

San Francisco Health Plan (SFHP) Quarterly Formulary and Prior Authorization Criteria Update January 2019

The following changes to SFHP formulary and prior authorization criteria were reviewed and approved by the SFHP Pharmacy and Therapeutics (P&T) Committee on 1/16/2019. Effective date for all changes is **2/20/2019**.

SFHP formulary can be accessed at <http://www.sfhp.org/providers/formulary/> and prior authorization criteria at <https://www.sfhp.org/providers/pharmacy-services/prior-authorization-requests/>.

Contents

Neurology: Multiple Sclerosis	2
Neurology: Parkinson’s Disease.....	2
Neurology: Alzheimer’s Disease and Dementia.....	2
Endocrinology: Lipodystrophy Disorders	2
Psychiatry: Opioid, Nicotine & Alcohol Dependence Disorders.....	2
Neurology: Calcitonin Gene-Related Peptide Receptor Antagonists	3
Neurology: Epidiolex™	3
Endocrinology: Growth Hormone Disorders	3
Endocrinology: Androgens	4
Pulmonology: Cystic Fibrosis.....	4
Supplements: Electrolytes, Vitamins & Minerals.....	4
Cardiology: Heart Failure & Angina.....	5
Immunology: Takhzyro™	5
Interim Prior Authorization Criteria Updates (9/29/18-12/28/18).....	6
New Criteria.....	6
Revisions to Existing Criteria	6
Interim Formulary Changes (9/29/18 – 12/28/18).....	7
New Drugs to Market.....	9

Formulary Maintenance Items

Neurology: Multiple Sclerosis

Formulary Update: Medi-Cal, Healthy Kids HMO, and Healthy Workers HMO

- No formulary changes made

Prior Authorization Criteria Update:

- No PA criteria changes made

Drug Utilization Review Update:

- No DUR changes made

Neurology: Parkinson's Disease

Formulary Update: Medi-Cal, Healthy Kids HMO, Healthy Workers HMO, and Healthy San Francisco

- Removed amantadine tablet from formulary tier 3 for Healthy Kids, HMO due to lack of place in therapy and lack of criteria for use

Prior Authorization Criteria Update:

- No PA criteria changes made

Drug Utilization Review Update:

- No DUR changes made

Neurology: Alzheimer's Disease and Dementia

Formulary Update: Medi-Cal, Healthy Kids HMO, Healthy Workers HMO, and Healthy San Francisco

- No formulary changes made

Prior Authorization Criteria Update:

- No PA criteria changes made (no active criteria)

Drug Utilization Review Update:

- No DUR changes made

Endocrinology: Lipodystrophy Disorders

Formulary Update: Medi-Cal, Healthy Kids HMO, and Healthy Workers HMO

- No formulary changes made

Prior Authorization Criteria Update:

- No PA criteria changes made

Drug Utilization Review Update:

- No DUR changes made

Psychiatry: Opioid, Nicotine & Alcohol Dependence Disorders

Formulary Update: Medi-Cal, Healthy Kids HMO, Healthy Workers HMO, and Healthy San Francisco

- No formulary changes made

Prior Authorization Criteria Update:

- No PA criteria changes made

Drug Utilization Review Update:

- No DUR changes made

Drug Class Reviews

Neurology: Calcitonin Gene-Related Peptide Receptor Antagonists

Formulary Update: Medi-Cal, Healthy Kids HMO, and Healthy Workers HMO

- Added Emgality™ to formulary tier 3 as the preferred CGRP RA and require prior authorization to ensure appropriate diagnosis and use of preferred alternatives
- Removed Aimovig™ from formulary due to preferred alternative Emgality™ and grandfather current users

Prior Authorization Criteria Update:

- Updated Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonists criteria to reflect formulary changes above

Drug Utilization Review Update:

- No DUR changes made

Neurology: Epidiolex™

Formulary Update: Medi-Cal, Healthy Kids HMO, Healthy Workers HMO, and Healthy San Francisco

- No formulary changes made

Prior Authorization Criteria Update:

- No PA criteria changes made (no active criteria)

Drug Utilization Review Update:

- No DUR changes made

Endocrinology: Growth Hormone Disorders

Formulary Update: Medi-Cal, Healthy Kids HMO, and Healthy Workers HMO

- Added Zomacton® to formulary tier 4, preferred for its labeled indications
- Removed Serostim® and Zorbtive® from formulary due to lack of utilization and no clear place in therapy
- Removed non-preferred formulations of growth hormone from formulary due to preferred alternatives available for other indications: Genotropin®, Humatrope®, Omnitrope®, Saizen®
- Removed Increlex® from formulary due to lack utilization and lack of criteria
- Added octreotide 50mcg/mL, 100mcg/mL, and 500mcg/mL vial to formulary due to comparative cost-effectiveness
- Removed Somatuline® Depot and Sandostatin® LAR Depot from formulary as these should be administered by a HCP available through the medical benefit

Prior Authorization Criteria Update:

- Updated Somatropin (Growth Hormone) criteria to reflect formulary changes above, to streamline requirements, and to remove indications for non-formulary products with limited/no place in therapy
- Updated Octreotide and Somavert® criteria to reflect formulary changes above

Drug Utilization Review Update:

- No DUR changes made

Endocrinology: Androgens

Formulary Update: Medi-Cal, Healthy Kids HMO, Healthy Workers HMO, and Healthy San Francisco

- No formulary changes made

Prior Authorization Criteria Update:

- Removed specific criteria for testosterone (Axiron®) solution pump due to comparable cost-effectiveness with other non-preferred options

Drug Utilization Review Update:

- No DUR changes made

Pulmonology: Cystic Fibrosis

Formulary Update: Medi-Cal, Healthy Kids HMO, Healthy Workers HMO, and Healthy San Francisco

- Removed Bethkis® (tobramycin) 300mg/4mL and tobramycin 300mg/5mL (Kitabis Pak®) from formulary due to lack of utilization and cost-effective alternative available

Prior Authorization Criteria Update:

- Updated Cystic Fibrosis criteria based on formulary changes above, and to allow Kalydeco® (ivacaftor) use in newly indicated age range

Drug Utilization Review Update:

- No DUR changes made

Supplements: Electrolytes, Vitamins & Minerals

Formulary Update: Medi-Cal, Healthy Kids HMO, and Healthy Workers HMO

- Added prenatal vitamins to formulary as a class to reduce barriers to use
 - Removed all quantity limits
 - Implement dollar limit per prescription based on further analysis to prevent fraud/waste/abuse
- Added thiamine mononitrate (B1) 100mg tab to formulary based on rejected claims and cost-effectiveness
- Removed PA requirement from calcitriol 1mcg/mL oral solution and maintain on formulary tier 1, with age limit to allow appropriate pediatric use
- Removed quantity limits from the following due to lack of abuse potential:
 - calcium phos/vit D3 (Risacal-D®) 105mg-120u tab
 - b complex/folic acid/c (Nephrovite®) 0.8mg tab
- Added age limits to the following medications to allow appropriate pediatric use:
 - ergocalciferol (vit D2) 8,000u/mL PO drops (OTC)
 - Tri-Vi-Sol® 750u-35mg-400u/mL PO drops (OTC)
 - children's chewable vitamin with iron tablet (OTC)
 - multivitamin with fluoride 0.5mg chew tab (OTC)
- Removed the following from formulary due to lack of utilization and PA criteria and list tier 5 non-formulary
 - Perikabiven® 2.36-6.8-3.5% IV emulsion
 - dextrose 5%-lactated ringer's IV soln

Prior Authorization Criteria Update:

- Retired "Vitamin D Analogs (Calcium Disorders)" criteria due to formulary changes above and use "Step Therapy Exception" criteria for doxercalciferol

Drug Utilization Review Update:

- No DUR changes made

Cardiology: Heart Failure & Angina

Formulary Update: Medi-Cal, Healthy Kids HMO, Healthy Workers HMO, and Healthy San Francisco

- No formulary changes made

Prior Authorization Criteria Update:

- No PA criteria changes made

Drug Utilization Review Update:

- No DUR changes made

Immunology: Takhzyro™

Formulary Update: Medi-Cal, Healthy Kids HMO, Healthy Workers HMO, and Healthy San Francisco

- Added Takhzyro™ to formulary tier 3 and require prior authorization to ensure appropriate diagnosis
- Removed Haegarda® from formulary due to preferred alternative Takhzyro™ and grandfather current users

Prior Authorization Criteria Update:

- Updated Hereditary Angioedema criteria based on formulary changes above, and to remove requirement to use danazol and Cinryze® prior to Takhzyro™ and require a minimum of one HAE attack per month for approval

Drug Utilization Review Update:

- No DUR changes made

Interim Prior Authorization Criteria Updates (9/29/18-12/28/18)

New Criteria

No new criteria were implemented in the interim since October 2018 P&T.

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 above with effective date 2/20/2019.

Title	Date Effective	Revision Summary
Hepatitis C	TBD	Update criteria to expand preferred regimens based on availability of generic formulations ledipasvir/sofosbuvir (Harvoni [®]) and sofosbuvir/velpatasvir (Epclusa [®]) <ul style="list-style-type: none"> Ledipasvir/sofosbuvir and sofosbuvir/velpatasvir were listed as preferred regimens for all clinical scenarios recommended by AASLD-IDSA, except when they require concomitant ribavirin where alternatives do not Mavyret[™] remains included among preferred regimens due to shorter duration of use
Fibric Acids	2/20/2018	Retire criteria <ul style="list-style-type: none"> Multiple formulary generics (tier 1) are available No tier 3 status drugs currently Use blanket criteria for non-formulary fibrates
GnRH Agonists-Pediatric	2/20/2018	Remove criteria for non-formulary IM injection Triptodur [®] (medical benefit only, to be administered by HCP)
Inhaled Corticosteroids (ICS)	2/20/2018	Retire criteria <ul style="list-style-type: none"> Multiple formulary brands (tier 2) are available No tier 3 status drugs currently Use blanket criteria for non-formulary ICS inhalers
Leukotriene Receptor Antagonists	2/20/2018	Retire criteria <ul style="list-style-type: none"> Multiple formulary generics (tier 1) are available No tier 3 status drugs currently Use blanket criteria for non-formulary leukotriene RAs and age limits
Xyrem [®] (sodium oxybate)	2/20/2018	Update criteria based on established treatment guidelines <ul style="list-style-type: none"> Remove requirement to trial stimulants prior to Xyrem[®] for narcolepsy with <u>cataplexy</u>, as stimulants are only effective for excessive daytime sleepiness Update minimum age of use to 7 years from 18 years based on FDA approval 10/26/2018

Interim Formulary Changes (9/29/18 – 12/28/18)

Therapeutic class	Medication	Formulary Status	Comment
Antineoplastic Systemic Enzyme Inhibitors	Copiktra (duvelisib) 15, 25 mg capsule	Medi-Cal, HK: T4 HW: T3 HSF, C-Wrap: X	New entity
Blood Sugar Diagnostics	Accu-Chek Guide test strips 100-count	Medi-Cal, HK, HW, HSF: T2 C-Wrap: X	New pack size
Antineoplastic Systemic Enzyme Inhibitors	Vizimpro (dacomitinib) 15, 30, 45 mg tablet	Medi-Cal, HK, HW: T3 (PA) HSF, C-Wrap: X	New entity
Direct Factor Xa Inhibitors	Xarelto (rivaroxaban) 2.5 mg tablet	Medi-Cal, HK, HW, HSF: T2 QL #60/30d C-Wrap: X	New strength
Antineoplastic Systemic Enzyme Inhibitors	Talzenna (talazoparib tosylate) 0.25, 1 mg capsule	Medi-Cal, HK: T4 HW: T3 HSF, C-Wrap: X	New entity
Glucocorticoids, Orally Inhaled	Qvar (beclomethasone) 40, 80 mcg/actuation aerosol inhaler	Medi-Cal, HK, HW, HSF, C-Wrap: X	Removed from market
Immunosuppressives	Zortress (everolimus) 1 mg tablet	Medi-Cal, HK, HW: T3 (PA) HSF, C-Wrap: X	New strength
Antivirals, General	Xofluza (baloxavir marboxil) 20, 40 mg tablet	Medi-Cal, HK, HW, HSF: T2 QL #2/180d C-Wrap: X	New entity
Monoclonal Antibodies To Immunoglobulin E (IGE)	Xolair (omalizumab) 75 mg/0.5 mL, 150 mg/mL SC syringe	Medi-Cal, HK, HW: T3 (PA) HSF, C-Wrap: X	New dosage form
Leukocyte (WBC) Stimulants	Granix (TBO-filgrastim) 300 mcg/mL, 480 mcg/1.6 mL SC solution	Medi-Cal, HK: T4 HW: T3 HSF, C-Wrap: X	New dosage form
Antineoplastic Systemic Enzyme Inhibitors	Lorbrena (lorlatinib) 25, 100 mg tablet	Medi-Cal, HK: T4 HW: T3 HSF, C-Wrap: X	New entity
Antipsychotics, Atypical, D2 Partial Agonist/5HT Mixed	Abilify MyCite 2, 5, 10, 15, 20, 30 mg tablet with sensor and patch	Medi-Cal: T5 HK, HW, HSF, C-Wrap: X	New dosage form
Antineoplastic Systemic Enzyme Inhibitors	Vitrakvi (larotrectinib) 25, 100 mg capsule	Medi-Cal, HK: T4 HW: T3 HSF, C-Wrap: X	New entity
Antineoplastic Systemic Enzyme Inhibitors	Vitrakvi (larotrectinib) 20 mg/mL oral solution	Medi-Cal, HK: T4 HW: T3 HSF, C-Wrap: X	New entity
Antineoplastic Systemic Enzyme Inhibitors	Xospata (gilteritinib) 40 mg tablet	Medi-Cal, HK: T4 HW: T3 HSF, C-Wrap: X	New entity
Antineoplastic - Hedgehog Pathway Inhibitor	Daurismo (glasdegib) 25, 100 mg tablet	Medi-Cal, HK: T4 HW: T3 HSF, C-Wrap: X	New entity
Sickle Cell Anemia Agents	Endari (glutamine) 5 g powder packet	Medi-Cal, HK: T4 HW: T3 HSF, S-Wrap: X	Added to Specialty
Eye Antihistamines	olopatadine 0.2% eye drop	Medi-Cal, HK, HW, HSF: T3 (step ketotifen) C-Wrap: X	Price reduction (MAC)
Viral/Tumorigenic Vaccines	Shingrix (varicella-zoster GE/AS01B/PF) 50 mcg/0.5 mL IM vial kit	Medi-Cal: T2 QL (1 vial/fill, 2 fills/lifetime) HK, HW, HSF, C-Wrap: X	Removed age limit

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.
T/5 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 Kids, Healthy Workers and Healthy San Francisco formularies unless otherwise indicated.

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

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

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 anti-inflammatory/analgesic 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

Therapeutic class	Medication	Comment
Tetracycline Antibiotics	Minolira ER (minocycline) 105, 135 mg ER tablet	New dosage form
Aminoglycoside Antibiotics	Arikayce (amikacin liposomal) 590 mg/8.4 mL suspension for inhalation via nebulization	New dosage form
Antidiuretic And Vasopressor Homones	Nocdurna (desmopressin) 25, 50 mcg SL disintegrating tablet	New dosage form*
Topical Antibiotics	Xepi (ozenoxacin) 1 % topical cream	New entity
Vitamin A Derivatives	Altreno (tretinoin) 0.05 % lotion	New dosage form
Influenza Virus Vaccines	EZ Flu 2018-19(Flucelvax)(PF) 60 mcg(15 mcg x 4)/0.5 mL IM syringe kit	New kit (syringe, vial on formulary)
Vaginal Estrogen For Sexual Dysfunction	Imvexxy (estradiol) Starter Pack 4, 10 mcg vaginal insert, dose pack	New dosage form
Amyotrophic Lateral Sclerosis Agents	Tiglutik (riluzole) 50 mg/10 mL oral suspension	New dosage form
Interleukin-4(IL-4) Receptor Alpha Antagonist, MAB	Dupixent (dupilumab) 200 mg/1.14 mL SC syringe	New strength
Amyloidosis Agents-Transthyretin (TTR) Suppression	Tegsedi (inotersen) 284 mg/1.5 mL SC syringe	New entity*
Topical Anti-Inflammatory Steroidal	Lexette (halobetasol propionate) 0.05 % topical foam	New dosage form
Antimalarial Drugs	Aarakoda (tafenoquine) 100 mg tablet	New entity
Sickle Cell Anemia Agents	Siklos (hydroxyurea) 1000 mg tablet	New dosage form
Anticonvulsant - Benzodiazepine Type	Sympazan (clobazam) 5, 10, 20 mg oral film	New dosage form
Miotics And Other Intraocular Pressure Reducers	Xelpros (latanoprost)0.005 % eye drop emulsion	New dosage form
Androgenic Agents	Xyosted 50 mg/0.5 mL, 75 mg/0.5 mL, 100 mg/0.5 mL SC auto-injector	New dosage form
Metabolic Dx Enzyme Replacemt, Sev. Comb. Immune Def.	Revcovi (elapegademase-lvr) 2.4 mg/1.5 mL (1.6 mg/mL) IM solution	New entity*
Topical Anti-Inflammatory Steroidal	Bryhali (halobetasol propionate) 0.01 % lotion	New strength
Anticholinergics, Orally Inhaled Long Acting	Yupelri (revefenacin) 175 mcg/3 mL solution for nebulization	New entity
Eye Anti-Inflammatory Agents	Inveltys (loteprednol etabonate) 1 % eye drops, suspension	New strength
Ophthalmic Human Nerve Growth Factor (HNGF)	Oxervate (cenegermin-bkbj) 0.002 % eye drops	New entity*
Ophthalmic Anti-Inflammatory Immunomodulator-Type	Cequa (cyclosporine) 0.09 % eye drops in a dropperette	New dosage form
Leukocyte (WBC) Stimulants	Udenyca (pegfilgrastim-cbqv) 6 mg/0.6 mL subcutaneous syringe	New biosimilar
Antifungal Agents	Tolsura (itraconazole) 65 mg oral solid dispersion capsule	New formulation
Tetracycline Antibiotics	Nuzyra (omadacycline) 150 mg tablet	New entity
Tetracycline Antibiotics	Seysara (sarecycline) 60, 100, 150 mg tablet	New entity

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 medical benefit or excluded. Non-formulary drugs may be covered through Prior Authorization process. Excluded drugs (e.g. FFS Medi-Cal) are not covered.

*Scheduled for review at upcoming P&T

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

FFS Carve Out=CO Excluded= X NF-NL = Non-Formulary, Not Listed

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

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 anti-inflammatory/analgesic combination kits (NF if separate ingredient products are available on formulary and/or available as OTC)
- Local anesthetics (NF if formulary agents are available)