GPI-10 (9025058502)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	Yes	No	Yes	Yes	No	Yes	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding for Selarsdi (ustekinumab-aekn) intravenous infusion route.

Requests for subcutaneous (SC/SQ) Selarsdi (ustekinumab-aekn) do not require Payment Determination.

1. Is the request for intravenous (IV) infusion of Selarsdi for the treatment of moderate tosevere Crohn's disease (CD) or moderate to severe ulcerative colitis (UC)?

   If yes, continue to #2.
   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

2. Is this a pharmacy call?

   If yes, continue to #4.
   If no, continue to #3.

3. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #4.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

4. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, continue to #7.
   If no, continue to #5.

5. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, continue to #7.
   If no, continue to #6.

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USTEKINUMAB-AEKN (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

6. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

7. Is the intravenous infusion administered via an external infusion pump?

   If yes, continue to #8.
   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

8. Is the drug specifically infused through an external infusion pump covered by Medicare?

   If yes, **approve Selarsdi 130 mg/26 mL (for the induction dose) for 12 months by GPID or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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USTEKINUMAB-AEKN (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   - Selarsdi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes**, approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist
   - The patient has psoriasis covering 3% or more of body surface area (BSA) OR psoriatic lesions affecting the hands, feet, genital area, scalp, or face
   - Selarsdi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, continue to #3.
   If no, continue to #4.

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USTEKINUMAB-AEKN (PART D)

INITIAL CRITERIA (CONTINUED)

3. Does the patient meet **ONE** of the following criteria?
   - The patient has had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy)
   - The patient has a contraindication or intolerance to both immunosuppressant and PUVA (phototherapy)
   - The patient is switching from a different biologic (e.g., Humira [adalimumab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Selarsdi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, **approve for 6 months by HICL or GPI-10 for all formulations.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

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USTEKINUMAB-AEKN (PART D)

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Selarsdi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, **approve for 6 months by HICL or GPI-10 for all formulations.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **USTEKINUMAB-AEKN (Selarsdi)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Psoriatic arthritis (PsA: a type of skin or joint condition)
      2. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
      3. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
      4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

   B. If you have psoriatic arthritis, approval also requires:
      1. You are 6 years of age or older
      2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (skin doctor)
      3. You will NOT use Selarsdi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

   (Initial denial text continued on next page)

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USTEKINUMAB-AEKN (PART D)

INITIAL CRITERIA (CONTINUED)

C. If you have moderate to severe plaque psoriasis, approval also requires:
1. You are 6 years of age or older
2. Therapy is prescribed by or in consultation with a dermatologist (skin doctor)
3. You have psoriasis covering 3% or more of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, genital area, scalp, or face
4. You will NOT use Selarsdi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis
5. You meet ONE of the following:
   a. You have had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy)
   b. You have a contraindication (harmful for you to use) or intolerance (side effect) to both immunosuppressant (a type of drug that decreases the body's immune response) and PUVA (phototherapy)
   c. You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication

D. If you have moderate to severe Crohn's disease, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
3. You will NOT use Selarsdi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease

E. If you have moderate to severe ulcerative colitis, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
3. You will NOT use Selarsdi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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USTEKINUMAB-AEKN (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Selarsdi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Selarsdi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) **AND** meet the following criterion?
   - Selarsdi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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USTEKINUMAB-AEKN (PART D)

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) **AND** meet the following criterion?
   - Selarsdi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **USTEKINUMAB-AEKN (Selarsdi)** requires the following rules be met for renewal:

   A. You have ONE of the following:
      1. Psoriatic arthritis (PsA: a type of skin or joint condition)
      2. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
      3. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
      4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

   B. If you have psoriatic arthritis, renewal also requires:
      1. You continue to benefit from the medication
      2. You will NOT use Selarsdi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

   C. If you have moderate to severe plaque psoriasis, renewal also requires:
      1. You continue to benefit from the medication
      2. You will NOT use Selarsdi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis

   (Renewal denial text continued on next page)

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RENEWAL CRITERIA (CONTINUED)

D. If you have moderate to severe Crohn's disease, renewal also requires:
1. You will NOT use Selarsdi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease

E. If you have moderate to severe ulcerative colitis, renewal also requires:
1. You will NOT use Selarsdi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Selarsdi.

The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B. Drugs administered via an external pump are covered under Part B if they are included under the local coverage policy of the applicable Medicare coverage policies (National and/or Local Coverage Policies). Drugs administered via an external pump that are not included under the applicable Medicare coverage policies are covered under Part D. A CMS website to assist with National and Local Coverage Determination for B versus D review is http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx.

REFERENCES

Selarsdi [Prescribing Information]. Parsippany, NJ: Teva Pharmaceuticals; February 2025.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed March 25, 2025].

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USTEKINUMAB-AEKN (PART D)

For Part D use only:

USTEKINUMAB-AEKN IV (PART D) USTEKINUMAB-AEKN SQ (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	INITIAL: PLAQUE PSORIASIS (PSO): PSORIASIS COVERING 3 PERCENT OR MORE OF BODY SURFACE AREA OR PSORIATIC LESIONS AFFECTING THE HANDS, FEET, GENITAL AREA, SCALP OR FACE.
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST. PSO: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST. CROHNS DISEASE (CD), ULCERATIVE COLITIS (UC): PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: PSO: 1) AT LEAST A 3 MONTH TRIAL OF ONE ORAL IMMUNOSUPPRESSANT (CYCLOSPORINE, METHOTREXATE, TACROLIMUS) OR PUVA (PHOTOTHERAPY), 2) CONTRAINDICATION OR INTOLERANCE TO BOTH IMMUNOSUPPRESSANT AND PUVA, OR 3) PATIENT IS SWITCHING FROM A DIFFERENT BIOLOGIC, PDE-4 INHIBITOR, OR JAK INHIBITOR FOR THE SAME INDICATION. INITIAL/RENEWAL: ALL INDICATIONS: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION. RENEWAL: PSA, PSO: CONTINUES TO BENEFIT FROM THE MEDICATION.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

USTEKINUMAB-KFCE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
USTEKINUMAB-KFCE	YESINTEK	50041		GPI-10 (5250407079, 9025058578)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	Yes	No	Yes	Yes	No	Yes	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding for Yesintek (ustekinumab-kfce) intravenous infusion route.

Requests for subcutaneous (SC/SQ) Yesintek (ustekinumab-kfce) do not require Payment Determination.

1. Is the request for intravenous (IV) infusion of Yesintek for the treatment of moderate to severe Crohn's disease (CD) or moderate to severe ulcerative colitis (UC)?

   If yes, continue to #2.
   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

2. Is this a pharmacy call?

   If yes, continue to #4.
   If no, continue to #3.

3. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #4.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

4. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, continue to #7.
   If no, continue to #5.

5. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, continue to #7.
   If no, continue to #6.

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USTEKINUMAB-KFCE (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

6. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

7. Is the intravenous infusion administered via an external infusion pump?

   If yes, continue to #8.
   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

8. Is the drug specifically infused through an external infusion pump covered by Medicare?

   If yes, **approve Yesintek 130 mg/26 mL (for the induction dose) for 12 months by GPID or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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USTEKINUMAB-KFCE (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
- The patient is 6 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
- Yesintek will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

If yes, **approve for 6 months by HICL or GPI-10.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #2.

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USTEKINUMAB-KFCE (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist
   - The patient has psoriasis covering 3% or more of body surface area (BSA) OR psoriatic lesions affecting the hands, feet, genital area, scalp, or face
   - Yesintek will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet **ONE** of the following criteria?
   - The patient has had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy)
   - The patient has a contraindication or intolerance to both immunosuppressant and PUVA (phototherapy)
   - The patient is switching from a different biologic (e.g., Humira [adalimumab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Yesintek will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, **approve for 6 months by HICL or GPI-10 for all formulations**.
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

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USTEKINUMAB-KFCE (PART D)

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Yesintek will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, **approve for 6 months by HICL or GPI-10 for all formulations**.
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **USTEKINUMAB-KFCE (Yesintek)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Psoriatic arthritis (PsA: a type of skin or joint condition)
      2. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
      3. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
      4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

   B. If you have psoriatic arthritis, approval also requires:
      1. You are 6 years of age or older
      2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (skin doctor)
      3. You will NOT use Yesintek concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

   (Initial denial text continued on next page)

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USTEKINUMAB-KFCE (PART D)

INITIAL CRITERIA (CONTINUED)

C. If you have moderate to severe plaque psoriasis, approval also requires:
1. You are 6 years of age or older
2. Therapy is prescribed by or in consultation with a dermatologist (skin doctor)
3. You have psoriasis covering 3% or more of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, genital area, scalp, or face
4. You will NOT use Yesintek concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis
5. You meet ONE of the following:
   a. You have had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy)
   b. You have a contraindication (harmful for you to use) or intolerance (side effect) to both immunosuppressant (a type of drug that decreases the body's immune response) and PUVA (phototherapy)
   c. You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication

D. If you have moderate to severe Crohn's disease, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
3. You will NOT use Yesintek concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease

E. If you have moderate to severe ulcerative colitis, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
3. You will NOT use Yesintek concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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USTEKINUMAB-KFCE (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Yesintek will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - Yesintek will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) **AND** meet the following criterion?
   - Yesintek will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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USTEKINUMAB-KFCE (PART D)

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) **AND** meet the following criterion?
   - Yesintek will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **USTEKINUMAB-KFCE (Yesintek)** requires the following rules be met for renewal:

   A. You have ONE of the following:
      1. Psoriatic arthritis (PsA: a type of skin or joint condition)
      2. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
      3. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
      4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

   B. If you have psoriatic arthritis, renewal also requires:
      1. You continue to benefit from the medication
      2. You will NOT use Yesintek concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

   C. If you have moderate to severe plaque psoriasis, renewal also requires:
      1. You continue to benefit from the medication
      2. You will NOT use Yesintek concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis

   (Renewal denial text continued on next page)

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USTEKINUMAB-KFCE (PART D)

RENEWAL CRITERIA (CONTINUED)

D. If you have moderate to severe Crohn's disease, renewal also requires:
1. You will NOT use Yesintek concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease

E. If you have moderate to severe ulcerative colitis, renewal also requires:
1. You will NOT use Yesintek concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Yesintek.

The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B. Drugs administered via an external pump are covered under Part B if they are included under the local coverage policy of the applicable Medicare coverage policies (National and/or Local Coverage Policies). Drugs administered via an external pump that are not included under the applicable Medicare coverage policies are covered under Part D. A CMS website to assist with National and Local Coverage Determination for B versus D review is http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx.

REFERENCES
Yesintek [Prescribing Information]. Cambridge, MA: Biocon Biologics Inc.; November 2024.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed March 10 2025].

For Part D use only:

USTEKINUMAB-KFCE IV (PART D) USTEKINUMAB-KFCE SQ (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	INITIAL: PLAQUE PSORIASIS (PSO): PSORIASIS COVERING 3 PERCENT OR MORE OF BODY SURFACE AREA OR

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	PSORIATIC LESIONS AFFECTING THE HANDS, FEET, GENITAL AREA, SCALP OR FACE.
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST. PSO: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST. CROHNS DISEASE (CD), ULCERATIVE COLITIS (UC): PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: PSO: 1) AT LEAST A 3 MONTH TRIAL OF ONE ORAL IMMUNOSUPPRESSANT (CYCLOSPORINE, METHOTREXATE, TACROLIMUS) OR PUVA (PHOTOTHERAPY), 2) CONTRAINDICATION OR INTOLERANCE TO BOTH IMMUNOSUPPRESSANT AND PUVA, OR 3) PATIENT IS SWITCHING FROM A DIFFERENT BIOLOGIC, PDE-4 INHIBITOR, OR JAK INHIBITOR FOR THE SAME INDICATION. INITIAL/RENEWAL: ALL INDICATIONS: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION. RENEWAL: PSA, PSO: CONTINUES TO BENEFIT FROM THE MEDICATION.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

USUALLY NON SELF-ADMINISTERED DRUGS (UNSAD) BVD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ALPHA-1-PROTEINASE INHIBITOR	GLASSIA, ARALAST NP, PROLASTIN C, ZEMAIRA	04529		GPI-10 (4510001010)	
BUPRENORPHINE	BRIXADI	23438		GPI-10 (6520001000)	BRAND = BRIXADI
CARBOPLATIN	KYXATA			GPI-14 (21100015002031, 21100015002041)	
DOCETAXEL/ ALBUMIN, HUMAN	BEIZRAY-ALBUMIN	50009		GPI-10 (2150000540)	
FLUOROURACIL	FAVLYXA		97459 97462	GPI-14 (21300030002002, 21300030002008)	
FOSFOMYCIN DISODIUM	CONTEPO	13223		GPI-10 (1600002320)	
GANCICLOVIR SODIUM	GANCICLOVIR SODIUM	04558		GPI-10 (1220003010)	
GEMCITABINE HCL	GEMCITABINE HCL INLEXZO, AVGEMSI	10798		GPI-10 (2130003410)	
GEMCITABINE HCL IN 0.9 % NACL	INFUGEM	45088		GPI-10 (2130003411)	
PACLITAXEL	PACLITAXEL	07625		GPI-10 (2150001200)	
PACLITAXEL PROTEIN-BOUND	ABRAXANE, PACLITAXEL PROTEIN-BOUND	26856		GPI-10 (2150001220)	
LENACAPAVIR SODIUM	SUNLENCA		53433	GPI-14 (12101555202030)	
VORICONAZOLE	VFEND IV, VORICONAZOLE		17499 58651	GPI-14 (11407080002120, 11407080002020)	
PHENOBARBITAL SODIUM	SEZABY		53189	GPI-14 (60100060102110)	
DEGARELIX ACETATE	FIRMAGON	36138		GPI-10 (2140552510)	

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USUALLY NON SELF-ADMINISTERED DRUGS (UNSAD) BVD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CEFTOBIPROLE MEDOCARIL	ZEVTERA	35916		GPI-10 (0250004020)	
NIPOCALIMAB-AAHU	IMAAVY	50526		GPI-10 (9939825501)	
LEUCOVORIN CALCIUM	VYKOURA			GPI-10 (2175504010)	BRAND = VYKOURA
INCLISIRAN SODIUM	LEQVIO	47350		GPI-10 (3935604040)	
TIVIDENOFUSP ALFA-EKNM	AVLAYAH	51241		GPI-10 (3090688000)	
ISATUXIMAB-IRFC	SARCLISA ESCENA	46389		GPI-10 (2135403320)	BRAND = SARCLISA ESCENA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

GUIDELINES FOR USE

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months under Part D for the requested drug. Please note: Multiple approvals by GPID or GPI-14 and/or HICL or GPI-10 may be necessary depending on the drug requested. Please refer to the drug list at the end of the guideline for approval instructions. (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #4.

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USUALLY NON SELF-ADMINISTERED DRUGS (UNSAD) BVD (PART D)

GUIDELINES FOR USE (CONTINUED)

4. Will the patient or caregiver pick up the medication from the pharmacy OR will the medication be shipped directly to the member, who then brings it to the healthcare provider's clinic/office for administration?

   If yes, **approve for 12 months under Part D for the requested drug. Please note: Multiple approvals by GPID or GPI-14 and/or HICL or GPI-10 may be necessary depending on the drug requested. Please refer to the drug list at the end of the guideline for approval instructions. (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #5.

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months under Part B for the requested drug.**
   Please note: Multiple approvals by GPID or GPI-14 and/or HICL or GPI-10 may be necessary depending on the drug requested. Please refer to the drug list at the end of the guideline for approval instructions. (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).

Drug List:

UNSAD Drug Requested	Approval Instructions	HICL	GPID	GPI-10	GPI-14
ALPHA-1-PROTEINASE INHIBITOR	Enter approval by HICL or GPI-10 as listed	04529		4510001010	
BUPRENORPHINE	Enter approval by GPID or GPI-14 as listed		47169 47174 47175 47176 47177 47178 47179		6520001000E523 6520001000E515 6520001000E518 6520001000E565 6520001000E570 6520001000E575 6520001000E560
CARBOPLATIN	Enter approval by GPI-14 as listed				21100015002031 21100015002041

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DOCETAXEL/ ALBUMIN, HUMAN	Enter approval by HICL or GPI-10 as listed	50009		2150000540	
FLUOROURACIL	Enter approval by GPID or GPI-14 as listed		97459 97462		21300030002002 21300030002008
FOSFOMYCIN DISODIUM	Enter approval by HICL as listed	13223		1600002320	
GANCICLOVIR SODIUM	Enter approval by HICL or GPI-10 as listed	04558		1220003010	
GEMCITABINE HCL	Enter approval by HICL or GPI-10 as listed	10798		2130003410	
GEMCITABINE HCL IN 0.9 % NACL	Enter approval by HICL or GPI-10 as listed	45088		2130003411	
PACLITAXEL, PACLITAXEL PROTEIN-BOUND	Enter multiple approvals by both HICLs or GPI-10s as listed	07625 26856		2150001200 2150001220	
LENACAPAVIR SODIUM	Enter approval by GPID or GPI-14 as listed		53433		12101555202030
VORICONAZOLE	Enter approval by GPID or GPI-14 as listed		17499 58651		11407080002120 11407080002020
PHENOBARBITAL SODIUM	Enter approval by GPID or GPI-14 as listed		53189		60100060102110
DEGARELIX ACETATE	Enter approval by HICL or GPI-10 as listed	36138		2140552510	
CEFTOBIPROLE MEDOCARIL	Enter approval by HICL or GPI-10 as listed	35916		0250004020	
NIPOCALIMAB-AAHU	Enter approval by HICL or GPI-10 as listed	50526		9939825501	
LEUCOVORIN CALCIUM	Enter approval by GPI-14 as listed				21755040102035 21755040102051
INCLISIRAN SODIUM	Enter approval by HICL or GPI-10 as listed	47350		3935604040	
TIVIDENOFUSP ALFA-EKNM	Enter approval by HICL or GPI-10 as listed	51241		3090688000	

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ISATUXIMAB-IRFC	Enter approval by GPID or GPI-14 as listed		59395		21354033202060

RATIONALE

The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed March 10, 2026].

For Part D use only:

USUALLY NON SELF-ADMINISTERED DRUGS (UNSAD)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	PART D DOES NOT COVER THIS DRUG WHEN NOT FILLED AT THE PHARMACY AND NOT DISPENSED DIRECTLY TO THE MEMBER/MEMBER REPRESENTATIVE.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 11/21
Effective: 08/22/26 Client Approval: 08/26 DMC Approval: 08/18/26

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VALBENAZINE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VALBENAZINE TOSYLATE	INGREZZA	44202		GPI-10 (6238008020)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of tardive dyskinesia (ICD-10 G24.01) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist, psychiatrist, or movement disorder specialist
   - The patient has a history of using agents that cause tardive dyskinesia (e.g., haloperidol, aripiprazole)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of chorea associated with Huntington's disease (ICD-10 G10) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist or movement disorder specialist

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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VALBENAZINE (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **VALBENAZINE (Ingrezza)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Tardive dyskinesia (uncontrolled body movements)
   2. Chorea (involuntary muscle movements) associated with Huntington's disease (a type of brain disorder)

B. If you have tardive dyskinesia, approval also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor), psychiatrist (a type of mental health doctor), or movement disorder specialist
   3. You have a history of using medications that cause tardive dyskinesia (such as haloperidol, aripiprazole)

C. If you have chorea associated with Huntington's disease, approval also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor) or movement disorder specialist

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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VALBENAZINE (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Ingrezza.

REFERENCES
Ingrezza [Prescribing Information]. San Diego, CA: Neurocrine Biosciences, Inc; August 2023.

For Part D use only:

VALBENAZINE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	TARDIVE DYSKINESIA (TD): PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST, PSYCHIATRIST, OR MOVEMENT DISORDER SPECIALIST. CHOREA ASSOCIATED WITH HUNTINGTONS DISEASE: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST OR MOVEMENT DISORDER SPECIALIST.
Coverage Duration	12 MONTHS
Other Criteria	TD: HISTORY OF USING AGENTS THAT CAUSE TARDIVE DYSKINESIA.

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25 Created: 04/17
Commercial Effective: N/A Client Approval: 06/24 P&T Approval: 04/24

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VAMOROLONE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VAMOROLONE	AGAMREE	49283		GPI-10 (2210007500)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Duchenne muscular dystrophy (DMD) (ICD-10 G71.01) and meet **ALL** of the following criteria?
   - The patient is 2 years of age and older
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient's diagnosis of DMD is confirmed by genetic testing

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Has the patient tried prednisone or prednisolone?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Did the patient experience an adverse effect (e.g., weight gain) on prednisone or prednisolone?

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

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VAMOROLONE (PART D)

INITIAL CRITERIA (CONTINUED)

4. Did the patient experience lack of efficacy with prednisone or prednisolone and meets **ALL** of the following criteria?
   - The patient is not in Stage 1 of the disease (the pre-symptomatic phase)
   - Steroid myopathy has been ruled out
   - The patient has experienced deterioration in ambulation, functional status, or pulmonary function that is consistent with advancing disease (stage 2 or higher)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VAMOROLONE (Agamree)** requires the following rules be met for approval:
   A. You have Duchenne muscular dystrophy (DMD: a type of muscle disorder)
   B. You are 2 years of age and older
   C. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nerve system doctor)
   D. Your diagnosis of DMD is confirmed by genetic testing
   E. You have tried prednisone or prednisolone and meet ONE of the following:
      1. You have experienced an adverse effect (side effects such as weight gain) on prednisone or prednisolone
      2. Prednisone or prednisolone did not work for you, and you meet ALL of the following:
         a. You are not in Stage 1 of the disease (the pre-symptomatic phase)
         b. There is no steroid myopathy (muscle disease due to steroid use)
         c. You have experienced a decrease in ambulation (walking), functional status, or pulmonary (lung) function that is consistent with advancing disease (stage 2 or higher)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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VAMOROLONE (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Duchenne muscular dystrophy (DMD) (ICD-10 G71.01)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the patient currently ambulatory **AND** meets the following criterion?
   - The patient has shown improvement while on Agamree, as assessed by a standard set of ambulatory or functional status measures (e.g., 6-minute walking distance [6MWD], ascending or descending 4 stairs, rise from floor time [Gower's maneuver], 10-meter (30 feet) run/walk time, North Star Ambulatory Assessment [NSAA])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Is the patient currently non-ambulatory **AND** meets the following criterion?
   - The patient has maintained or demonstrated a less than expected decline in pulmonary function or upper limb strength while on Agamree, as assessed by standard measures (e.g., pulmonary function [FVC, PFTs], upper limb strength)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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VAMOROLONE (PART D)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **VAMOROLONE (Agamree)** requires the following rules be met for renewal:

A. You have Duchenne muscular dystrophy (DMD: a type of muscle disorder)

B. If you are currently ambulatory (can walk), approval also requires:

1. You have shown improvement while on Agamree as measured by a standard set of ambulatory or functional status measures (such as, the 6-minute walking distance [6MWD], going up or down 4 stairs, time to rise from the floor [Gower's maneuver], 10-meter (30 feet) run/walk time, North Star Ambulatory Assessment [NSAA: a tool for evaluating Duchenne muscular dystrophy])

C. If you are currently non-ambulatory (cannot walk), approval also requires:

1. You have maintained or had a less than expected decrease in pulmonary (lung) function or upper limb strength while on Agamree as assessed by standard measures (such as pulmonary function [forced vital capacity, pulmonary function tests], upper limb strength)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Agamree.

REFERENCES

Agamree [Prescribing Information]. Burlington, MA: Santhera Pharmaceuticals; October 2023.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VAMOROLONE (PART D)

For Part D use only:

VAMOROLONE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	DUCHENNE MUSCULAR DYSTROPHY (DMD): INITIAL: DIAGNOSIS CONFIRMED BY GENETIC TESTING.
Age Restrictions	N/A
Prescriber Restrictions	DMD: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	DMD: INITIAL: TRIAL OF PREDNISONE OR PREDNISOLONE AND EXPERIENCED: 1) ADVERSE EFFECTS, OR 2) LACK OF EFFICACY AND: (A) NOT IN STAGE 1 (PRE-SYMPTOMATIC PHASE), (B) STEROID MYOPATHY HAS BEEN RULED OUT, AND (C) EXPERIENCED DETERIORATION IN AMBULATION, FUNCTIONAL STATUS, OR PULMONARY FUNCTION CONSISTENT WITH ADVANCING DISEASE. RENEWAL: 1) AMBULATORY AND HAS SHOWN IMPROVEMENT AS MEASURED BY A STANDARD SET OF AMBULATORY OR FUNCTIONAL STATUS MEASURES (E.G., 6-MINUTE WALKING DISTANCE, ASCENDING OR DESCENDING 4 STAIRS, RISE FROM FLOOR TIME, 10 METER RUN/WALK TIME, NORTH STAR AMBULATORY ASSESSMENT), OR 2) NON-AMBULATORY AND HAS MAINTAINED OR HAD A LESS THAN EXPECTED DECREASE IN PULMONARY FUNCTION OR UPPER LIMB STRENGTH AS ASSESSED BY STANDARD MEASURES (E.G., PULMONARY FUNCTION [FVC, PFTS], UPPER LIMB STRENGTH).

Created: 01/24
Effective: 01/01/25 Client Approval: 08/24 P&T Approval: 10/23

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VANDETANIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VANDETANIB	CAPRELSA	37531		GPI-10 (2153308500)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the patient currently stable on the requested medication?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have diagnosis of symptomatic or progressive medullary thyroid cancer (ICD-10 C73) **AND** meet the following criterion?
   - The patient's cancer is unresectable locally advanced or metastatic

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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VANDETANIB (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline for **VANDETANIB (Caprelsa)** requires ONE of the following rule(s) be met for approval:

A. You are currently stable on the requested medication
B. You have symptomatic or progressive medullary thyroid cancer with unresectable locally advanced or metastatic disease (advanced thyroid cancer that cannot be removed with surgery and has spread to nearby tissue, lymph nodes, or other parts of the body)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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VANDETANIB (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Caprelsa.

REFERENCS
Caprelsa [Prescribing Information]. Cambridge, MA: Genzyme Corporation; March 2022.

For Part D use only:

VANDETANIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	CURRENTLY STABLE ON CAPRELSA REQUIRES NO EXTRA CRITERIA.

Core	Advantage	Plus
Yes	Yes	Yes

Created: 05/11
Effective: 01/01/25 Client Approval: 08/24 P&T Approval: 11/14

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ADVANTAGE AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VANZACAFTOR-TEZACAFTOR-DEUTIVACAFTOR (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VANZACAFTOR/ TEZACAF/ DEUTIVACAF	ALYFTREK	50120		GPI-10 (4530990385)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of cystic fibrosis (CF) (ICD-10 Group E84) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a pulmonologist or cystic fibrosis expert
   - Alyftrek will NOT be used concurrently with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (e.g., medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)
   - The patient has at least ONE variant in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is either responsive to Alyftrek based on clinical or in vitro data or that results in the production of CFTR protein

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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VANZACAFTOR-TEZACAFTOR-DEUTIVACAFTOR (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **VANZACAFTOR-TEZACAFTOR-DEUTIVACAFTOR (Alyftrek)** requires the following rule(s) be met for approval:

A. You have cystic fibrosis (CF: a type of lung disorder)
B. You are 6 years of age or older
C. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or cystic fibrosis expert
D. You will NOT use Alyftrek concurrently (at the same time) with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (such as a type of medication containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)
E. You have at least ONE variant in the cystic fibrosis transmembrane conductance regulator (CFTR) gene (a type of gene) that is either responsive to Alyftrek based on clinical or in vitro data (testing outside of the body in a tube) or that results in the production of CFTR protein

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VANZACAFTOR-TEZACAFTOR-DEUTIVACAFTOR (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of cystic fibrosis (CF) (ICD-10 Group E84) and meet **ALL** of the following criteria?
   - The patient has experienced an improvement in clinical status
   - Alyftrek will NOT be used concurrently with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (e.g., medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)

   If yes, **approve for lifetime by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VANZACAFTOR-TEZACAFTOR-DEUTIVACAFTOR (Alyftrek)** requires the following rule(s) be met for renewal:
   A. You have cystic fibrosis (CF: a type of lung disorder)
   B. You have experienced an improvement in your clinical status
   C. You will NOT use Alyftrek concurrently (at the same time) with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (such as a type of medication containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Alyftrek.

REFERENCES

Alyftrek [Prescribing Information]. Boston, MA: Vertex Pharmaceuticals Incorporated; March 2026.

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ADVANTAGE AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VANZACAFTOR-TEZACAFTOR-DEUTIVACAFTOR (PART D)

For Part D use only:

VANZACAFTOR-TEZACAFTOR-DEUTIVACAFTOR (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	CF: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A PULMONOLOGIST OR CYSTIC FIBROSIS EXPERT.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: LIFETIME.
Other Criteria	CF: INITIAL: NO CONCURRENT USE WITH ANOTHER CFTR MODULATOR. RENEWAL: 1) IMPROVEMENT IN CLINICAL STATUS, AND 2) NO CONCURRENT USE WITH ANOTHER CFTR MODULATOR.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VARENICLINE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VARENICLINE TARTRATE	TYRVAYA		51384	GPI-10 (8628008020)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of dry eye disease (ICD-10 Group H04.12) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an ophthalmologist or optometrist
   - The patient has at least one positive diagnostic test (e.g., tear breakup time, tear film osmolarity, ocular surfacing staining, Schirmer test)
   - The patient had a trial of or contraindication to BOTH preferred agents: Xiidra (lifitegrast) and Miebo (perfluorohexyloctane)

   If yes, **approve for 3 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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VARENICLINE (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **VARENICLINE (Tyrvaya)** requires the following rule(s) be met for approval:

A. You have dry eye disease
B. Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or optometrist (a type of eye doctor)
C. You have at least one positive diagnostic test (such as tear breakup time, tear film osmolarity, ocular surfacing staining, Schirmer test)
D. You have tried or have a contraindication to (harmful for you to use) BOTH preferred medications: Xiidra (lifitegrast) and Miebo (perfluorohexyloctane)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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VARENICLINE (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of dry eye disease (ICD-10 Group H04.12) **AND** meet the following criterion?
   - The patient has demonstrated improvement of dry eye disease

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VARENICLINE (Tyrvaya)** requires the following rule(s) be met for renewal:
   A. You have dry eye disease
   B. You have demonstrated improvement of dry eye disease

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Tyrvaya.

REFERENCES
Tyrvaya [Prescribing Information]. Princeton, NJ: Oyster Point Pharma, Inc.; February 2024.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VARENICLINE (PART D)

For Part D use only:

VARENICLINE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	DRY EYE DISEASE: INITIAL: AT LEAST ONE POSITIVE DIAGNOSTIC TEST (E.G., TEAR BREAKUP TIME, TEAR FILM OSMOLARITY, OCULAR SURFACE STAINING, SCHIRMER TEST)
Age Restrictions	N/A
Prescriber Restrictions	DRY EYE DISEASE: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH AN OPHTHALMOLOGIST OR OPTOMETRIST
Coverage Duration	DRY EYE DISEASE: INITIAL: 3 MO. RENEWAL: 12 MO.
Other Criteria	DRY EYE DISEASE: INITIAL: TRIAL OF OR CONTRAINDICATION TO BOTH PREFERRED AGENTS: XIIDRA AND MIEBO. RENEWAL: IMPROVEMENT OF DRY EYE DISEASE.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VEDOLIZUMAB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VEDOLIZUMAB	ENTYVIO	41146		GPI-10 (5250308000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Entyvio will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Selarsdi/Yesintek/ustekinumab-aauz, Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima, Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Tremfya (guselkumab)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

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VEDOLIZUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Entyvio will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Selarsdi/Yesintek/ustekinumab-aauz, Xeljanz (tofacitinib IR or XR), Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima, Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Tremfya (guselkumab)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VEDOLIZUMAB (Entyvio)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
      2. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   B. If you have moderate to severe Crohn's disease, approval also requires:
      1. You are 18 years of age or older
      2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
      3. You will NOT use Entyvio concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease
      4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Selarsdi/Yesintek/ustekinumab-aauz, Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima, Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Tremfya (guselkumab)

   (Initial denial text continued on next page)

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VEDOLIZUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

C. If you have moderate to severe ulcerative colitis, approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
3. You will NOT use Entyvio concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis
4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Selarsdi/Yesintek/ustekinumab-aauz, Xeljanz (tofacitinib immediate-release or extended-release), Humira (adalimumab)/Cyltezo/Yuflyma (adalimumab-aaty)/Hadlima, Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Tremfya (guselkumab)

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VEDOLIZUMAB (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) **AND** meet the following criterion?
   - Entyvio will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) **AND** meet the following criterion?
   - Entyvio will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VEDOLIZUMAB (Entyvio)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
      2. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

   B. If you have moderate to severe Crohn's disease, renewal also requires:
      1. You will NOT use Entyvio concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease

   (Renewal denial text continued on next page)

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VEDOLIZUMAB (PART D)

RENEWAL CRITERIA (CONTINUED)

C. If you have moderate to severe ulcerative colitis, renewal also requires:

1. You will NOT use Entyvio concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Entyvio.

REFERENCES

Entyvio [Prescribing Information]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; February 2026.

For Part D use only:

VEDOLIZUMAB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: CROHNS DISEASE (CD), ULCERATIVE COLITIS (UC): PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL:12 MONTHS.
Other Criteria	INITIAL: CD: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: SELARSDI/YESINTEK/USTEKINUMAB-AAUZ, HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, RINVOQ, SKYRIZI, TREMFYA. UC: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: SELARSDI/YESINTEK/USTEKINUMAB-AAUZ, XELJANZ, HUMIRA/CYLTEZO/YUFLYMA/HADLIMA, RINVOQ, SKYRIZI, TREMFYA. INITIAL/RENEWAL: ALL INDICATIONS: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VELMANASE ALFA-TYCV BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VELMANASE ALFA-TYCV	LAMZEDE	46263		GPI-10 (3090238070)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	Yes	No	No	Yes	No	No	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is the drug administered via an implantable pump?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B. (Populate the B vs. D field with 'B' in the PA override field. If MI does not process Part B for the client, refer the caller/request back to the Health plan)**

   If no, continue to #2.

2. Is the drug administered via an external pump?

   If yes, continue to #3.

   If no, **approve for 12 months by HICL or GPI-10 under Part D. (Populate the B vs. D field with 'D' in the PA override field)**

3. Is the drug specifically infused through an external infusion pump covered by Medicare?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B. (Populate the B vs. D field with 'B' in the PA override field. If MI does not process Part B for the client, refer the caller/request back to the Health plan)**

   If no, **approve for 12 months by HICL or GPI-10 under Part D. (Populate the B vs. D field with 'D' in the PA override field)**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VELMANASE ALFA-TYCV BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of alpha-mannosidosis (ICD-10 E77.1) **AND** meet the following criterion?
   - Lamzede will be used for the treatment of non-central nervous system manifestations of alpha-mannosidosis

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VELMANASE ALFA-TYCV (Lamzede)** requires the following rule(s) be met for approval:
   A. You have alpha-mannosidosis (a type of rare genetic condition)
   B. Lamzede will be used for the treatment of non-central nervous system manifestations (symptoms outside of the brain and spinal cord) of alpha-mannosidosis

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VELMANASE ALFA-TYCV (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lamzede.

The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs administered by an implantable pump are covered under Part B. Drugs administered via an external pump are covered under Part B if they are included under the local coverage policy of the applicable Medicare coverage policies (National and/or Local Coverage Policies). Drugs administered via an external pump that are not included under the applicable Medicare coverage policies are covered under Part D. A CMS website to assist with National and Local Coverage Determination for B versus D review is http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx.

REFERENCES

Lamzede [Prescribing Information]. Cary, NC: Chiesi USA, Inc.; February 2023.

Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Appendix C- Summary of Coverage Policy Medicare Part B Versus Part D Coverage Issues. Rev 10, 02-19-10. Available at: http://www.cms.gov/PrescriptionDrugCovContra/12_PartDManuals.asp. [Accessed February 28, 2024].

For Part D use only:

VELMANASE ALFA-TYCV (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VEMURAFENIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VEMURAFENIB	ZELBORAF	37837		GPI-10 (2153208000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic melanoma (ICD-10 Group C43) and meet **ALL** of the following criteria?
   - The patient has a BRAF V600E mutation as detected by an FDA-approved test
   - Zelboraf will be used alone or in combination with Cotellic (cobimetinib)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of Erdheim-Chester disease (ICD-10 E88.89) **AND** meet the following criterion?
   - The patient has a BRAF V600 mutation

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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VEMURAFENIB (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **VEMURAFENIB (Zelboraf)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Unresectable or metastatic melanoma (a type of skin cancer that cannot be completely removed by surgery or has spread to other parts of the body)
   2. Erdheim-Chester disease (a type of multisystem condition)

B. If you have unresectable or metastatic melanoma, approval also requires:
   1. You have a BRAF V600E mutation (a type of abnormal change in a gene) as detected by a Food and Drug Administration (FDA)-approved test
   2. Zelboraf will be used alone or in combination with Cotellic (cobimetinib)

C. If you have Erdheim-Chester disease, approval also requires:
   1. You have a BRAF V600 mutation (a type of abnormal change in a gene)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zelboraf.

REFERENCES

Zelboraf [Prescribing Information]. South San Francisco, CA: Genentech USA, Inc; May 2020.

For Part D use only:

VEMURAFENIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	MELANOMA: ZELBORAF WILL BE USED ALONE OR IN COMBINATION WITH COTELLIC

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VEMURAFENIB (PART D)

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 08/11
Client Approval: 06/24
P&T Approval: 04/22

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VENETOCLAX (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VENETOCLAX	VENCLEXTA	43284		GPI-10 (2147008000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic lymphocytic leukemia (CLL) (ICD-10 Group C91.1) or small lymphocytic lymphoma (SLL) (ICD-10 Group C83.0) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of acute myeloid leukemia (AML) (ICD-10 Group C92.0) and meet **ALL** of the following criteria?
   - The patient has newly-diagnosed AML
   - Venclexta will be used in combination with azacitidine, OR decitabine, OR low-dose cytarabine

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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VENETOCLAX (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient meet **ONE** of the following criteria?
   - The patient is 75 years of age or older
   - The patient is 18 years of age or older with comorbidities that preclude the use of intensive induction chemotherapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VENETOCLAX (Venclexta)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Chronic lymphocytic leukemia (CLL: a type of blood cancer)
      2. Small lymphocytic lymphoma (SLL: a type of blood cancer)
      3. Acute myeloid leukemia (AML: a type of blood and bone marrow cancer)
   B. If you have chronic lymphocytic leukemia or small lymphocytic lymphoma, approval also requires:
      1. You are 18 years of age or older
   C. If you have acute myeloid leukemia, approval also requires:
      1. You have newly-diagnosed acute myeloid leukemia
      2. You are 75 years of age or older, OR you are 18 years of age or older with comorbidities (additional diseases) that prevent the use of intensive induction chemotherapy (a type of therapy to treat cancer)
      3. Venclexta will be used in combination with azacitidine or decitabine or low-dose cytarabine

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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VENETOCLAX (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Venclexta.

REFERENCES

Venclexta [Prescribing Information]. North Chicago, IL: Abbvie Inc.; June 2022.

For Part D use only:

VENETOCLAX (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 04/16
Client Approval: 06/24
P&T Approval: 07/19

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STANDARD PART D
PRIOR AUTHORIZATION GUIDELINES

VEPDEGESTRANT (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VEPDEGESTRANT	VEPPANU	51300		GPI-10 (2140378000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of advanced or metastatic breast cancer (ICD-10 Group C50) and meet **ALL** of the following criteria?
   - You are 18 years of age or older
   - The patient's cancer is estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative with estrogen receptor-1 (ESR1) gene mutation(s), as detected by an FDA-authorized test
   - The patient has had disease progression following at least ONE line of endocrine therapy (e.g., anastrozole, letrozole)
   - Therapy is prescribed by or in consultation with an oncology specialist
   - Veppanu will NOT be used concurrently with another selective estrogen receptor degrader (SERD) (e.g., Orserdu [elacestrant], Faslodex [fulvestrant], Inluriyo [imlunestrant])

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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VEPDEGESTRANT (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT:

Our guideline named **VEPDEGESTRANT (Veppanu)** requires the following rule(s) be met for approval:

A. You have advanced or metastatic breast cancer (a type of cancer that has spread from where it started to nearby tissue or lymph nodes or to other parts of the body)
B. You are 18 years of age or older
C. Your cancer is estrogen receptor (ER: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative with estrogen receptor-1 (ESR1) gene mutation(s) (abnormal changes in a type of gene), as detected by a Food and Drug Administration (FDA)-authorized test
D. You have had disease progression (worsening) following at least ONE line of endocrine therapy (a type of hormone therapy such as anastrozole, letrozole)
E. Therapy is prescribed by or in consultation with an oncology specialist (a type of cancer doctor)
F. You will NOT use Veppanu concurrently (at the same time) with a selective estrogen receptor degrader (SERD: a type of hormone therapy such as Orserdu [elacestrant], Faslodex [fulvestrant], Inluriyo [imlunestrant])

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STANDARD PART D
PRIOR AUTHORIZATION GUIDELINES

VEPDEGESTRANT (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of advanced or metastatic breast cancer (ICD-10 Group C50) and meet **ALL** of the following criteria?
   - The patient's cancer is estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative with estrogen receptor-1 (ESR1) gene mutation(s), as detected by an FDA-authorized test
   - The patient has demonstrated clinical benefit while on therapy as shown by a partial or complete response OR stable disease
   - Veppanu will NOT be used concurrently with another selective estrogen receptor degrader (SERD) (e.g., Orserdu [elacestrant], Faslodex [fulvestrant], Inluriyo [imlunestrant])

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT:

   Our guideline named **VEPDEGESTRANT (Veppanu)** requires the following rule(s) be met for renewal:
   A. You have advanced or metastatic breast cancer (a type of cancer that has spread from where it started to nearby tissue or lymph nodes or to other parts of the body)
   B. Your cancer is estrogen receptor (ER: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative with estrogen receptor-1 (ESR1) gene mutation(s) (abnormal changes in a type of gene), as detected by a Food and Drug Administration (FDA)-authorized test
   C. You have experienced clinical benefit while on therapy as shown by a partial (cancer has shrunk but did not go away) or complete response (cancer went away completely) OR stable disease (disease has stopped growing or spreading)
   D. You will NOT use Veppanu concurrently (at the same time) with a selective estrogen receptor degrader (SERD: a type of hormone therapy such as Orserdu [elacestrant], Faslodex [fulvestrant], Inluriyo [imlunestrant])

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Veppanu.

REFERENCES
Veppanu [Prescribing Information]. New Haven, CT: Arvinas Operations, Inc.; May 2026.

Created: 08/26
Effective: 09/01/26 DMC Approval: 08/18/26

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VERICIGUAT (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VERICIGUAT	VERQUVO	47075		GPI-10 (4090008500)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of chronic heart failure (ICD-10 Group I50) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has an ejection fraction of less than 45%
   - The patient had a trial of, contraindication, or intolerance to ONE preferred SGLT-2 inhibitor (e.g., Farxiga [dapagliflozin], Xigduo XR [dapagliflozin/metformin], Jardiance [empagliflozin])
   - Verquvo will NOT be used concurrently with Adempas (riociguat) or PDE-5 inhibitors (e.g., vardenafil, tadalafil)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Did the patient have a trial of, contraindication, or intolerance to **ONE** agent from any of the following standard of care classes?
   - ACE inhibitor (e.g., enalapril, lisinopril), ARB (e.g., valsartan, candesartan), or ARNI (e.g., Entresto [sacubitril/valsartan])
   - Beta-blocker (bisoprolol, carvedilol, metoprolol succinate)
   - Aldosterone antagonists (spironolactone, eplerenone)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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VERICIGUAT (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **VERICIGUAT (Verquvo)** requires the following rule(s) be met for approval:

A. You have chronic heart failure (a type of heart condition)
B. You are 18 years of age or older
C. You have an ejection fraction (heart function) of less than 45%
D. You have tried, have a contraindication (harmful for you to use), or intolerance to (side effect) ONE preferred sodium-glucose transporter-2 (SGLT-2) inhibitor (such as Farxiga [dapagliflozin], Xigduo XR [dapagliflozin/metformin], Jardiance [empagliflozin])
E. You will not use Verquvo concurrently (at the same time) with Adempas (riociguat) or phosphodiesterase-5 (PDE-5) inhibitors (such as vardenafil, tadalafil)
F. You have tried, have a contraindication (harmful for you to use), or intolerance to (side effect) ONE medication from any of the following standard of care classes:
    1. Angiotensin converting enzyme (ACE) inhibitor (such as enalapril, lisinopril), angiotensin II receptor blocker (ARB: such as valsartan, candesartan), or angiotensin receptor neprilysin inhibitor (ARNI: such as Entresto [sacubitril/valsartan])
    2. Beta-blocker (bisoprolol, carvedilol, metoprolol succinate)
    3. Aldosterone antagonists (spironolactone, eplerenone)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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VERICIGUAT (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of chronic heart failure (ICD-10 Group I50) and meet **ALL** of the following criteria?
   - The patient has an ejection fraction of less than 45%
   - Verquvo will NOT be used concurrently with Adempas (riociguat) or PDE-5 inhibitors (e.g., vardenafil, tadalafil)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VERICIGUAT (Verquvo)** requires the following rule(s) be met for renewal:
   A. You have chronic heart failure (a type of heart condition)
   B. You have an ejection fraction (heart function) of less than 45%
   C. You will NOT use Verquvo concurrently (at the same time) with Adempas (riociguat) or phosphodiesterase-5 (PDE-5) inhibitors (such as vardenafil, tadalafil)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Verquvo.

REFERENCES

Verquvo [Prescribing Information]. Rahway, NJ: Merck Sharp & Dohme LLC, May 2023.

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VERICIGUAT (PART D)

For Part D use only:

VERICIGUAT (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	HEART FAILURE (HF): INITIAL: 1) TRIAL OF, CONTRAINDICATION, OR INTOLERANCE TO ONE PREFERRED SGLT-2 INHIBITOR, AND 2) TRIAL OF, CONTRAINDICATION, OR INTOLERANCE TO ONE AGENT FROM ANY OF THE FOLLOWING STANDARD OF CARE CLASSES: (A) ACE INHIBITOR, ARB, OR ARNI, (B) BETA BLOCKER (BISOPROLOL, CARVEDILOL, METOPROLOL SUCCINATE), OR (C) ALDOSTERONE ANTAGONIST (SPIRONOLACTONE, EPLERENONE). INITIAL/RENEWAL: NO CONCURRENT USE WITH RIOCIGUAT OR PDE-5 INHIBITORS.

Created: 05/21
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 10/20

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VESTRONIDASE ALFA-VJBK BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VESTRONIDASE ALFA-VJBK	MEPSEVII	44653		GPI-10 (3090768020)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	Yes	No	No	Yes	No	No	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, continue to #6.
   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, continue to #6.
   If no, continue to #5.

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VESTRONIDASE ALFA-VJBK BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enterany override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

6. Is the drug administered via an implantable pump?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, continue to #7.

7. Is the drug administered using an external pump?

   If yes, continue to #8.
   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

8. Is the drug specifically infused through an external infusion pump covered by Medicare?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with 'D' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VESTRONIDASE ALFA-VJBK BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of mucopolysaccharidosis VII (MPS VII, Sly syndrome) (ICD-10 E76.29) as confirmed by **ALL** of the following criteria?
   - The patient's urinary GAG (glycosaminoglycan) level is greater than three times the upper level of normal based on the laboratory assay
   - The patient has beta-glucuronidase enzyme activity deficiency or had genetic testing
   - The patient has ONE of the following clinical signs of MPS VII: enlarged liver and spleen, joint limitations, airway obstructions or pulmonary dysfunction

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a physician specializing in genetic or metabolic disorders
   - The patient has NOT undergone successful bone marrow or stem cell treatment for MPS VII
   - The patient has limitation in mobility, but remains sufficiently ambulatory (e.g., 6MWT [6-minute walk test] can be measured)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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VESTRONIDASE ALFA-VJBK BvD (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **VESTRONIDASE ALFA-VJBK (Mepsevii)** requires the following rule(s) be met for approval:

A. You have mucopolysaccharidosis VII (MPS VII, Sly syndrome: a type of genetic metabolism disorder)
B. Therapy is prescribed by or in consultation with a physician specializing in genetic or metabolic disorders
C. Your diagnosis is confirmed by ALL of the following:
    1. Your urinary glycosaminoglycan (GAG: a type of molecule) level is greater than three times the upper level of normal based on the laboratory test
    2. You have beta-glucuronidase enzyme activity deficiency (absence of a type of enzyme that breaks down molecules) or had genetic testing
    3. You have ONE of the following clinical signs of MPS VII: enlarged liver and spleen, joint limitations, airway obstructions or pulmonary (lung/breathing) dysfunction
D. You have NOT undergone successful bone marrow or stem cell treatment for mucopolysaccharidosis VII
E. You have limitation in mobility, but remain sufficiently ambulatory [able to walk] (for example, you can perform and be measured for a 6MWT [6-minute walk test])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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VESTRONIDASE ALFA-VJBK BvD (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of mucopolysaccharidosis VII (MPS VII, Sly syndrome) (ICD-10 E76.29) **AND** meet the following criterion?
   - The patient has improved, maintained, or demonstrated a less-than-expected decline in ambulatory ability from baseline (e.g., measured by 6MWT)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VESTRONIDASE ALFA-VJBK (Mepsevii)** requires the following rule(s) be met for renewal:
   A. You have mucopolysaccharidosis VII (MPS VII, Sly syndrome: a type of genetic metabolism disorder)
   B. You have improved, maintained, or demonstrated a less-than-expected decline in ambulatory (walking) ability compared to baseline (such as measured by the 6-minute walk test)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Mepsevii.

The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B. Drugs administered by an implantable pump are covered under Part B. Drugs administered via an external pump are covered under Part B if they are included under the local coverage policy of the applicable Medicare coverage policies (National and/or Local Coverage Policies). Drugs administered via an external pump that are not included under the applicable Medicare coverage policies are covered under Part D. A CMS website to assist with National and Local Coverage Determination for B versus D review is http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx.

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VESTRONIDASE ALFA-VJBK BvD (PART D)

REFERENCES

Mepsevii [Prescribing Information]. Novato, CA: Ultragenyx Pharmaceutical Inc.; December 2020.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed July 23, 2025].

For Part D use only:

VESTRONIDASE ALFA-VJBK (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	MUCOPOLYSACCHARIDOSIS VII (MPS VII): INITIAL: DIAGNOSIS CONFIRMED BY: 1) URINARY GAG (GLYCOSAMINOGLYCAN) LEVEL IS GREATER THAN THREE TIMES THE UPPER LEVEL OF NORMAL BASED ON THE LABORATORY ASSAY, 2) BETA-GLUCURONIDASE ENZYME ACTIVITY DEFICIENCY OR GENETIC TESTING, AND 3) ONE CLINICAL SIGN OF MPS VII: ENLARGED LIVER AND SPLEEN, JOINT LIMITATIONS, AIRWAY OBSTRUCTIONS, OR PULMONARY DYSFUNCTION.
Age Restrictions	N/A
Prescriber Restrictions	MPS VII: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A PHYSICIAN SPECIALIZING IN GENETIC OR METABOLIC DISORDERS.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	MPS VII: INITIAL: 1) HAS NOT UNDERGONE SUCCESSFUL BONE MARROW OR STEM CELL TREATMENT FOR MPS VII, AND 2) LIMITATION IN MOBILITY, BUT REMAINS SUFFICIENTLY AMBULATORY. RENEWAL: IMPROVED, MAINTAINED, OR DEMONSTRATED A LESS THAN EXPECTED DECLINE IN AMBULATORY ABILITY FROM BASELINE.

Created: 03/19
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 01/18

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VIGABATRIN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VIGABATRIN	VIGABATRIN, SABRIL, VIGADRONE, VIGPODER		64315 64314	GPI-14 (72170085000320, 72170085003020)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
Yes	No	No	Yes	No	No	Yes	No	No	Yes	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of refractory complex partial seizures (CPS) (ICD-10 Group G40.2) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - The requested medication will be used as adjunctive therapy
   - The potential benefits outweigh the potential risk of vision loss
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient had a trial of or contraindication to TWO antiepileptic agents (e.g., carbamazepine, oxcarbazepine, levetiracetam IR/ER, gabapentin, zonisamide, topiramate, lamotrigine, tiagabine)

     If yes, **approve for 12 months by GPID or GPI-14 for all formulations: tablet and powder packet.**
     APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

     If no, continue to #2.

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VIGABATRIN (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of infantile spasms (ICD-10 Group G40.82) and meet **ALL** of the following criteria?
   - The patient is 1 month to 2 years of age
   - The requested medication will be used as monotherapy
   - The potential benefits outweigh the potential risk of vision loss
   - Therapy is prescribed by or in consultation with a neurologist

   If yes, **approve for 12 months by GPID or GPI-14 for the powder packet.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VIGABATRIN (Sabril, Vigadrone, Vigpoder)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Refractory complex partial seizures (a type of seizure)
      2. Infantile spasms (a type of seizure disorder in infancy and childhood)
   B. If you have refractory complex partial seizures, approval also requires:
      1. You are 2 years of age or older
      2. The requested medication will be used as adjunctive (add-on) therapy
      3. The potential benefits outweigh the potential risk of vision loss
      4. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
      5. You have tried or have a contraindication to (harmful for you to use) TWO antiepileptic medications (medications used to treat seizures such as carbamazepine, oxcarbazepine, levetiracetam immediate-release or extended-release, gabapentin, zonisamide, topiramate, lamotrigine, tiagabine)
   C. If you have infantile spasms, approval also requires:
      1. You are 1 month to 2 years of age
      2. The requested medication will be used as monotherapy (one drug treatment)
      3. The potential benefits outweigh the potential risk of vision loss
      4. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VIGABATRIN (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of refractory complex partial seizures (CPS) (ICD-10 Group G40.2)?

   If yes, **approve for 12 months by GPID or GPI-14 for all formulations: tablet and powder packet.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of infantile spasms (ICD-10 Group G40.82) **AND** meet the following criterion?
   - The patient is 1 month to 2 years of age

   If yes, **approve for 12 months by GPID or GPI-14 for the powder packet.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VIGABATRIN (Sabril, Vigadrone, Vigpoder)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Refractory complex partial seizures (a type of seizure)
      2. Infantile spasms (a type of seizure disorder in infancy and childhood)
   B. If you have infantile spasms, renewal also requires:
      1. You are 1 month to 2 years of age

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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VIGABATRIN (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sabril, Vigadrone, and Vigpoder.

REFERENCES

Sabril [Prescribing Information]. Deerfield, IL: Lundbeck Pharmaceuticals; December 2021.
Vigadrone [Prescribing Information]. Maple Grove, MN: Upsher-Smith Laboratories, LLC.; January 2024.
Vigpoder [Prescribing Information]. Parsippany, NJ: Pyros Pharmaceuticals, Inc; July 2023.

For Part D use only:

VIGABATRIN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	INITIAL: REFRACTORY COMPLEX PARTIAL SEIZURES (CPS), INFANTILE SPASMS: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS
Other Criteria	INITIAL: CPS: TRIAL OF OR CONTRAINDICATION TO TWO ANTIEPILEPTIC AGENTS.

Created: 10/19
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 07/25

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PLUS DRUG OPEN FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VIGABATRIN SOLUTION (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VIGABATRIN	VIGAFYDE		55889	GPI-14 (72170085002020)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of infantile spasms (ICD-10 Group G40.82) and meet **ALL** of the following criteria?
   - The patient is 1 month to 2 years of age
   - Vigafyde will be used as monotherapy
   - The potential benefits outweigh the potential risk of vision loss
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient had a trial of or contraindication to generic vigabatrin powder

   If yes, **approve for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   INITIAL DENIAL TEXT: See the initial denial text at the end of the guideline.

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VIGABATRIN SOLUTION (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **VIGABATRIN SOLUTION (Vigafyde)** requires the following rule(s) be met for approval:

A. You have infantile spasms (a type of seizure disorder in infancy and childhood)
B. You are 1 month to 2 years of age
C. Vigafyde will be used as monotherapy (one medication treatment)
D. The potential benefits outweigh the potential risk of vision loss
E. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
F. You have tried or have a contraindication to (harmful for you to use) generic vigabatrin powder

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS DRUG OPEN FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VIGABATRIN SOLUTION (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of infantile spasms (ICD-10 Group G40.82) **AND** meet the following criterion?
   - The patient is 1 month to 2 years of age

   If yes, **approve for 12 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VIGABATRIN SOLUTION (Vigafyde)** requires the following rule(s) be met for renewal:
   A. You have infantile spasms (a type of seizure disorder in infancy and childhood)
   B. You are 1 month to 2 years of age

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Vigafyde.

REFERENCES
Vigafyde [Prescribing Information]. Maple Grove, MN: Upsher-Smith Laboratories, LLC; February 2025.

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PLUS DRUG OPEN FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VIGABATRIN SOLUTION (PART D)

For Part D use only:

VIGABATRIN SOLUTION (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	INFANTILE SPASMS (IS): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST.
Coverage Duration	INITIAL/RENWEAL: 12 MONTHS
Other Criteria	IS: INITIAL: TRIAL OF OR CONTRAINDICATION TO GENERIC VIGABATRIN POWDER.

Created: 11/24
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 07/25

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VILTOLARSEN (PART D)

Generic	Brand	HICL	GCN	Exception/Other
VILTOLARSEN	VILTEPSO	46773		

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Duchenne muscular dystrophy (DMD) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient has a confirmed mutation of the DMD gene that is amenable to exon 53 skipping therapy
   - The patient is ambulatory
   - The patient is currently receiving treatment with or has a contraindication to corticosteroids (e.g., prednisone, prednisolone)

   If yes, **approve for 6 months by HICL.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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VILTOLARSEN (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **VILTOLARSEN (Viltepso)** requires the following rule(s) be met for approval:

A. You have Duchenne muscular dystrophy (DMD: a type of muscle disorder)
B. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor)
C. You have a confirmed mutation of the DMD gene that will respond to exon 53 skipping therapy (a process that allows a protein to still function with sections of faulty genetic code)
D. You are ambulatory (able to walk)
E. You are currently receiving treatment with or you have a contraindication (harmful for) to corticosteroids (such as prednisone, prednisolone)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VILTOLARSEN (PART D)

RENEWAL CRITERIA

1. Does the patient meet **ONE** of the following criteria?
   - The patient has maintained or demonstrated a less than expected decline in ambulatory ability based on muscle function assessments (e.g., 6-minute walk test)
   - The patient has maintained or demonstrated a less than expected decline in other muscle function (i.e., pulmonary or cardiac function)

   If yes, **approve for 12 months by HICL.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VILTOLARSEN (Viltepso)** requires ONE of the following rule(s) be met for renewal:
   A. You have maintained or demonstrated a less than expected decline in ambulatory ability (ability to walk) based on muscle function assessments (such as the 6-minute walk test)
   B. You have maintained or demonstrated a less than expected decline in other muscle function (pulmonary [lung] or cardiac [heart] function)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monographs for Viltepso.

REFERENCES

Viltepso [Prescribing Information]. Paramus, NJ: NS Pharma, Inc.; January 2023.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VILTOLARSEN (PART D)

For Part D use only:

VILTOLARSEN (PART D)	
Covered uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	DUCHENNE MUSCULAR DYSTROPHY (DMD): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS
Other Criteria	DMD: INITIAL: AMBULATORY AND CURRENTLY RECEIVING TREATMENT WITH OR HAS A CONTRAINDICATION TO CORTICOSTEROIDS. RENEWAL: MAINTAINED OR DEMONSTRATED A LESS THAN EXPECTED DECLINE IN AMBULATORY ABILITY IN MUSCLE FUNCTION ASSESSMENTS OR OTHER MUSCLE FUNCTION (I.E., PULMONARY OR CARDIAC FUNCTION)

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/24
Commercial Effective: N/A
Created: 10/20
Client Approval: 10/23
P&T Approval: 10/20

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VIMSELTINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VIMSELTINIB	ROMVIMZA	50284		GPI-10 (2153178000)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of symptomatic tenosynovial giant cell tumor (TGCT) (ICD-10 D48.1; Group M12.2) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Surgical resection of the tumor may cause worsening functional limitation or severe morbidity

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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VIMSELTINIB (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **VIMSELTINIB (Romvimza)** requires the following rule(s) be met for approval:

A. You have symptomatic tenosynovial giant cell tumor (TGCT: a type of tumor that affects joints)
B. You are 18 years of age or older
C. Surgical resection (removal by surgery) of the tumor may cause worsening functional limitation or severe morbidity (illness)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Romvimza.

REFERENCES

Romvimza [Prescribing Information]. Waltham, MA: Deciphera Pharmaceuticals, LLC; February 2025.

For Part D use only:

VIMSELTINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 03/25
Effective: 04/01/25 Client Approval: 03/25 P&T Approval: 04/25

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VISMODEGIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VISMODEGIB	ERIVEDGE	38455		GPI-10 (2137007000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic basal cell carcinoma (ICD-10 C44.01, C44.41, C44.81, C44.91; Groups C44.11, C44.21, C44.31, C44.51, C44.61, C44.71) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of locally advanced basal cell carcinoma (ICD-10 C44.01, C44.41, C44.81, C44.91; Groups C44.11, C44.21, C44.31, C44.51, C44.61, C44.71) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer has recurred following surgery OR the patient is not a candidate for surgery or radiation

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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VISMODEGIB (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **VISMODEGIB (Erivedge)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Metastatic basal cell carcinoma (a type of skin cancer that has spread to other parts of the body)
   2. Locally advanced basal cell carcinoma (a type of skin cancer that has spread from where it started to nearby tissue or lymph nodes)

B. If you have metastatic basal cell carcinoma, approval also requires:
   1. You are 18 years of age or older

C. If you have locally advanced basal cell carcinoma, approval also requires:
   1. You are 18 years of age or older
   2. Your cancer has returned after surgery OR you are not a candidate for surgery or radiation.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Erivedge.

REFERENCES

Erivedge [Prescribing Information]. South San Francisco, CA: Genentech USA, Inc., March 2023.

For Part D use only:

VISMODEGIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VISMODEGIB (PART D)

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 02/12
Client Approval: 06/24
P&T Approval: 01/22

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VOCLOSPORIN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VOCLOSPORIN	LUPKYNIS	47077		GPI-10 (9940208000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of lupus nephritis (LN) (ICD-10 M32.14) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist or nephrologist
   - Lupkynis will be used in combination with a background immunosuppressive therapy regimen (e.g., mycophenolate mofetil, corticosteroids [e.g., prednisone])

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VOCLOSPORIN (Lupkynis)** requires the following rule(s) be met for approval:
   A. You have lupus nephritis (LN: a type of immune condition that affects the kidneys)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or nephrologist (a type of kidney doctor)
   D. Lupkynis will be used in combination with a background immunosuppressive therapy regimen (such as mycophenolate mofetil, corticosteroids [such as prednisone])
   (Initial denial text continued on next page)

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VOCLOSPORIN (PART D)

INITIAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VOCLOSPORIN (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of lupus nephritis (LN) (ICD-10 M32.14) **AND** meet the following criterion?
   - The patient has had improvement in renal response from baseline laboratory values (i.e., eGFR or proteinuria) and/or clinical parameters (e.g., fluid retention, use of rescue drugs, glucocorticoid dose)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VOCLOSPORIN (Lupkynis)** requires the following rule(s) be met for renewal:
   A. You have lupus nephritis (LN: a type of immune condition that affects the kidneys)
   B. You have had improvement in kidney response as compared to baseline laboratory values (estimated glomerular filtration rate [eGFR: a tool for evaluating kidney function] or proteinuria [level of protein in urine]) and/or clinical parameters (such as fluid retention, use of rescue drugs, steroid dose)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Lupkynis.

REFERENCES
Lupkynis [Prescribing Information]. Victoria, BC: Aurinia Pharmaceuticals Inc.; January 2021.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VOCLOSPORIN (PART D)

For Part D use only:

VOCLOSPORIN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	LUPUS NEPHRITIS (LN): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST OR NEPHROLOGIST
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	LN: RENEWAL: IMPROVEMENT IN RENAL RESPONSE FROM BASELINE LABORATORY VALUES (I.E., EGFR OR PROTEINURIA) AND/OR CLINICAL PARAMETERS.

Core	Advantage	Plus
No	No	Yes

Created: 02/21
Effective: 01/01/25 Client Approval: 08/24 P&T Approval: 01/21

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VONOPRAZAN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VONOPRAZAN FUMARATE	VOQUEZNA	48007		GPI-10 (4927508710)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of *Helicobacter pylori* (*H. pylori*) infection (ICD-10 B96.81) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Voquezna will be used in combination with amoxicillin OR amoxicillin and clarithromycin

   If yes, **approve for 30 days by HICL or GPI-10 for one fill.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

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VONOPRAZAN (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of erosive esophagitis (ICD-10 Group K20) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to TWO proton pump inhibitors (e.g., lansoprazole capsules, esomeprazole magnesium capsules, rabeprazole, omeprazole, pantoprazole) at the maximum dose for 8 weeks each

   If yes, **approve for 8 weeks by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Does the patient have a diagnosis of non-erosive gastroesophageal reflux disease (ICD-10 Group K21 except for K21.01) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient does not have a previous treatment failure with Voquezna in the last 12 months
   - The patient had a trial of or contraindication to ONE proton pump inhibitor (e.g., lansoprazole capsules, esomeprazole magnesium capsules, rabeprazole, omeprazole, pantoprazole) at the maximum dose for 8 weeks

   If yes, **approve for 4 weeks by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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VONOPRAZAN (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **VONOPRAZAN (Voquezna)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. *Helicobacter pylori* (*H. pylori*: a type of bacteria) infection
   2. Erosive esophagitis (a type of digestive disorder)
   3. Non-erosive gastroesophageal reflux disease (a type of digestive disorder)

B. If you have a *Helicobacter pylori* infection, approval also requires:
   1. You are 18 years of age or older
   2. Voquezna will be used in combination with amoxicillin OR amoxicillin and clarithromycin

C. If you have erosive esophagitis, approval also requires:
   1. You are 18 years of age or older
   2. You had a trial of or contraindication to (harmful for you to use) TWO proton pump inhibitors (such as lansoprazole capsules, esomeprazole magnesium capsules, rabeprazole, omeprazole, pantoprazole) at the maximum dose for 8 weeks each

D. If you have non-erosive gastroesophageal reflux disease, approval also requires:
   1. You are 18 years of age or older
   2. You do not have a previous treatment failure (drug did not work) with Voquezna in the last 12 months
   3. You have tried or have a contraindication to (harmful for you to use) ONE proton pump inhibitor (such as lansoprazole capsules, esomeprazole magnesium capsules, rabeprazole, omeprazole, pantoprazole) at the maximum dose for 8 weeks

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VONOPRAZAN (PART D)

RENEWAL CRITERIA

NOTE: For the diagnosis of *Helicobacter pylori* (*H. pylori*) infection or non-erosive gastroesophageal reflux disease, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of erosive esophagitis (ICD-10 Group K20)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the request for a continuation of treatment (i.e., the patient recently received an initial prior authorization approval for 8 weeks)?

   If yes, continue to #3.
   If no, refer to Initial Criteria.

3. Has the patient maintained a clinical response while on Voquezna?

   If yes, **approve for 24 weeks by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VONOPRAZAN (Voquezna)** requires the following rule(s) be met for renewal:
   A. You have erosive esophagitis (a type of digestive disorder)
   B. You have maintained a clinical response on Voquezna (the treatment is working)

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VONOPRAZAN (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Voquezna.

REFERENCES

Voquezna [Prescribing Information]. Buffalo Grove, IL: Phathom Pharmaceuticals, Inc.; November 2025.

For Part D use only:

VONOPRAZAN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	INITIAL: H PYLORI: 30 DAYS. EE: 8 WEEKS. NERD: 4 WEEKS. RENEWAL: EE: 24 WEEKS.
Other Criteria	INITIAL: EROSIVE ESOPHAGITIS (EE): TRIAL OF OR CONTRAINDICATION TO TWO PROTON PUMP INHIBITORS AT MAXIMUM DOSE FOR 8 WEEKS EACH. NON-EROSIVE GASTROESOPHAGEAL REFLUX DISEASE (NERD): 1) NO PREVIOUS TREATMENT FAILURE WITH VOQUEZNA IN THE LAST 12 MONTHS, AND 2) TRIAL OF OR CONTRAINDICATION TO ONE PROTON PUMP INHIBITOR AT MAXIMUM DOSE FOR 8 WEEKS. RENEWAL: EE: MAINTAINED A CLINICAL RESPONSE ON VOQUEZNA.

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Effective: 08/27/26 Client Approval: 08/26 P&T Approval: 04/24

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VORASIDENIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VORASIDENIB CITRATE	VORANIGO	49796		GPI-10 (2153518000)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Grade 2 astrocytoma or oligodendroglioma (ICD-10 C71.9) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient's cancer has a susceptible isocitrate dehydrogenase-1 (IDH1) or isocitrate dehydrogenase-2 (IDH2) mutation
   - Voranigo will be used following surgery, including biopsy, sub-total resection, or gross total resection

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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VORASIDENIB (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **VORASIDENIB (Voranigo)** requires the following rule(s) be met for approval:

A. You have Grade 2 astrocytoma or oligodendroglioma (types of brain cancer)
B. You are 12 years of age or older
C. Your cancer has a susceptible isocitrate dehydrogenase-1 (IDH1) or isocitrate dehydrogenase-2 (IDH2) mutation (abnormal changes in types of genes that increase the risk of certain diseases)
D. Voranigo will be used following surgery, including biopsy (removal of cells or tissue from the body for examination), sub-total resection (partial removal of tumor), or gross total resection (complete removal of tumor)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Voranigo.

REFERENCES

Voranigo [Prescribing Information]. Boston, MA: Servier Pharmaceuticals LLC; August 2024.

For Part D use only:

VORASIDENIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Part D Effective: 09/01/24
Commercial Effective: N/A
Created: 08/24
Client Approval: 08/24
P&T Approval: 10/24

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VORICONAZOLE SUSPENSION (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VORICONAZOLE	VFEND, VORICONAZOLE		21513	GPI-14 (11407080001920)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
Yes	No	No	Yes	No	No	Yes	No	No	Yes	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Is the request for continuation of therapy after the patient was started on voriconazole in the hospital?

   If yes, continue to #2.
   If no, continue to #3.

2. Is the request for **ONE** of the following?
   - Treatment of invasive aspergillosis (ICD-10 B44.0)
   - Treatment of candidemia or deep tissue Candida infection (e.g., infections in skin, abdomen, kidney, bladder wall, wounds) (ICD-10 Group B37 except B37.81 and Group B37.3)
   - Treatment of esophageal candidiasis (ICD-10 B37.81)
   - Treatment of serious fungal infection caused by Scedosporium apiospermum or Fusarium species (ICD-10 B48.8)

   If yes, **approve for 6 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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VORICONAZOLE SUSPENSION (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Is the request for the treatment of invasive aspergillosis (ICD-10 B44.0) and the patient meets **ALL** of the following criteria?
- The patient is 2 years of age or older
- The patient is unable to swallow tablets

If yes, **approve for 6 months by GPID or GPI-14.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #4.

4. Is the request for the treatment of candidemia or other deep tissue Candida infection (e.g., infections in skin, abdomen, kidney, bladder wall, wounds) (ICD-10 Group B37 except B37.81 and Group B37.3) and the patient meets **ALL** of the following criteria?
- The patient is 2 years of age or older
- The patient has a contraindication to or is unable to swallow fluconazole tablets

If yes, **approve for 3 months by GPID or GPI-14.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #5.

5. Is the request for the treatment of esophageal candidiasis (ICD-10 B37.81) **AND** the patient meets the following criterion?
- The patient is 2 years of age or older

If yes, **approve for 6 months by GPID or GPI-14.**
APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

If no, continue to #6.

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VORICONAZOLE SUSPENSION (PART D)

GUIDELINES FOR USE (CONTINUED)

6. Is the request for the treatment of a serious fungal infection caused by Scedosporium apiospermum or Fusarium species (ICD-10 B48.8) and the patient meets **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - The patient is unable to swallow tablets

   If yes, **approve for 6 months by GPID or GPI-14.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VORICONAZOLE SUSPENSION (Vfend)** requires the following rule(s) be met for approval:

   A. The request is for ONE of the following:
      1. Invasive aspergillosis (a type of fungal infection)
      2. Candidemia or other deep tissue Candida infections (a type of fungal infection)
      3. Esophageal candidiasis (fungal infection of the throat to the stomach)
      4. Serious fungal infection caused by Scedosporium apiospermum or Fusarium species (types of fungal infection)

   B. If you have invasive aspergillosis, approval also requires:
      1. You are 2 years of age or older
      2. You are unable to swallow tablets

   C. If you have candidemia or other deep tissue Candida infection, approval also requires:
      1. You are 2 years of age or older
      2. You have a contraindication to (harmful for you to use) or are unable to swallow fluconazole

   D. If you have esophageal candidiasis, approval also requires:
      1. You are 2 years of age or older

   E. If you have a serious fungal infection caused by Scedosporium apiospermum or Fusarium species, approval also requires:
      1. You are 2 years of age or older
      2. You are unable to swallow tablets

   F. Request for continuation of therapy after hospital discharge does not require extra criteria

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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VORICONAZOLE SUSPENSION (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Vfend.

REFERENCES
Vfend [Prescribing Information]. New York, NY: Pfizer; October 2022.

For Part D use only:

VORICONAZOLE SUSPENSION (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	CANDIDA INFECTIONS: 3 MOS. CONTINUATION OF THERAPY, ALL OTHER INDICATIONS: 6 MOS.
Other Criteria	CANDIDA INFECTIONS: CONTRAINDICATION TO OR UNABLE TO SWALLOW FLUCONAZOLE TABLETS. ALL INDICATIONS EXCEPT ESOPHAGEAL CANDIDIASIS: UNABLE TO SWALLOW TABLETS. CONTINUATION OF THERAPY AFTER HOSPITAL DISCHARGE REQUIRES NO EXTRA CRITERIA.

Created: 11/21
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 04/21

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VOSORITIDE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VOSORITIDE	VOXZOGO	47677		GPI-10 (3095008000)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of achondroplasia (ICD-10 Q77.4) **AND** meet the following criterion?
   - The patient has open epiphyses

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VOSORITIDE (Voxzogo)** requires the following rule(s) be met for approval:
   A. You have achondroplasia (a type of genetic bone growth disorder)
   B. You have open epiphyses (when the end parts of long bones still allow growth)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VOSORITIDE (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Voxzogo.

REFERENCES
Voxzogo [Prescribing Information]. Novato, CA: BioMarin Pharmaceutical Inc., October 2023.

For Part D use only:

VOSORITIDE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25
Commercial Effective: N/A
Created: 11/21
Client Approval: 06/24
P&T Approval: 01/24

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VUTRISIRAN BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VUTRISIRAN SODIUM	AMVUTTRA	48059		GPI-10 (6270609010)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	Yes	No	No	Yes	No	No	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit).**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #5.

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VUTRISIRAN BvD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
   - **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

   If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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VUTRISIRAN BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hereditary transthyretin-mediated amyloidosis with polyneuropathy (hATTR-PN) (ICD-10 E85.1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist, cardiologist, physician at an amyloidosis treatment center, or medical geneticist
   - The patient is ambulatory (i.e., Familial Amyloid Polyneuropathy [FAP] stage 1 - 2 OR Polyneuropathy Disability [PND] stage I - IIIb polyneuropathy)
   - Amvuttra will NOT be used concurrently with other hATTR-PN agents (e.g., Wainua [eplontersen], Tegsedi [inotersen], Onpattro [patisiran])

   If yes, continue to #2.
   If no, continue to #3.

2. Is the patient's diagnosis confirmed by **ONE** of the following?
   - Biopsy of tissue/organ to confirm amyloid presence AND chemical typing to confirm presence of TTR (transthyretin) protein
   - DNA genetic sequencing to confirm hATTR mutation

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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VUTRISIRAN BvD (PART D)

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of cardiomyopathy of wild-type transthyretin-mediated amyloidosis (ICD-10 E85.82) or hereditary transthyretin-mediated amyloidosis (ATTR-CM) (ICD-10 E85.4) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a cardiologist, transthyretin amyloidosis (ATTR) specialist, or medical geneticist
   - The patient has New York Heart Association (NYHA) Class I, II, or III heart failure

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Is the patient's diagnosis confirmed by **ONE** of the following?
   - Bone scan (scintigraphy) strongly positive for myocardial uptake of TC-99m-PYP
     (Note: Strongly positive defined as heart to contralateral lung [H/CL] ratio of at least 1.5 or Grade 2 or greater localization to the heart using the Perugini Grade 1-3 scoring system)
   - Biopsy of tissue of affected organ(s) (cardiac and possibly non-cardiac sites) to confirm amyloid presence **AND** chemical typing to confirm presence of transthyretin (TTR) protein

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VUTRISIRAN (Amvuttra)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Hereditary transthyretin-mediated amyloidosis with polyneuropathy (hATTR-PN: a rare genetic disorder with widespread nerve pain/damage)
      2. Cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM: heart disease caused by a build-up of a type of protein)

   (Initial denial text continued on next page)

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VUTRISIRAN BvD (PART D)

INITIAL CRITERIA (CONTINUED)

B. If you have hereditary transthyretin-mediated amyloidosis with polyneuropathy, approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nerve doctor), cardiologist (a type of heart doctor), physician at an amyloidosis treatment center, or medical geneticist (doctor who treats gene disorders)
3. You are ambulatory (able to walk) (you have Familial Amyloid Polyneuropathy [FAP: a tool used to evaluate disease severity] stage 1 to 2 OR Polyneuropathy Disability [PND: a tool used to evaluate disease severity] stage I to IIIb polyneuropathy)
4. You will NOT use Amvuttra concurrently (at the same time) with other hATTR-PN medications (such as Wainua [eplontersen], Tegsedi [inotersen], Onpattro [patisiran])
5. Your diagnosis is confirmed by ONE of the following:
   a. Biopsy (removal of cells from the body for examination) of tissue/organ to confirm amyloid (a type of abnormal protein) presence AND chemical typing to confirm presence of TTR (transthyretin) protein
   b. DNA (deoxyribonucleic acid) genetic sequencing (a type of lab test) to confirm hATTR mutation (a type of abnormal gene)

C. If you have cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis, approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor), transthyretin amyloidosis (ATTR) specialist, or medical geneticist (doctor who treats gene disorders)
3. You have New York Heart Association (NYHA) Class I, II, or III heart failure (classification of heart failure symptoms)
4. Your diagnosis is confirmed by ONE of the following:
   a. Bone scan (scintigraphy) strongly positive for myocardial uptake of TC-99m-PYP (a type of imaging test) (Note: Strongly positive defined as heart to contralateral lung [H/CL] ratio of at least 1.5 or Grade 2 or greater localization to the heart using the Perugini Grade 1-3 scoring system)
   b. Biopsy of tissue of the affected organ(s) (removal of cells or tissue from the body for examination) (can be heart or non-heart related organs) to confirm amyloid (type of protein) presence AND chemical typing to confirm presence of transthyretin (TTR) protein

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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VUTRISIRAN BvD (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary transthyretin-mediated amyloidosis with polyneuropathy (hATTR-PN) (ICD-10 E85.1) and meet **ALL** of the following criteria?
   - The patient has NOT progressed to Familial Amyloid Polyneuropathy (FAP) stage 3 or Polyneuropathy Disability (PND) stage 4 polyneuropathy, as evidenced by functional decline (e.g., wheelchair-bound, bedridden)
   - Amvuttra will NOT be used concurrently with other hATTR-PN agents (e.g., Wainua [eplontersen], Tegsedi [inotersen], Onpattro [patisiran])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of cardiomyopathy of wild-type transthyretin-mediated amyloidosis (ICD-10 E85.82) or hereditary transthyretin-mediated amyloidosis (ATTR-CM) (ICD-10 E85.4)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VUTRISIRAN (Amvuttra)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Hereditary transthyretin-mediated amyloidosis with polyneuropathy (hATTR-PN: a rare genetic disorder with widespread nerve pain/damage)
      2. Cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM: heart disease caused by a build-up of a type of protein)

   (Renewal denial text continued on next page)

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RENEWAL CRITERIA (CONTINUED)

B. If you have hereditary transthyretin-mediated amyloidosis with polyneuropathy, renewal also requires:

1. You have NOT progressed to Familial Amyloid Polyneuropathy (FAP: a tool used to evaluate disease severity) stage 3 OR Polyneuropathy Disability (PND: a tool used to evaluate disease severity) stage 4 polyneuropathy, as shown by functional decline (such as being wheelchair-bound, being bedridden)
2. You will NOT use Amvuttra concurrently (at the same time) with other hATTR-PN medications (such as Wainua [eplontersen], Tegsedi [inotersen], Onpattro [patisiran])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Amvuttra. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Amvuttra [Prescribing Information]. Cambridge, MA: Alnylam Pharmaceuticals, Inc.; March 2025.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed April 3, 2025].

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PLUS OPEN DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VUTRISIRAN BvD (PART D)

For Part D use only:

VUTRISIRAN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	HEREDITARY TRANSTHYRETIN-MEDIATED AMYLOIDOSIS WITH POLYNEUROPATHY (HATTR-PN): INITIAL: DIAGNOSIS CONFIRMED BY 1) BIOPSY OF TISSUE/ORGAN TO CONFIRM AMYLOID PRESENCE AND CHEMICAL TYPING TO CONFIRM PRESENCE OF TTR PROTEIN, OR 2) DNA GENETIC SEQUENCING TO CONFIRM HATTR MUTATION. CARDIOMYOPATHY OF WILD TYPE OR HEREDITARY TRANSTHYRETIN-MEDIATED AMYLOIDOSIS (ATTR-CM): INITIAL: 1) NEW YORK HEART ASSOCIATION (NYHA) CLASS I, II, OR III HEART FAILURE, AND 2) DIAGNOSIS CONFIRMED BY (A) BONE SCAN (SCINTIGRAPHY) STRONGLY POSITIVE FOR MYOCARDIAL UPTAKE OF TC-99M-PYP, OR (B) BIOPSY OF TISSUE OF AFFECTED ORGAN(S) (CARDIAC AND POSSIBLY NON-CARDIAC SITES) TO CONFIRM AMYLOID PRESENCE AND CHEMICAL TYPING TO CONFIRM PRESENCE OF TRANSTHYRETIN (TTR) PROTEIN.
Age Restrictions	N/A
Prescriber Restrictions	HATTR-PN: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST, CARDIOLOGIST, PHYSICIAN AT AN AMYLOIDOSIS TREATMENT CENTER, OR MEDICAL GENETICIST. ATTR-CM: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST, ATTR SPECIALIST, OR MEDICAL GENETICIST.
Coverage Duration	INITIAL: HATTR-PN: 6 MONTHS, ATTR-CM: 12 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	HATTR-PN: INITIAL: 1) FAMILIAL AMYLOID POLYNEUROPATHY (FAP) STAGE 1 OR 2, OR UP TO POLYNEUROPATHY DISABILITY (PND) STAGE IIIB POLYNEUROPATHY, AND 2) NO CONCURRENT USE WITH OTHER HATTR-PN AGENTS. RENEWAL: 1) NOT PROGRESSED TO FAP STAGE 3 OR PND STAGE 4 POLYNEUROPATHY AS EVIDENCED BY FUNCTIONAL DECLINE, AND 2) NO CONCURRENT USE WITH OTHER HATTR-PN AGENTS.

Created: 06/22
Effective: 01/01/26 Client Approval: 10/25 P&T Approval: 01/25

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ZANIDATAMAB-HRII BvD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ZANIDATAMAB-HRII	ZIIHERA	50014		GPI-10 (2117009001)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	Yes	No	Yes	Yes	No	Yes	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is the drug administered via an implantable pump?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B. (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, continue to #2.

2. Is the drug administered via an external pump?

   If yes, continue to #3.

   If no, **approve for 12 months by HICL or GPI-10 under Part D. (Populate the B vs. D field with a 'D' in the PA override field).**

3. Is the drug specifically infused through an external infusion pump covered by Medicare?

   If yes, **approve for 12 months by HICL or GPI-10 under Part B. (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field.).**

   If no, **approve for 12 months by HICL or GPI-10 under Part D. (Populate the B vs. D field with a 'D' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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ZANIDATAMAB-HRII BvD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of previously treated, unresectable or metastatic biliary tract cancer (BTC) (ICD-10 Group C24) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer is human epidermal growth factor receptor 2 (HER2)-positive (IHC 3+), as detected by an FDA-authorized test

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of gastric, gastroesophageal junction, or esophageal adenocarcinoma (GEA) (ICD-10 Groups C15, C16) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer is unresectable locally advanced or metastatic

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - The patient's cancer is HER2-positive (IHC 3+ or IHC 2+/ISH+), as detected by an FDA-authorized test, AND Ziihera will be used in combination with fluoropyrimidine- (e.g., fluorouracil, capecitabine) and platinum-containing chemotherapy (e.g., cisplatin, oxaliplatin) and Tevimbra (tislelizumab-jsgr)
   - The patient's cancer is HER2-positive (IHC 3+), as detected by an FDA-authorized test, AND Ziihera will be used in combination with fluoropyrimidine- and platinum-containing chemotherapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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ZANIDATAMAB-HRII BvD (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ZANIDATAMAB-HRII (Ziihera)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Biliary tract cancer (BTC: a type of bile duct or gallbladder cancer)
   2. Gastric, gastroesophageal junction, or esophageal adenocarcinoma (GEA: a type of digestive system cancer)

B. If you have biliary tract cancer, approval also requires:
   1. You are 18 years of age or older
   2. Your cancer is previously treated, unresectable (unable to remove by surgery) or metastatic (cancer has spread to other parts of the body)
   3. Your cancer is human epidermal growth factor receptor 2 (HER2)-positive immunohistochemistry 3+ (IHC 3+), as detected by a Food and Drug Administration (FDA)-authorized test

C. If you have gastric, gastroesophageal junction, or esophageal adenocarcinoma, approval also requires:
   1. You are 18 years of age or older
   2. Your cancer is unresectable (cannot be removed by surgery) locally advanced (cancer that has spread from where it started to nearby tissue or lymph nodes) or metastatic (has spread to other parts of the body)
   3. You meet ONE of the following:
      a. Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive (IHC 3+ or IHC 2+/ISH+), as detected by a Food and Drug Adminstration (FDA)-authorized test, AND Ziihera will be used in combination with fluoropyrimidine- (such as fluorouracil, capecitabine) and platinum-containing chemotherapy (such as cisplatin, oxaliplatin) and Tevimbra (tislelizumab-jsgr)
      b. Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive (IHC 3+), as detected by a Food and Drug Administration (FDA)-authorized test, AND Ziihera will be used in combination with fluoropyrimidine- (such as fluorouracil, capecitabine) and platinum-containing chemotherapy (such as cisplatin, oxaliplatin)

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ZANIDATAMAB-HRII BvD (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ziihera. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs administered by an implantable pump are covered under Part B. Drugs administered via an external pump are covered under Part B if they are included under the local coverage policy of the applicable Medicare coverage policies (National and/or Local Coverage Policies). Drugs administered via an external pump that are not included under the applicable Medicare coverage policies are covered under Part D. A CMS website to assist with National and Local Coverage Determination for B versus D review is http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx

REFERENCES

Ziihera [Prescribing Information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; August 2026.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: http://www.cms.gov/PrescriptionDrugCovContra/12_PartDManuals.asp. [Accessed August 26, 2026].

For Part D use only:

ZANIDATAMAB-HRII (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 12/24
Effective: 08/29/26 DMC Approval: 09/26

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ZANUBRUTINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ZANUBRUTINIB	BRUKINSA	46212		GPI-10 (2153219500)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of mantle cell lymphoma (MCL) (ICD-10 Group C83.1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received at least ONE prior therapy (e.g., R-CHOP [rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone])
   - The patient had an intolerance to Calquence (acalabrutinib)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of Waldenström's macroglobulinemia (WM) (ICD-10 C88.0) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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ZANUBRUTINIB (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of relapsed or refractory marginal zone lymphoma (MZL) (ICD-10 Group C83.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received at least ONE anti-CD20-based regimen (e.g., rituximab)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #4.

4. Does the patient have a diagnosis of chronic lymphocytic leukemia (CLL) (ICD-10 Group C91.1) or small lymphocytic lymphoma (SLL) (ICD-10 Group C83.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had an intolerance to Calquence (acalabrutinib) or Imbruvica (ibrutinib)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #5.

5. Does the patient have a diagnosis of relapsed or refractory follicular lymphoma (FL) (ICD-10 Group C82) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Brukinsa will be used in combination with Gazyva (obinutuzumab)
   - Brukinsa will be used after at least TWO lines of systemic therapy (e.g., lenalidomide with rituximab)

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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ZANUBRUTINIB (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ZANUBRUTINIB (Brukinsa)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Mantle cell lymphoma (MCL: a type of blood cancer)
   2. Waldenstrom's macroglobulinemia (WM: a type of blood cancer)
   3. Relapsed or refractory marginal zone lymphoma (MZL: a type of blood cancer that has returned or did not respond to treatment)
   4. Chronic lymphocytic leukemia (CLL: a type of blood cancer)
   5. Small lymphocytic lymphoma (SLL: a type of blood cancer)
   6. Relapsed or refractory follicular lymphoma (FL: a type of blood cancer that has returned or did not respond to treatment)

B. If you have mantle cell lymphoma, approval also requires:
   1. You are 18 years of age or older
   2. You have received at least ONE prior therapy (such as R-CHOP [rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone])
   3. You had an intolerance to (side effect) to Calquence (acalabrutinib)

C. If you have Waldenstrom's macroglobulinemia, approval also requires:
   1. You are 18 years of age or older

D. If you have relapsed or refractory marginal zone lymphoma, approval also requires:
   1. You are 18 years of age or older
   2. You have received at least ONE anti-CD20-based regimen (a type of blood cancer treatment plan, such as rituximab)

E. If you have chronic lymphocytic leukemia or small lymphocytic lymphoma, approval also requires:
   1. You are 18 years of age or older
   2. You had an intolerance to (side effect) to Calquence (acalabrutinib) or Imbruvica (ibrutinib)

F. If you have relapsed or refractory follicular lymphoma, approval also requires:
   1. You are 18 years of age or older
   2. Brukinsa will be used in combination with Gazyva (obinutuzumab)
   3. Brukinsa will be used after at least TWO lines of systemic therapy (treatment that targets the entire body such as lenalidomide with rituximab)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ZANUBRUTINIB (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Brukinsa.

REFERENCES

Brukinsa [Prescribing Information]. San Mateo, CA: BeiGene USA, Inc.; January 2025.

For Part D use only:

ZANUBRUTINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	MANTLE CELL LYMPHOMA: INTOLERANCE TO CALQUENCE. CHRONIC LYMPHOCYTIC LEUKEMIA, SMALL LYMPHOCYTIC LYMPHOMA: INTOLERANCE TO CALQUENCE OR IMBRUVICA. WALDENSTROMS MACROGLOBULINEMIA: NO STEP REQUIRED.

Created: 12/19
Effective: 01/01/26 Client Approval: 12/25 P&T Approval: 04/24

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ZAVEGEPANT (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ZAVEGEPANT HCL	ZAVZPRET	48771		GPI-10 (6770109020)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for the acute treatment of migraines (ICD-10 Group G43 except G43.7 and G43.E) and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Zavzpret will NOT be used concurrently with other cGRP inhibitors (e.g., Ubrelvy [ubrogepant]) for the acute treatment of migraines
   - The patient had a trial of or contraindication to ONE triptan (e.g., Maxalt [rizatriptan], Imitrex [sumatriptan], Axert [almotriptan])
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Ubrelvy (ubrogepant), Nurtec ODT (rimegepant)
   - The patient is unable to tolerate oral medications

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ZAVEGEPANT (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ZAVEGEPANT (Zavzpret)** requires the following rule(s) be met for approval:

A. The request is for the acute (quick onset) treatment of migraines (a type of headache)
B. You are 18 years of age or older
C. You will NOT use Zavzpret concurrently (at the same time) with other calcitonin gene-related peptide (cGRP) inhibitors (such as Ubrelvy [ubrogepant]) for the acute treatment of migraines
D. You have tried or have a contraindication to (harmful for you to use) ONE triptan (such as Maxalt [rizatriptan], Imitrex [sumatriptan], Axert [almotriptan])
E. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Ubrelvy (ubrogepant), Nurtec ODT (rimegepant)
F. You are NOT able to tolerate oral medications

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ZAVEGEPANT (PART D)

RENEWAL CRITERIA

1. Is the request for the acute treatment of migraines (ICD-10 Group G43 except G43.7 and G43.E) **AND** the patient meets the following criterion?
   - Zavzpret will NOT be used concurrently with other cGRP inhibitors (e.g., Ubrelvy [ubrogepant]) for the acute treatment of migraines

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has experienced an improvement from baseline in a validated acute treatment patient-reported outcome questionnaire (e.g., Migraine Assessment of Current Therapy [Migraine-ACT])
   - Therapy works consistently in a majority of migraine attacks

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ZAVEGEPANT (Zavzpret)** requires the following rule(s) be met for renewal:
   A. The request is for the acute (quick onset) treatment of migraines (a type of headache)
   B. You will NOT use Zavzpret concurrently (at the same time) with other calcitonin gene-related peptide (cGRP) inhibitors (such as Ubrelvy [ubrogepant]) for the acute treatment of migraines
   C. You meet ONE of the following:
      1. You have experienced an improvement from baseline in a validated acute treatment patient-reported outcome questionnaire (assessment tool used to help guide treatment such as migraine assessment of current therapy [MIGRAINE-ACT])
      2. Treatment works consistently in a majority of migraine attacks

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ZAVEGEPANT (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zavzpret.

REFERENCES

Zavzpret [Prescribing Information]. New York, NY: Pfizer, Inc.; March 2023.

For Part D use only:

ZAVEGEPANT (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	ACUTE MIGRAINE TREATMENT: INITIAL: 1) NO CONCURRENT USE WITH OTHER CGRP INHIBITORS FOR ACUTE MIGRAINE TREATMENT, 2) TRIAL OF OR CONTRAINDICATION TO ONE TRIPTAN (E.G., SUMATRIPTAN, RIZATRIPTAN), 3) TRIAL OF OR CONTRAINDICATION TO ONE OF THE FOLLOWING PREFERRED AGENTS: UBRELVY OR NURTEC ODT, AND 4) UNABLE TO TOLERATE ORAL MEDICATIONS. RENEWAL: 1) NO CONCURRENT USE WITH OTHER CGRP INHIBITORS FOR ACUTE MIGRAINE TREATMENT, AND 2) ONE OF THE FOLLOWING: (A) IMPROVEMENT FROM BASELINE IN A VALIDATED ACUTE TREATMENT PATIENT-REPORTED OUTCOME QUESTIONNAIRE, OR (B) THERAPY WORKS CONSISTENTLY IN MAJORITY OF MIGRAINE ATTACKS.

Part D Effective: 01/01/25 Created: 06/23
Commercial Effective: N/A Client Approval: 06/24 P&T Approval: 10/23

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ZENOCUTUZUMAB-ZBCO BVD (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ZENOCUTUZUMAB-ZBCO	BIZENGRI	50048		GPI-10 (2135979201)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	Yes	No	Yes	Yes	No	Yes	Yes	No	Yes	Yes

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding.

1. Is this a pharmacy call?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #3.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

3. Is the internal HQ code AHF01, ATR01, CCA05, CEN10, CLH01, GLD01/02, HPJ01, IHH01, KHS01, MCP01, MRI03, RPS01, SFP01, or any MVS HQs?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #4.

4. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, **approve for 12 months by HICL or GPI-10 under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

   If no, continue to #5.

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ZENOCUTUZUMAB-ZBCO BVD (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

5. Is the internal HQ code ML500, SFC01, or SUM03?

If yes, **refer to plan. (The health plan makes the final payment determination decision)**

- **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAD BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
- **For PAC's: Send an email to plan (reference UNSAD section of PACIP).**

If no, **approve for 12 months by HICL or GPI-10 under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

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ZENOCUTUZUMAB-ZBCO BVD (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced unresectable or metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer is neuregulin 1 (NRG1) gene fusion-positive
   - The patient has disease progression while on or after prior systemic therapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

2. Does the patient have a diagnosis of advanced unresectable or metastatic pancreatic adenocarcinoma (ICD-10 Group C25) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer is neuregulin 1 (NRG1) gene fusion-positive
   - The patient has had disease progression while on or after prior systemic therapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

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ZENOCUTUZUMAB-ZBCO BVD (PART D)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of advanced unresectable or metastatic cholangiocarcinoma (ICD-10 C22.1, C24.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer is neuregulin 1 (NRG1) gene fusion-positive
   - The patient has disease progression while on or after prior systemic therapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ZENOCUTUZUMAB-ZBCO (Bizengri)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Advanced unresectable or metastatic non-small cell lung cancer (NSCLC) (a type of lung cancer that cannot be removed by surgery or has spread to other parts of the body)
      2. Advanced unresectable or metastatic pancreatic adenocarcinoma (a type of pancreas cancer that cannot be removed by surgery or has spread to other parts of the body)
      3. Advanced unresectable or metastatic cholangiocarcinoma (a type of bile duct cancer that cannot be removed by surgery or has spread to other parts of the body)

   B. If you have advanced unresectable or metastatic non-small cell lung cancer, approval also requires:
      1. You are 18 years of age or older
      2. Your cancer is neuregulin 1 (NRG1) gene fusion-positive (abnormal change in a type of gene)
      3. Your disease has progressed (worsened) while on or after prior systemic therapy (treatment that targets the entire body)

   C. If you have advanced unresectable or metastatic pancreatic adenocarcinoma, approval also requires:
      1. You are 18 years of age or older
      2. Your cancer is neuregulin 1 (NRG1) gene fusion-positive (abnormal change in a type of gene)
      3. Your disease has progressed (worsened) while on or after prior systemic therapy (treatment that targets the entire body)

   (Denial text continued on next page)

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ZENOCUTUZUMAB-ZBCO BVD (PART D)

GUIDELINES FOR USE (CONTINUED)

D. If you have advanced unresectable or metastatic cholangiocarcinoma, approval also requires:

1. You are 18 years of age or older
2. Your cancer is neuregulin 1 (NRG1) gene fusion-positive (abnormal change in a type of gene)
3. Your disease has progressed (worsened) while on or after prior systemic therapy (treatment that targets the entire body)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Bizengri. The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B.

REFERENCES

Bizengri [Prescribing Information]. Lexington, MA: Partner Therapeutics, Inc.; May 2026.
Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Rev 18, 01-15-16. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. [Accessed May 27, 2026].

For Part D use only:

ZENOCUTUZUMAB-ZBCO (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 01/25
Effective: 06/03/26 Client Approval: 06/26 P&T Approval: 07/26

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ZIFTOMENIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ZIFTOMENIB	KOMZIFTI	51002		GPI-10 (2148009000)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory acute myeloid leukemia (AML)(ICD-10 C92.02, C92.00) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a susceptible nucleophosmin 1 (NPM1) mutation
   - The patient has no satisfactory alternative treatment options

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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ZIFTOMENIB (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ZIFTOMENIB (Komzifti)** requires the following rule(s) be met for approval:

A. You have relapsed or refractory acute myeloid leukemia (AML: a type of blood cancer that has returned or did not respond to treatment)
B. You are 18 years of age or older
C. You have a susceptible nucleophosmin 1 (NPM1) mutation (an abnormal change in atype of gene)
D. You have no satisfactory alternative treatment options

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Komzifti.

REFERENCES

Komzifti [Prescribing Information]. San Diego, CA: Kura Oncology, Inc.; November 2025.

For Part D use only:

ZIFTOMENIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Created: 02/26
Effective: 02/07/26 Client Approval: 02/26 P&T Approval: 01/26

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ZILUCOPLAN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ZILUCOPLAN SODIUM	ZILBRYSQ	49273		GPI-10 (8580509520)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	No	No	No	No	No	No	No	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of generalized myasthenia gravis (gMG) (ICD-10 Group G70.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is anti-acetylcholine receptor (AChR) antibody positive
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient is Myasthenia Gravis Foundation of America class II, III, or IV
   - The patient had a trial of or contraindication to ONE corticosteroid (e.g., prednisone)
   - The patient had a trial of or contraindication to ONE non-steroidal immunosuppressive therapy (e.g., azathioprine, cyclophosphamide, methotrexate)
   - Zilbrysq will NOT be used concurrently with another neonatal Fc receptor blocker (e.g., Rystiggo [rozanolixizumab-noli], Vyvgart [efgartigimod alfa-fcab]) or complement inhibitor (e.g., Ultomiris [ravulizumab-cwvz], Soliris [eculizumab]) for the treatment of gMG

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ZILUCOPLAN (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ZILUCOPLAN (Zilbrysq)** requires the following rule(s) be met for approval:

A. You have generalized myasthenia gravis (gMG: a chronic autoimmune disorder)
B. You are 18 years of age or older
C. You are anti-acetylcholine receptor (AChR) antibody positive (shows that you have myasthenia gravis)
D. Therapy is prescribed by or in consultation with a neurologist (type of brain doctor)
E. You have Myasthenia Gravis Foundation of America class II, III, or IV (indicates severity of disease)
F. You have tried or have a contraindication to (harmful for you to use) ONE corticosteroid (such as, prednisone)
G. You have tried or have a contraindication to (harmful for you to use) ONE non-steroidal immunosuppressive therapy (such as, azathioprine, cyclophosphamide, methotrexate)
H. You will NOT use Zilbrysq concurrently (at the same time) with another neonatal Fc receptor blocker (such as Rystiggo [rozanolixizumab-noli], Vyvgart [efgartigimod alfa-fcab]) or complement inhibitor (such as Ultomiris [ravulizumab-cwvz], Soliris [eculizumab]) for the treatment of genralized mysasthenia gravis

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ZILUCOPLAN (PART D)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of generalized myasthenia gravis (gMG) (ICD-10 Group G70.0) and meet **ALL** of the following criteria?
   - The patient had clinical benefit compared to baseline (e.g., Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool)
   - Zilbrysq will NOT be used concurrently with another neonatal Fc receptor blocker (e.g., Rystiggo [rozanolixizumab-noli], Vyvgart [efgartigimod alfa-fcab]) or complement inhibitor (e.g., Ultomiris [ravulizumab-cwvz], Soliris [eculizumab]) for the treatment of gMG

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ZILUCOPLAN (Zilbrysq)** requires the following rule(s) be met for renewal:
   A. You have generalized myasthenia gravis (gMG: a chronic autoimmune disorder)
   B. You have had clinical benefit compared to baseline (for example, as shown by the Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool)
   C. You will NOT use Zilbrysq concurrently (at the same time) with another neonatal Fc receptor blocker (such as Rystiggo [rozanolixizumab-noli], Vyvgart [efgartigimod alfa-fcab]) or complement inhibitor (such as Ultomiris [ravulizumab-cwvz], Soliris [eculizumab]) for the treatment of genralized mysasthenia gravis

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zilbrysq.

REFERENCES

- Zilbrysq [Prescribing Information]. Smyrna, GA: UCB, Inc.; April 2024.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ZILUCOPLAN (PART D)

For Part D use only:

ZILUCOPLAN (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	GENERALIZED MYASTHENIA GRAVIS (GMG): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST.
Coverage Duration	GMG: INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS
Other Criteria	GMG: INITIAL: 1) MYASTHENIA GRAVIS FOUNDATION OF AMERICA CLASS II, III, OR IV, 2) TRIAL OF OR CONTRAINDICATION TO ONE CORTICOSTEROID, 3) TRIAL OF OR CONTRAINDICATION TO ONE NON-STEROIDAL IMMUNOSUPPRESSIVE THERAPY, AND 4) NO CONCURRENT USE WITH ANOTHER NEONATAL FC RECEPTOR BLOCKER (E.G., RYSTIGGO, VYVGART) OR COMPLEMENT INHIBITOR (E.G., ULTOMIRIS, SOLIRIS) FOR GMG. RENEWAL: 1) CLINICAL BENEFIT COMPARED TO BASELINE, AND 2) NO CONCURRENT USE WITH ANOTHER NEONATAL FC RECEPTOR BLOCKER (E.G., RYSTIGGO, VYVGART) OR COMPLEMENT INHIBITOR (E.G., ULTOMIRIS, SOLIRIS) FOR GMG.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ZIV-AFLIBERCEPT (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ZIV-AFLIBERCEPT	ZALTRAP		32988 32989	GPI-10 (2133501010)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic colorectal cancer (mCRC) (ICD-10 C19) and meet **ALL** of the following criteria?
   - Zaltrap will be used in combination with FOLFIRI (fluorouracil or 5-FU, leucovorin, irinotecan)
   - The patient has tried an oxaliplatin-containing regimen (e.g., FOLFOX [fluorouracil, leucovorin, oxaliplatin])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ZIV-AFLIBERCEPT (Zaltrap)** requires the following rule(s) be met for approval:
   A. You have metastatic colorectal cancer (mCRC: a type of digestive cancer that has spread to other parts of the body)
   B. Zaltrap will be used in combination with FOLFIRI (a cancer treatment that consists of fluorouracil or 5-FU, leucovorin, irinotecan)
   C. You have tried an oxaliplatin-containing regimen (such as FOLFOX [[fluorouracil, leucovorin, oxaliplatin])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ZIV-AFLIBERCEPT (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Zaltrap.

REFERENCES
Zaltrap [Prescribing Information]. Bridgewater, NJ: Sanofi-Aventis U.S. LLC; December 2023.

For Part D use only:

ZIV-AFLIBERCEPT (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Core	Advantage	Plus
No	No	Yes

Part D Effective: 01/01/25 Created: 02/13
Commercial Effective: N/A Client Approval: 06/24 P&T Approval: 11/14

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ZOLBETUXIMAB-CLZB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ZOLBETUXIMAB-CLZB	VYLOY	49949		GPI-10 (2135519005)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced unresectable or metastatic gastric or gastroesophageal junction (GEJ) adenocarcinoma (ICD-10 Group C16) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer is human epidermal growth factor receptor 2 (HER2)-negative
   - The patient's tumor is claudin (CLDN) 18.2 positive, as determined by an FDA-approved test
   - Vyloy will be used in combination with fluoropyrimidine- and platinum-containing chemotherapy (e.g., mFOLFOX6 [fluorouracil, leucovorin, oxaliplatin], CAPOX [capecitabine, oxaliplatin])

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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ZOLBETUXIMAB-CLZB (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ZOLBETUXIMAB-CLZB (Vyloy)** requires the following rule(s) be met for approval:

A. You have locally advanced unresectable or metastatic gastric or gastroesophageal junction (GEJ) adenocarcinoma (a type of digestive system cancer that cannot be surgically removed, has spread to nearby tissue, or has spread to other parts of the body)
B. You are 18 years of age or older
C. Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-negative
D. Your tumor is claudin (CLDN) 18.2 (a type of protein) positive, as determined by a Food and Drug Administration (FDA)-approved test
E. Vyloy will be used in combination with fluoropyrimidine- and platinum-containing chemotherapy (a type of cancer treatment such as mFOLFOX6 [fluorouracil, leucovorin, oxaliplatin], CAPOX [capecitabine, oxaliplatin])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vyloy.

REFERENCES

Vyloy [Prescribing Information]. Northbrook, IL: Astellas Pharma US, Inc.; October 2024.

For Part D use only:

ZOLBETUXIMAB-CLZB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

Part D Effective: 11/04/24 Created: 10/24
Commercial Effective: N/A Client Approval: 10/24 P&T Approval: 01/25

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STANDARD PART D
PRIOR AUTHORIZATION GUIDELINES

ZOLIFLODACIN (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ZOLIFLODACIN	NUZOLVENCE	51065		GPI-10 (1600009500)	

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of uncomplicated urogenital gonorrhea (ICD-10 Group A54.0) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient's infection is caused by *Neisseria gonorrhoeae*
   - The patient had a trial of or contraindication to the clinical standard of care agent: ceftriaxone

   If yes, **approve for 1 month by HICL or GPI-10 for 1 fill.**
   If no, do not approve.

   DENIAL TEXT: Our guideline named **ZOLIFLODACIN (Nuzolvence)** requires the following rule(s) be met for approval:
   A. You have uncomplicated urogenital gonorrhea (a type of bacterial infection)
   B. You are 12 years of age or older
   C. Your infection is caused by Neisseria gonorrhoeae (a type of bacteria)
   D. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: ceftriaxone

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Nuzolvence.

REFERENCES
Nuzolvence [Prescribing Information]. Waltham, MA: Entasis Therapeutics, Inc.; December 2025.

Created: 09/26
Effective: 09/12/26 Client Approval: 09/26 DMC Approval: 09/09/26

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ZONGERTINIB (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ZONGERTINIB	HERNEXEOS	50811		GPI-10 (2117009200)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure the requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic non-squamous non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's tumors have HER2 (ERBB2) tyrosine kinase domain activating mutations, as detected by an FDA-approved test

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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ZONGERTINIB (PART D)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ZONGERTINIB (Hernexeos)** requires the following rule(s) be met for approval:

A. You have unresectable (unable to remove by surgery) or metastatic (cancer that has spread to other parts of the body) non-squamous non-small cell lung cancer (NSCLC: a type of lung cancer)
B. You are 18 years of age or older
C. Your tumors have HER2 (ERBB2) tyrosine kinase domain activating mutations (abnormal change in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Hernexeos.

REFERENCES

Hernexeos[Prescribing Information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; February 2026.

For Part D use only:

ZONGERTINIB (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 MONTHS
Other Criteria	N/A

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CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ZURANOLONE (PART D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ZURANOLONE	ZURZUVAE	49127		GPI-10 (5806009000)	

Core			Advantage			Plus (Closed)			Plus (Open)		
Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD	Generic	Brand	BvD
No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of postpartum depression (PPD) (ICD-10 F53.0) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 14 days by HICL or GPI-10.**
   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ZURANOLONE (Zurzuvae)** requires the following rule(s) be met for approval:
   A. You have postpartum depression (PPD: a type of depression that occurs after giving birth)
   B. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ZURANOLONE (PART D)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Zurzuvae.

REFERENCES
Zurzuvae [Prescribing Information]. Cambridge, MA: Biogen Inc.; August 2023.

For Part D use only:

ZURANOLONE (PART D)	
Covered Uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	14 DAYS
Other Criteria	N/A

Created: 11/23
Effective: 01/01/25 Client Approval: 08/24 P&T Approval: 07/23

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