San Francisco Health Plan (SFHP)
Quarterly Formulary and Prior Authorization Criteria Update
July 2025

The following changes to SFHP formulary and prior authorization criteria were reviewed and approved by the SFHP Pharmacy and Therapeutics (P&T) Committee on Wednesday, July 16th, 2025. Effective date for all changes is **August 20th, 2025**.

SFHP formulary and prior authorization (PA) criteria can be accessed at http://www.sfhp.org/providers/formulary/. Generic criteria are linked in the searchable formulary preamble for each line of business, and drug- and drug-class specific criteria are linked to the formulary listing for each relevant drug.

Contents

Drug Class Reviews and Monographs (main agenda)

Drug Class Reviews (main agenda)

Endocrinology: Anti-Obesity

Formulary Update: Healthy Workers HMO and Healthy San Francisco

- No changes recommended

Prior Authorization Criteria Recommendations:

- Reviewed Anti-Obesity criteria changes that were made via interim change

Drug Utilization Review Update:

- No DUR changes made

Endocrinology: Tryngolza™

Formulary Update: Healthy Workers HMO and Healthy San Francisco

- Maintained Tryngolza™ (olezarsen) as non-formulary at this time due to lack of utilization

Prior Authorization Criteria Recommendations:

- Implemented new PA criteria

Drug Utilization Review Update:

- No DUR changes made

Gastroenterology: Iqirvo® and Livdelzi®

Formulary Update: Healthy Workers HMO and Healthy San Francisco

- Maintained Iqirvo® (elafibranor) and Livdelzi® (seladelpar) as non-formulary
- Removed Ocaliva® (obeticholic acid) from formulary due to no utilization and available alternatives

Prior Authorization Criteria Recommendations:

- Changed the Ocaliva® (obeticholic acid) PA criteria name to Primary Biliary Cholangitis and add Iqirvo® (elafibranor) and Livdelzi® (seladelpar) to the criteria

Drug Utilization Review Update:

- No DUR changes made

Nephrology: Chronic Kidney Disease-Mineral Bone Disorder

Formulary Update: Healthy Workers HMO and Healthy San Francisco

- Maintained Xphozah® (tenapanor) as non-formulary due to cost-effective alternatives available
- Moved cinacalcet (Sensipar®) to Tier 1 (preferred generic) and removed PA criteria requirements

Prior Authorization Criteria Recommendations:

- Added Xphozah® criteria to the Phosphate Binder PA criteria
- Retired PA criteria for cinacalcet (Sensipar®)

Drug Utilization Review Update:

- No DUR changes made

Pain: Journavx®

Formulary Update: Healthy Workers HMO and Healthy San Francisco

- Maintained Journavx® (suzetrigine) as non-formulary due to alternatives available on formulary

Prior Authorization Criteria Recommendations:

- Utilize Non-Formulary PA criteria for any requests
- Will review Journavx® PA criteria at October P&T

Drug Utilization Review Recommendations:

- Monitor for any PA requests and utilization

Psychiatry: Attention Deficit Hyperactivity Disorder

Formulary Update: Healthy Workers HMO and Healthy San Francisco

- No formulary changes made

Prior Authorization Criteria Recommendations:

- No PA criteria changes made

Drug Utilization Review Recommendations:

- No DUR changes made

Interim Prior Authorization Criteria Changes (4/3/25 – 7/2/25)

The following is a summary of changes to SFHP prior authorization (PA) criteria including new criteria and revisions to existing criteria. Current prior authorization criteria can be found at SFHP website at https://www.sfhp.org/providers/pharmacy-services/sfhp-formulary/.

New Criteria

The following new criteria were implemented in the interim since April 2024 P&T.

- Rezdiffra® (resmetirom)
- Tarpeyo® (budesonide)
- Arcalyst® (rilonacept)
- Infertility Medications

REZDIFFRA® (RESMETIROM)
Standard/Specific Therapeutic Class: *thyroid hormone receptor (thr) agonist* **Formulary Status:** • Non-formulary   ○ Rezdiffra® (resmetirom) *Multi-source brand drugs are NF; requests must also follow Brand Name Medication criteria in addition to this criteria*
Coverage Duration: Initial: 12 months; Renewal: 12 months
Diagnosis Considered for Coverage: • Noncirrhotic metabolic dysfunction–associated steatotic liver disease • Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies
Prescribing Restriction • Quantity limit*: #30 per 30 days • Prescriber: Restricted to specialist **Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*
Clinical Information Required for Review • Diagnosis • Previous therapy • Dose
Coverage Criteria: **I. Initiation of Therapy:** Rezdiffra® will be approved when **ALL** the following are met: 1. The patient has a diagnosis of noncirrhotic nonalcoholic steatohepatitis (NASH) or metabolic dysfunction associated steatohepatitis (MASH) (medical records required) **AND** 2. The patient has stage F2 or F3 fibrosis as confirmed by BOTH of the following (prior to therapy with the requested agent):   a. A FIB-4 score consistent with stage F2 or F3 fibrosis adjusted for age **AND**   b. The patient has ONE of the following: i. A liver biopsy within the past 2 years **OR**

REZDIFFRA® (RESMETIROM)

ii. Transient elastography **OR**
iii. Enhanced liver fibrosis (ELF) score **OR**
iv. Magnetic resonance elastography (MRE) **AND**

3. If the patient has an FDA labeled indication, then ONE of the following:
   a. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**
   b. There is support for using the requested agent for the patient's age for the requested indication **AND**
4. The patient has ONE of the following:
   a. A BMI greater than or equal to 25 kg/m^2 **OR**
   b. A BMI greater than or equal to 23 kg/m^2 if the patient is of South Asian, Southeast Asian, or East Asian descent
5. ONE of the following:
   a. If the patient's sex is female then the patient's alcohol consumption is less than 20 grams/day (Note: one standard alcoholic drink contains roughly 14 grams of pure alcohol, which is found in 12 ounces of regular beer, 5 ounces of wine, or 1.5 ounces of distilled spirits) **OR**
   b. If the patient's sex is male then the patient's alcohol consumption is less than 30 grams/day (Note: one standard alcoholic drink contains roughly 14 grams of pure alcohol, which is found in 12 ounces of regular beer, 5 ounces of wine, or 1.5 ounces of distilled spirits) **AND**
6. The patient is being monitored and/or treated for any comorbid conditions (e.g., cardiovascular disease, diabetes, dyslipidemia, hypertension) **AND**
7. BOTH of the following:
   a. The patient is currently on a weight management regimen of a low-calorie diet, increased physical activity, and behavioral modifications **AND**
   b. The patient will continue the weight management regimen in combination with the requested agent **AND**
8. The patient does NOT have ANY of the following:
   a. Decompensated cirrhosis **AND**
   b. Moderate to severe hepatic impairment (Child-Pugh Class B or C) **AND**
   c. Any other liver disease (e.g., Wilson's disease, hepatocellular carcinoma, hepatitis) **AND**
9. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hepatologist, gastroenterologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**
10. The patient does NOT have any FDA labeled contraindications to the requested agent

II. Continuation of Therapy

Rezdiffra® will be approved when ALL of the following are met:

1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND**
2. ONE of the following:
   a. If the patient's sex is female then the patient's alcohol consumption is less than 20 grams/day (Note: one standard alcoholic drink contains roughly 14 grams of pure alcohol, which is found in 12 ounces of regular beer, 5 ounces of wine, or1.5 ounces of distilled spirits) **OR**

REZDIFFRA® (RESMETIROM)
b. If the patient's sex is male then the patient's alcohol consumption is less than 30 grams/day (Note: one standard alcoholic drink contains roughly 14 grams of pure alcohol, which is found in 12 ounces of regular beer, 5 ounces of wine, or 1.5 ounces of distilled spirits) **AND** 3. BOTH of the following: a. The patient is currently on a weight management regimen of a low-calorie diet, increased physical activity, and behavioral modifications **AND** b. The patient will continue the weight management regimen in combination with the requested agent **AND** 4. The patient does NOT have ANY of the following: a. Decompensated cirrhosis **AND** b. Moderate to severe hepatic impairment (Child-Pugh Class B or C) **AND** c. Any other liver disease (e.g., Wilson's disease, hepatocellular carcinoma, hepatitis) **AND** 5. The patient has had clinical benefit with the requested agent **AND** 6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hepatologist, gastroenterologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 7. The patient does NOT have any FDA labeled contraindications to the requested agent
References: N/A
Last review/revision date: 5/2025 New Criteria

TARPEYO® (BUDESONIDE)
Standard/Specific Therapeutic Class: *Glucocorticoids* **Formulary Status:** • Non-formulary ○ Tarpeyo® (budesonide delayed release) *Multi-source brand drugs are NF; requests must also follow Brand Name Medication criteria in addition to this criteria*
Coverage Duration: 10 months
Diagnosis Considered for Coverage: • Primary immunoglobulin A nephropathy (IgAN) • Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies
Prescribing Restriction • Quantity*: ○ Tarpeyo®: #120 per 30 days • Prescriber: Restricted to specialist **Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*
Clinical Information Required for Review • Diagnosis • Previous therapy • Dose
Coverage Criteria:

TARPEYO® (BUDESONIDE)

Approve when ALL the following are met:

1. The patient has a diagnosis of primary immunoglobulin A nephropathy (IgAN) confirmed by kidney biopsy **AND**
2. The requested agent will be used to reduce the loss of kidney function in a patient at risk for disease progression **AND**
3. ONE of the following:
    A. The patient has a urine protein-to-creatinine ratio (UPCR) greater than or equal to 0.8 g/g **OR**
    B. The patient has proteinuria greater than or equal to 1 g/day **AND**
4. The patient's eGFR is greater than or equal to 30 mL/min/1.73 m^2 **AND**
5. If the patient has an FDA labeled indication, then ONE of the following:
    A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**
    B. There is support for using the requested agent for the patient's age for the requested indication **AND**
6. ONE of the following:
    A. BOTH of the following:
        i. The patient has tried and had an inadequate response after at least 3 months of therapy with maximally tolerated ACEI or ARB (e.g., benazepril, lisinopril, losartan), or a combination medication containing an ACEI or ARB **AND**
        ii. The patient will be using an ACEI or ARB or a combination medication containing an ACEI or ARB in combination with the requested agent **OR**
    B. B. The patient has an intolerance or hypersensitivity to an ACEI or ARB, or a combination medication containing an ACE or ARB **OR**
    C. The patient has an FDA labeled contraindication to ALL ACEI or ARB **AND**
7. ONE of the following:
    A. The patient has an intolerance or hypersensitivity to oral generic budesonide that is not expected to occur with the requested agent **OR**
    B. The patient has an FDA labeled contraindication to oral generic budesonide that is not expected to occur with the requested agent **AND**
8. ONE of the following:
    A. The patient has not previously been treated with a course of therapy (9 months) with the requested agent **OR**
    B. The patient has previously been treated with a course of therapy with the requested agent, AND there is support for an additional course of therapy with the requested agent **AND**
9. The prescriber is a specialist in the area of the patient's diagnosis (e.g., nephrologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**
10. The patient does NOT have any FDA labeled contraindications to the requested agent

References: N/A

Last review/revision date: 6/2025
New Criteria

ARCALYST® (RILONACEPT)

Standard/Specific Therapeutic Class: *Anti-Inflammatory Interleukin-1 Receptor Antagonist*
Formulary Status:

- Non-formulary
  - Arcalyst® (rilonacept)

Multi-source brand drugs are NF; requests must also follow Brand Name Medication criteria in addition to this criteria

Coverage Duration: Initial: 12 months; Renewal: 12 months

Diagnosis Considered for Coverage:

- Cryopyrin Associated Periodic Syndrome (CAPS)
- Familial Cold Auto-Inflammatory Syndrome (FCAS)
- Muckle-Wells Syndrome (MWS)
- Deficiency of interleukin-1 receptor antagonist (DIRA)
- Recurrent pedicarditis (RP)
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction

- Quantity*:
  - Arcalyst® (rilonacept) for injection: #8 vials per 28 days
- Prescriber: Restricted to specialist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review

- Diagnosis
- Previous therapy
- Dose

Coverage Criteria:
III. Initiation of Therapy:

Arcalyst will be approved if the patient meets **ALL** of the following:

1. **ONE** of the following:
   - A. **BOTH** of the following:
     1. The patient has **ONE** of the following indications:
        a. Cryopyrin Associated Periodic Syndrome (CAPS) **OR**
        b. Familial Cold Auto-Inflammatory Syndrome (FCAS) **OR**
        c. Muckle-Wells Syndrome (MWS) **AND**
     2. **BOTH** of the following:
        a. The patient has elevated pretreatment serum inflammatory markers (C-reactive protein/serum amyloid A) **AND**
        b. The patient has at least TWO symptoms typical for CAPS (i.e., urticaria-like rash, cold/stress triggered episodes, sensorineural hearing loss, musculoskeletal symptoms of arthralgia/arthritis/myalgia, chronic aseptic meningitis, skeletal abnormalities of epiphyseal overgrowth/frontal bossing) **OR**
   - B. **BOTH** of the following:
     1. The patient has a diagnosis of deficiency of interleukin-1 receptor antagonist **AND**

ARCALYST® (RILONACEPT)

2. The requested agent is being used for maintenance of remission **OR**

C. The patient has a diagnosis of recurrent pericarditis AND ONE of the following:
1. **BOTH** of the following:
a. The patient has tried and had an inadequate response to at least a 6-month trial of colchicine **AND**
b. **ONE** of the following:
i. Colchicine was used concomitantly with at least a 1 week trial of a non-steroidal anti-inflammatory drug (NSAID) AND a corticosteroid **OR**
ii. The patient has an intolerance or hypersensitivity to BOTH an NSAID AND a corticosteroid **OR**
iii. The patient has an FDA labeled contraindication to ALL NSAIDs AND ALL corticosteroids **OR**
2. The patient has an intolerance or hypersensitivity to colchicine **OR**
3. The patient has an FDA labeled contraindication to colchicine **OR**
4. The patient has tried and had an inadequate response to an oral immunosuppressant (i.e., azathioprine, methotrexate, mycophenolate) used in the treatment of recurrent pericarditis **OR**
5. The patient has an intolerance or hypersensitivity to oral immunosuppressants used in the treatment of recurrent pericarditis **OR**
6. The patient has an FDA labeled contraindication to oral immunosuppressants used in the treatment of recurrent pericarditis **OR**

D. The patient has another FDA approved indication for the requested agent **AND**
E. If the patient has an FDA approved indication, then ONE of the following:
1. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**
2. There is support for using the requested agent for the patient's age for the requested indication **OR**

F. The patient has another indication that is supported in compendia (AHFS or DrugDex 1 or 2a level of evidence) for the requested agent **AND**

2. The prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist, immunologist, pediatrician, cardiologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**
3. ONE of the following:
A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR**
B. The patient will be using the requested agent in combination with another immunomodulatory agent AND **BOTH** of the following:
1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND**
2. There is support for the use of combination therapy (copy of support required, e.g., clinical trials, phase III studies, guidelines) **AND**
4. The patient does NOT have any FDA labeled contraindications to the requested agent

For off-label indications or dosing, approve if:

ARCALYST® (RILONACEPT)

- No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
- Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
- Requested use can be supported by at least two published peer reviewed clinical studies

IV. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

1. The patient is stable and continuing the medication AND
2. The patient has had clinical benefit with the requested agent AND
3. The prescriber is a specialist in area of the patient's diagnosis (e.g., allergist, immunologist, pediatrician, cardiologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND
4. ONE of the following:
    a. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) OR
    b. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following:
        i. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent AND
        ii. There is support for use of combination therapy (copy of support required, e.g., clinical trials, phase III studies, guidelines) AND
5. The patient does NOT have any FDA labeled contraindications to the requested agent

V. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

1. The patient has been previously approved for the requested agent through plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] AND
2. The patient has had clinical benefit with the requested agent AND
3. The prescriber is a specialist in area of the patient's diagnosis (e.g., allergist, immunologist, pediatrician, cardiologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND
4. ONE of the following:
    a. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) OR
    b. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following:
        i. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent AND
        ii. There is support for use of combination therapy (copy of support required, e.g., clinical trials, phase III studies, guidelines) AND
5. The patient does NOT have any FDA labeled contraindications to the requested agent

References: N/A

Last review/revision date: 7/2025
New Criteria

INFERTILITY MEDICATIONS
Standard/Specific Therapeutic Class: *Progestational Agents, GnRH agonist, GnRH antagonist, Fertility Stimulating Preparations,non-FSH, Follicle Stimulating Hormone (FSH), Follicle-Stimulating And Luteinizing Hormones, Human Chorionic Gonadotropin (HCG)* **Formulary Status:** • Formulary, PA required   ○ Leuprolide acetate   ○ Clomiphene tablet   ○ Crinone gel   ○ Endometrin insert • Non-formulary   ○ Cetrorelix Acetate (Cetrotide)   ○ Follistim AQ   ○ Ganirelix Acetate   ○ Fyremadel   ○ Gonal-F (Follitropin Alfa)   ○ Gonal-F RFF (Follitropin Alfa)   ○ Gonal-F RFF Rediject (Follitropin Alfa)   ○ Menopur (Menotropins)   ○ Novarel (Chorionic Gonadotropin)   ○ Ovidrel (Choriogonadotropin Alfa)   ○ Pregnyl (Chorionic Gonadotropin) *Multi-source brand drugs are NF; requests must also follow Brand Name Medication criteria in addition to this criteria*
Coverage Duration: see criteria below
Diagnosis Considered for Coverage: • Ovulation Induction • Assisted Reproductive Technology • Hypogonatropic Hypogonadism • Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies
Prescribing Restriction • Quantity*:   ○ Choriogonadotropin Alfa Inj 250 MCG/0.5ML: #2 syringes per 30 days   ○ Cetrorelix Acetate (Cetrotide) For Inj Kit 0.25 MG: #5 kits per 30 days   ○ Follistim AQ 300 Unit/0.36 mL: #15 cartridges per 30 days   ○ Follistim AQ 600 Unit/0.72 mL: #8 cartridges per 30 days   ○ Follistim AQ 900 Unit/1.08 mL: #5 cartridges per 30 day   ○ Ganirelix Acetate, Fyremadel Soln Prefilled Syringe 250 MCG/0.5mL: #5 syringes per 30 days   ○ Gonal-F (Follitropin Alfa) For Inj 1050 Unit: #4 syringes per 30 days   ○ Gonal-F (Follitropin Alfa) For Inj 450 Unit: #10 syringes per 30 days   ○ Gonal-F RFF (Follitropin Alfa) For SQ Inj 75 Unit: #20 syringes per 30 days   ○ Gonal-F RFF Rediject (Follitropin Alfa) For SQ Inj 300 Unit/0.5mL: #15 pens per 30 days   ○ Gonal-F RFF Rediject (Follitropin Alfa) For SQ Inj 450 Unit/0.75mL: #10 pens per 30 days   ○ Gonal-F RFF Rediject (Follitropin Alfa) For SQ Inj 900 Unit/1.5mL: #5 pens per 30 days   ○ Menopur (Menotropins) For Subcutaneous Inj 75 Unit: #60 vials per 30 days   ○ Novarel (Chorionic Gonadotropin) For IM Inj 5000 Unit: #4 vials per 30 days   ○ Ovidrel (Choriogonadotropin Alfa) Inj 250 MCG/0.5ML: #2 syringes per 30 days

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- Pregnyl (Chorionic Gonadotropin) For IM Inj 10,000 Unit: #2 vials per 30 days
- Clomiphene 50mg tablet: up to #10 tablets per 5 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review

- Diagnosis
- Previous therapy
- Dose

Coverage Criteria:

Initiation of Therapy:

<u>Follicle Stimulating Hormone Evaluation</u>

Follistim AQ, **Gonal-F, Gonal-F RFF** will be approved when ALL of the following are met:

1. ONE of the following:
    a. The requested agent will be used for **ovulation induction** and ALL of the following:
        i. ONE of the following:
            1. The patient has tried and had an inadequate response to 3 courses of at least 50 mg daily for 5 days of clomiphene citrate **OR**
            2. The patient has an intolerance or hypersensitivity to clomiphene citrate **OR**
            3. The patient has an FDA labeled contraindication to clomiphene citrate **AND**
        ii. The patient is NOT pregnant **AND**
        iii. The patient does NOT have primary ovarian failure **AND**
        iv. The patient will receive human chorionic gonadotropin (hCG) following completion of the requested agent unless there are risks present for ovarian hyperstimulation syndrome (OHSS) **OR**
    b. The requested agent will be used for the development of multiple follicles as part of an **assisted reproductive technology (ART)** [e.g., invitro fertilization (IVF), gamete intrafallopian transfer (GIFT), zygote intrafallopian transfer (ZIFT), tubal embryo transfer (TET), cryopreservation, intracytoplasmic sperm injection (ICSI)] and ALL of the following:
        i. The patient is NOT pregnant **AND**
        ii. The patient does NOT have primary ovarian failure **AND**
        iii. The patient will receive human chorionic gonadotropin (hCG) following completion of the requested agent unless there are risks present for ovarian hyperstimulation syndrome (OHSS) **OR**
    c. The requested agent will be used for **hypogonadotropic hypogonadism** AND ALL of the following:
        i. The requested agent is Follistim AQ or Gonal-F **AND**
        ii. The patient does not have primary testicular failure **AND**
        iii. The requested agent will be used in combination with human chorionic gonadotropin (hCG) **AND**
        iv. The requested agent will not be started until the patient's serum testosterone level is at normal levels **AND**
2. The patient has undergone a complete medical and endocrinologic evaluation **AND**
3. The fertility status of the patient's partner has been evaluated (if applicable) **AND**

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4. The patient does NOT have any FDA labeled contraindications to the requested agent

Length of approval:

3 months for ART or ovulation induction

6 months for hypogonadotropic hypogonadism

Gonadotropin Releasing Hormone (GnRH) Analogs Evaluation

Ganirelix acetate, **cetrorelix acetate, Fyremadel** or **leuprolide acetate*** will be approved when ALL of the following are met:

1.ONE of the following:

a. The patient is undergoing **ovarian stimulation** and meets ALL of the following:
   i. The patient is NOT pregnant **AND**
   ii. The patient has undergone a complete medical and endocrinologic evaluation **AND**
   iii. The fertility status of the patient's partner has been evaluated (if applicable) **AND**
   iv. The patient will receive human chorionic gonadotropin (hCG) following completion of the requested agent unless there are risks present for ovarian hyper-stimulation syndrome (OHSS) **AND**

2.The patient does NOT have any FDA labeled contraindications to the requested agent

Length of Approval: 3 months

*Note: Formulary and non-formulary medications in this section utilize the same criteria above and do not require step therapy through formulary options unless otherwise noted

Human Chorionic Gonadotropin Evaluation

Novarel, **Ovidrel**, **Pregnyl**, **and Chorionic gonadotropin** will be approved when BOTH of the following are met:

1. ONE of the following:
   a. The requested agent will be used for a diagnosis of **hypogonadotropic hypogonadism** AND BOTH of the following:
      i. The requested agent is Novarel, Pregnyl, or hCG **AND**
      ii. ONE of the following:
         1. The patient is not currently receiving treatment for the diagnosis AND has ONE of the following pretreatment levels:
            a. Total serum testosterone level that is below the testing laboratory's normal range or is less than 300 ng/dL **OR**
            b. Free serum testosterone level that is below the testing laboratory's normal range **OR**

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2. The patient is currently receiving treatment for the diagnosis AND has ONE of the following current levels:
    a. Total serum testosterone level that is within OR below the testing laboratory's normal range OR is less than 300 ng/dL **OR**
    b. Free serum testosterone level is within OR below the testing laboratory's normal range **OR**

b. The requested agent will be used for the development of multiple follicles as part of an **assisted reproductive technology (ART)** [e.g., invitro fertilization (IVF), gamete intrafallopian transfer (GIFT), zygote intrafallopian transfer (ZIFT), tubal embryo transfer (TET), cryopreservation, intracytoplasmic sperm injection (ICSI)] OR for ovulation induction **AND**:
    i. ALL of the following:
        1. The patient is NOT pregnant **AND**
        2. The patient does NOT have primary ovarian failure **AND**
        3. The patient will receive follicle stimulating hormone (FSH) OR clomiphene before the requested agent unless there are risks present for ovarian hyperstimulation syndrome (OHSS) **AND**
        4. The patient has undergone a complete medical and endocrinologic evaluation **AND**
        5. The fertility status of the partner been evaluated (if applicable) **AND**

2. The patient does NOT have any FDA labeled contraindications to the requested agent

Length of Approval:

3 months for ovulation induction or ART

6 months for hypogonadotropic hypogonadism

<u>Menotropins Evaluation</u>

Menopur will be approved when ALL of the following are met:

1. ONE of the following:

    a. The requested agent will be used for the development of multiple follicles as part of an assisted reproductive technology (ART) [e.g., invitro fertilization (IVF), gamete intrafallopian transfer (GIFT), zygote intrafallopian transfer (ZIFT), tubal embryo transfer (TET), cryopreservation, intracytoplasmic sperm injection (ICSI)] **AND**
        i. The patient is NOT pregnant **AND**
        ii. The patient does NOT have primary ovarian failure **AND**
        iii. The patient will receive human chorionic gonadotropin (hCG) following completion of the requested agent unless there are risks present for ovarian hyperstimulation syndrome (OHSS) **AND**
        iv. The patient has undergone a complete medical and endocrinologic evaluation **AND**
        v. The fertility status of the patient's partner has been evaluated (if applicable) **OR**

2. The patient does NOT have any FDA labeled contraindications to the requested agent

INFERTILITY MEDICATIONS

Length of Approval:

3 months

Progesterone Evaluation

Crinone gel or endometrin vaginal insert will be approved when ALL of the following are met:

1. Patient meets the definition of male or female infertility, defined as one of the following:
    a. A licensed physician's findings, based on a patient's medical, sexual, and reproductive history, age, physical findings, diagnostic testing, or any combination of those factors **OR**
    b. A person's inability to reproduce either as an individual or with their partner without medical intervention **OR**
    c. The failure to establish a pregnancy or to carry a pregnancy to live birth after regular, unprotected sexual intercourse **AND**
2. Individual is using as part of an Assisted Reproductive Technology treatment

Length of Approval:

12 months

Clomiphene Evaluation

Clomiphene will be approved when ALL of the following are met:

1.Patient meets the definition of male or female infertility, defined as one of the following:
    a. A licensed physician's findings, based on a patient's medical, sexual, and reproductive history, age, physical findings, diagnostic testing, or any combination of those factors **OR**
    b. A person's inability to reproduce either as an individual or with their partner without medical intervention **OR**
    c. The failure to establish a pregnancy or to carry a pregnancy to live birth after regular, unprotected sexual intercourse

Length of Approval:

12 months

For off-label indications or dosing, approve if:

i. No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
ii. Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
iii. Requested use can be supported by at least two published peer reviewed clinical studies

Continuation of Therapy (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

INFERTILITY MEDICATIONS
References: • American Society for Reproductive Medicine (ASRM), Practice Committee. "Definition of Infertility: A Committee Opinion." Fertility and Sterility, 2023
Last review/revision date: 7/1/2025 New Criteria

Revisions to Existing Criteria

In accordance with the National Committee for Quality Assurance (NCQA) health plan accreditation requirements, all criteria not yet evaluated by P&T within the last year were reviewed. Criteria were evaluated to check formulary status, review for clinical appropriateness and applicability as well as review for formatting and reference check. Criteria with recommended updates are included in the table below with an effective date of August 20th, 2025 unless otherwise noted.

Title	Date Effective	Revision Summary
Incretin Mimetics	5/20/2025	Changed step therapy requirements to include “any diabetic product” to remain rebate compliant
Anti-Obesity Medications	7/1/2025	Removed requirement for documentation of lifestyle interventions and changed to provider attestation to remain rebate compliant. Added criteria for reduction of risk of serious cardiovascular events in patients with cardiovascular disease and obesity and overweight for Wegovy® and moderate to severe obstructive sleep apnea (OSA) in adults with obesity for Zepbound®.
Topical Anti-inflammatory Medications	7/1/2025	Listed accepted off-label uses for tacrolimus ointment listed in the standard clinical decision support resources to streamline PA review
Hepatitis C	8/1/2025	Changed the quantity limit of 14 days to 28 days for better accessibility for members

Appendix: Annual Review

Criteria in the following table were evaluated per the annual review process described above, and no clinically significant changes were made.

Criteria Name	Prior Review
TOPICAL NSAIDS	7/2024
LOVAZA® AND VASCEPA®	7/2024
FINACEA®, AZELEX® (AZELAIC ACID)	7/2024
ORAL ISOTRETINOIN	7/2024
TOPICAL COMBINATIONS FOR ACNE	7/2024
CHEMET® (SUCCIMER)	7/2024
DEFERASIROX (EXJADE®, JADENU®)	7/2024
DEFLAZACORT (EMFLAZA®)	7/2024
GENITOURINARY ANTI-SPASMODICS AND ANTI-CHOLINERGICS	7/2024
LUPUS	7/2024
AZOLE ANTIFUNGALS	7/2024
ONYCHOMYCOSIS	7/2024
FUZEON® (ENFUVIRTIDE)	7/2024
TAVNEOS® (AVACOPAN)	7/2024
VOWST™ (FECAL MICROBIOTA SPORES, LIVE-BRPK)	7/2024
SYMTUZA® (DARUNAVIR-COVISISTAT-EMTRICITABINE-TENOFOVIR AF)	7/2024

Interim Formulary Changes (3/9/2025 – 7/1/2025)

Pharmacy Benefit Medications

Date	Therapeutic class	Medication	Formulary Status	Comment
3/22/25	ANTI-INFLAMMATORY TUMOR NECROSIS FACTOR INHIBITOR	SIMLANDI(CF) (ADALIMUMAB-RYVK)AI 80 MG/0.8 ML	HW: NF→T3/PA HSF: NF	New dosage form
3/22/25	ANTINEOPLASTIC SYSTEMIC ENZYME INHIBITORS	REVUFORJ (REVUMENIB CITRATE) 25 MG TABLET	HW: NF→T3/PA HSF: NF	New dosage form
4/19/25	ANTIVIRAL - MAIN PROTEASE (MPRO) INHIBITOR	PAXLOVID (NIRMATRELVIR/RITONAVIR) 300/150-100MG(SEVERE)	HW: NF→T2 HSF: NF→T2	New dosage form
4/24/25	HIV INTEGRASE INHIBITOR ANTIRETROVIRALS	APRETUDE (CABOTEGRAVIR) ER 600 MG/3 ML VIAL	HW: Medical benefit→T2	Improve access for members
5/3/25	THYROID HORMONES	RENTHYROID (THYROID,PORK) 15, 30, 60, 90, 120 MG TABLET	HW: NF→T2 HSF: NF→T2	New entity
5/17/25	ANTINEOPLASTIC - MEK KINASE INHIBITORS	AVMAPKI (AVUTOMETINIB POTASSIUM) 0.8 MG CAPSULE	HW: NF→T3/PA HSF: NF	New entity
5/17/25	ANTINEOPLASTIC - SYSTEMIC ENZYME INHIBITORS COMBS	AVMAPKI-FAKZYNJA (AVUTOMETINIB POTASSIUM/DEFACTINIB HYDROCHLORIDE) CO-PACK	HW: NF→T3/PA HSF: NF	New entity
5/17/25	ANTINEOPLASTIC SYSTEMIC ENZYME INHIBITORS	FAKZYNJA (DEFACTINIB HYDROCHLORIDE) 200 MG TABLET	HW: NF→T3/PA HSF: NF	New entity
5/17/25	INFLUENZA VIRUS VACCINES	FLUZONE TRIV SOUTH HEM2025 SYR (INFLUENZA VIRUS VACC TRIVAL 2025 SOUTH HEM (6 MOS AND UP)/PF)	HW: NF→T2 HSF: NF	New dosage form
6/7/25	ANTINEOPLASTIC SYSTEMIC ENZYME INHIBITORS	ENSACOVE (ENSARTINIB HYDROCHLORIDE) 25, 100 MG CAPSULE	HW: NF→T3/PA HSF: NF	New entity
7/1/25	FERTILITY STIMULATING PREPARATIONS,NON-FSH	CLOMIPHENE CITRATE 50 MG TAB	HW: exclusion→T3/PA	SB-729
7/1/25	PREGNANCY FACILITATING/MAINTAINING AGENT,HORMONAL	CRINONE (PROGESTERONE) 8% GEL	HW: exclusion→T3/PA	SB-729

	Status	Definition
T1	Formulary Drug, Generic (can have quantity limits, age, gender and other code 1 restrictions as defined by Medi-Cal)	Drug is a generic and is covered at point of sale if quantity limits, age, gender, and other code 1 restrictions are met (NOTE: If quantity limits, age, gender, and other code 1 restrictions are not met, drug may still be covered through Prior Authorization process).
T2	Formulary Drug, Brand (can have quantity limits, age, gender and other code 1 restrictions)	Drug is a brand and is covered at point of sale if quantity limits, age, gender, and other code 1 restrictions are met (NOTE: If quantity limits, age, gender, and other code 1 restrictions are not met, drug may still be covered through Prior Authorization process).
T3	Formulary Drug, Step Therapy or Prior Authorization required	Drug is a brand or generic and is covered through Prior Authorization process or at point of sale if step therapy criteria are met.

NF	Non-Formulary Drug	Drug is non-formulary or excluded. Non-formulary drugs may be covered through Prior Authorization process. Excluded drugs are not covered.

All changes apply to Healthy Workers HMO, and Healthy San Francisco formularies unless otherwise indicated. T3 products are NF for HSF. Excluded= X

The following new products are not listed in above table:

- Newly generic formulary products moved to tier 1 from tier 2
- Bulk chemicals (excluded from benefit)
- Products that are not FDA approved including emollients (excluded from benefit)
- Topical combination kits (NF if separate ingredient products are available on formulary and/or available as OTC)

New Drugs to Market, Nonformulary

Date	Therapeutic Class	Medication	Comment
3/15/2025	ADRENOCORTICOTROPHIC HORMONES	CORTROPHIN GEL 80 UNIT/ML SYR	New Dosage Form
3/15/2025	THIAZIDE AND RELATED DIURETICS	INZIRQO (HYDROCHLOROTHIAZIDE) 10 MG/ML ORAL SUSP	New Dosage Form
3/22/2025	ANTIMIGRAINE PREPARATIONS	SYMBRAVO (RIZATRIPTAN BENZOATE/MELOXICAM) 20-10 MG TABLET	New Dosage Form
3/29/2025	IL-23 RECEPTOR ANTAGONIST, MONOCLONAL ANTIBODY	TREMFYA (GUSELKUMAB) 100 MG/ML PEN	New Entity
3/29/2025	HUMAN INTERLEUKIN 12/23 (IL-12/13) INHIBITORS, MAB	USTEKINUMAB-TTWE (USTEKINUMAB-TTWE) 45MG/0.5ML SY	New Entity
4/5/2025	ANTI-OBESITY - ANOREXIC AGENTS	VYKAT (DIAZOXIDE CHOLINE) XR 25, 75, 150 MG TABLET	New Entity
4/5/2025	HEMOPHILIA TREATMENT AGENTS,NON-FACTOR REPLACEMENT	QFITLIA (FITUSIRAN SODIUM) 50 MG/0.5 ML PEN	New Entity
4/12/2025	ANTIHYPERTENSIVES,ENDOTHELIN RECEPTOR ANTAGONISTS	VANRAFIA (ATRASENTAN HYDROCHLORIDE) 0.75 MG TABLET	New Entity
4/12/2025	NSAID ANALGESIC AND NON-SALICYLATE ANALGESIC COMB	COMBOGESIC (IBUPROFEN/ACETAMINOPHEN) 325-97.5 MG TABLET	New Entity
4/19/2025	ANTIRETROVIRAL - CAPSID INHIBITORS	SUNLENCA (LENACAPAVIR SODIUM) 300 MG TABLET	New Entity
4/19/2025	NEONATAL FC RECEPTOR (FCRN) INHIBITORS	VYVGART HYTRULO (EFGARTIGIMOD ALFA-HYALURONIDASE-QVFC) 1,000MG-10,000	New Dosage Form
5/3/2025	THIAZIDE AND RELATED DIURETICS	HEMICLOR (CHLORTHALIDONE) 12.5 MG TABLET	New Entity
5/10/2025	LEUKOCYTE (WBC) STIMULANTS	RYZNEUTA (EFBEMALENOGRASTIM ALFA-VUXW) 20 MG/ML SYRINGE	New Entity
5/31/2025	BONE FORMATION STIM. AGENTS - PARATHYROID HORMONE	BONSITY (TERIPARATIDE) 560 MCG/2.24 ML PEN	New Entity
5/31/2025	JANUS KINASE (JAK) INHIBITORS	LEQSELVI (DEURUXOLITINIB PHOSPHATE) 8 MG TABLET	New Entity
5/31/2025	PULMONARY ANTIHYPERTENSIVES, PROSTACYCLIN-TYPE	YUTREPIA (TREPROSTINIL SODIUM) 26.5, 79.5, 53, 106 MCG INHAL CAP	New Entity
6/7/2025	TOPICAL NITRIC OXIDE RELEASING AGENTS	ZELSUVMI (BERDAZIMER SODIUM) 10.3% GEL	New Entity
6/7/2025	INSULINS	MERILOG SOLOSTAR (INSULIN ASPART-SZJJ) 100 UNIT/ML	New Entity
6/7/2025	GLUCOCORTICOIDS	KHINDIVI (HYDROCORTISONE) 1 MG/ML SOLUTION	New Dosage Form
6/14/2025	PITUITARY SUPPRESSIVE AGENTS	CRENESSITY (CRINECERFONT) 25 MG CAPSULE	New Dosage Form

*Scheduled for review at upcoming P&T

The following new products are not listed in above table:

- Bulk chemicals (excluded from benefit)
- Products that are not FDA approved including emollients (excluded from benefit)
- Topical combination kits (NF if separate ingredient products are available on formulary and/or available as OTC)

New Drugs to Market, Medical Benefit

Date	Therapeutic Class	Drug Name, Strengths, and Dosage Form
3/15/2025	ANTIHEMOPHILIC FACTORS	SEVENFACT(COAGULATION FACTOR VIIA RECOMBINANT-JNCW) 2 MG VIAL
3/15/2025	COMPLEMENT INHIBITORS	EPYSQLI (ECULIZUMAB-AAGH) 300 MG/30 ML VIAL
3/15/2025	BETA-ADRENERGIC BLOCKING AGENTS	RAPIBLYK (LANDIOLOL HCL) 280 MG VIAL
3/22/2025	HUMAN INTERLEUKIN 12/23 (IL-12/13) INHIBITORS, MAB	SELARSDI (USTEKINUMAB-AEKN) 130 MG/26 ML VIAL
3/29/2025	OPHTHALMIC CELL/GENE THERAPY AGENTS	ENCELTO IMPLANT (REVAKINAGENE TARORETCEL-LWEY)
5/3/2025	ANTINEOPLASTIC - ALKYLATING AGENTS	TEPYLUTE (THIOTEPA) 100 MG/10 ML VIAL
5/3/2025	NEONATAL FC RECEPTOR (FCRN) INHIBITORS	IMAAVY (NIPOCALIMAB-AAHU) 1,200 MG/6.5 ML VIAL
5/10/2025	BONE RESORPTION INHIBITORS	JUBBONTI (DENOSUMAB-BBDZ) 60 MG/ML SYRINGE
5/10/2025	BONE RESORPTION INHIBITORS	WYOST (DENOSUMAB-BBDZ) 120 MG/1.7 ML VIAL
5/24/2025	ANTINEOPLASTICS ANTIBODY/ANTIBODY-DRUG COMPLEXES	EMRELIS (TELISOTUZUMAB VEDOTIN-TLLV) 20, 100 MG VIAL
5/31/2025	GENE THERAPY AGENTS - CONNECTIVE TISSUE DISORDERS	ZEVASKYN (PRADEMAGENE ZAMIKERACEL) SHEET
6/7/2025	BONE RESORPTION INHIBITORS	STOBOCLO (DENOSUMAB-BMWO) 60 MG/ML SYRINGE
6/7/2025	BONE RESORPTION INHIBITORS	OSENVELT (DENOSUMAB-BMWO) 120 MG/1.7 ML VIAL

The following products are not listed in the above table:

- Allergenic extracts
- Diagnostic preparations
- Parenteral amino acid solutions and combinations
- IV fat emulsions