

## San Francisco Health Plan (SFHP) Quarterly Formulary and Prior Authorization Criteria Update July 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, 7/20/2022. Effective date for all changes is **8/20/2022**.

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.

### Contents

#### *Drug Class Reviews*

Dermatology: Atopic Dermatitis .....	2
Endocrinology: Systemic and Topical Steroids .....	2
Gastroenterology: Bylavy™ (odevixibat)/Livmarli™ (maralixibat) .....	2
Infectious Disease: Systemic and Topical Antifungals .....	3
Ophthalmology: Ophthalmology Miscellaneous Preparations .....	3
Pain: Systemic and Topical Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) .....	3
Pulmonology: Asthma and Chronic Obstructive Pulmonary Disease (COPD) .....	4
Pulmonology: Pulmonary Biologics .....	4
Rheumatology: Tavneos® (avacopan) .....	4
Interim Prior Authorization Criteria Changes (4/3/22 – 7/2/22) .....	5
New Criteria .....	5
Revisions to Existing Criteria .....	5
Interim Formulary Changes (4/3/22 – 7/2/22) .....	7
Pharmacy Benefit Medications .....	7
New Drugs to Market, Unlisted .....	9
New Drugs to Market, Medical Benefit .....	10

## Drug Class Reviews

### Dermatology: Atopic Dermatitis

**Formulary Update:** Healthy Workers HMO only

- Added Cibinqo™ (abrocitinib) to formulary tier 3 with PA required, on par with Dupixent® (dupilumab) to allow an oral option for atopic dermatitis inadequately controlled or not amenable to topical treatments

**Prior Authorization Criteria Recommendations:**

- Updated Atopic Dermatitis criteria to incorporate requirements for newly approved systemic therapies

**Drug Utilization Review Recommendations:**

- No drug utilization review (DUR) changes made

### Endocrinology: Systemic and Topical Steroids

**Formulary Update:** Healthy Workers HMO and Healthy San Francisco

- Added desoximetasone (Topicort®) 0.25% ointment to formulary with quantity limit based on comparative cost-effectiveness and PA requests
- Expanded quantity limit for fluticasone 0.05% cream from #60 to #240 grams per 30 days to align with other dosage forms
- Removed the following from formulary based on no/minimal use and cost-effective alternatives available:
  - betamethasone dipropionate augmented 0.05% gel
  - fluocinolone (Synalar®) 0.025% cream
  - prednisolone sodium phosphate 15mg/5mL and 5mg base/5mL (Pediapred®) oral solutions
- Removed OTC formulations of hydrocortisone 1% cream and ointment from formulary to align with evidence of coverage; members may continue to utilize prescription formulations
- Maintained Tarpeyo™ (budesonide) non-formulary at this time due to minimal data available and niche indication; utilize general Non-Formulary Drugs criteria for any requests, which would allow approval based on FDA-approved indication

**Prior Authorization Criteria Update:**

- Updated Topical Steroids criteria to reflect formulary changes above and remove obsolete and OTC listings

**Drug Utilization Review Update:**

- No DUR changes made

### Gastroenterology: Bylavy™ (odevixibat)/Livmarli™ (maralixibat)

**Formulary Update:** Healthy Workers HMO and Healthy San Francisco

- Maintained both Bylavy™ and Livmarli™ non-formulary at this time due to limited place in therapy and lack of utilization/requests

**Prior Authorization Criteria Recommendations:**

- No prior authorization (PA) criteria changes made; utilize general Non-Formulary Medications criteria for any requests

**Drug Utilization Review Recommendations:**

- No DUR changes made

## Infectious Disease: Systemic and Topical Antifungals

### **Formulary Update:** Healthy Workers HMO and Healthy San Francisco

- Removed PA requirement for itraconazole (Sporanox®) 100mg capsule and moved to tier 1 based on comparable cost-effectiveness and 100% PA approval
- Added ciclopirox (Loprox®) 1% shampoo to formulary tier 1 with quantity limit #120 mL per 30 days to align with other dosage forms based on comparable cost-effectiveness and 100% PA approval
- Added quantity limit to clotrimazole 1% solution #180 mL per 30 days to align with other dosage forms
- Removed OTC formulation of clotrimazole (Lotrimin® AF) 1% cream from formulary to align with plan exclusions (maintain Rx formulation tier 1)

### **Prior Authorization Criteria Recommendations:**

- Updated Azole Antifungals criteria and Onychomycosis criteria to reflect formulary change for itraconazole capsule and reflect market removal of Onmel® (itraconazole) tablet

### **Drug Utilization Review Update:**

- No DUR changes made

## Ophthalmology: Ophthalmology Miscellaneous Preparations

### **Formulary Update:** Healthy Workers HMO and Healthy San Francisco

- Added Natacyn® (natamycin) 5% suspension drops to formulary tier 2 due to lack of formulary alternatives
- Removed Blephamide® (sulfacetamide-prednisolone) 10%-0.2% suspension drops and ointment from formulary tier 3 (step) due to lack of utilization and cost-effective alternatives available
- Removed Xiidra® (lifitegrast) 5% dropperette from formulary tier 3 (PA required) due to cost-effective alternative (generic cyclosporine) available
- Maintained Tyrvaya™ (varenicline) and Verkazia® (cyclosporine) as non-formulary due to lack of use/requests and cost-effective alternatives available; utilize general Non-Formulary Medications criteria for any requests

### **Prior Authorization Criteria Recommendations:**

- Updated Ophthalmic Anti-Inflammatory Immunomodulators criteria to reflect formulary changes above
- Updated Ophthalmic Antihistamines criteria to list Zerviate® (cetirizine) as non-formulary (not currently listed)

### **Drug Utilization Review Update:**

- No DUR changes made

## Pain: Systemic and Topical Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)

### **Formulary Update:** Healthy Workers HMO and Healthy San Francisco

- Removed naproxen (Naprosyn®) 125mg/5mL and Indocin® (indomethacin) 25mg/5mL suspensions from formulary due to lack of use, available alternatives, and no pediatric population

### **Prior Authorization Criteria Update:**

- No PA criteria changes made

### **Drug Utilization Review Update:**

- No DUR changes made

## **Pulmonology: Asthma and Chronic Obstructive Pulmonary Disease (COPD)**

**Formulary Update:** Healthy Workers HMO and Healthy San Francisco

- Removed Proair® Respiclick® (albuterol) from formulary due to lack of utilization and cost-effective alternatives available

**Prior Authorization Criteria Update:**

- No PA criteria changes made

**Drug Utilization Review Update:**

- Reviewed separate DUR analysis of adherence and regimen selection

## **Pulmonology: Pulmonary Biologics**

**Formulary Update:** Healthy Workers HMO and Healthy San Francisco

- Maintained Xolair® (omalizumab) prefilled syringe (for self-administration) non-formulary due to available alternative and safety concerns

**Prior Authorization Criteria Update:**

- Updated Pulmonary Biologics criteria to include coverage requirements for Xolair® based on labeling changes allowing self-administration

**Drug Utilization Review Update:**

- No DUR changes made

## **Rheumatology: Tavneos® (avacopan)**

**Formulary Update:** Healthy Workers HMO and Healthy San Francisco

- Added Tavneos® to formulary tier 3 with PA required to confirm appropriate diagnosis and adjunct therapy

**Prior Authorization Criteria Update:**

- Implemented new criteria for Tavneos® requiring documentation of diagnosis with appropriate testing and induction treatment regimen

**Drug Utilization Review Update:**

- No DUR changes made

## Interim Prior Authorization Criteria Changes (4/3/22 – 7/2/22)

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 April 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 August 20<sup>th</sup>, 2022.

Title	Date Effective	Revision Summary
SGLT-2 INHIBITORS	6/20/2022	Clarified diagnosis and documentation requirements based on review of appealed case(s) to allow appropriate Farxiga® (dapagliflozin) approval for patients with chronic kidney disease
TESTOSTERONE REPLACEMENT	8/20/2022	Updated to list Tlando® (testosterone undecanoate) oral capsule as non-formulary, preferring injectable and transdermal formulations, due to recent FDA approval in March 2022.
PROBIOTICS	8/20/2022	Retired due to exclusion of OTC probiotic coverage for Healthy Workers HMO (criteria pertained to Medi-Cal only)
PROTON PUMP INHIBITORS	8/20/2022	Updated to reflect formulary status of lansoprazole ODT which was previously covered under Medi-Cal Rx with pediatric age limit but is nonformulary for Healthy Workers HMO
DIFICID® (FIDAXOMICIN)	8/20/2022	Updated criteria to allow first-line use in patients at risk of recurrence based on 2021 Infectious Diseases Society of America treatment guidelines for clostridium difficile infection: <ul style="list-style-type: none"> <li>For <b>Dificid®</b> for clostridium difficile, approve if: <ul style="list-style-type: none"> <li>There is documentation of trial and failure, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, pregnancy in first trimester, etc.) to use oral <b>vancomycin</b> (capsule, compound or oral solution) <b>OR</b></li> <li><b>Patient has a risk factor for recurrent CDI (prior CDI, age 65 years, immunocompromise, severe infection, and/or ribotype 027/078,244 infection)</b></li> </ul> </li> </ul>
ORAL FLUOROQUINOLONES	8/20/2022	Updated to reflect formulary status of levofloxacin and ciprofloxacin solutions which were previously covered under Medi-Cal Rx with pediatric age limit but are nonformulary for Healthy Workers HMO
FUZEON® (ENFUVIRTIDE)	8/20/2022	Updated to clarify language on required trial and failure of preferred regimens for HIV-1 based on 2022 Department of Health and Human Services guideline updates: <p>For HIV-1:</p> <ul style="list-style-type: none"> <li>Documented treatment failure of at least one sensitivity-assisted antiretroviral therapy regimen and at least two drug regimens that included two different NRTIs and two or more <b>agents from other classes (INSTI, NNRTI, or boosted PI)</b>, OR patient has documented reason for not trying two drug regimens that included two different NRTIs and two or more <b>drugs from other classes PIs</b></li> </ul>

Title	Date Effective	Revision Summary
ANTITUBERCULAR ANTIBIOTICS	8/20/2020	Updated to include durations and all alternative regimens from current Sanford Guide and World Health Organization guidelines

## Interim Formulary Changes (4/3/22 – 7/2/22)

### Pharmacy Benefit Medications

Date*	Therapeutic class	Medication	Formulary Status	Comment
04/04/2022	Antihypergly, Incretin Mimetic (GLP-1 Recep. Agonist)	Ozempic (semaglutide) 2 mg/dose (8 mg/3 mL) SC pen injector	HW, HSF: T3-F/ST (metformin) QL #9 mL/84 days	New strength
04/23/2022	Antiviral – Main Protease (MPRO) Inhibitor	Paxlovid (nirmatrelvir-ritonavir) 150-100 mg pack (EUA)	HW, HSF: T2-F QL #6/day	New dosage form
04/23/2022	Prenatal Vitamin Preparations	Prenatal Plus Vitamin-Mineral (PNV #180-ferrous fumarate-folic acid) tablet	HW, HSF: T2-F	Covered as a class
04/26/2022	COVID-19 Vaccines	Comirnaty (Pfizer) 30mcg/0.3mL vac-gray	HW: T2-F QL #2/365d HSF: X	New dosage form
04/26/2022	COVID-19 Vaccines	Moderna COVID-19 booster (EUA)	HW: T2-F QL HSF: X	New dosage form
05/24/2022	Direct Factor Xa Inhibitors	Xarelto (rivaroxaban) 1 mg/mL suspension	HW, HSF: NF → T2-F QL #30mL/30d	Align with tablet for rebate purposes
06/18/2022	Janus Kinase (JAK) Inhibitors	Olumiant (baricitinib) 4 mg tablet	HW: T3-F/PA HSF: X	New strength
06/06/2022	COVID-19 Vaccines	Spikevax (Moderna) COVID (18Y up) vaccine 100 mcg/0.5 mL vial	HW: T2-F HSF: X	New dosage form
06/06/2022	COVID-19 Vaccines	Comirnaty (Pfizer), Pfizer COVID (12Y up) vaccine-gray, Pfizer COVID vaccine-purple 30 mcg/0.3 mL vaccine vial	HW: T2-F QL #2/365d → T2-F HSF: X	Removed QL from all
06/06/2022	COVID-19 Vaccines	Janssen COVID-19 vaccine (EUA) 0.5 mL vial	HW: T2-F QL #1/365d → T2-F HSF: X	Removed QL from all
06/06/2022	COVID-19 Vaccines	Moderna COVID (12Y up) vaccine (EUA) 100 mcg/0.5 mL vial, Moderna COVID booster (EUA) 50 mcg/0.5 mL vial	HW: T2-F QL #1/365d → T2-F HSF: X	Removed QL from all

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:

- 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
04/09/2022	Laxatives and Cathartics	lactulose 10 gm/15 mL oral solution	New dosage form
04/09/2022	Antiretroviral-NRTIS and Integrase Inhibitors Comb	Triumeq (abacavir sulfate-dolutegravir sodium-lamivudine) 60-5-30 mg tab suspension	New dosage form
04/09/2022	Androgenic Agents	Tlando (testosterone undecanoate) 112.5 mg capsule	New dosage form
04/16/2022	Systemic Enzyme Inhibitors	Vijoice (alpelisib) 50, 125 mg tablet, 250 mg daily dose pack	New entity*
04/16/2022	Sedative-Hypnotics, Non-Barbiturate	Quviviq (daridorexant HCl) 25, 50 mg tablet	New entity
04/30/2022	Calcium Channel Blockers	Norliqva (amlodipine besylate) 1 mg/mL oral solution	New dosage form
04/30/2022	COVID-19 Vaccines	Moderna COVID 6M-5Y, 6-11Y (MRNA, LNP-S, pediatric) vaccines (unapproved)	New dosage form
04/30/2022	Drugs to Treat Movement Disorders	Austedo TD (deutetrabenazine) 6-9 mg pak (week 1-2) tablet dose pack	Sample pack
05/07/2022	Cardiac Myosin Inhibitor	Camzyos (mavacamten) 2.5, 5, 10, 15 mg capsule	New entity*
05/14/2022	Rosacea Agents, Topical	Epsolay (benzoyl peroxide) 5% cream pump	New dosage form
05/21/2022	Skeletal Muscle Relaxants	Lyvispah (baclofen) 5, 10, 20 mg granule packet	New dosage form
05/21/2022	Amyotrophic Lateral Sclerosis	Radicava ORS (edaravone) 105 mg/5 mL oral suspension, starter kit	New dosage form*
05/21/2022	Antihyperglycemic - Incretin Mimetics Combination	Mounjaro (tirzepatide) 2.5, 5, 7.5, 10, 12.5, 15 mg/0.5 mL SC pen injector	New entity*
05/27/2022	Antipsoriatics Agents	Vtama (tapinarof) 1% cream	New entity
05/27/2022	Anti-Ulcer-H. Pylori Agents	Voquenza (vonoprazan fumarate-amoxicillin trihydrate-clarithromycin) Dual, Triple Pak comb	New combination
05/27/2022	Antihyperglycemic, Biguanide Type	metformin HCl 625 mg tablet	New strength
06/04/2022	Cholinesterase Inhibitors	Adlarity (donepezil HCl) 5, 10 mg/day patch	New dosage form
06/11/2022	Pulmonary Antihypertensives, Prostacyclin-Type	Tyvaso (treprostinil) DPI 16, 32, 48, 64 mcg cartridge, 16-32, 16-32-48 mcg titration kit, 32-48 mcg maintenance kit cartridge for inhalation	New dosage form
06/18/2022	Neuroactive Steroid GABA-A Receptor Modulator	Ztalmy (ganaxolone) 50 mg/mL oral suspension	New entity

\*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
Opioid Antagonists	nalmefene HCl 2 mg/2 mL vial
Acid and Alkali Poison Antidotes	Provayblue (methylene blue) 50 mg/10 mL vial
Local Anesthetics	buffered lidocaine 0.5%/epinephrine in sodium chloride inj syringe
Cephalosporin Antibiotics - 3rd Generation	ceftriaxone 250 mg vial inj
Antineoplastic LHRH(GNRH) Agonist, Pituitary Suppr.	Camcevi (leuprolide mesylate) 42 mg SC syringe
Vitamin K Preparation	phytonadione (Vit K1) 1 mg/0.5 mL, 10 mg/mL vial inj
Sedative-Hypnotics, Non-Barbiturate	Igalmi (dexmedetomidine HCl) 120, 180 mcg sublingual film
Penicillin Antibiotics	piperacillin-tazobactam 2.25 gram IV vial
Sodium/Saline Preparations	sodium chloride 200 mEq/50 mL IV syringe
Antineoplastic Systemic Enzyme Inhibitors	bortezomib 1, 2.5 mg vial inj
Potassium Replacement	potassium chloride in water for injection 100 mEq/50 mL IV syringe
Ophth. VEGF-A Receptor Antag. RCMB MC Antibody	Beovu (brolucizumab-dblI) 6 mg/0.05 mL intraocular syringe
Penicillin Antibiotics	ampicillin 125 mg vial inj
Antineoplastic – Alkylating Agents	carboplatin 50 mg/5 mL vial inj
Sedative-Hypnotics – Benzodiazepine	lorazepam 40 mg/10 mL vial inj
Neuromuscular Blocking Agents	rocuronium 50 mg/5 mL vial inj
Antineoplastic Hum VEGF Inhibitor Recomb MC Antibody	Alymsys (bevacizumab-maly) 100 mg/4 mL, 400 mg/16 mL IV vial
Local Anesthetics	Posimir (bupivacaine) 660 mg/5 mL vial inj
Antineoplastic – Antimetabolites	pemetrexed disodium 750 mg, 1 gram vial inj
Penicillin Antibiotics	ampicillin 2 gram vial inj
Ophth. VEGF-A Receptor Antag. RCMB MC Antibody	Byooviz (ranibizumab-nuna) 0.5 mg/0.05 mL vial intraocular vial
Vaccine/Toxoid Preparations, Combinations	Priorix (measles, mumps, and rubella vaccine live/PF) SC vial

The following products are not listed in the above table:

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