The following changes to SFHP formulary and prior authorization criteria were reviewed and approved by the SFHP Pharmacy and Therapeutics (P&T) Committee on 10/17/2018. Effective date for all changes is 11/20/2018.

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

Hematology: White Blood Cell Stimulants ................................................................. 2
Pain: NSAIDs ............................................................................................................... 2
Infectious Disease: Antiparasitics .............................................................................. 2
Infectious Disease: Systemic and Topical Antibiotics ............................................... 3
Infectious Disease: Oral and Topical Antifungals ...................................................... 3
Infectious Disease: Antivirals .................................................................................... 3
Infectious Disease: Immunizations .......................................................................... 4
Hematology: Erythropoietin Stimulating Agents ...................................................... 4
Hematology: Thrombocytopenia ................................................................................. 4
Neurology: Anticonvulsants ..................................................................................... 5
Pain: Non-Opioid ....................................................................................................... 5
Rheumatology: Olumiant® ....................................................................................... 5
Topical: Antiseptics .................................................................................................. 5
Probiotics ................................................................................................................... 6

Interim Prior Authorization Criteria Updates (6/30/18-9/28/18) .................................. 7
New Criteria .............................................................................................................. 7
Revisions to Existing Criteria .................................................................................. 9

Interim Formulary Changes (6/30/18 – 9/28/18) ......................................................... 11
New Drugs to Market ............................................................................................... 14
Formulary Maintenance Items

Hematology: White Blood Cell Stimulants

Formulary Update: Medi-Cal, Healthy Kids HMO, and Healthy Workers HMO
- No formulary changes made

Prior Authorization Criteria Update:
- Updated White Blood Cell Stimulators criteria to include Nivestym™ and Fulphila™ as non-formulary

Drug Utilization Review Update:
- No DUR changes made

Pain: NSAIDs

Formulary Update: Medi-Cal, Healthy Kids HMO, Healthy Workers HMO, and Healthy San Francisco
- Added diclofenac potassium to formulary tier 1 and ketorolac to formulary tier 1 with quantity limit to ensure appropriate use
- Added indomethacin ER capsule to formulary due to some use and prior authorization approval rate
- Added age limit to naproxen suspension to ensure appropriate use in pediatrics
- Removed the following tier 3 medications from formulary due to no utilization and lack of drug specific prior authorization criteria:
  - meloxicam oral suspension
  - ketoprofen IR and ER capsules
  - meclofenamate capsule
  - mefenamic acid capsule
  - tolmetin capsule and tablet
  - fenoprofen capsule

Prior Authorization Criteria Update:
- Updated Topical NSAIDs criteria to reflect current diclofenac 1% gel quantity limit

Drug Utilization Review Update:
- No DUR changes made

Infectious Disease: Antiparasitics

Formulary Update: Medi-Cal, Healthy Kids HMO, Healthy Workers HMO, and Healthy San Francisco
- Extended quantity limit of Albenza® to reflect typical dosing for intestinal roundworms
- Added quantity limit to praziquantel tablet to reflect typical dosing for tapeworms
- Removed Pin-X® chewable tablet from formulary due to lack of utilization (obsolete) and available alternatives
- Removed Pentam® 300 IV solution from formulary as it is a medical benefit drug

Prior Authorization Criteria Update:
- No PA criteria changes made

Drug Utilization Review Update:
- No DUR changes made
Drug Class Reviews

**Infectious Disease: Systemic and Topical Antibiotics**

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

- Removed prior authorization from cefadroxil 500 mg capsule and maintained on formulary tier 1 due to cost effectiveness
- Removed step therapy requirement from vancomycin capsules and Firvanq® suspension and maintained on formulary tier 1 with quantity limits to align with guideline recommendations
- Remove days’ supply limits from amoxicillin-clavulanate due to lack of concern for overuse
- Added age limit, maximum of 12 years to the following solutions, suspensions, and chewable tablets to align with other liquid and chewable formulations on formulary:
  - amoxicillin 125 mg/5 mL, 200 mg/5mL, 250 mg/5 mL, 400 mg/5 mL suspension reconstituted
  - amoxicillin/clavulanate 600-42.9 mg/5 mL oral suspension
  - penicillin V potassium 125 mg/5 mL, 250 mg/5 mL suspension
  - amoxicillin 125, 250 mg chewable tablet
  - amoxicillin/clavulanate 200-28.5, 400-57 mg chewable tablet
  - azithromycin 100mg/5mL, 200mg/5mL suspension reconstituted
  - sulfamethoxazole/trimethoprim 200-400mg/5mL oral suspension
  - cephalexin 125mg/5mL, 250mg/5mL oral suspension
  - nitrofurantoin 25mg/5mL oral suspension
- Removed the following medications from formulary and remove prior authorization due to lack of utilization and no drug-specific prior authorization criteria:
  - cefadroxil 250mg/5mL, 500mg/5mL suspension reconstituted
  - cefadroxil 1g tablet
  - celditoren 200, 400mg tablet
- Removed Primsol® 50mg/5mL oral solution from tier 5, and maintain as non-formulary as it is no longer listed on the Fee-For-Service Contract Drugs List

**Prior Authorization Criteria Update:**

- Updated Clostridium Difficile Infections criteria to reflect the formulary changes for vancomycin and Firvanq®

**Drug Utilization Review Update:**

- No DUR changes made

**Infectious Disease: Oral and Topical Antifungals**

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

- Removed ketoconazole 2% foam and Xologel® 2% from formulary and remove prior authorization due to lack of utilization/drug-specific criteria and cost-effective alternatives available

**Prior Authorization Criteria Update:**

- No PA criteria changes made

**Drug Utilization Review Update:**

- No DUR changes made

**Infectious Disease: Antivirals**

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

- Added valganciclovir tablet to formulary with prior authorization required to align with current prior authorization criteria
- Removed age limit from oseltamivir 30mg capsule to allow for appropriate renal dosing in adults
- Added fill limit to oseltamivir oral solution to align with other dosage forms, and apply max days’ supply limit per fill to ensure appropriate use

**Prior Authorization Criteria Update:**

- No PA criteria changes made

**Drug Utilization Review Update:**

- No DUR changes made
• Added age limit to acyclovir oral suspension to ensure appropriate pediatric use
• Added quantity limits to famciclovir tablets to ensure appropriate use:
  o 125 mg: #2 tablets/day (max 1 tablet BID for episodic/recurrent herpes in immunocompetent patients)
  o 250 mg: #3 tablets/day (max 1 tablet TID for initial herpes episode)
  o 500 mg: #4 tablets/day (max 2 tablets BID for episodic/recurrent herpes)
• Removed rimantadine from formulary due to removal of ACIP recommendations and lack of other indications

Prior Authorization Criteria Update:
• Updated Valganciclovir (Valcyte®) criteria to include oral solution and require inability/difficulty swallowing solid oral dosage form for use

Drug Utilization Review Update:
• No DUR changes made

Infectious Disease: Immunizations
Formulary Update: Medi-Cal
  • No formulary changes made
Prior Authorization Criteria Update:
  • No PA criteria changes made (no active criteria)
Drug Utilization Review Update:
  • No DUR changes made

Hematology: Erythropoietin Stimulating Agents
Formulary Update: Medi-Cal, Healthy Kids HMO, and Healthy Workers HMO
  • Added Retacrit™ to formulary with prior authorization required to ensure appropriate diagnosis
Prior Authorization Criteria Update:
  • Updated Erythropoietin Stimulating Agents (ESAs) criteria to prefer Retacrit™ over alternatives
Drug Utilization Review Update:
  • No DUR changes made

Hematology: Thrombocytopenia
Formulary Update: Medi-Cal, Healthy Kids HMO, and Healthy Workers HMO
  • No formulary changes made
Prior Authorization Criteria Update:
  • Updated Thrombocytopenia criteria:
    o Prefer Promacta® based on range of indications and comparative cost-effectiveness
    o Include Tavalisse® second-line after TPA
    o Include Doptelet® and Mulpleta® listed as non-formulary, preferring Mulpleta® over Doptelet® for thrombocytopenia associated with chronic liver disease in patients requiring elective procedure
Drug Utilization Review Update:
  • No DUR changes made
Neurology: Anticonvulsants

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

- Removed quantity limits from Dilantin® 30 mg ER capsule and divalproex 125 mg DR sprinkles to align with other anticonvulsants due to lack of safety concerns and to allow titration.
- Added age restriction, limiting to members 16 years of age or younger to the following medications, to align with other non-solid dosage formulations on formulary (updated all to ≤16 years):
  - ethosuximide 250 mg/5 mL solution
  - phenytoin 50 mg chewable tablet
  - carbamazepine 100 mg chewable tablet
  - phenobarbital 25 mg/5 mL elixir
- Removed the following medications from formulary due to lack of utilization or requests:
  - Peganone® 250 mg tablet
  - Lamotrigine IR dose packs
  - Celontin® 300 mg capsule
  - Phenytoin 50 mg/5 mL vial (medical benefit)
  - Banzel® 40 mg/mL oral suspension

Prior Authorization Criteria Update:
- No PA criteria changes made (no active criteria)

Drug Utilization Review Update:
- No DUR changes made

Pain: Non-Opioid

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

- Added the following to formulary tier 1 due to some utilization and cost-effectiveness:
  - pramoxine 1% lotion
  - lidocaine 4% cream, with quantity limit of #60g/30 days to align with other formulary options
  - lidocaine 4% OTC patch
- Removed prior authorization requirement for Lyrica® and maintained tier 3, step therapy (gabapentin) required.
- Added age limit, maximum age of 16 years, to gabapentin 250 mg/5 mL solution to align with other liquid anticonvulsant formulations and allow appropriate pediatric use.
- Removed gabapentin 250 mg/5 mL unit dose solution from formulary due to lack of utilization.

Prior Authorization Criteria Update:
- Updated Lyrica® (Pregabalin) criteria to reflect step and include extended release formulation quantity limit.

Drug Utilization Review Update:
- No DUR changes made

Rheumatology: Olumiant®

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

- No formulary changes made.

Prior Authorization Criteria Update:
- Updated Disease Modifying Biologics criteria to list Olumiant® as non-formulary.

Drug Utilization Review Update:
- No DUR changes were made.

Topical: Antiseptics

Formulary Update: Medi-Cal, Healthy Kids HMO, Healthy Workers HMO, and Healthy San Francisco
Pharmacy and Therapeutics Committee
Quarterly Formulary and Prior Authorization Criteria Update
October 2018

- No formulary changes made

Prior Authorization Criteria Update:
- No PA criteria changes made (no active criteria)

Drug Utilization Review Update:
- No DUR changes made

Probiotics

Formulary Update: Medi-Cal, Healthy San Francisco
- Added the following probiotic products to formulary based on utilization, low cost, and available literature:
  - saccharomyces boulardii (Florastor®) tier 1
  - Culturelle® (lactobacillus rhamnosus GG[LGG]) tier 2
- Added VSL#3® to formulary tier 3 based on guideline recommendations and utilization, with prior authorization required to ensure appropriate diagnosis (Medi-Cal only)

Prior Authorization Criteria Update:
- Updated Probiotics criteria to address all probiotics requests

Drug Utilization Review Update:
- No DUR changes made
Interim Prior Authorization Criteria Updates (6/30/18-9/28/18)

New Criteria
The criteria below were implemented 8/20/2018 based on specific regulatory requirements. These criteria address the handling of requests determined to be for experimental/investigational use, or terminal illness, respectively.

<table>
<thead>
<tr>
<th>EXPERIMENTAL/INVESTIGATIONAL USES</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Formulary Status:</strong> Formulary, PA or Non-formulary</td>
</tr>
<tr>
<td><strong>Coverage Duration:</strong> 1 year</td>
</tr>
<tr>
<td><strong>Diagnosis Considered for Coverage:</strong></td>
</tr>
<tr>
<td>- Experimental or investigational use, as defined below</td>
</tr>
<tr>
<td><strong>Prescribing Restriction:</strong></td>
</tr>
<tr>
<td>- Prescriber restriction: provider is a board-certified specialist in the area of requested therapy</td>
</tr>
<tr>
<td><strong>Clinical Information Required for Review:</strong></td>
</tr>
<tr>
<td>- Diagnosis</td>
</tr>
<tr>
<td>- Previous therapy</td>
</tr>
<tr>
<td>- Supporting documentation</td>
</tr>
<tr>
<td><strong>Coverage Criteria:</strong></td>
</tr>
<tr>
<td>Per Evidence of Coverage (EOC) document page 64, SFHP does not cover experimental or investigational care, defined as care that:</td>
</tr>
<tr>
<td>- Is not seen as safe and effective by generally accepted medical standards to treat a condition, or</td>
</tr>
<tr>
<td>- Has not been approved by the government to treat a condition</td>
</tr>
</tbody>
</table>

I. **Initiation of Therapy:**

- Requests not meeting criteria below will be denied per the Investigational/Experimental Section of the PBM-SFHP Prior Authorization (PA) First-Level Review Desktop Procedure
- If ALL of the following are met, a request for experimental or investigational use will be reviewed by the SFHP Medical Director
  - The requested therapy is for a life-threatening (likely to cause death unless the course of disease is interrupted) or seriously debilitating (causes major irreversible morbidity) condition
    - If requested therapy is not for a life-threatening or seriously debilitating condition, utilize “Off-Label Uses” criteria
  - The requested therapy is a therapy approved by the FDA
  - Documentation is provided meeting any of the following for each standard therapy for the diagnosis:
    - Trial and failure of standard therapy(ies)
    - Contraindication to standard therapy(ies)
EXPERIMENTAL/INVESTIGATIONAL USES

- Documentation that the requested therapy is likely to be more beneficial to the member than standard therapy(ies):
  a. as evidenced by two documents from medical and scientific evidence (including peer-reviewed medical literature, federal research institutes findings, medical compendia and/or guidelines) OR
  b. as certified in writing by provider, and the provider is an in-network physician
  c. If the request is denied following review by SFHP Medical Director due to not meeting criteria (a) and (b) above, SFHP’s decision will be sent for examination via the independent medical review process for investigational/experimental uses

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:
  • Refer to “Initiation of Therapy” section

III. 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:
  • Patient is stable and continuing the medication

References:

MEDICATIONS FOR TERMINAL ILLNESS

Formulary Status: Formulary, PA or Non-formulary
Coverage Duration: 1 year
Diagnosis Considered for Coverage:
  • Terminal illness, as defined below
Prescribing Restriction:
  • Prescriber restriction: provider is a board-certified specialist in the area of requested therapy
Clinical Information Required for Review:
  • Diagnosis
  • Previous therapy
  • Supporting documentation
Coverage Criteria:
California Health and Safety Code Section 1368.1 refers to terminal illness as an incurable or irreversible condition that has a high probability of
MEDICATIONS FOR TERMINAL ILLNESS

causing death within one year or less.

I. Initiation of Therapy:
- If a request for treatment is for terminal illness as defined above, approve if medication and dose are appropriate based on nature and severity of the terminal illness, and is not considered likely to cause undue harm
  - Criteria above overrides drug-specific criteria, Non-Formulary Medications criteria, and Off-Label Uses criteria when requested for terminal illness
  - If request is for experimental/investigational use in terminal illness, Experimental/Investigational Uses criteria must also be met
- For requests that are denied due to not meeting corresponding criteria above, the following will be provided to the enrollee within five business days of the denial:
  - A statement setting forth the specific medical and scientific reasons for denying coverage
  - A description of alternative treatment, services or supplies covered by the plan, if any

References:

Last review/revision date: 10/2018

Revisions to Existing Criteria

<table>
<thead>
<tr>
<th>Title</th>
<th>Date Effective</th>
<th>Revision Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hepatitis C</td>
<td>07/01/2018</td>
<td>• Removed medical necessity criteria (fibrosis stage or comorbidity) based on DHCS policy update&lt;br&gt;• Approve for members ≥ 13 years old with life expectancy ≥ 12 months, regardless of fibrosis stage or comorbidity, if regimen is appropriate per AASLD/IDSA guidelines and is SFHP-preferred</td>
</tr>
<tr>
<td>PCSK-9 Inhibitors</td>
<td>07/01/2018</td>
<td>• Extended Coverage Duration:&lt;br&gt;  o Initial: 6 months (from 4 months)&lt;br&gt;  o Continuation: indefinite (from 6 months)</td>
</tr>
<tr>
<td>Ampyra® (dalfampridine)</td>
<td>11/20/2018</td>
<td>• Removed criteria that patient not have h/o seizure, moderate-severe renal impairment, or treatment with other forms of 4-aminopyridine</td>
</tr>
<tr>
<td>Duvalidan® (isoxsuprine)</td>
<td>11/20/2018</td>
<td>• Retire criteria due to lack of use&lt;br&gt;• Utilize step criteria for any requests for isoxsuprine</td>
</tr>
<tr>
<td>Low Molecular Weight Heparin</td>
<td>11/20/2018</td>
<td>• Retire criteria after expanding quantity limits for enoxaparin&lt;br&gt;• Utilize Non-Formulary Medication criteria for Fragmin®, Arixtra®</td>
</tr>
<tr>
<td>Title</td>
<td>Date Effective</td>
<td>Revision Summary</td>
</tr>
<tr>
<td>-------------------------------</td>
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<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| Stadol NS® (butorphanol)      | 11/20/2018     | • Retire criteria due to lack of use, numerous preferred alternatives for migraine  
• Utilize Non-Formulary Medication criteria for any requests  

| All drug-specific criteria    | 11/20/2018     | • Based on DHCS audit feedback, update all drug-specific criteria to incorporate off-label criteria:  
**Diagnosis Considered for Coverage:**  
Off-Label indications (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.  
**Initiation of therapy:**  
• Approve if:  
  o No other formulary medication has a medically accepted use for the patient’s specific diagnosis as referenced in the medical compendia AND  
  o 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  
  o Requested use can be supported by at least two published peer reviewed clinical studies  

• Standardize continuation of therapy criteria for new members:  
**Continuation of Therapy for NEW Members (within the last 6 months), approve if:**  
• Prescriber attests that member has been on this medication continuously before joining SFHP, AND  
• Request is for generic or single source Brand, AND  

The diagnosis and dosage provided meets criteria, FDA labeling, and/or would meet the off-label criteria
## Interim Formulary Changes (6/30/18 – 9/28/18)

<table>
<thead>
<tr>
<th>Therapeutic class</th>
<th>Medication</th>
<th>Formulary Status</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antineoplastic - MEK1 and MEK2 Kinase Inhibitors</td>
<td>Mektovi (binimetinib) 15 mg tablet</td>
<td>Medi-Cal, HK: T4 HW: T3 HSF, C-Wrap: X</td>
<td>New entity</td>
</tr>
<tr>
<td>Antineoplastic - BRAF Kinase Inhibitors</td>
<td>Braftovi (encorafenib) 50, 75 mg capsule</td>
<td>Medi-Cal, HK: T4 HW: T3 HSF, C-Wrap: X</td>
<td>New entity</td>
</tr>
<tr>
<td>Antineoplastic - Antiandrogenic Agents</td>
<td>Yonsa (abiraterone submicronized) 125 mg tablet</td>
<td>Medi-Cal, HK: T4 HW: T3 HSF, C-Wrap: X</td>
<td>New dosage form</td>
</tr>
<tr>
<td>Influenza Virus Vaccines</td>
<td>Fluarix Quad 2018-2019 (PF) 60 mcg (15 mcg x 4)/0.5 mL IM syringe</td>
<td>Medi-Cal: T2 AL ≥19 yo, QL #1/270d HK, HW, HSF, C-Wrap: X</td>
<td>New entity</td>
</tr>
<tr>
<td>Influenza Virus Vaccines</td>
<td>Flulaval Quad 2018-2019 (PF) 60 mcg (15 mcg x 4)/0.5 mL IM syringe</td>
<td>Medi-Cal: T2 AL ≥19 yo, QL #1/270d HK, HW, HSF, C-Wrap: X</td>
<td>New entity</td>
</tr>
<tr>
<td>Influenza Virus Vaccines</td>
<td>Fluzone Quad 2018-2019 60 mcg (15 mcg x 4)/0.5 mL suspension</td>
<td>Medi-Cal: T2 AL ≥19 yo, QL #1/270d HK, HW, HSF, C-Wrap: X</td>
<td>New entity</td>
</tr>
<tr>
<td>Influenza Virus Vaccines</td>
<td>Fluzone Quad 2018-2019 (PF) 60 mcg (15 mcg x 4)/0.5 mL IM suspension</td>
<td>Medi-Cal: T2 AL ≥19 yo, QL #1/270d HK, HW, HSF, C-Wrap: X</td>
<td>New entity</td>
</tr>
<tr>
<td>Influenza Virus Vaccines</td>
<td>Flublok Quad 2018-2019 (PF) 180 mcg (45 mcg x 4)/0.5 mL IM syringe</td>
<td>Medi-Cal: T2 AL ≥19 yo, QL #1/270d HK, HW, HSF, C-Wrap: X</td>
<td>New entity</td>
</tr>
<tr>
<td>Antipsychotics, Atyp, D2 Partial Agonist/5ht Mixed</td>
<td>Aristada Initio (aripiprazole lauroxil, submicronized) 675 mg/2.4 mL suspension, ER IM syringe</td>
<td>Medi-Cal: T5 HK, HW, HSF, C-Wrap: X</td>
<td>Carve out</td>
</tr>
<tr>
<td>NSAIDs, Cyclooxygenase Inhibitor-Type Analgesics</td>
<td>ketoprofen 25mg capsule</td>
<td>Medi-Cal, HK, HW: T3/PA HSF, C-Wrap: X</td>
<td>Return of generic to market</td>
</tr>
<tr>
<td>Antivirals, General</td>
<td>valacyclovir 1000 mg tablet</td>
<td>Medi-Cal, HK, HW, HSF: T1 QL #3/day #4/day C-Wrap: X</td>
<td>Prospective DUR report- increased QL</td>
</tr>
<tr>
<td>Topical Anti-Inflammatory, NSAIDS</td>
<td>diclofenac sodium 1% topical gel</td>
<td>Medi-Cal, HK, HW, HSF: T1 QL #100g/30d #300g/30d C-Wrap: X</td>
<td>Prospective DUR report- increased QL</td>
</tr>
<tr>
<td>Platelet Aggregation Inhibitors</td>
<td>aspirin 81 mg chewable tablet</td>
<td>Medi-Cal, HSF, C-Wrap: T1 AL &lt;12y → T1 HK, HW: X</td>
<td>Prospective DUR report- removed AL</td>
</tr>
<tr>
<td>Smoking Deterrent Agents (Ganglionic Stim, Others)</td>
<td>nicotine polacrilex2, 4 mg lozenge</td>
<td>Medi-Cal, HK, HW, HSF, C-Wrap: T1 QL #360/30d → #600/30d</td>
<td>Prospective DUR report- increased QL</td>
</tr>
<tr>
<td>Therapeutic class</td>
<td>Medication</td>
<td>Formulary Status</td>
<td>Comment</td>
</tr>
<tr>
<td>-------------------------------------------</td>
<td>-----------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------</td>
<td>--------------------------------------</td>
</tr>
<tr>
<td>Antidiarrheals</td>
<td>Iloperamide 2 mg tablet</td>
<td>Medi-Cal, HSF, C-Wrap: T1 → T1 QL #30/30d HK, HW: X</td>
<td>Safety/potential for abuse</td>
</tr>
<tr>
<td>Antidiarrheals</td>
<td>Iloperamide 1 mg/5 mL oral liquid</td>
<td>Medi-Cal, HSF, C-Wrap: T1 → T1 QL #150mL/30d HK, HW: X</td>
<td>Safety/potential for abuse</td>
</tr>
<tr>
<td>Influenza Virus Vaccines</td>
<td>Alluria 2018-2019 45 mcg (15 mcg x 3)/0.5 mL intramuscular suspension</td>
<td>Medi-Cal: T2 AL≥19yo, QL #1/270d HK, HW, HSF, C-Wrap: X</td>
<td>New entity</td>
</tr>
<tr>
<td>Influenza Virus Vaccines</td>
<td>Alluria Quad 2018-2019 60 mcg/0.5 mL intramuscular suspension</td>
<td>Medi-Cal: T2 AL≥19yo, QL #1/270d HK, HW, HSF, C-Wrap: X</td>
<td>New entity</td>
</tr>
<tr>
<td>Influenza Virus Vaccines</td>
<td>Alluria Quad 2018-2019 (PF) 60 mcg/0.5 mL intramuscular syringe</td>
<td>Medi-Cal: T2 AL≥19yo, QL #1/270d HK, HW, HSF, C-Wrap: X</td>
<td>New entity</td>
</tr>
<tr>
<td>Influenza Virus Vaccines</td>
<td>Alluria 2018-2019 (PF) 45 mcg (15 mcg x 3)/0.5 mL intramuscular syringe</td>
<td>Medi-Cal: T2 AL≥19yo, QL #1/270d HK, HW, HSF, C-Wrap: X</td>
<td>New entity</td>
</tr>
<tr>
<td>Influenza Virus Vaccines</td>
<td>Fludix 2018-19 65yr up (PF) 45 mcg (15 mcg x 3)/0.5 mL intramuscular syringe</td>
<td>Medi-Cal: T2 AL≥85yr, QL #1/270d HK, HW, HSF, C-Wrap: X</td>
<td>New entity</td>
</tr>
<tr>
<td>Antiretroviral-Nucleoside, Nucleotide,</td>
<td>Sylmuza (darunavir/ cobicistat/ emtricitabine/ tenofovir AF)</td>
<td>Medi-Cal: T5 HK, HW, HSF, C-Wrap: X</td>
<td>Carve out</td>
</tr>
<tr>
<td>Protease Inh.</td>
<td>800 mg-150 mg-200 mg-10 mg tablet</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Influenza Virus Vaccines</td>
<td>Flucelvax Quad 2018-2019 60 mcg (15 mcg x 4)/0.5 mL IMP suspension</td>
<td>Medi-Cal: T2 AL≥19yo, QL #1/270d HK, HW, HSF, C-Wrap: X</td>
<td>New entity</td>
</tr>
<tr>
<td>Influenza Virus Vaccines</td>
<td>Flucelvax Quad 2018-2019 (PF) 60 mcg (15 mcg x 4)/0.5 mL IMP suspension</td>
<td>Medi-Cal: T2 AL≥19yo, QL #1/270d HK, HW, HSF, C-Wrap: X</td>
<td>New entity</td>
</tr>
<tr>
<td>Antineoplastic-Isocitrate Dehydrogenase</td>
<td>Tisboto (ivosidenib) 250 mg tablet</td>
<td>Medi-Cal, HK: T4 HW: T3 HSF, C-Wrap: X</td>
<td>New entity</td>
</tr>
<tr>
<td>Inhibitors</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Selective Serotonin 5-HT2A Inverse</td>
<td>Nuplazid (pimavanserin) 10, 34 mg tablet</td>
<td>Medi-Cal: T5 HK, HW, HSF, C-Wrap: X</td>
<td>Carve out</td>
</tr>
<tr>
<td>Agonists (SSIA)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anti-Inflammatory Tumor Necrosis Factor</td>
<td>Humira (adalimumub) Pen Crohn's-Ulcerative Collitis-Hidradenitis Suppurativa</td>
<td>Medi-Cal, HK: T4 HW: T3 HSF, C-Wrap: X</td>
<td>Carve out</td>
</tr>
<tr>
<td>Inhibitor</td>
<td>80 mg/0.8 mL SC kit</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anti-Inflammatory Tumor Necrosis Factor</td>
<td>Humira (adalimumub) Pen Psoriasis-Uveitis 80 mg/0.8 mL SC kit</td>
<td>Medi-Cal, HK: T4 HW: T3 HSF, C-Wrap: X</td>
<td>New kit</td>
</tr>
<tr>
<td>Inhibitor</td>
<td>1(1)-40 mg/0.4 mL(2) SC kit</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Viral/Tumorigenic Vaccines</td>
<td>Heplisav-B (PF) 20 mcg/0.5 mL IM syringe</td>
<td>Medi-Cal: T2 AL≥19yo HK, HW, HSF, C-Wrap: X</td>
<td>New dosage form</td>
</tr>
<tr>
<td>Prenatal Vitamin Preparations</td>
<td>prenatal vitamin 19/iron ps, heme/folic/DHA (Prefera-OB One)</td>
<td>Medi-Cal, HSF: NF-NL HK, HW, C-Wrap: X</td>
<td>Generic no longer available</td>
</tr>
<tr>
<td>Cystic Fibrosis - CFTR Potentiator-</td>
<td>Orkambi (lumacaftor/ivacaftor) 100-125, 150-188 mg granule packet</td>
<td>Medi-Cal, HK: T4 HW: T3 HSF, C-Wrap: X</td>
<td>New dosage form/new strength</td>
</tr>
<tr>
<td>Corrector Combin.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Influenza Virus Vaccines</td>
<td>FlumistQuad 2018-2019 10exp 6.5-7.5 FF unit/0.2 mL nasal spraysyringe</td>
<td>Medi-Cal: T2 AL≥19yo, QL #1/270d HK, HW, HSF, C-Wrap: X</td>
<td>New entity</td>
</tr>
<tr>
<td>Antipsychotic, Atypical, Dopamine,</td>
<td>Perseris 90 mg, 120 mg abdominal ER syringe kit</td>
<td>Medi-Cal: T5 HK, HW, HSF, C-Wrap: X</td>
<td>Carve out</td>
</tr>
<tr>
<td>Serotonin Antagonist</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Therapeutic class</td>
<td>Medication</td>
<td>Formulary Status</td>
<td>Comment</td>
</tr>
<tr>
<td>-------------------------------------------------------</td>
<td>----------------------------------------------------------------------------</td>
<td>----------------------------------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>Antineoplastic Systemic Enzyme Inhibitors</td>
<td>Lenvima 4 mg capsule, 12 mg/day (4 mg x 3) capsule</td>
<td>Medi-Cal, HK: T4 HW: T3 HSF, C-Wrap: X</td>
<td>New strength</td>
</tr>
<tr>
<td>Antihemophilic Factors</td>
<td>Jivi (Factor VIII, recombinant human pegylated) 500, 1000, 2000, 3000 (+/-) unit IV solution</td>
<td>Medi-Cal: T5 HK, HW, HSF, C-Wrap: X</td>
<td>Carve out</td>
</tr>
<tr>
<td>Antivirals, HIV-Specific, Non-Nucleoside, RTI</td>
<td>Pifeltro (doravirine) 100 mg tablet</td>
<td>Medi-Cal: T5 HK, HW, HSF, C-Wrap: X</td>
<td>Carve out</td>
</tr>
<tr>
<td>ARTV Nucleoside, Nucleotide, Non-Nucleoside RTI Comb</td>
<td>Delstrigo (doravirine/lamivudine/tenofovir DF) 100 mg-300 mg-300 mg tablet</td>
<td>Medi-Cal: T5 HK, HW, HSF, C-Wrap: X</td>
<td>Carve out</td>
</tr>
</tbody>
</table>

**Status**

<table>
<thead>
<tr>
<th>T1 Formulary Drug, Generic (can have quantity limits, age, gender and other code 1 restrictions as defined by Medi-Cal)</th>
<th>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).</th>
</tr>
</thead>
<tbody>
<tr>
<td>T2 Formulary Drug, Brand (can have quantity limits, age, gender and other code 1 restrictions)</td>
<td>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).</td>
</tr>
<tr>
<td>T3 Formulary Drug, Step Therapy or Prior Authorization required</td>
<td>Drug is a brand or generic and is covered through Prior Authorization process or at point of sale if step therapy criteria are met.</td>
</tr>
<tr>
<td>T4 Formulary Specialty Drug, Prior Authorization required</td>
<td>Drug requires distribution through a specialty pharmacy or is a limited distribution drug (LDD). Prior authorization process is required.</td>
</tr>
<tr>
<td>T/5 Non-Formulary Drug</td>
<td>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.</td>
</tr>
</tbody>
</table>

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 Carveout= 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

<table>
<thead>
<tr>
<th>Therapeutic class</th>
<th>Medication</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>NSAID And Topical Irritant Counter-Irritant Comb.</td>
<td>NuDroxiPAK I-800 (ibuprofen/capsaicin/methyl-salicylate/menthol) 800 mg-0.025 %-25 %-6 % kit: liquid, tablet</td>
<td>New kit</td>
</tr>
<tr>
<td>NSAID And Topical Irritant Counter-Irritant Comb.</td>
<td>NuDroxiPAK (celecoxib/capsaicin/methyl-salicylate/menthol) 200 mg-0.025 %-25 %-%6 % kit: liquid, capsule</td>
<td>New kit</td>
</tr>
<tr>
<td>Analgesic, Non-Salicylate And Barbiturate Comb.</td>
<td>butalbital 50 mg-acetaminophen 300 mg capsule</td>
<td>Line extension</td>
</tr>
<tr>
<td>Anti-Inflammatory, Interleukin-1 Beta Blockers</td>
<td>ilaris (canakinumab) PF 150 mg/mL SC powder for solution</td>
<td>Line extension</td>
</tr>
<tr>
<td>NSAID And Topical Irritant Counter-Irritant Comb.</td>
<td>NuDroxiPAK (diclofenac/capsaicin/methyl-salicylate/menthol) DSDR-50 mg-0.025 %-%25 %-6 % kit: liquid, DR tablet</td>
<td>New kit</td>
</tr>
<tr>
<td>NSAID And Topical Irritant Counter-Irritant Comb.</td>
<td>NuDroxiPAK (diclofenac/capsaicin/methyl-salicylate/menthol) DSDR-75 mg-0.025 %-%25 %-6 % kit: liquid, DR tablet</td>
<td>New kit</td>
</tr>
<tr>
<td>LHRH(GNRH) Antagonist, Pituitary Suppressant Agents</td>
<td>Orilissa (elagolix) 150, 200 mg tablet</td>
<td>New entity*</td>
</tr>
<tr>
<td>NSAID And Topical Irritant Counter-Irritant Comb.</td>
<td>NuDroxiPAK E-400 (etodolac/capsaicin/methyl-salicylate/menthol) 400 mg-0.025 %-%25 %-6 % kit: liquid, tablet</td>
<td>New kit</td>
</tr>
<tr>
<td>Beta-Adrenergic Blocking Agents</td>
<td>Kapsargo Sprinkle 25, 50, 100, 200 mg ER capsule</td>
<td>New dosage form</td>
</tr>
<tr>
<td>NSAID And Topical Irritant Counter-Irritant Comb.</td>
<td>NuDroxiPAK N-500 (nabumetone/capsaicin/methyl-salicylate/menthol) 500 mg-%0.025 %-25 %-6 % kit: topical liquid, tablet</td>
<td>New kit</td>
</tr>
<tr>
<td>Electrolyte Depleters</td>
<td>Lokelma (sodium zirconium cyclosilicate) 5, 10 gram oral powder packet</td>
<td>New entity*</td>
</tr>
<tr>
<td>Laxatives and Cathartics</td>
<td>Plenvu (PEG3350/Sod. Sulfate/NaCl/KCl/ASB/C) 140-9-5.2 gm powder packet</td>
<td>New strength</td>
</tr>
<tr>
<td>Topical Anti-Inflammatory Steroidal</td>
<td>SilaLite Pak 0.1 % kit, ointment and sheet</td>
<td>New kit</td>
</tr>
<tr>
<td>Pharmacological Chaperone-alpha-galactosid. A Stabz</td>
<td>Galafold (migalastat) 123 mg capsule</td>
<td>New entity*</td>
</tr>
<tr>
<td>Antipsoriatic Agents, Systemic</td>
<td>Ilumya (tildrokizumab) 100 mg/mL SC syringe</td>
<td>New entity*</td>
</tr>
<tr>
<td>Plasma Kallikrein Inhibitors</td>
<td>Takkyzyro (lanadelumab-FLYO) 300 mg/2 mL (150 mg/mL) SC solution</td>
<td>New entity*</td>
</tr>
<tr>
<td>Somatostatic Agents</td>
<td>Signifor (pasireotide pamoate) LAR 10, 30 mg IM suspension</td>
<td>New strength</td>
</tr>
<tr>
<td>Topical Anti-Inflammatory Nsaid-Local Anesthetic</td>
<td>TriXylital (diclofenac/lidocaine) 1.5 %-3.88 % tape kit, cream solution</td>
<td>New kit</td>
</tr>
<tr>
<td>Topical Anticholinergic Hyperhidrosis Tx Agents</td>
<td>Qbrexza (glycopyrronium) 2.4 % towelette</td>
<td>New entity</td>
</tr>
<tr>
<td>Antimigraine Preparations</td>
<td>Ajovy (fremanezumab-fnm) 225 mg/1.5 ml subcutaneous syringe</td>
<td>New entity*</td>
</tr>
<tr>
<td>Topical Local Anesthetics</td>
<td>Ztilido (lidocaine) 1.8 % topical patch</td>
<td>New strength</td>
</tr>
</tbody>
</table>

### Status

<table>
<thead>
<tr>
<th>Status</th>
<th>Definition</th>
</tr>
</thead>
</table>
| T1     | Formulary Drug, Generic (can have quantity limits, age, gender and other code 1) 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
<table>
<thead>
<tr>
<th>T2</th>
<th>Formulary Drug, Brand (can have quantity limits, age, gender and other code 1 restrictions)</th>
<th>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).</th>
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</thead>
<tbody>
<tr>
<td>T3</td>
<td>Formulary Drug, Step Therapy or Prior Authorization required</td>
<td>Drug is a brand or generic and is covered through Prior Authorization process or at point of sale if step therapy criteria are met.</td>
</tr>
<tr>
<td>T4</td>
<td>Formulary Specialty Drug, Prior Authorization required</td>
<td>Drug requires distribution through a specialty pharmacy or is a limited distribution drug (LDD). Prior authorization process is required.</td>
</tr>
<tr>
<td>T5</td>
<td>Non-Formulary Drug</td>
<td>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.</td>
</tr>
</tbody>
</table>

*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:

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