

San Francisco Health Plan (SFHP) Quarterly Formulary and Prior Authorization Criteria Update April 2022

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, 4/20/2022. Effective date for all changes is **Friday, 5/20/2022**.

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.

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Drug Class Reviews

Cardiology: Dyslipidemia

Formulary Update: Healthy Workers HMO and Healthy San Francisco

- No formulary changes made

Prior Authorization Criteria Recommendations:

- Updated PCSK9 Inhibitors criteria to include Leqvio® as non-formulary and maintain Repatha® as preferred Praluent® based on comparable cost-effectiveness

Drug Utilization Review Recommendations:

- No DUR changes made

Cardiology: Heart Failure, Angina and Coronary Artery Disease

Formulary Update: Healthy Workers HMO only

- Based on current guideline recommendations, removed step requirement for Entresto® (moved to tier 2) to allow initiation upon diagnosis of symptomatic heart failure and use regardless of ejection fraction per current guidelines

Prior Authorization Criteria Update:

- Retired Entresto® criteria based on formulary change above
- Updated SGLT2 Inhibitors criteria to incorporate expanded FDA-approval of Jardiance® to include heart failure with preserved ejection fraction

Drug Utilization Review Update:

- Reviewed separate DUR analysis assessing adherence and regimen selection for Medi-Cal members on medications to treat heart failure, with recommendations on member and provider education

Immunology: Rezurock™ (belumosudil)

Formulary Update: Healthy Workers HMO only

- Added Rezurock™ to formulary tier 3 with PA required to ensure appropriate diagnosis

Prior Authorization Criteria Recommendations:

- None; utilize existing Oral and Intravenous Oncolytics general criteria for any requests, allowing approval per NCCN guidelines

Drug Utilization Review Recommendations:

- No DUR changes made

Infectious Disease: Antiparasitics

Formulary Update: Healthy Workers HMO and Healthy San Francisco

- Removed Alinia® (nitazoxanide) 100mg/5mL oral suspension from formulary due to lack of utilization and whole tablet dosage form available

Prior Authorization Criteria Recommendations:

- No PA criteria changes made

Drug Utilization Review Update:

- No DUR changes made

Infectious Disease: Vemlidy® (tenofovir alafenamide) Formulary Modification Request

Formulary Update: Healthy Workers HMO only

- No formulary changes made; maintained Vemlidy® on formulary tier 3, PA required, with entecavir and tenofovir disoproxil fumarate preferred

Prior Authorization Criteria Recommendations:

- No PA criteria changes made

Drug Utilization Review Update:

- No DUR changes made

Neurology: Qulipta™ (atogepant)

Formulary Update: Healthy Workers HMO

- Added Qulipta™ to formulary tier 3 with PA required to ensure appropriate diagnosis and use of preferred alternatives

Prior Authorization Criteria Update:

- Updated Migraine Prevention criteria to incorporate Qulipta™ on par with Emgality® and preferred over Nurtec® ODT

Drug Utilization Review Update:

- No DUR changes made

Neurology: Trudhesa™ (dihydroergotamine)

Formulary Update: Healthy Workers HMO and Healthy San Francisco

- Maintained non-formulary at this time; utilize general Non-Formulary Medications criteria for any requests

Prior Authorization Criteria Update:

- No PA criteria changes made

Drug Utilization Review Update:

- No DUR changes made

Rheumatology: Biologic and Non-Biologic Disease-Modifying Anti-Rheumatic Drugs (DMARDs)

Formulary Update: Healthy Workers HMO and Healthy San Francisco

- Removed the following biologic DMARDs from formulary tier 3 based on non-preferred status per criteria and minimal utilization (authorize continuity): Cimzia® (certolizumab), Simponi® (golimumab), Kineret® (anakinra), Xeljanz®/XR (tofacitinib)
- Removed Trexall® (methotrexate) tablet from formulary tier 3 due to lack of drug-specific criteria for use and no utilization

Prior Authorization Criteria Update:

- Updated Disease Modifying Biologics Criteria to incorporate recently approved FDA indications:
 - Juvenile idiopathic arthritis and ankylosing spondylitis for Xeljanz®/XR
 - Psoriatic arthritis for Tremfya®, Skyrizi®, and Rinvoq®

Drug Utilization Review Update:

- No DUR changes made

Interim Prior Authorization Criteria Changes (1/1/22 – 4/2/22)

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

In the interim since January 2022 P&T, no new criteria were implemented.

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 effective date May 20th, 2022.

Title	Date Effective	Revision Summary
STEP THERAPY EXCEPTION	3/21/2022	Updated wording to reflect Department of Managed Health Care (DHMC) All Plan Letter 22-004 Step Therapy Exception Coverage Guidance definitions. Approval may be granted for any one of the following: <ul style="list-style-type: none"> • Sufficient prior trial and failure of the required step therapy drug(s) (e.g., due to lack of efficacy, diminished effect, or adverse event) OR • Contraindication or inability to use required step therapy drug(s) OR • Medical justification why required step therapy drug(s) would be ineffective or the requested drug would be superior for the member's condition OR • Medical justification why required step therapy drug(s) has the potential to cause physical or mental harm or deterioration of the member's condition OR • Medical justification why the required step therapy drug(s) is expected to do any of the following: <ul style="list-style-type: none"> ○ Worsen a comorbid condition ○ Decrease the capacity to maintain a reasonable functional ability in performing daily activities ○ Pose a significant barrier to adherence to, or compliance with, the current drug regimen or plan of care
DISEASE MODIFYING BIOLOGICS	2/25/2022	Updated to incorporate the following recently approved diagnoses (non-preferred after Enbrel®, Humira®, Cosentyx®, Taltz®): <ul style="list-style-type: none"> • Skyrizi® (risankizumab) for psoriatic arthritis • Xeljanz® (tofacitinib) for ankylosing spondylitis
NON-FORMULARY MEDICATIONS	5/20/2022	Updated to remove references specific to Medi-Cal (i.e., review of requests for physician-administered drugs)
ORAL AND INTRAVENOUS ONCOLYTICS	5/20/2022	Updated to remove references specific to Medi-Cal (i.e., review of requests for physician-administered drugs)
DIRECT FACTOR XA INHIBITORS	5/20/2022	Updated to include criteria for Xarelto® (rivaroxaban) oral suspension (non-formulary), to approve if: <ul style="list-style-type: none"> • There is documentation of trial and failure, intolerance, contraindication, or inability (e.g. inability to swallow, etc.) to use tablet formulation AND • The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria

Title	Date Effective	Revision Summary
DDAVP® (DESMOPRESSIN)	5/20/2022	Updated to remove listing and criteria for 10% rhinal tube dosage from due to market removal
GENITOURINARY ANTI- SPASMODICS AND ANTI- CHOLINERGICS	5/20/2022	Updated to remove listing and coverage criteria for Oxytrol® for Women over-the-counter transdermal patch (previously covered for Medi-Cal only)
WHITE BLOOD CELL STIMULATORS	5/20/2022	Updated to list most recently approved biosimilar Releuko® (filgrastim-ayow) as non-formulary (Nivestym® preferred). Indications among biosimilars are identical.
HEPATITIS C	5/20/2022	Updated to remove recommendations for pediatric patients, due to lack of pediatric population/dependents under Healthy Workers HMO.

Interim Formulary Changes (1/1/22 - 4/2/22)

Pharmacy Benefit Medications

Date*	Therapeutic class	Medication	Formulary Status	Comment
01/06/2022	Antiviral - RNA Polymerase Inhibitor	molnupiravir 200 mg capsule (EUA)	HW, HSF: T1-F QL #40 (5-day course), AL ≥ 18y	New entity
01/21/2022	Miotics And Other Intraocular Pressure Reducers	brimonidine-timolol (Combigan) 0.2%-0.5%	HW, HSF: T1-F	New generic
02/17/2022	Metabolic Deficiency Agents	betaine 1 gram/1.9 mL oral powder	HW: T1-F, HSF: X	New generic
02/17/2022	Ophthalmic Anti-Inflammatory Immunomodulator-Type	cyclosporine (Restasis) 0.05% eye emulsion ophthalmic dropperette	HW: T3-F/PA, HSF: X	New generic
02/17/2022	Antivirals, HIV-Specific, CCR5 Co-Receptor Antag.	maraviroc (Selzentry) 150, 300 mg tablet	HW: T1-F, HSF: X	New generic
02/25/2022	COVID-19 Vaccines	Comirnaty (COVID-19 MRNA) 30 mcg/0.3 mL vaccine PF IM vial	HW: T2-F QL #2/365d, HSF: X	New dosage form
03/03/2022	Antineoplastic Systemic Enzyme Inhibitors	Talzenna (talazoparib tosylate) 0.5, 0.75 mg capsule	HW: T3-F/PA, HSF: X	New strength
03/03/2022	COVID-19 Vaccines	Moderna COVID-19 (MRNA) vaccine PF IM vial	HW: T2-F QL #1/365d, HSF: X	New dosage form
03/10/2022	Antineoplastic Immunomodulator Agents	lenalidomide (Revlimid) 5, 10, 15, 25 mg capsule	HW: T3-F/PA, HSF: X	New generic
03/16/2022	Antineoplastic Systemic Enzyme Inhibitors	Vonjo (pacritinib citrate) 100 mg capsule	HW: T3-F/PA, HSF: X	New entity
03/24/2022	Anticonvulsants	lacosamide (Vimpat) 50, 100, 150, 200 mg tablet	HW, HSF: T1-F	New generic

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.
T4 Formulary Specialty Drug, Prior Authorization required	Drug requires distribution through a specialty pharmacy or is a limited distribution drug (LDD). Prior authorization process is required.
T5 Non-Formulary Drug	Drug is non-formulary, provided through a Medi-Cal benefit or excluded. Non-formulary drugs may be covered through Prior Authorization process. Excluded drugs (e.g. FFS Medi-Cal) are not covered.

All changes apply to Medi-Cal, Healthy Workers HMO, and Healthy San Francisco formularies unless otherwise indicated.

*Applies to Medi-Cal formulary only. FFS Carve Out=CO Excluded=X

All Rx-only products are excluded for Medicare/Medi-Cal. T3 & 4 products are NF for HSF

The following new products are not listed in above table:

Here for you

- 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)
- Local anesthetics (NF if formulary agents are available)

New Drugs to Market, Unlisted

Date	Therapeutic class	Medication	Comment
01/06/2022	Direct Factor XA Inhibitors	Xarelto (rivaroxaban) 1 mg/mL suspension	New dosage form
01/11/2022	Glucocorticoids	Tarpeyo DR (budesonide) 4 mg capsule	New dosage form
01/11/2022	Anticholinergics, Quaternary Ammonium	Dartisla ODT (glycopyrrolate) 1.7 mg orally disintegrating tablet	New dosage form
01/11/2022	Thymic Stromal Lymphopoietin (TSLP) Inhibitors	Tezspire (Tezepelumab-ekko) 200 mg/1.91 mL SC syringe	New entity*
01/19/2022	Adrenal Steroid Inhibitors	Recorlev (levoketoconazole) 150 mg tablet	New entity
01/19/2022	Interleukin-13 (IL-13) Inhibitors, MAB	Adbry (tralokinumab-ldrm) 150 mg/mL syringe	New entity*
01/27/2022	Janus Kinase (JAK) Inhibitors	Rinvoq ER (upadacitinib) 30 mg tablet	New dosage form*
02/03/2022	Opioid Antagonists	Zimhi (naloxone) 5 mg/0.5 mL SC syringe	New dosage form
02/10/2022	Opioid Analgesic and NSAID Combination	Seglantis (tramadol hcl- celecoxib) 56 mg-44 mg tablet	New combination
02/17/2022	Janus Kinase (JAK) Inhibitors	Cibinqo (abrocitinib) 50, 100, 200 mg tablet	New entity*
02/17/2022	Skeletal Muscle Relaxants	Fleqsuvy (baclofen) 25 mg/5 mL oral suspension	New dosage form
03/03/2022	Plasma Kallikrein Inhibitors	Takhzyro (lanadelumab-flyo) 300 mg/2 mL syringe	New dosage form
03/03/2022	Acne Agents, Topical	Twyneo (tretinoin-benzoyl peroxide) 0.1 %-3 % cream	New combination
03/03/2022	Selective Serotonin Reuptake Inhibitor (SSRI)	citalopram HBr 30 mg capsule	New dosage form
03/10/2022	Antivirals, HIV-Spec, Nucleoside-Nucleotide Analog	Descovy (emtricitabine-tenofovir alafenamide fumarate) 120-15 mg tablet	New strength
03/10/2022	Leukocyte (WBC) Stimulants	Releuko (filgrastim-ayow) 300 mcg/0.4 mL, 480 mcg/0.8 mL SC syringe, inj vial	New entity
03/10/2022	Pyruvate Kinase Activators	Pyrukynd 5, 20, 50 mg tablet, taper pack	New entity
03/16/2022	Antiemetic/Antivertigo Agents	Antivert (meclizine HCl) 25 mg chewable tablet	New dosage form
03/16/2022	IBS Agents, Sodium-Hydrogen Exchanger 3(NHE3) Inhibitor	Ibsrela (tenapanor HCl) 50 mg tablet	New entity*
03/24/2022	Anti-Anxiety – Benzodiazepines	Loreev XR (lorazepam) 1.5 mg capsule	New strength
03/24/2022	Loop Diuretics	Soanz (torsemide) 40, 60 mg tablet	New dosage form
03/31/2022	Agents to Treat Multiple Sclerosis	Mayzent (siponimod) 1 mg tablet, 0.25 mg start-1 mg maintenance pack	New dosage form
03/31/2022	Janus Kinase (JAK) Inhibitors	Rinvoq (upadacitinib) ER 45 mg tablet	New strength*

*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)
- Local anesthetics (NF if formulary agents are available)

New Drugs to Market, Medical Benefit

Therapeutic Class	Drug Name, Strengths, and Dosage Form
Mineral Replacement, Miscellaneous	selenious acid 12 mcg/2 mL vial
Ophthalmic VEGF-A and ANG-2 Inhib, Bispecific AB	Vabysmo (faricimab-svoa) 6 mg/0.05 mL vial
Complement Inhibitors	Enjaymo (sutimlimab-jome) 1,100 mg/22 mL IV vial
Adrenergic Agents, Catecholamines	norepinephrine bitartrate in sterile water 16 mg/8 mL-water
Vaccine/Toxoid Preparations, Combinations	Quadracef DTAP-ipv (diphtheria, pertussis (acellular), tetanus, polio vaccine PF syringe
Antineoplastic EGF Receptor Blocker Mclon Antibody	Herceptin (trastuzumab) 420 mg vial
Antidiuretic and Vasopressor Hormones	Vasopressin (vasopressin) 20, 40 unit/100 mL IV infusion bottle
Ophthalmic Antifibrotic Agents	Mitomycin in sterile water 0.2 mg/mL (0.02%), 0.4 mg/mL (0.04%) PF ophthalmic syringe
Antineoplastic - CAR-T Cell Immunotherapy	Carvykti (ciltacabtagene autoleucel) IV infusion bag-cassette
Sympathomimetic Agents	Rezipres (ephedrine HCl) 23.5 mg/5 mL IV ampule
Antipruritics, Systemic	Korsuva (difelikefalin acetate) 65 mcg/1.3 mL IV vial
Sympathomimetic Agents	Akovaz (ephedrine sulfate) 25 mg/5 mL IV syringe
Cephalosporin Antibiotics – 1 st Generation	cefazolin 2 gm vial injection
Antihemophilic Factors	Nuwiq (antihemophilic factor VIII rec hek cell, B-domain deleted) 1,500 unit vial, vial pack
Antineoplastic-Immunotherapy Checkpoint Inhib Comb	Opdualag (nivolumab-relatlimab-rmbw) 240-80 mg/20 mL IV vial

The following products are not listed in the above table:

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