Regular Meeting of the

## Santa Clara County Health Authority
## Pharmacy and Therapeutics (P&T) Committee

Thursday, April 30, 2020, 6:00-8:00 PM
Santa Clara Family Health Plan
6201 San Ignacio Ave, San Jose, CA 95119

Via Teleconference
(669) 900-6833
Meeting ID: 966 4888 0811
Password: 8i.b+p27

# AGENDA

| | | | | |
|---|---|---|---|---|
| 1. | **Roll Call / Establish Quorum** | Dr. Lin | 6:00 | 5 min |
| **2.** | **Public Comment**<br>Members of the public may speak to any item not on the agenda; two minutes per speaker. The Committee reserves the right to limit the duration of public comment period to 30 minutes. | Dr. Lin | 6:05 | 5 min |
| **3.** | **Open Meeting Minutes**<br>Review Santa Clara Family Health Plan (SCFHP) 4Q2019 P&T Open Minutes<br>**Possible Action:** Approve SCFHP P&T Open Minutes | Dr. Lin | 6:10 | 2 min |
| **4.** | **Standing Agenda Items** | | | |
| a. | Chief Medical Officer Health Plan Updates | Dr. Nakahira | 6:12 | 5 min |
| b. | Plan/Global Medi-Cal Drug Use Review | Dr. Otomo | 6:17 | 3 min |
| c. | Appeals & Grievance 4Q2019 Report | Mr. Breakbill | 6:20 | 3 min |
| d. | Annual Pharmacy Policy Review | Dr. Huynh | 6:23 | 10 min |

**i. <u>New or Revised Policy</u>**

PH.10 Cal MediConnect Part D Transition (2020)

**ii. <u>Annual Review</u>**

1. PH.01 Pharmacy and Therapeutics Committee
2. PH.02 Formulary Development and Guideline Management
3. PH.03 Prior Authorization
4. PH.04 Pharmacy Clinical Programs and Quality Monitoring
5. PH.05 Continuity of Care for Pharmacy Services
6. PH.06 Pharmacy Communications
7. PH.07 Drug Recalls
8. PH.08 Pain Management Drugs for Terminally Ill
9. PH.09 Medications for Members with Behavioral Health Conditions
10. PH.11 340B Program Compliance

11. PH.14 Medications for Cancer Clinical Trial
**Possible Action:** Approve policies

***Adjourn to Closed Session***
*Pursuant to Welfare and Institutions Code Section 14087.36 (w)*

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|---|---|---|---|---|
| **5.** | **Closed Meeting Minutes**<br>Review SCFHP 4Q2019 P&T Closed Minutes<br>**Possible Action:** Approve SCFHP P&T Closed Minutes | Dr. Lin | 6:33 | 2 min |
| **6.** | **Metrics & Financial Updates** | | | |
| | a. Membership Report | Dr. Nakahira | 6:35 | 2 min |
| | b. Pharmacy Dashboard | Dr. Otomo | 6:37 | 2 min |
| | c. Drug Use Evaluation | Dr. Otomo | 6:39 | 1 min |
| | d. Drug Utilization & Spend | Dr. Huynh | 6:40 | 5 min |
| **7.** | **Discussion and Recommendations for Changes to SCFHP's Cal MediConnect Formulary & Coverage Determination Criteria** | | | |
| | a. Pharmacy Benefit Manager 4Q2019 P&T Minutes | Dr. Huynh | 6:45 | 2 min |
| | b. Pharmacy Benefit Manager 1Q2020 P&T Part D Actions<br>**Possible Action:** Approve MedImpact Minutes & Actions | | | |
| **8.** | **Discussion and Recommendations for Changes to SCFHP's Medi-Cal & Prior Authorization Criteria** | | | |
| | a. Old Business/Follow-Up<br>i. Statin Adherence<br>ii. Diabetes Type I & Type II | Dr. Huynh | 6:47 | 3 min |
| | b. Formulary Modifications<br>**Possible Action:** Approve recommendations | Dr. Otomo | 6:50 | 5 min |
| | c. Fee-for-Service Contract Drug List Comparability<br>**Possible Action:** Approve recommendations | Dr. Huynh | 6:55 | 5 min |
| | d. Prior Authorization Criteria | Dr. Nguyen | 7:00 | 10 min |
| | **i. <u>New or Revised Criteria</u>**<br>1. Deferasirox<br>2. Diroximel fumarate<br>3. Fingolimod<br>4. Reauthorization - Opioids<br>5. Glatiramer acetate<br>6. Interferon beta-1a<br>7. Oxycodone extended-release<br>8. Tacrolimus ointment | | | |
| | **ii. <u>Annual Review</u>**<br>1. Ambrisentan<br>2. General Utilization Management<br>3. Milnacipran<br>4. Raloxifene<br>**Possible Action:** Approve criteria | | | |
| 9. | **New Drugs and Class Reviews**<br>**a. <u>Informational Only</u>** | Dr. Huynh | 7:10 | 2 min |

i. Multiple sclerosis – Ozanimod
ii. Migraine Update – Eptinezumab
iii. Hyperlipidemia – Nexletol, Nexlizet
iv. Acute Hepatic Porphyria – Givlaari
v. Epilepsy – Xcopri
vi. Ulcerative Colitis Update
vii. Sickle Cell Anemia Update
viii. Oncology Update
ix. Cystic Fibrosis Update
x. Biosimilars Update
xi. Autoimmune updates
xii. New derivatives/formulations/combinations
xiii. New and Expanded Label

***Reconvene in Open Session***

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|---|---|---|---|
| **10. Discussion Items** | | | |
| a. New and Generic Pipeline | Dr. Huynh | 7:12 | 3 min |
| **11. Adjournment**<br>Next meeting Thursday, June 18, 2020 | Dr. Lin | 7:15 | |

**Notice to the Public—Meeting Procedures**

- Persons wishing to address the Committee on any item on the agenda are requested to advise the Recorder so that the Chairperson can call on them when the item comes up for discussion.
- The Committee may take other actions relating to the issues as may be determined following consideration of the matter and discussion of the possible action.
- In compliance with the Americans with Disabilities Act, those requiring accommodations in this meeting should notify Nancy Aguirre 48 hours prior to the meeting at 408-874-1835.
- To obtain a copy of any supporting document that is available, contact Nancy Aguirre at 408-874-1835. Agenda materials distributed less than 72 hours before a meeting can be inspected at the Santa Clara Family Health Plan offices at 6201 San Ignacio Ave, San Jose, CA 95119.
- This agenda and meeting documents are available at www.scfhp.com

Santa Clara Family Health Plan™

# Pharmacy & Therapeutics Committee

# OPEN MEETING MINUTES

Regular Meeting of the

## Santa Clara County Health Authority
## Pharmacy and Therapeutics Committee

Thursday, December 19, 2019, 6:00 PM - 8:00 PM
Santa Clara Family Health Plan, Redwood Conference Room
6201 San Ignacio Ave, San Jose, CA 95119

# MINUTES (OPEN)

DRAFT

**Members Present**
Ali Alkoraishi, MD
Dang Huynh, PharmD, Director of Pharmacy
Jesse Parashar-Rokicki, MD
Jimmy Lin, MD, Chair
Laurie Nakahira, DO, Chief Medical Officer
Peter Nguyen, DO
Xuan Cung, PharmD

**Members Absent**
Amara Balakrishnan, MD
Dolly Goel, MD
Hao Bui, BS, RPh
Minh Thai, MD
Narinder Singh, PharmD

**Staff Present**
Duyen Nguyen, PharmD
Nancy Aguirre, Administrative Assistant
Tami Otomo, PharmD

**Others Present**
Alan Kaska, Abbott Labs, Public
Amy McCarty, PharmD, MedImpact

### 1. Roll Call

Jimmy Lin, MD, Chair, called the meeting to order at 6:06pm. Roll call was taken and a quorum was not established.

### 2. Public Comment

Alan Kaska, Abbott Labs, talked about continuous glucose monitoring (CGM) devices for diabetes care. Abbott's CGM product, FreeStyle Libre, involves reading a person's blood glucose level with a reader and sensor instead of using the traditional fingerstick method. Mr. Kaska shared that Abbott Labs introduced the FreeStyle Libre CGM products at a lower cost than competitors.

### 3. Open Meeting Minutes

The review of the 3Q2019 Pharmacy and Therapeutics Committee open meeting minutes was deferred until a quorum was established.

## 4. Standing Agenda Items

### a. Chief Medical Officer Health Plan Updates

Laurie Nakahira, DO, Chief Medical Officer, Santa Clara Family Health Plan (SCFHP), reviewed the following Health Plan updates:

I. The Healthy Kids line of business has ended. The children who were enrolled in Healthy Kids were transitioned into the Medi-Cal line of business, which offers more benefits. All but two of the 3,500 children were transitioned into Medi-Cal on October 1, 2019. The two children (siblings) who did not meet criteria for Medi-Cal are being transitioned into Valley Kids. This transition should take full effect on January 1, 2020. Until that date, the two siblings will be covered by SCFHP.

II. One of SCFHP's durable medical equipment (DME) providers, California Home Medical Equipment (CHME), contract is terminating. Their contract ends on December 31, 2019.

III. SCFHP completed the Centers for Medicare and Medicaid Services (CMS) audit with a total of five findings. There will be one more audit to complete.

IV. Dr. Nakahira announced that SCFHP signed a lease for a new Community Resource Center (CRC) located in San Jose, near McKee Road and North Capitol Avenue. Member engagement, educational classes, and physical activity classes are a few of the resources that will be available to members within the CRC.

V. SCFHP has a new website and launched a new mobile app. The mobile app is user friendly and feedback on this new resource is highly encouraged.

VI. Presently, developmental screenings are being conducted during well child visits. However, providers have not been billing for them. Proposition 56 offers an extra payment to providers for performing this task. SCFHP will be working with some of the clinics to ensure providers obtain credit for completed developmental screenings.

### b. Plan/Global Medi-Cal Drug Use Review

Tami Otomo, PharmD, SCFHP, provided the final update on the Retrospective Drug Utilization Review (DUR) Morphine Equivalency Initiative program, which aimed to improve the quality of pain treatment and prevent opioid overdose in members with at least one month of prescription opioid claims exceeding 120 morphine equivalent daily dose (MEDD).

Dr. Otomo noted that opioid safety edits at point-of-sale (POS) were implemented on October 1, 2019 for all Medi-Cal members.

Ali Alkoraishi, MD, Committee Member, asked where SCFHP acquired their data. Dr. Otomo explained that the data was obtained from approved pharmacy claims for opioid prescriptions.

*Peter Nguyen, DO, Committee Member, arrived at 6:18pm. A quorum was established at this time.*

### c. Appeals & Grievance 3Q2019 Report

Dang Huynh, PharmD, Director of Pharmacy, SCFHP, presented the 3Q2019 Grievance & Appeals Report.

Dr. Nguyen asked about the number of prior authorization requests with subsequent appeals. Dr. Huynh explained that there is a 24-hour turnaround time for Medi-Cal. If the initial request does not have the necessary information, SCFHP will conduct telephonic outreach to the requesting provider to gather

supporting information. If the provider's office does not submit the supporting information within the turnaround time, then a denial will be made due to not having enough information to approve the request.

For Cal MediConnect (CMC), the majority of appeals are requests for high risk medications (HRM). HRM authorization requests require providers to submit an attestation acknowledging that the medication they are prescribing is considered high risk, but the benefits outweigh the risks for their patient. Dr. Lin asked if this is a state requirement. Dr. Huynh replied that CMS encourages the monitoring of HRM drugs. Dr. Huynh will request that Appeals & Grievances provide details about the other types of appeals for the next P&T Committee meeting.

**d. National Committee for Quality Assurance (NCQA) Member Connection Standards – 2019 Pharmacy Report**

Duyen Nguyen, PharmD, SCFHP, reported that there were no issues found in the required annual NCQA self-audit of SCFHP's member portal, resulting in a score of 100% in all measurements of quality and accuracy.

**e. CY2020 Utilization Management Drug PA Grid**

Dr. Otomo presented the Utilization Management Drug Prior Authorization (PA) grid for CY2020 and noted that it was approved at the most recent 4Q2019 Utilization Management Committee meeting.

SCFHP added newly released and soon-to-be released biosimilars to the PA grid. Dr. Otomo noted that if a biosimilar is available, SCFHP requires a step therapy for the brand name product.

*At 6:30pm, Dr. Lin resumed the Committee's review of the 3Q2019 Pharmacy and Therapeutics Committee open meeting minutes, as a quorum was established upon Dr. Nguyen's arrival.*

Dr. Nguyen motioned to accept the open meeting minutes as presented, and it was seconded by Dr. Alkoraishi. Motion carried.

***Adjourn to Closed Session***
*Pursuant to Welfare and Institutions Code Section 14078.36 (w)*

**5. Closed Meeting Minutes**

The 3Q2019 Pharmacy and Therapeutics Committee closed meeting minutes were reviewed as presented.

Dr. Nguyen motioned to accept the closed meeting minutes as presented, and it was seconded by Dr. Alkoraishi. Motion carried.

**6. Metrics and Financial Updates**

**a. Membership Report**

Dr. Nakahira presented the membership report.

**b. Pharmacy Dashboard**

Dr. Otomo presented the pharmacy dashboard.

**c. Drug Use Evaluation**

Dr. Huynh presented a follow-up to the 1Q19 Drug Use Evaluation (DUE) program.

**d. Drug Utilization & Spend**

Dr. McCarty presented the Drug Utilization & Spend.

7. **Discussion and Recommendations for Changes to SCFHP's CMC Formulary & Coverage Determination Criteria**

   a. **Pharmacy Benefit Manager 3Q2019 P&T Minutes**

   b. **Pharmacy Benefit Manager 4Q2019 P&T Part D Actions**

   Dr. McCarty presented the PBM's Medicare Part D Pharmacy & Therapeutics minutes and actions.

   Dr. Nguyen motioned to accept the PBM's 3Q2019 P&T Minutes and 4Q2019 P&T Part D Actions, and it was seconded by Dr. Nakahira. Motion carried.

8. **Discussion and Recommendations for Changes to SCFHP's Medi-Cal & Prior Authorization Criteria**

   a. **Old Business/Follow-Up**

      i. **Continuous Glucose Monitors (CGM)**
      Dr. Huynh reviewed the cost of Abbott FreeStyle Libre's CGM sensor.

      ii. **Opioid Point-of-Sale Safety Edits**
      Dr. Huynh reviewed the provider memo faxed out on October 1, 2019 with details about these opioid safety edits.

      iii. **Insulin Vial and Insulin Pen**
      Dr. Huynh reviewed the cost difference between an insulin pen and an insulin vial.

      iv. **Prior Authorization Approval Length**
      Dr. Huynh addressed Dr. Nguyen's question from the previous P&T Committee meeting regarding the consideration of approving PAs.

   b. **Formulary Modifications**

   Dr. Otomo presented Medi-Cal formulary changes.

   Dr. Nguyen motioned to accept the Formulary Modifications, and it was seconded by Jesse Parashar-Rokicki, MD, Committee Member. Motion carried.

   c. **Fee-for-Service Contract Drug List Comparability**

   Dr. McCarty reviewed the summary of changes to the Medi-Cal Fee-for-Service (FFS) Contract Drug List (CDL).

   Dr. Nguyen motioned to accept the recommendation that no action was needed by SCFHP, and it was seconded by Dr. Parashar-Rokicki. Motion carried.

   d. **Prior Authorization Criteria**

   Dr. Duyen Nguyen presented the following PA criteria:

   i. **New or Revised Criteria:**
      1. Non-Formulary
      2. Hepatitis C Policy
      3. Epclusa
      4. Mavyret
      5. Norditropin Flexpro
      6. Retacrit

   ii. **Annual Review:**
      1. Zarxio

Dr. Nguyen motioned to accept the PA criteria as presented, and it was seconded by Dr. Alkoraishi. Motion carried.

**9. New Drug and Class Reviews**

Dr. McCarty presented the following new drugs and class reviews:

**a. Review**

i. **Vumerity (diroximel fumarate)**
ii. **Nourianz (istradefylline)**
iii. **Glucagon-like peptide-1 (GLP-1) Class – Diabetes**

Dr. Nguyen motioned to accept the New Drugs and Class Reviews as presented, and it was seconded by Dr. Cung. Motion carried.

**b. Informational Only**

i. Adakveo (crizanlizumab) – Sickle Cell Disease
ii. Beovu (brolucizamab) – Age-Related Macular Degeneration
iii. Nubeqa (darolutamide) – Prostate Cancer
iv. Rozlytrek (entrectinib) – Oncology
v. Inrebic (fedratinib) – Oncology
vi. Reyvow (lasmiditan) – Migraine
vii. Ubrogepant – Migraine
viii. Rimegepant – Migraine
ix. Palforzia (AR101) – Peanut Allergy
x. Bonsity (teriparatide) – Osteoporosis
xi. Pretomainid – Tuberculosis
xii. Aklief (triparatide) – Acne
xiii. Guideline Updates – Pulmonary Arterial Hypertension
xiv. Biosimilar Update
xv. New and Expanded Indications

No questions were asked about the Informational Only items.

***Reconvene in Open Session***

**10. Discussion Items**

**a. New and Generic Pipeline**

Dr. McCarty noted an upcoming high impact-interest agent coming in 1Q2020 for peanut allergies. A second agent for peanut allergies will be released in the second half of 2020.

Dr. McCarty shared that generic Novolog Flexpen and Novolog vial will be available early 2020. These drugs are not on SCFHP's Medi-Cal formulary.

**11. Adjournment**

The next Pharmacy and Therapeutics Committee meeting will be on March 19, 2020. The meeting was adjourned at 7:37pm.

_____ _____

Jimmy Lin, MD, Chair of Pharmacy &Therapeutics Committee Date

Santa Clara Family Health Plan™

# Pharmacy & Therapeutics Committee

# STANDING AGENDA ITEMS

Santa Clara Family Health Plan™

# Appeals & Grievance 4Q2019 Report

# Appeals & Grievance 4Q2019 Report

| Pharmacy Appeals - Q4 2019 | | | |
|---|---|---|---|
| | Disposition | | |
| Case Type | Overturn | Uphold | Grand Total |
| Cal MediConnect Post Service Part D Appeal | | 2 | 2 |
| Cal MediConnect Pre-Service Part D Appeal | 23 | 18 | 41 |
| Medi-Cal Pre Service Pharmacy Appeal | 55 | 107 | 162 |
| Grand Total | 78 | 127 | 205 |

Santa Clara Family Health Plan

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|---|---|---|---|
| **Policy Title:** | **Cal MediConnect Part D Transition** | **Policy No.:** | PH10 |
| **Replaces Policy Title (if applicable):** | Cal MediConnect Part D Transition Policy | **Replaces Policy No. (if applicable):** | PM100 |
| **Issuing Department:** | Pharmacy | **Policy Review Frequency:** | Annual |
| **Lines of Business (check all that apply):** | ☐ Medi-Cal | ~~☐ Healthy Kids~~ | ☒ CMC |

## I. Purpose

To describe the process for transition of care and ensure that continued drug coverage is provided to new and current Medicare-Medicaid Plan (MMP) members. The transition process allows for a temporary supply of drugs and sufficient time for members to work with their health care providers to select a therapeutically appropriate formulary alternative, or to request a formulary exception based on medical necessity. Transition processes will be administered~~t~~ in a manner that is timely, accurate and compliant with all relevant CMS guidance and requirements as per 42 CFR §423.120(b)(3).

## II. Policy

A. Overview
   1. This policy is necessary with respect to:
      a. new enrollees into prescription drug plans following the annual coordinated election period
      b. the transition of newly eligible Medicare Medicaid beneficiaries from other coverage
      c. the transition of enrollees who switch from one plan to another after the start of a contract year
      d. enrollees residing in long-term care (LTC) facilities
      e. in some cases, current enrollees affected by negative formulary changes across contract years
   2. The plan ensures that its transition policy will apply to non-formulary drugs, meaning both (1) drugs that are not on the plan's formulary, and (2) drugs that are on the plan's formulary but require prior authorization or step therapy, or that have an approved quantity limit lower than the beneficiary's current dose, under the plan's utilization management rules. The plan ensures that its policy addresses procedures for medical review of non-formulary drug requests, and when appropriate, a process for switching new MMP plan enrollees to therapeutically appropriate formulary alternatives failing an affirmative medical necessity determination.
   3. The plan ensures that drugs excluded from Part D coverage due to Medicare statute are not eligible to be filled through the transition process. However, to the extent that the plan covers certain excluded drugs under an Enhanced or MMP benefit, those drugs should be treated the same as Part D drugs for the purposes of the transition process.

B. Transition of Care for State Covered Drugs
   1. The plan will apply transition of care logic to non-Part D drugs, drugs covered by the state. The logic is similar to the Part D functionality and allows new enrollees a transition fill for a defined period of time (e.g., 90 day minimum) for a specific day supply limit (e.g., 31 day supply). These transition claims are also included in the daily notification files used for member and prescriber letter generation.

C. Transition Population
   1. The plan will maintain an appropriate transition process consistent with 42 CFR §423.120(b)(3) that includes a written description of how, for enrollees whose current drug therapies may not be included in their new MMP plan's formulary, it will effectuate a meaningful transition for:
      a. new enrollees into prescription drug plans following the annual coordinated election period

b. newly eligible Medicare Medicaid members from other coverage
c. enrollees who switch from one plan to another after the start of a contract year
d. enrollees residing in long-term care (LTC) facilities, and
e. current enrollees affected by negative formulary changes across contract years.

D. Transition Period
1. The plan allows the CMS required minimum of 90 days from the start of coverage under a new plan. The 90 days are calculated from the member's plan start date. The plan will extend its transition policy across contract years should a member enroll in a plan with an effective enrollment date of either November 1 or December 1 and need access to a transition supply.
2. The transition start date will load from a daily membership file to the plan's pharmacy benefit manager (PBM) and the transition start date process will run simultaneously and analyze the member's group number assignment and the member's effective date within that group.
    a. For members that are new to the health plan or that are re-enrolling but had a break in coverage, the process will set the transition start date to match the member's effective date within the group.
    b. For existing (non-new) members that are assigned to a new group within the same health plan, the process will analyze the change in group number assignment to determine if it results in a new CMS contract and/or plan assignment.
        i. If the change in group number resulted in a new CMS contract and/or plan assignment, the member's transition start date will be updated to mirror the effective date of the group change.
        ii. If the change in group number did not result in a new CMS contract and/or plan assignment, the member's transition start date will remain as is and will not be updated.
3. This process logic aligns with guidance issued by CMS stating Plans must effectuate transition for members that change either CMS contract or plan, irrespective of whether or not the change resulted in a new Part D formulary assignment.
4. The plan will ensure that it will apply all transition processes to a brand-new prescription for a non-formulary drug if it cannot make the distinction between a brand-new prescription for a non-formulary drug and an ongoing prescription for a non-formulary drug at the point-of-sale.

E. Implementation Statement
1. Claims Adjudication System: The plan will provide a temporary supply of non-formulary Part D drugs in order to accommodate the immediate needs of an enrollee, as well as to allow the Plan and/or the enrollee sufficient time to work with the prescriber to make an appropriate switch to a therapeutically equivalent medication or the completion of an exception request to maintain coverage of an existing drug based on medical necessity reasons.
2. Pharmacy Notification at Point-Of-Sale: The plan utilizes the current NCPDP Telecommunication Standard to provide POS messaging. The plan reviews NCPDP reject and approval codes developed during the External Codes List (ECL) process. Pharmacy messages are modified based on industry standards.
3. Edits During Transition: The plan will only apply the following utilization management edits during transition at point-of-sale: edits to determine Part A or B versus Part D coverage, edits to prevent coverage of non-Part D drugs, edits to help determine Part D coverage (i.e., member level PAs) and edits to promote safe utilization of a drug. Step therapy and prior authorization edits must be resolved at point-of-sale.
    a. The plan provides refills for transition prescriptions dispensed for less than the written amount due to quantity limit safety edits or drug utilization edits that are based on approved product labeling.
    b. As outlined in 42 CFR §423.153 (b), the plan has implemented Point-of-Sale (POS) PA edits to determine whether a drug is covered under Medicare Parts A or B as prescribed and administered, is being used for a Part D medically accepted indication or is a drug or drug class or its medical use that is excluded from coverage or otherwise restricted under Part D (Transmucosal Immediate Release Fentanyl (TIRF) and Cialis drugs as an example).
4. Pharmacy Overrides at Point-Of-Sale: During the member's transition period, all edits (with the exception of those outlined in section E.3) associated with non-formulary drugs are automatically overridden at the point-of-sale. Pharmacies can also contact the plan's Pharmacy Help Desk directly for immediate assistance with point-of-sale overrides. The plan can also accommodate overrides at point-of-sale for emergency fills as described in section H.

F. Transition Fills for New Members in the Outpatient (Retail) Setting

1. The plan will ensure that in the retail setting, the transition policy provides for up to a one-time, temporary 1 month's supply day fill (unless the enrollee presents with a prescription written for less than 31 days in which case the Plan must allow multiple fills to provide up to a total of 31 days of medication.) anytime during the first 90 days of a member's enrollment in a plan, beginning on the enrollee's effective date of coverage.
2. If a brand medication is being filled under transition, the previous claim must also be brand (based on Comprehensive NDC SPL Data Elements File [NSDE] marketing status). If a generic medication is being filled under transition, the previous claim can be either brand or generic (based on NSDE marketing status)

G. Transition Fills for New Members in the LTC Setting
1. The plan will ensure that in the long-term care setting:
    a. the transition policy provides for a 1 month supply day fill consistent with the applicable dispensing increment in the long-term care setting (unless the enrollee presents with a prescription written for less), with refills provided if needed during the first 90 days of a member's enrollment in a plan, beginning on the enrollee's effective date of coverage;
    b. after the transition period has expired, the transition policy provides for a 31- day emergency supply of non-formulary Part D drugs (unless the enrollee presents with a prescription written for less than 31 days) while an exception or prior authorization is requested; and
    c. for enrollees being admitted to or discharged from a LTC facility, early refill edits are not used to limit appropriate and necessary access to their benefit, and such enrollees are allowed to access a refill upon admission or discharge.

H. Emergency Supplies and Level of Care Changes for Current Members
1. An Emergency Supply is defined by CMS as a one-time fill of a non-formulary drug that is necessary with respect to current members in the LTC setting. Current members that are in need of a one-time Emergency Fill or that are prescribed a non-formulary drug as a result of a level of care change can be placed in transition via an NCPDP pharmacy submission clarification code.
2. Upon receiving an LTC claim transaction where the pharmacy submitted a Submission Clarification Code (SCC) value of "18", which indicates that the claim transaction is for a new dispensing of medication due to the patient's admission or readmission into an LTC facility, the plan's claims adjudication system will recognize the current member as being eligible to receive transition supplies and will only apply the point-of-sale edits described in section E.3 of this policy.

I. Transition Across Contract Years
1. For current enrollees whose drugs will be affected by negative formulary changes in the upcoming year, the Sponsor will effectuate a meaningful transition by providing a transition process at the start of the new contract year
2. Current members will be allowed to access transition supplies at the point-of-sale when their claims history from the previous calendar year contains an approved claim for the same drug that the member is attempting to fill through transition and the drug is considered a negative change from one plan year to the next. If a brand medication is being filled under transition, the previous claim must also be brand (based on NSDE drug classification). If a generic medication is being filled under transition, the previous claim can be either brand or generic (based on NSDE drug classification).
3. Negative changes are changes to a formulary that result in a potential reduction in benefit to members. These changes can be associated to removing the covered Part D drug from the formulary, changing its preferred or tiered cost-sharing status, or adding utilization management. The transition across contract year process is applicable to all drugs associated to mid-year and across plan-year negative changes.

J. Transition Extension
1. The plan will continue to provide necessary drugs to enrollees via an extension of the transition period, on a case-by-case basis, to the extent that their exception requests or appeals have not been processed by the end of the minimum transition period and until such time as a transition has been made (either through a switch to an appropriate formulary drug or a decision on an exception request). On a case-by-case basis, point-of-sale overrides can also be entered by the Plan in order to provide continued coverage of the transition drug(s).

K. Cost-sharing for Transition supplies
1. The plan will ensure that cost-sharing for a temporary supply of drugs provided under its transition process will never exceed the statutory maximum co-payment amounts for low-income subsidy (LIS) eligible enrollees. For non-LIS enrollees, a sponsor must charge the same cost sharing for non-formulary Part D drugs provided during the transition that would apply for non- formulary drugs approved through a formulary exception in accordance with 42 CFR §-423.578(b) and the same cost sharing for formulary drugs subject to utilization

management edits provided during the transition that would apply if the utilization management criteria are met.

L. Six Classes of Clinical Concern
   1. Per CMS guidance, members transitioning to a plan while taking a drug within the six classes of clinical concern must be granted continued coverage of therapy for the duration of treatment, up to the full duration of active enrollment in the plan. Utilization management restrictions and/or non- formulary status, which may apply to new members naïve to therapy, are not applied to those members transitioning to the MMP plan on agents within these key categories. The six classes include:
      a. Antidepressant;
      b. Antipsychotic;
      c. Anticonvulsant;
      d. Antineoplastic;
      e. Antiretroviral; and
      f. Immunosuppressant (for prophylaxis of organ transplant rejection).

M. Member Notification
   1. The plan will send written notice via U.S. first class mail to enrollee within three business days of adjudication of a temporary transition fill. The notice must include
      a. an explanation of the temporary nature of the transition supply an enrollee has received;
      b. instructions for working with the plan sponsor and the enrollee's prescriber to satisfy utilization management requirements or to identify appropriate therapeutic alternatives that are on the plan's formulary;
      c. an explanation of the enrollee's right to request a formulary exception; and
      d. a description of the procedures for requesting a formulary exception.
   2. For long-term care residents dispensed multiple supplies of a drug in increments of 14-days-or-less, consistent with the requirements under 42 CFR 423.154(a)(1)(i), the written notice must be provided within 3 business days after adjudication of the first temporary fill. The plan will use the CMS model Transition Notice via the file-and-use process or submit a non- model Transition Notice to CMS for marketing review subject to a 45-day review. The plan will ensure that reasonable efforts are made to notify prescribers of affected enrollees who receive a transition notice.
   3. The plan will make its transition policy available to enrollees via link from Medicare Prescription Drug Plan Finder to plan's website and include in pre- and post-enrollment marketing materials as directed by CMS.

N. Provider Notification
   1. The plan sends a notification letter to be mailed to the prescriber at the same time the transition letter is mailed to the member. The file/letter includes the following:
      a. Prescriber information
      b. Member information
      c. Transition claim details

O. CMS Submission
   1. The plan will submit a copy of its transition process policy to CMS.

P. Exception Process
   1. The plan follows an overall transition plan for MMP members; a component of which includes the exception process. The plan's exception process integrates with the overall transition plan for these members in the following areas:
      a. The plan's exception process complements other processes and strategies to support the overall transition plan. The exception process follows the guidelines set forth by the transition plan when applicable.
      b. When evaluating an exception request for transitioning members, the plan's exception evaluation process includes a medical review that considers the clinical aspects of the drug, including any risks involved in switching~~, when evaluating an exception request for transitioning members.~~.
      c. This medical review process includes the following steps:
         a. Outreach is made to the provider to offer therapeutically appropriate formulary alternatives.
         b. This provides the prescriber an opportunity to switch the member to a covered formulary medication.

~~a.~~c. If the prescriber feels the formulary alternatives are not clinically appropriate for the member, they can provide attestation that the alternatives would not be as effective or would cause adverse effects, which would lead to an approval of the requested medication.

~~b.~~d. The exception policy includes a process for switching new MMP plan members to therapeutically appropriate formulary alternatives failing an affirmative medical necessity determination. The Prescriber Transition Letter provides prescribers with instructions to access the plan's formulary, as well as instructions on additional information to provide in a supporting statement for an exception request.

2. The plan will make available prior authorization or exceptions request forms upon request to both enrollees and prescribing physicians via a variety of mechanisms, including mail, fax, email, and on Plan web sites.

## III. Responsibilities

A. The Director of Pharmacy is responsible for overseeing this policy is effectuated in compliance with CMS requirements and for overseeing any portion of this delegated to the PBM.

## IV. References


1. Federal Register, Vol. 76, No. 73, Part II, 42 CFR, §423.120(b)(3), §423.154, §423.578(b)
2. Medicare Prescription Drug Benefit Manual, Chapter 6 Part D Drug and Formulary Requirements, 30.4 Transition
3. Medicare Marketing Guidelines


## I. Approval/Revision History

| First Level Approval | | | Second Level Approval | |
|---|---|---|---|---|
| | | | | |
| **Version Number** | **Change (Original/ Reviewed/ Revised)** | **Reviewing Committee (if applicable)** | **Committee Action/Date (Recommend or Approve)** | **Board Action/Date (Approve or Ratify)** |
| **1** | **Original** | **Pharmacy & Therapeutics Committee** | **Approved 6/15/2017** | |
| **1** | **Reviewed** | **Pharmacy & Therapeutics Committee** | **Approved 3/15/2018** | |
| **2** | **Revised** | **Pharmacy & Therapeutics Committee** | **Approved 9/20/2018** | |
| **3** | **Revised** | **Pharmacy & Therapeutics Committee** | **Pending** | |

# POLICY

Santa Clara Family Health Plan

| | | | |
|---|---|---|---|
| **Policy Title:** | **Pharmacy and Therapeutics Committee** | **Policy No.:** | PH01 |
| **Replaces Policy Title (if applicable):** | Pharmaceutical and Therapeutics Committee | **Replaces Policy No. (if applicable):** | PM 114 |
| **Issuing Department:** | Pharmacy | **Policy Review Frequency:** | Annually |
| **Lines of Business (check all that apply):** | ☒ Medi-Cal | ☒ ~~Healthy Kids~~ | ☒ CMC |

## I. Purpose

To describe the process on how the Plan establishes the composition, functions, and responsibilities of the Pharmacy & Therapeutics Committee.

## II. Policy

A. SCFHP maintains a practitioner based Pharmacy & Therapeutics (P&T) Committee within the Quality Improvement Committee structure
B. The P&T Reports directly the QI Committee
C. The P&T Committee will be defined by a Committee Charter which is reviewed annually and defines voting membership, quorum, meeting frequency, along with goals and objectives of the committee
D. The P&T Committee membership shall reflect the membership of the Plan and will include a pediatrician, a practitioner who specializes in the care of the elderly, a community based pharmacist, and psychiatrist or other prescribing Behavioral Health practitioner

## III. Responsibilities

A. Chief Medical Officer, or designee, shall ensure the P&T Committee follows this policy.
B. Director of Pharmacy, or designee, shall coordinate and prepare clinical materials for the meeting. He/she shall also oversee delegates that perform duties from this policy.

## IV. References

1. CA Health and Safety Code section 1367.24(e)(2)
2. Department of Managed Health Care Technical Assistance Guide, Rx Drug TAG Module, Requirement RX-004: Formulary Development for Psycho-pharmacologic Drugs
3. Medicare Prescription Drug Benefit Manual, Chapter 6 Part D Drugs and Formulary Requirements, 30.1 Pharmacy and Therapeutics (P&T) Committee
4. SCFHP DHCS Contract
5. NCQA, Quality Management and Improvement, QI7: Practice Guidelines
6. NCQA, Quality Management and Improvement, UM4: Appropriate Professionals

## V. Approval/Revision History

| First Level Approval | Second Level Approval |
|---|---|
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| Version Number | Change (Original/ Reviewed/ Revised) | Reviewing Committee (if applicable) | Committee Action/Date (Recommend or Approve) | Board Action/Date (Approve or Ratify) |
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| 1 | Original | Pharmacy & Therapeutics Committee | Approved 3/24/2016 | |
| 1 | Reviewed | Pharmacy & Therapeutics Committee | Approved 3/16/2017 | |
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| 1 | Reviewed | Pharmacy & Therapeutics Committee | Approved 3/21/2019 | |
| 2 | Revised | Pharmacy & Therapeutics Committee | Pending | |

# POLICY

Santa Clara Family Health Plan

| | | | |
|---|---|---|---|
| **Policy Title:** | **Formulary Development and Guideline Management** | **Policy No.:** | PH.02 |
| **Replaces Policy Title (if applicable):** | Provider Non-Formulary Drug Review Requests | **Replaces Policy No. (if applicable):** | PM 107 |
| **Issuing Department:** | Pharmacy | **Policy Review Frequency:** | Annually |
| **Lines of Business (check all that apply):** | ☒ Medi-Cal | ☒ ~~Healthy Kids~~ | ☒ CMC |

## I. Purpose

To define the process of the development and maintenance of the SCFHP formulary and clinical guidelines.

## II. Policy

A. SCFHP annually establishes and adopts a formulary and clinical guidelines to authorize, modify or deny pharmacy services. The formulary shall be based on benefit design as well as being based on sound clinical evidence as defined by generally accepted medical compendia and professional practice guidelines.
B. SCFHP adopts the formulary on defined methodology to address drug classifications, and
C. Where applicable the annual formulary will be submitted to appropriate regulators for review and approval, including the Centers for Medicare and Medicaid Services (CMS) for the Cal MediConnect line of business and to the California Department of Health Care Services (DHCS) for the Medi-Cal lines of business
D. The Plan involves actively practicing and prescribing practitioners in the development of the annual formulary which is then approved by the Pharmacy & Therapeutics Committee
E. The Plan involves a pediatrician and prescribing licensed behavioral health practitioner in the development of the formulary for psycho-pharmacologic drugs
F. The Plan involves a pediatrician and licensed prescribing behavioral health practitioner in the development of pertinent pharmacy management processes, including but not limited to costs-control measures, therapeutic substitution and step-therapy
G. SCFHP shall develop mechanisms to make the formulary and applicable review criteria available to practitioners as well as to the members and public upon request

## III. Responsibilities

A. Chief Medical Officer, or designee, shall ensure the P&T Committee follows this policy.
B. Director of Pharmacy, or designee, shall coordinate and prepare clinical materials. He/she shall also oversee delegates that perform duties from this policy.

## IV. References

1. CA Health and Safety Code section 1363.5(b)
2. 28 CCR 1300.67.24(b)(2) and (3)
3. Department of Managed Health Care Technical Assistance Guide, Rx Drug TAG Module, Requirement RX-004: Formulary Development for Psycho-pharmacologic Drugs

4. CA Health and Safety Code section 1367.20
5. CA Health and Safety Code section 1368.016
6. Department of Managed Health Care Technical Assistance Guide, Grievances and Appeals, Requirement GA-002: Grievance Filing
7. Medicare Prescription Drug Benefit Manual, Chapter 6 Part D Drugs and Formulary Requirements, 10.9 DESI Drugs
8. Medicare Prescription Drug Benefit Manual, Chapter 6 Part D Drugs and Formulary Requirements, 30.2 Provision of Adequate Formulary
9. SCFHP DHCS Contract
10. NCQA, Quality Management and Improvement, 2016, QI7: Practice Guidelines and UM 4, Appropriate Professionals

## V. Approval/Revision History

| First Level Approval | | | Second Level Approval | |
|---|---|---|---|---|
| | | | | |
| **Version Number** | **Change (Original/ Reviewed/ Revised)** | **Reviewing Committee (if applicable)** | **Committee Action/Date (Recommend or Approve)** | **Board Action/Date (Approve or Ratify)** |
| **1** | **Original** | **Pharmacy & Therapeutics Committee** | **Approved 3/24/2016** | |
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| **1** | **Reviewed** | **Pharmacy & Therapeutics Committee** | **Approved 3/21/2019** | |
| **2** | **Revised** | **Pharmacy & Therapeutics Committee** | **Pending** | |

# POLICY

Santa Clara Family Health Plan

| | | | |
|---|---|---|---|
| **Policy Title:** | **Prior Authorization** | **Policy No.:** | PH.03 |
| **Replaces Policy Title (if applicable):** | Issuing Notices to providers and Members of a Pharmacy Medication PA Request Denial<br><br>Prior Authorization<br><br>Member Notification Regarding Drug PA Determinations | **Replaces Policy No. (if applicable):** | PM 102<br><br>PM 106<br><br>PM 125 |
| **Issuing Department:** | Pharmacy | **Policy Review Frequency:** | Annually |
| **Lines of Business (check all that apply):** | ☒ Medi-Cal | ~~☒ Healthy Kids~~ | ☒ CMC |

## I. Purpose

To support a process for members to obtain authorization for medically necessary prior authorization (PA) and non-formulary (NF) drugs and to ensure this process is communicated in the EOC and disclosure forms.

## II. Policy

A. SCFHP maintains written procedures and processes on how to conduct Utilization Management prior authorization
B. SCFHP defines how prior authorization procedures and processes address the adoption of review criteria, application of criteria, and review of consistency of applying the criteria
C. The Plan defines the prior authorization turn-around times including the handling of routine requests and expedited requests including the Plans conversion of a routine to expedited or expedited to routine requests
D. The Plan provides clear and concise requirements of prior authorization denial notifications to members and requesting providers and practitioners
E. The Plan defines the mechanisms on how prior authorization requests can be submitted and by whom
    1. The Plan allows both practitioners/providers as well as members to submit requests for prior authorization
F. The Plan defines how requests for second opinions are handled through the prior authorization process

## III. Responsibilities

A. Chief Medical Officer, or designee, shall make appropriate PA determinations based of clinical criteria and evidence.
B. Director of Pharmacy, or designee, shall monitor and ensure compliance with this policy including review time frames and oversight of any delegation including the pharmacy benefit manager.

## IV. References

1. Department of Managed Health Care Technical Assistance Guide, Rx Drug TAG Module, Requirement RX-001: Non-Formulary Prescription Drug Authorization

2. Department of Managed Health Care Title 28 California Code of Regulations Section 1300.67.241 Prescription Drug Prior Authorization Form Process Control No. 2012-3880
3. CA Health and Safety Code sections 1367.01(e), (h)(1) through (4)
4. CA Health and Safety Code sections 1367.24(a), (b) and (d)
5. Medicare Prescription Drug Manual, Chapter 6 Part D Drugs and Formulary Requirements, 10.6 Medically-Accepted Indication
6. Medicare Prescription Drug Manual, Chapter 18 Part D Enrollee Grievances, Coverage Determinations, and Appeals, 30.1 Prior Authorization and Other Utilization Management Requirements
7. Medicare Prescription Drug Manual, Chapter 18 Part D Enrollee Grievances, Coverage Determinations, and Appeals, 30.2 Exceptions
8. SCFHP DHCS Contract
9. NCQA, Quality Management and Improvement, UM4: Appropriate Professionals
10. NCQA, Quality Management and Improvement, UM5: Timeliness of UM Decisions
11. NCQA, Quality Management and Improvement, UM6: Clinical Information
12. NCQA, Quality Management and Improvement, UM7: Denial Notices

## V. Approval/Revision History

| First Level Approval | | | Second Level Approval | |
|---|---|---|---|---|
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| **Version Number** | **Change (Original/ Reviewed/ Revised)** | **Reviewing Committee (if applicable)** | **Committee Action/Date (Recommend or Approve)** | **Board Action/Date (Approve or Ratify)** |
| **1** | **Original** | **Pharmacy & Therapeutics Committee** | **Approve 3/24/2016** | |
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| **1** | **Reviewed** | **Pharmacy & Therapeutics Committee** | **Approved 3/21/2019** | |
| **2** | **Revised** | **Pharmacy & Therapeutics Committee** | **Pending** | |

# POLICY

Santa Clara Family Health Plan

| | | | |
|---|---|---|---|
| **Policy Title:** | **Pharmacy Clinical Programs and Quality Monitoring** | **Policy No.:** | PH.04 |
| **Replaces Policy Title (if applicable):** | Pharmacy Over and Under Utilization Policy<br>Inter-Rater Reliability Policy<br>Medicare Coverage Determination Oversight Policy | **Replaces Policy No. (if applicable):** | PM 109<br>PM 126<br>PM 226 |
| **Issuing Department:** | Pharmacy | **Policy Review Frequency:** | Bi-annually |
| **Lines of Business (check all that apply):** | ☒ Medi-Cal | ~~Healthy Kids~~ | ☒ CMC |

## I. Purpose

To define the process how the Plan provides for continuous quality improvement of the plan's pharmacy services, including member safety.

## II. Policy

A. SCFHP maintains written procedures on how Pharmacy Services and Drug Utilization Review (DUR) [Section 1927(g) of the Social Security and 42 CFR 456, Subpart K]activities are monitored for effectiveness, member outcomes, and member safety
B. SCFHP defines specific member safety review monitors in the Pharmacy Quality oversight process including a sampling of the reviews in the organization-wide Quality Improvement (QI) annual Work Plan
C. SCFHP defines that various monitors may be utilized in measuring, analyzing and driving improvements in the Pharmacy QI process. These monitors will be defined to include but not be limited to HEDIS measures, medication reconciliations, Case and Disease Management programs, Opioid utilization, acetaminophen utilization, member compliance with medication therapy, medication therapy management and psychotropic medication adherence
D. The Plan further defines how pharmacy operations are measures for effectiveness which includes items such as inter-rater reliability to measure the consistency of applying criteria, decision turn-around times, content of denial notifications, and review of claims as applicable

## III. Responsibilities

A. Director of Pharmacy, or designee, will ensure continuous quality improvement for pharmacy services.
B. Director of Quality Improvement, or designee, will work with the Director of Pharmacy to ensure pharmacy programs support the plan's quality initiatives.

## IV. References

1. SCFHP DHCS Contract
2. NCQA, Quality Management and Improvement, QI1: Program Structure, Element A, Factor 3: Patient Safety

3. NCQA, Quality Management and Improvement, QI5: Complex Case Management NCQA, Quality Management and Improvement, QI6: Disease Management
4. NCQA, Quality Management and Improvement, QI8: Continuity and Coordination of Medical Care
5. NCQA, Quality Management and Improvement, QI9: Continuity and Coordination Between Medical Care and Behavioral Healthcare

## V. Approval/Revision History

| First Level Approval | | | Second Level Approval | |
|---|---|---|---|---|
| | | | Signature | |
| **Version Number** | **Change (Original/ Reviewed/ Revised)** | **Reviewing Committee (if applicable)** | **Committee Action/Date (Recommend or Approve)** | **Board Action/Date (Approve or Ratify)** |
| 1 | Original | Pharmacy & Therapeutics Committee | Approved 3/24/2016 | |
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| 2 | Revised | Pharmacy & Therapeutics Committee | Approved 6/15/2017 | |
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| 2 | Reviewed | Pharmacy & Therapeutics Committee | Approved 3/21/2019 | |
| 3 | Revised | Pharmacy & Therapeutics Committee | Pending | |

# POLICY

Santa Clara Family Health Plan

| | | | |
|---|---|---|---|
| **Policy Title:** | **Continuity of Care for Pharmacy Services** | **Policy No.:** | PH.05 |
| **Replaces Policy Title (if applicable):** | Cal MediConnect Transition Policy<br><br>Emergency Supply of Medications from a Retail Pharmacy<br><br>Pharmacy Network Access | **Replaces Policy No. (if applicable):** | PM 100<br><br>PM 108<br><br>PM 112<br><br>PM 122 |
| **Issuing Department:** | Pharmacy | **Policy Review Frequency:** | Annually |
| **Lines of Business (check all that apply):** | ☒ Medi-Cal | ~~Healthy Kids~~ | ☒ CMC |

## I. Purpose

To define the process how continuity of care for prescription drugs when medically appropriate is used to support the needs of members.

## II. Policy

A. SCFHP shall define how and when medication management procedures allow for continuity of care for identified medical conditions, taking into consideration the safest and most effective method of treatment the member condition

B. SCFHP defines the pharmacy network and the network's availability to the member
   1. It is the policy of SCFHP that there are 24-hour pharmacies available to members for after-hour prescription dispensing

C. The Plan will define the timing of medication dispensing including the amount of medication and coverage days to be included
   1. It is the policy of SCFHP that Cal MediConnect (CMC) members shall be provided with transition fills for non-formulary medications within the first 90 days of coverage under the new plan
   2. It is the policy of SCFHP that CMC members shall be provided with transition fills within the first 90 days of coverage in a new benefit under an existing plan if there are negative changes between benefit years

D. SCFHP defines in its written procedures the handling of medications in the long-term care setting

E. SCFHP defines how communication of transition medication management will be done with the member

F. Specific to the Medi-Cal line of business, SCFHP defines how an emergency 72-hour supply of medications are available on all drugs regardless of formulary status to support transition of care
   1. The Plan shall define how members will be allowed to continue to use any (single source) drugs that are part of a prescribed therapy in effect for the member immediately prior to the date of enrollment, whether or not the drug is covered, until the prescribed therapy is no longer prescribed by the provider.

## POLICY

### III. Responsibilities

A. Director of Pharmacy, or designee, will ensure continuity of care for pharmacy services is provided appropriately.

### IV. References

1. Department of Managed Health Care Technical Assistance Guide, Rx Drug TAG Module, Requirement RX-002: Plan's Obligations Relating to Drug Previously Approved for Enrollee Medical Condition
2. Medicare Prescription Drug Benefit Manual, Chapter 6 Part D Drug and Formulary Requirements, 30.4 Transition
3. SCFHP DHCS Contract
4. NCQA, Quality Management and Improvement, QI8: Continuity and Coordination of Medical Care
5. Department of Health Care Services, All Plan Letter 14-021.

### V. Approval/Revision History

| First Level Approval | | | Second Level Approval | |
|---|---|---|---|---|
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| **Version Number** | **Change (Original/ Reviewed/ Revised)** | **Reviewing Committee (if applicable)** | **Committee Action/Date (Recommend or Approve)** | **Board Action/Date (Approve or Ratify)** |
| **1** | **Original** | **Pharmacy & Therapeutics Committee** | **Approved 3/24/2016** | |
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| **2** | **Revised** | **Pharmacy & Therapeutics Committee** | **Pending** | |

# POLICY

Santa Clara Family Health Plan

| | | | |
|---|---|---|---|
| **Policy Title:** | **Pharmacy Communications** | **Policy No.:** | PH.06 |
| **Replaces Policy Title (if applicable):** | Furnishing of the SCFHP Drug Formulary to Members and Providers | **Replaces Policy No. (if applicable):** | PM 103 |
| **Issuing Department:** | Pharmacy | **Policy Review Frequency:** | Annually |
| **Lines of Business (check all that apply):** | ☒ Medi-Cal | ☒ ~~Healthy Kids~~ | ☒ CMC |

## I. Purpose

To address how the plan communicates to members and providers regarding pharmacy services.

## II. Policy

A. SCFHP shall define how communications and materials are developed, maintained and distributed to members and providers
B. SCFHP shall specifically define how the formulary for both Medi-Cal and CalMediConnect (CMC) lines of business are communicated to the members and providers
C. SCFHP shall include in defining material to be communicated include criteria and step therapy protocols
D. SCFHP defines how a 24 hours a day health information telephone line that is staffed by licensed nurses or clinicians where members can get answers to questions about medication
E. The Plan's process for communications to members and providers shall be defined in a written procedure and will include and address the prior authorization process, member notification of denial notices, and the appeals process

## III. Responsibilities

A. Director of Pharmacy, or designee, will ensure all required communications are sent or posted as appropriate to the plan's website.
B. Director of Marketing, or designee, will ensure all member materials are compliant with state and federal requirements.

## IV. References

1. Medicare Prescription Drug Benefit Manual, Chapter 6 Part D Drugs and Formulary Requirements, 30.3 Formulary Changes
2. SCFHP DHCS Contract
3. NCQA, Quality Management and Improvement, QI7: Practice Guidelines
4. NCQA, Quality Management and Improvement, MEM4: Pharmacy Benefit Information
5. NCQA, Quality Management and Improvement, UM7: Denial Notices

## V. Approval/Revision History

| First Level Approval | | | Second Level Approval | |
|---|---|---|---|---|
| | | | | |
| **Version Number** | **Change (Original/ Reviewed/ Revised)** | **Reviewing Committee (if applicable)** | **Committee Action/Date (Recommend or Approve)** | **Board Action/Date (Approve or Ratify)** |
| 1 | Original | Pharmacy & Therapeutics Committee | Approved 3/24/2016 | |
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| 1 | Reviewed | Pharmacy & Therapeutics Committee | Approved 3/21/2019 | |
| 2 | Revised | Pharmacy & Therapeutics Committee | Pending | |

# POLICY

Santa Clara Family Health Plan

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|---|---|---|---|
| **Policy Title:** | **Drug Recalls** | **Policy No.:** | PH.07 |
| **Replaces Policy Title (if applicable):** | | **Replaces Policy No. (if applicable):** | |
| **Issuing Department:** | Pharmacy | **Policy Review Frequency:** | Annually |
| **Lines of Business (check all that apply):** | ☐ Medi-Cal | ☐ ~~Healthy Kids~~ | ☒ CMC |

## I. Purpose

To define the mechanism to notify members and prescribing practitioners of appropriate notification during drug safety recalls.

## II. Policy

A. SCFHP adopts a written process to describe how the Plan will notify members and prescribing practitioners affected by a Class II recall or voluntary drug withdrawals from the market for safety reasons within 30 calendar days of the FDA notification.

B. The plan defines how members and prescribing practitioners for Class I recalls are notified within 15 days or as soon as possible, not to exceed 30 days of the FDA notification.

## III. Responsibilities

A. Director of Pharmacy, or designee, will monitor drug recalls for Class I and II and ensure letters are sent to affected members and their prescribing physicians.

B. Director of Marketing, or designee, will write and maintain a draft letter template that is CMS approved and available for use when there is a drug recall.

## IV. References


1. US Department of Food and Drug Administration (FDA)
2. 21 CFR Part 7, Subparts A and C - Recalls - General guidelines
3. 21 CFR Regulatory Procedures Manual, Chapter 7, Recall Procedures
4. 21 CFR Part 107, Subpart E - Mandatory recall of Infant Formula

## V. Approval/Revision History

| First Level Approval | | | Second Level Approval | |
|---|---|---|---|---|
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| **Version Number** | **Change (Original/ Reviewed/ Revised)** | **Reviewing Committee (if applicable)** | **Committee Action/Date (Recommend or Approve)** | **Board Action/Date (Approve or Ratify)** |
| 1 | Original | Pharmacy & Therapeutics Committee | Approve 3/24/2016 | |
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| 1 | Reviewed | Pharmacy & Therapeutics Committee | Approved 3/21/2019 | |
| 2 | Revised | Pharmacy & Therapeutics Committee | Pending | |

# POLICY

Santa Clara Family Health Plan

| | | | |
|---|---|---|---|
| **Policy Title:** | **Pain Management Drugs for Terminally Ill** | **Policy No.:** | PH.08 |
| **Replaces Policy Title (if applicable):** | | **Replaces Policy No. (if applicable):** | |
| **Issuing Department:** | Pharmacy | **Policy Review Frequency:** | Annually |
| **Lines of Business (check all that apply):** | ☒ Medi-Cal | ~~☒ Healthy Kids~~ | ☐ CMC |

## I. Purpose

To define the processes for the timely processing of requests for prescribed pain management for terminally ill patients when medically necessary

## II. Policy

A. SCFHP shall define the process how pain management drugs are managed with members who are terminally ill
B. SCFHP adopts a process that is aligned with current UM practices requiring that only a physician or pharmacist may make a denial decision based on medical necessity
C. The Plan adopts a written procedure that requires UM decisions to be made within 24 hours or the end of the next business day when a request is received for pain management medications for a terminally ill member. It is the policy of the Plan that a decision will never exceed 72 hours
D. If the Plan fails to make a determination within 72 hours, the requested treatment shall be deemed authorized
E. The Plan shall monitor compliance with the handling and approval of pain management drugs for the terminally ill members

## III. Responsibilities

A. Director of Pharmacy, or designee, will ensure pain management medications for terminally ill patients are processed in the appropriate timeframe.

## IV. References

1. Department of Managed Health Care Technical Assistance Guide, Rx Drug TAG Module, Requirement RX-003: Coverage for Pain Management Medications for Terminally Ill Patients

## V. Approval/Revision History

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| **Version Number** | **Change (Original/ Reviewed/ Revised)** | **Reviewing Committee (if applicable)** | **Committee Action/Date (Recommend or Approve)** | **Board Action/Date (Approve or Ratify)** |
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| 2 | Reviewed | Pharmacy & Therapeutics Committee | Approved 3/21/2019 | |
| 3 | Revised | Pharmacy & Therapeutics Committee | Pending | |

# POLICY

Santa Clara Family Health Plan

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|---|---|---|---|
| **Policy Title:** | **Medications for Members with Behavioral Health Conditions** | **Policy No.:** | PH.09 |
| **Replaces Policy Title (if applicable):** | | **Replaces Policy No. (if applicable):** | |
| **Issuing Department:** | Pharmacy | **Policy Review Frequency:** | Annually |
| **Lines of Business (check all that apply):** | ☒ Medi-Cal | ~~Healthy Kids~~ | ☒ CMC |

## I. Purpose

To define processes that maintain formulary coverage parity of behavioral health drugs compared to drugs for all other medical conditions.

## II. Policy

A. Santa Clara Family Health Plan (SCFHP) shall maintain written procedures on how the plan provides prescription coverage for the diagnosis and medically necessary treatment of behavioral health parity diagnoses under the same terms and conditions applied to other medical conditions.

B. The plan shall not impose quantitative or non-quantitative treatment limitations more stringent on mental health and substance use disorder drug as compared to medical/surgical drugs prescriptions [42 CFR 438.900 et seq.]

C. The Plan shall address the application of co-payments for psycho-pharmacologic drugs that are to be consistent with and not more stringent than limits for drugs for other medical conditions.

## III. Responsibilities

Director of Pharmacy, or designee, will make certain that drugs for behavioral health conditions are reviewed and assessed appropriately at Pharmacy and Therapeutic (P&T) Committee meetings.

Chief Medical Officer, or designee, will ensure the Pharmacy and Therapeutics Committee involves psychiatrists, pediatricians, or other mental health prescribing practitioners in the development of the formulary for psycho-pharmacologic drugs and pertinent pharmacy management processes, including, but not limited to, cost-control measures, therapeutic substitution, and step-therapy.

## IV. References


1. California Health and Safety Code sections 1374.72(a) and (b)(4)
2. Department of Managed Health Care Technical Assistance Guide, Rx Drug TAG Module, Requirement RX-004: Formulary Development for Psycho-pharmacologic Drugs
3. Department of Managed Health Care Technical Assistance Guide, Rx Drug TAG Module, Requirement RX-005: Coverage for Mental Health Parity Prescriptions
4. SCFHP-Department of Health Care Services Contract

## V. Approval/Revision History

| First Level Approval | Second Level Approval |
|---|---|
| | |

| Version Number | Change (Original/ Reviewed/ Revised) | Reviewing Committee (if applicable) | Committee Action/Date (Recommend or Approve) | Board Action/Date (Approve or Ratify) |
|---|---|---|---|---|
| 1 | Original | Pharmacy & Therapeutics Committee | Approved 3/24/2016 | |
| 1 | Reviewed | Pharmacy & Therapeutics Committee | Approved 3/16/2017 | |
| 2 | Revised | Pharmacy & Therapeutics Committee | Approved 3/15/2018 | |
| 2 | Reviewed | Pharmacy & Therapeutics Committee | Approved 3/21/2019 | |
| 3 | Revised | Pharmacy & Therapeutics Committee | Pending | |

# POLICY

Santa Clara Family Health Plan

| | | | |
|---|---|---|---|
| **Policy Title:** | **340B Program Compliance** | **Policy No.:** | PH.11 |
| **Replaces Policy Title (if applicable):** | | **Replaces Policy No. (if applicable):** | |
| **Issuing Department:** | Pharmacy | **Policy Review Frequency:** | Annually |
| **Lines of Business (check all that apply):** | ☒ Medi-Cal | ☒ Healthy Kids | ☐ CMC |

## I. Purpose

To outline the requirements of Santa Clara Family Health Plan (SCFHP) Pharmacy Department's processes for complying with Federal and State 340B regulations.

## II. Policy

A. SCFHP Pharmacy Department will comply with all requirements and restrictions of the Public Health Service Act Section 340B pertaining to a managed care organization (MCO) and the prohibition against duplicate discount/rebates under Medicaid pertaining.

B. The department will work with the Finance and Information Technology Departments to ensure the Department of Health Care Services 340B data reporting requirements are met [Patient Protection and Affordable Care Act of 2010, Public Law 111-148].

## III. Responsibilities

A. Director of Pharmacy, or designee, will maintain knowledge of regulation and policy changes that impact 340B program including, but not limited to, Health Resources & Service Administration/Office of Pharmacy Affairs rules.

B. Director of Pharmacy, or designee, with the Pharmacy Benefit Manager (PBM) will ensure claims system availability of National Council for Prescription Drug Programs (NCPDP) Submission Clarification code 20 for 340B eligibility claim identification [California's W&I Code Section 14105.46].

C. Directory of Pharmacy, or designee, with the PBM will assist the Finance Department integrity audits.

## IV. References


1. Section 340B of the Public Health Service Act.
2. Health Resources and Services Administration, Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Duplicate Discounts and Rebates on Drug Purchases, 58 Fed Reg. 27293 (May 7, 1993).
3. State Plan under Title XIX of the Social Security Act State: California. Methods and Standards for Establishing Payment Rates –Prescribed Drugs. Supplement 2 to Attachment 4. 19-B. TN No. 09-21B. (January 30, 2014).
4. National Council for Prescription Drug Programs, Inc. 340B Information Exchange. Reference Guide Version 1.0. July 2011.

## V. Approval/Revision History

| First Level Approval | | | Second Level Approval | |
|---|---|---|---|---|
| | | | | |
| **Version Number** | **Change (Original/ Reviewed/ Revised)** | **Reviewing Committee (if applicable)** | **Committee Action/Date (Recommend or Approve)** | **Board Action/Date (Approve or Ratify)** |
| 1 | Original | Pharmacy & Therapeutics Committee | Approved 09/21/2017 | |
| 1 | Reviewed | Pharmacy & Therapeutics Committee | Approved 03/15/2018 | |
| 1 | Reviewed | Pharmacy & Therapeutics Committee | Approved 3/21/2019 | |
| 2 | Revised | Pharmacy & Therapeutics Committee | Pending | |

# POLICY

Santa Clara Family Health Plan

| | | | |
|---|---|---|---|
| **Policy Title:** | **Medications for Cancer Clinical Trial** | **Policy No.:** | PH.14 |
| **Replaces Policy Title (if applicable):** | | **Replaces Policy No. (if applicable):** | |
| **Issuing Department:** | Pharmacy | **Policy Review Frequency:** | Annually |
| **Lines of Business (check all that apply):** | ☒ Medi-Cal | ~~Healthy Kids~~ | ☐ CMC |

## I. Purpose

To define the process that provides prescription drug coverage to members diagnosed with cancer and accepted into a phase I, phase II, phase III, or phase IV clinical trial for cancer with therapeutic intended endpoints and not exclusively defined to test toxicity.

## II. Policy

A. SCFHP shall define the process for coverage of routine patient care costs related to the clinical trial, including drugs that would otherwise be covered under the plan if those drugs were not provided in connection with an approved clinical trial program.

B. Routine patient care costs does not include the costs associated with the provision of:
   a. Drugs or devices that have not been approved by the federal Food and Drug Administration (FDA) and that are associated with the clinical trial.

C. The plan shall provide coverage of routine patient care costs, including other drug coverage given that the cancer clinical trial involves a drug that is exempt under federal regulations from a new drug application or approved by one of the following:
   a. National Institutes of Health (NIH);
   b. The federal FDA, in the form of an investigational new drug application;
   c. Department of Defense; or
   d. Veterans' Administration.

D. The plan may restrict coverage for clinical trials to participating hospitals and physicians in California if the protocol for the clinical trial is not provided.

## III. Responsibilities

A. Director of Pharmacy, or designee, will ensure medications for cancer clinical trial members are processed in the appropriate timeframe.

## IV. References

1. Health and Safety Code Section 1370.6
2. Welfare and Institutions Code Sections 14087.11, 14132.98, and 1412.99.
3. Senate Bill 37, Chapter 172, Amended March 13, 2001.

## V. Approval/Revision History

| First Level Approval | | | Second Level Approval | |
|---|---|---|---|---|
| | | | | |
| **Version Number** | **Change (Original/ Reviewed/ Revised)** | **Reviewing Committee (if applicable)** | **Committee Action/Date (Recommend or Approve)** | **Board Action/Date (Approve or Ratify)** |
| 1 | Original | Pharmacy & Therapeutics Committee | Approved 9/21/2017 | |
| 1 | Reviewed | Pharmacy & Therapeutics Committee | Approved 3/15/2018 | |
| 1 | Reviewed | Pharmacy & Therapeutics Committee | Approved 3/21/2019 | |
| 2 | Revised | Pharmacy & Therapeutics Committee | Pending | |

Santa Clara Family Health Plan™

# Pharmacy & Therapeutics Committee

# DISCUSSION ITEMS

# High Impact-Interest Agent Pipeline

**June 2019 Updates**
Vyleesi (HSDD)-C

**October 2019**
Beovu (AMD)-C†
Descovy (HIV PrEP indication)-NI,C
Vumerity (MS)-C
Bonsity (osteoporosis)-C
Reyvow (migraine)-C
Trikafta (cystic fibrosis)-A

**2nd Quarter 2020**
DS-8201 (breast cancer)-C†
obeticholic acid (NASH)-BT
Orilissa-NI, C

**August 2019**
Wakix (narcolepsy)-C
Rinvoq (RA)-C
Inrebic (myelofibrosis)-C

**December 2019**
cabotegravir/rilpivirine (HIV)-C†
lumateperone (schizophrenia)-C
Vascepa (CV indication)-NI,A


**September 2019**
Rybelsus (type 2 diabetes)-C

**November 2019**
crizanlizumab (sickle cell disease)-A†

**1st Quarter 2020**
AR101 (peanut allergy)-BT
bempedoic acid (hypercholesterolemia)-A
voxelotor (sickle cell disease)-BT
ozanimod (MS)-C

**2nd Half 2020**
Viaskin Peanut (peanut allergy)-C
Rolontis (neutropenia)-C

**Not Yet Filed**
BCX7353 (HAE)-C
BMN 270 (valrox)-BT
filgotinib (RA)-C
inclisiran (hypercholesterolemia)-C
leronlimab (HIV)-A
risdiplam (SMA)-C
roxadustat (anemia of CKD)-C
relugolix (uterine fibroids)-C

**KEY**
**C** = Agent will **compete** with current standard of care
**A** = Agent will be used in **addition** to current therapy or expands the patient population treated
**BT** = Agent is a **breakthrough**/novel treatment in an area where no comparable drug therapy previously existed
**NI** = Previously approved agent with a **new indication** (high impact)
† = *Medical Cost*
* = *Complete Response Letter*

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# Generic Pipeline

## *HIGH IMPACT*

**Jan 2020**
Novolog ǂ
Novolog Flexpenǂ
Novolog Mix Flexpenǂ
Symbicortǂ

**2020**
Restasis*
Thalomid

**Sept 2020**
**Truvada**
**200mg/300mg**
**Tecfidera**

**1Q2020** | **2Q2020** | **3Q2020**

**Jan 2020**
Zohydro ERǂ
Aczoneǂ
Depen
Silenorǂ

**March 2020**
Zortress

**2020**
**Nexium pkt for oral susp**
Zytiga 500mg
Byetta
Cuvposa

**June 2020**
Afinitor 10mg*

**Sept 2020**
**Atripla**
**Omnaris**

## *MEDIUM / LOW IMPACT*

**Bold font-new to slide**
***Red font-launched***
****NO exclusivity***
**ǂ Authorized Generic**

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