Regular Meeting of the

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

Thursday, March 18, 2020, 6:00 - 8:00 PM
Santa Clara Family Health Plan
6201 San Ignacio Ave, San Jose, CA 95119

**Via Teleconference**
(408) 638-0968
Meeting ID: 950 9421 9058
Passcode: **pharmacy21**
https://zoom.us/j/95094219058

# 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 the public comment period to 30 minutes. | Dr. Lin | 6:05 | 5 min |
| **3.** | **Open Meeting Minutes**<br>Review Santa Clara Family Health Plan (SCFHP) 4Q 2020 P&T Open Session Minutes.<br>**Possible Action:** Approve SCFHP P&T Open Session Minutes | Dr. Lin | 6:10 | 2 min |
| **4.** | **Standing Agenda Items** | | | |
| **a.** | Chief Medical Officer Health Plan Updates | Dr. Nakahira | 6:12 | 10 min |
| **b.** | Annual P&T Charter Review<br>**Possible Action:** Approve P&T Charter | Dr. Huynh | 6:22 | 3 min |
| **c.** | Medi-Cal Rx Update | Dr. Huynh | 6:25 | 5 min |
| **d.** | Grievance & Appeals Report – 4Q 2020 | Ms. Luong | 6:30 | 5 min |
| **e.** | Annual Policy Review | Dr. Huynh | 6:35 | 3 min |
| **i.** | PH.01 Pharmacy and Therapeutics Committee | | | |
| **ii.** | PH.02 Formulary Development and Guideline Management | | | |
| **iii.** | PH.03 Prior Authorization | | | |
| **iv.** | PH.04 Pharmacy Clinical Programs and Quality Monitoring | | | |
| **v.** | PH.05 Continuity of Care for Pharmacy Services | | | |
| **vi.** | PH.06 Pharmacy Communications | | | |
| **vii.** | PH.07 Drug Recalls | | | |
| **viii.** | PH.08 Pain Management Drugs for Terminally Ill | | | |
| **ix.** | PH.09 Medications for Members with Behavioral Health Conditions | | | |
| **x.** | PH.11 340B Program Compliance | | | |
| **xi.** | PH.14 Medications for Cancer Clinical Trial | | | |
| | **Possible Action**: Approve Pharmacy Policies | Dr. Otomo | 6:38 | 2 min |
| **f.** | Plan/Global Medi-Cal Drug Use Review | Dr. Nguyen | 6:40 | 5 min |
| **g.** | Emergency Supply Report – 1Q 2020 | | | |

***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 4Q 2020 P&T Closed Session Minutes.<br>**Possible Action:** Approve SCFHP P&T Closed Session Minutes | Dr. Lin | 6:45 | 2 min |
| **6.** | **Metrics & Financial Updates** | | | |
| | **a.** Membership Report | Dr. Nakahira | 6:47 | 3 min |
| | **b.** Pharmacy Dashboard | Dr. Otomo | 6:50 | 3 min |
| | **c.** Pharmacy Member Portal Stats – 2H 2020 | Dr. Huynh | 6:53 | 1 min |
| | **d.** Drug Utilization & Spend – 4Q 2020 | Dr. McCarty | 6:54 | 10 min |
| **7.** | **Discussion and Recommendations for Changes to SCFHP's Cal MediConnect Formulary & Coverage Determination Criteria**<br>**a.** Pharmacy Benefit Manager 4Q 2020 P&T Minutes<br>**b.** Pharmacy Benefit Manager 1Q 2021 P&T Part D Actions<br>**Possible Action:** Approve MedImpact Minutes & Actions | Dr. McCarty | 7:04 | 5 min |
| **8.** | **Discussion and Recommendations for Changes to SCFHP's Medi-Cal Formulary & Prior Authorization Criteria** | | | |
| | **a.** Old Business/Follow-Up | Dr. Otomo | 7:09 | 5 min |
| | **b.** Formulary Modifications<br>**Possible Action:** Approve Formulary Addition and Modification Recommendations | | 7:14 | 3 min |
| | **c.** Fee-for-Service Contract Drug List Comparability<br>**Possible Action:** Approve CDL Comparability Formulary Recommendations | Dr. McCarty | 7:17 | 3 min |
| | **d.** Prior Authorization Criteria | Dr. Nguyen | 7:20 | 5 min |
| | **i.** **New Criteria**<br>1. Movantik (Naloxegol) | | | |
| | **ii.** **Annual Review**<br>1. Letairis (Ambrisentan)<br>2. Jadenu (Deferasirox)<br>3. Vumerity (Diroximel fumarate)<br>4. Gilenya (Fingolimod)<br>5. General utilization management<br>6. Copaxone (Glatiramer acetate)<br>7. Avonex & Rebif (Interferon beta-1a)<br>8. Savella (Milnacipran)<br>9. Opioid - Reauthorization<br>10. Oxycontin (Oxycodone)<br>11. Evista (Raloxifene)<br>**Possible Action:** Approve PA Criteria Recommendations | | | |
| **9.** | **New Drugs and Class Review**<br>**a.** Nexletol & Nexlizet – Hyperlipidemia<br>**b.** Aducanumab - Alzheimer's Disease Review<br>**c.** COVID-19 Treatments<br>**Possible Action:** Approve New Drug and Class Recommendations | Dr. McCarty | 7:25 | 30 min |
| | **d.** **Informational Only**<br>**i.** Ponesimod – Multiple Sclerosis<br>**ii.** Umbralisib – Lymphoma | | | |

**iii.** Dasiglucagon – Hypoglycemia
**iv.** New & Expanded Indications
**v.** New Derivatives, Formulations, & Combinations

***Reconvene in Open Session***

| | | | |
|---|---|---|---|
| **10. Discussion Items** | | | |
| a. New and Generic Pipeline | Dr. McCarty | 7:55 | 5 min |
| **11. Adjournment** | Dr. Lin | 8:00 | |
| Next meeting Thursday, June 17, 2021 | | | |

**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 & Therapeutics Committee

Thursday, December 17, 2020, 6:00 PM – 8:00 PM

Santa Clara Family Health Plan

6201 San Ignacio Ave, San Jose, CA 95119

# Minutes (Open) - Draft



**Members Present**
Jimmy Lin, MD, Chair
Ali Alkoraishi, MD
Amara Balakrishnan, MD
Hao Bui, BS, RPh
Xuan Cung, PharmD
Dang Huynh, PharmD, Director of Pharmacy and UM
Laurie Nakahira, DO, Chief Medical Officer
Peter Nguyen, DO

**Members Absent**
Dolly Goel, MD
Jesse Parashar-Rokicki, MD
Narinder Singh, PharmD

**Staff Present**
Duyen Nguyen, PharmD, Clinical Pharmacist
Tami Otomo, PharmD, Clinical Pharmacist
Kristine Zhang, PharmD, PGY-2 Administration Pharmacy Resident
Mike Gonzalez, Manager, Community Resource Center
Jayne Giangreco, Manager, Administrative Services
Nancy Aguirre, Administrative Assistant

**Others Present**
Amy McCarty, PharmD
Shelly Palsingh

**1. Roll Call**

Jimmy Lin, MD, Chair, called the meeting to order at 6:09 pm. Roll call was taken and a quorum was established.

**2. Public Comment**

There were no public comments.

**3. Meeting Minutes**

The 3Q2020 P&T Committee Open meeting minutes were reviewed.

**It was moved, seconded and** the open minutes of the September 17, 2020 P&T meeting were **unanimously approved.**

**Motion:** Dr. Lin
**Second:** Dr. Cung
**Ayes:** Dr. Alkoraishi, Dr. Balakrishnan, Ms. Bui, Dr. Cung, Dr. Huynh, Dr. Lin, Dr. Nakahira
**Absent:** Dr. Goel, Dr. Nguyen, Dr. Parashar-Rokicki, Dr. Singh

## 4. Standing Agenda Items

### a. Chief Medical Officer Health Plan Updates

Dr. Nakahira shared that Santa Clara Family Health Plan (SCFHP) and Anthem Blue Cross collaborated to host 10 flu shot clinics; the last one is scheduled on December 30. The clinics are free to everyone, including those without health insurance. Further information is available on the SCFHP website.

The current Plan membership is about 270,000 members. Numbers have been increasing due to not disenrolling some of the Medi-Cal (MC) and Cal MediConnect (CMC) members.

Dr. Nakahira announced that the DHCS and DMHC audits will be taking place in March 2021.

Regarding CalAIM, Dr. Nakahira was pleased to announce that CalAIM will be brought back after being put on hold due to COVID-19. The new start date for CalAIM with enhanced Case Management in lieu of services is January 2022.

Dr. Nakahira briefly mentioned that the Medi-Cal Rx pharmacy carve out was due to start on January 1, 2021, but has been postponed to April 1, 2021.

Dr. Nakahira reported that as of December 16, SCFHP has approximately 3,400 members who have tested positive for COVID-19 and about 1,300 of those members have been hospitalized. 95 members passed away from COVID-19; 50 of them were at a skilled nursing facility (SNF) and 45 were outside of a hospital. This represents about 17% of deaths within the county.

Dr. Nakahira updated the committee with the latest news regarding the recently approved Pfizer COVID-19 vaccine. The county started vaccinating, beginning with Phase 1A. Phase 1A includes frontline workers and long-term care residents and workers. The State estimates California will receive approximately 1.8 million vaccines by the end of this year. This reflects approximately 4.5% of the state's population. There are about 1.7 million healthcare workers in California and about 640,000 nursing home residents and workers.

Dr. Nakahira added that SCFHP is working with the Public Health Department and the State to develop ways to message our population and the community about risks involved in taking vs. not taking the vaccine.

### b. Medi-Cal Rx Update

Dr. Huynh presented the Medi-Cal Rx update. As mentioned by Dr. Nakahira, the Medi-Cal Rx pharmacy carve out has been delayed to start on April 1, 2021. DHCS will communicate the delay with all Medi-Cal beneficiaries, including SCFHP members.

### c. Policy Review

#### i. PH10 CMC Part D Transition

Dr. Huynh reviewed the pharmacy policy PH10 CMC Part D Transition (2021). This policy is required by CMS annually. There were no changes from 2020 to 2021.

**It was moved, seconded and** the pharmacy policy PH10 CMC Part D Transition (2021) was **unanimously approved**.

**Motion:** Dr. Lin
**Second:** Dr. Balakrishnan
**Ayes:** Dr. Alkoraishi, Dr. Balakrishnan, Ms. Bui, Dr. Cung, Dr. Huynh, Dr. Lin, Dr. Nakahira
**Absent:** Dr. Goel, Dr. Nguyen, Dr. Parashar-Rokicki, Dr. Singh

**d. Drug Use Evaluation Update**

Dr. Otomo shared the results from SCFHP's quarterly retrospective Drug Use Evaluation (DUE) program. The clinical topics and data are chosen and provided by MedImpact. Two recent programs were for Asthma and Polypharmacy.

Asthma: This program identified members who received four or more prescriptions for an asthma medication within a 12 month period, but did not receive an asthma controller medication. The success rate was 61% for Medi-Cal and 57% for CMC. This program was again conducted in 4Q20 for both lines of business, and provider letters were mailed out on November 3.

Polypharmacy: This program identified members receiving more than 10 unique, chronic medications from three or more prescribers over a three month period. The success rate was 45% for CMC. This program was not conducted for the Medi-Cal line of business. This program was again conducted in 4Q20 for CMC, and provider letters were mailed out on November 3.

**e. 2019 4th Quarter Emergency Supply Report**

Dr. Nguyen reviewed the 2019 4th Quarter Emergency Supply Report. Approved claims were appropriate. For denied claims, one member had a denied claim for Monurol. Chart notes were requested, but none were received after multiple outreach attempts. There were also members who were prescribed medication at discharge, but did not have any pharmacy claims. There were no readmissions for urinary tract infection (UTI) were found for the sampled members from the previous quarter (3Q20). There is an opportunity for improvement in the process of obtaining chart notes for future reporting, as the Plan did not receive chart notes for many of the members in this quarter's report.

**f. Grievance & Appeals Pharmacy Report: 2020 1st – 3rd Quarter Reports**

Dr. Huynh presented the G&A Pharmacy Reports for Q1-Q3 of 2020. Q1 and Q2 reports were rerun due to inconsistencies in data that were identified during the last P&T Committee meeting.

For Q1 Medi-Cal, the number of February overturns was changed from 18 to 19.

For Q2 CMC, the 'Non Covered benefit' rationale was added.

For Q3 Medi-Cal and CMC, Dr. Huynh reviewed the Appeals Volume, Appeals by Decision, and Appeals by Rationale.

***Adjourned to Closed Session at 6:36 p.m.***
***Pursuant to Welfare and Institutions Code Section 14087.36 (w)***

**5. Closed Meeting Minutes**

The 3Q2020 P&T Committee Closed meeting minutes were reviewed.

**It was moved, seconded and** the closed minutes of the September 17, 2020 P&T meeting were **unanimously approved**.

**Motion:** Dr. Lin
**Second:** Ms. Bui
**Ayes:** Dr. Alkoraishi, Dr. Balakrishnan, Ms. Bui, Dr. Cung, Dr. Huynh, Dr. Lin, Dr. Nakahira
**Absent:** Dr. Goel, Dr. Nguyen, Dr. Parashar-Rokicki, Dr. Singh

**6. Metrics and Financial Updates**

**a. Membership Report**

The Plan's membership was reviewed by Dr. Nakahira during the CMO Health Plan Updates.

**b. Pharmacy Dashboard**
Dr. Otomo reviewed the Pharmacy Dashboard for August through November.

**c. Pharmacy Member Portal Stats**
Dr. Huynh presented the Pharmacy Member Portal Stats for the first half of the year.

**d. Drug Utilization & Spend**
Dr. McCarty presented the Drug Utilization and Spend for 3Q20.

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

**a. Pharmacy Benefit Manager 3Q2020 P&T Minutes**
Dr. McCarty reviewed the Pharmacy Benefit Manager 3Q2020 P&T Minutes.

**b. Pharmacy Benefit Manager 4Q2020 P&T Part D Actions**
Dr. McCarty reviewed the Pharmacy Benefit Manager 4Q2020 P&T Part D Actions.

**It was moved, seconded and** the Pharmacy Benefit Manager 3Q2020 and 4Q2020 Part D Actions were **unanimously approved**.

**Motion:** Dr. Huynh
**Second:** Dr. Lin
**Ayes:** Dr. Alkoraishi, Dr. Balakrishnan, Ms. Bui, Dr. Cung, Dr. Huynh, Dr. Lin, Dr. Nakahira
**Absent:** Dr. Goel, Dr. Nguyen, Dr. Parashar-Rokicki, Dr. Singh

**c. 2021 Medical Benefit Drug Prior Authorization Grid**
Dr. Otomo reviewed the 2021 Medical Benefit Drug Prior Authorization Grid.

**It was moved, seconded and** the 2021 Medical Benefit Drug Prior Authorization Grid for CMC was **unanimously approved**.

**Motion:** Dr. Huynh
**Second:** Dr. Lin
**Ayes:** Dr. Alkoraishi, Dr. Balakrishnan, Ms. Bui, Dr. Cung, Dr. Huynh, Dr. Lin, Dr. Nakahira
**Absent:** Dr. Goel, Dr. Nguyen, Dr. Parashar-Rokicki, Dr. Singh

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

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

**i. Cefdinir Point-of-sale Message Update**
Dr. Nguyen provided a follow-up to the 3Q19 Emergency Supply Report.

**b. Formulary Modifications**
Dr. Otomo presented the changes made to the Medi-Cal formulary since the last P&T Committee meeting in September 2020.

**It was moved, seconded and** the Medi-Cal Formulary Modifications were **unanimously approved**.

**Motion:** Dr. Lin
**Second:** Dr. Cung
**Ayes:** Dr. Alkoraishi, Dr. Balakrishnan, Ms. Bui, Dr. Cung, Dr. Huynh, Dr. Lin, Dr. Nakahira
**Absent:** Dr. Goel, Dr. Nguyen, Dr. Parashar-Rokicki, Dr. Singh

**c. Fee-for-Service Contract Drug List Comparability**
Dr. McCarty reviewed the Fee-for-Service Contract Drug List (CDL) Comparability for Medi-Cal.

**It was moved, seconded and** the Fee-for-Service Contract Drug List Comparability proposed actions were **unanimously approved**.

**Motion:** Dr. Lin
**Second:** Dr. Nakahira
**Ayes:** Dr. Alkoraishi, Dr. Balakrishnan, Ms. Bui, Dr. Cung, Dr. Huynh, Dr. Lin, Dr. Nakahira
**Absent:** Dr. Goel, Dr. Nguyen, Dr. Parashar-Rokicki, Dr. Singh

**d. 2021 Medical Benefit Drug Prior Authorization Grid**

Dr. Otomo reviewed the same 2021 Medical Benefit Drug Prior Authorization Grid that was reviewed in section 7.c of the agenda.

**It was moved, seconded and** the 2021 Medical Benefit Drug Prior Authorization Grid for Medi-Cal was **unanimously approved**.

**Motion:** Dr. Huynh
**Second:** Dr. Lin
**Ayes:** Dr. Alkoraishi, Dr. Balakrishnan, Ms. Bui, Dr. Cung, Dr. Huynh, Dr. Lin, Dr. Nakahira
**Absent:** Dr. Goel, Dr. Nguyen, Dr. Parashar-Rokicki, Dr. Singh

**e. Prior Authorization Criteria**

Dr. Nguyen reviewed the Prior Authorization Criteria.

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

1. Protopic ointment
2. Non-Formulary

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

1. Norditropin Flexpro
2. Zarxio

***Peter Nguyen joined the meeting at approximately 7:21 p.m.***

**It was moved, seconded and** the Prior Authorization Criteria was **unanimously approved.**

**Motion:** Dr. Lin
**Second:** Dr. Nguyen
**Ayes:** Dr. Alkoraishi, Dr. Balakrishnan, Ms. Bui, Dr. Cung, Dr. Huynh, Dr. Lin, Dr. Nakahira, Dr. Nguyen
**Absent:** Dr. Goel, Dr. Parashar-Rokicki, Dr. Singh

**9. New Drugs and Class Reviews**

**a. Tardive Dyskinesia Review**.

Dr. Zhang presented a background of tardive dyskinesia and the current treatments.

**b. COVID-19 Vaccines**.

Dr. Zhang reviewed the COVID-19 vaccines.

**c. Asthma Review**

Dr. McCarty reviewed the Global Initiative for Asthma (GINA) guidelines.

**d. Hereditary Angioedema (HAE)** – **Orladeyo**

Dr. McCarty reviewed Orladeyo for HAE prophylaxis.

**e. New & Expanded Indications – Epidiolex, Spravato, Tremfya, and Simponi Aria**

Dr. McCarty reviewed the new & expanded indications for Epidiolex, Spravato, Tremfya, and Simponi Aria.

**It was moved, seconded and** the recommendations for New Drugs and Class Reviews were **unanimously approved.**

**Motion:** Dr. Huynh
**Second:** Dr. Nguyen
**Ayes:** Dr. Alkoraishi, Dr. Balakrishnan, Ms. Bui, Dr. Cung, Dr. Huynh, Dr. Lin, Dr. Nakahira, Dr. Nguyen
**Absent:** Dr. Goel, Dr. Parashar-Rokicki, Dr. Singh

**f. Informational Only**

i. Anemia Chronic Kidney Disease – Roxadustat
ii. Systemic Lupus Erythematosus – Anifrolumab and Voclosporin
iii. Acne – Winlevi
iv. Duchenne Muscular Dystrophy – Viltepso
v. Pain from Osteoarthritis – Tanezumab
vi. Schizophrenia – Olanzapine/Samidorphan
vii. Fatty Acid Metabolism – Dojolvi
viii. Attention Deficit Hyperactivity Disorder – Viloxazine
ix. Overactive Bladder – Vibegron
x. Heart Failure – Vericiguat
xi. Chemo-induced Neutropenia – Rolontis
xii. Hyperlipidemia – Inclisiran
xiii. Ophthalmic NSAIDs
xiv. New Derivatives, Formulations, and Combinations

***Reconvene in Open Session at 7:44 p.m.***

**10. Discussion Items**

**a. New and Generic Pipeline**

Dr. McCarty reviewed the New and Generic Pipeline.

High interest/impact pipeline: Roxadustat, an oral drug for anemia of chronic kidney disease, was released in 4Q20 and will compete with the injectable drugs. Aducanumab will be a new drug for Alzheimer's disease. Teplizumab, which is expected in 3Q21, is a drug to delay the onset of type 1 diabetes.

Generic pipeline: The generic of Vascepa was released, but it only has the indication for high triglycerides and does not have the newer cardiovascular indication.

***Dr. Huynh noted that a member from the public, Shelly Palsingh, a Pharmacy student, joined the Open Session.***

***Dr. Balakrishnan announced her retirement from the Pharmacy & Therapeutics Committee.***

**11. Adjournment**

The meeting adjourned at 7:58 p.m. The next P&T Committee meeting will be on Thursday, March 18, 2021.

_____ _____
Jimmy Lin, MD, Chair Date

Santa Clara Family Health Plan™

# Pharmacy & Therapeutics Committee

# STANDING AGENDA ITEMS

# Santa Clara County Health Authority

## Pharmacy and Therapeutics Committee Charter

### Purpose

The Pharmacy and Therapeutics Committee shall provide oversight of the Santa Clara Family Health Plan (SCFHP) pharmacy program to promote safe, efficacious, and cost-effective drug therapies through policies, formularies, and clinical criteria.

The P&T Committee reports to the Quality Improvement committee (QIC). Signed minutes of the Committee are presented to the QIC by the Chair or designee.

### Members

The Pharmacy and Therapeutics (P&T) Committee shall have a sufficient number of members to provide the necessary expertise and work effectively as a group. Membership shall include physicians and pharmacists with a specialty mix that reflects the medical needs of the populations of the SCFHP membership, including a pediatrician, a community based pharmacist, and a psychiatrist or other prescribing behavioral health practitioner.

All P&T Committee members, including the Chairperson, shall be appointed by the Health Plan's Chief Executive Office (CEO). All members, including the Chairperson, can serve up to three two-year terms. Additional terms may be appointed at the discretion of the CEO, provided that the member is in compliance with the requirements set forth in this charter. The plan's Chief Medical Officer and Director of Pharmacy shall be automatically designated as voting P&T Commitee members.

No person who holds a direct financial interest in an affiliated heatlh care entity is eligible for appointment. P&T Committee members shall annually sign a Confidentiality Agreement, Conflict of Interest, and Non-Discrimination Agreement. Failure to sign the

agreement or abide by the terms of the agreement shall result in removal from the committee.

## Meetings

Regular meeting of the P&T Committee shall be scheduled quarterly. Additional special meetings, or meeting cancellations, may occur as circumstances dictate. Committee members must attend at least two meetings per year. Attendance may be in person or via teleconferencing. Teleconferencing shall be conducted pursuant to California Government Code section 54953(d). The presence of a majority of voting members shall constitue a quorum for the transaction of business.

The Committee may invite other individuals, such as members of management, auditors, or other technical experts to attend meetings and provide pertinent information relating to an agenda item, as necessary.

Meetings of the P & T Committee shall be open and public pursuant to the Ralph M. Brown Act (Gov. Code § 54950 et seq.).

## Responsibilities

The following goals and objectives shall serve as a guide with the understanding that the Committee may carry out additional functions as may be appropriate in light of changing business, regulatory, legal and other conditions:

A. Review pharmacy department policies annually and changes as needed.
B. Review of therapeutic drug classes, standards of practice, peer review medical literature, and clinical practice guidelines.
C. Provide oversight of the plan's formulary development and maintenance.
D. Oversee the development and maintenance of clinical criteria for prior authorization.
E. Verify that the pharmacy department functions meet the standards and requirements of regulatory and licensing bodies.
F. Review utilization reports for patterns of under and over utilization.
G. Promote the delivery of quality patient care in an efficient and cost effective manner

## Duration of Charter

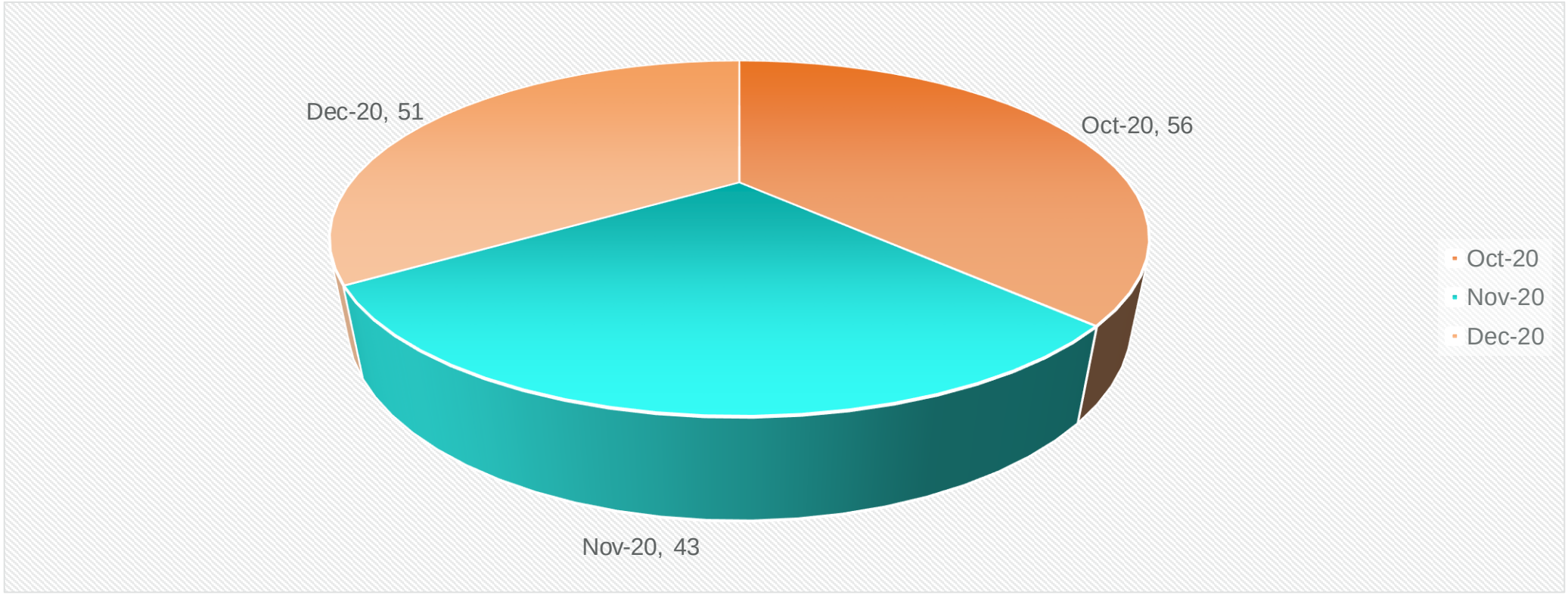
The plan's Director of Pharmacy will review this charter annually.

| CY Version | Change (Original/ Reviewed / Revised) | Reviewing Director of Pharmacy | Director of Pharmacy Review Date | Reviewing Committee (if applicable) | Committee Action/Date (Recommend or Approve) |
|---|---|---|---|---|---|
| 2017 | Revised | Johanna Liu, PharmD, MBA | 09/05/2017 | Pharmacy & Therapeutics Committee | 09/21/2017 |
| 2018 | Revised | Johanna Liu, PharmD, MBA | 08/29/2018 | Pharmacy & Therapeutics Committee | 09/20/2018 |
| 2019 | Revised | Dang Huynh, PharmD | 08/29/2019 | Pharmacy & Therapeutics Committee | 09/19/2019 |
| 2020 | Reviewed | Dang Huynh, PharmD | 12/31/2020 | Pharmacy & Therapeutics Committee | Pending Q1 2021 |

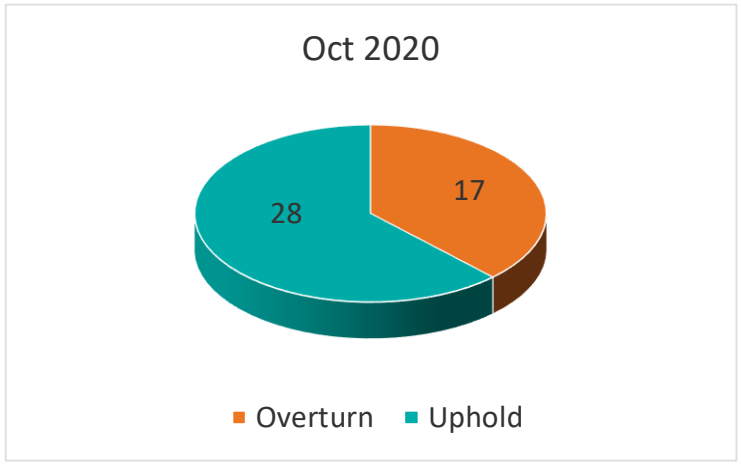
Santa Clara Family Health Plan™

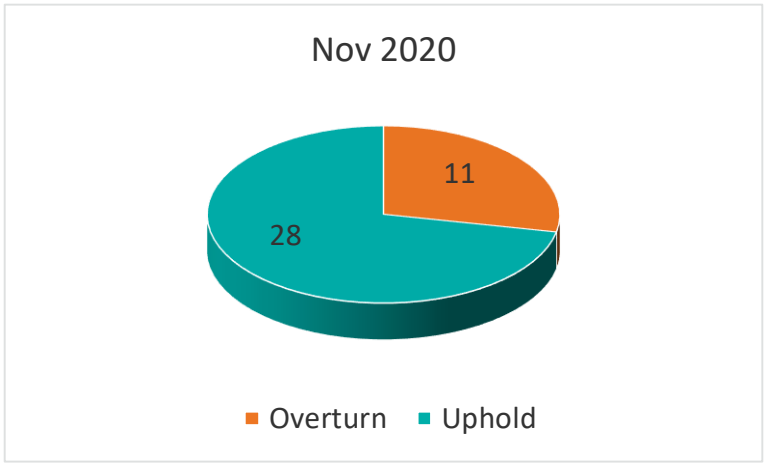
# Grievance & Appeals Department
# Q4 2020 Reporting

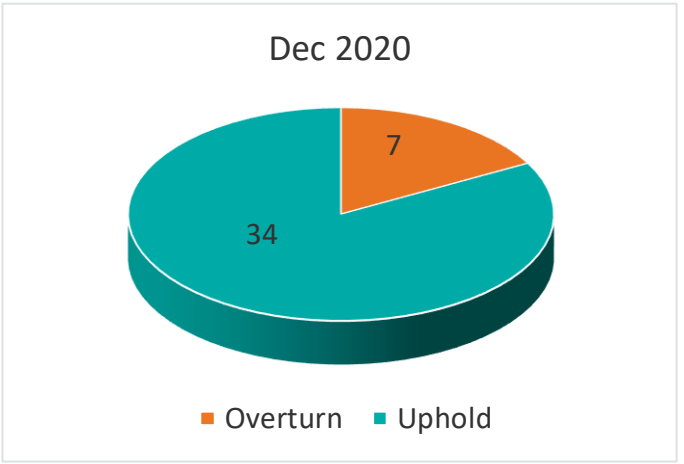
# Q4 2020 MC Appeals Volume



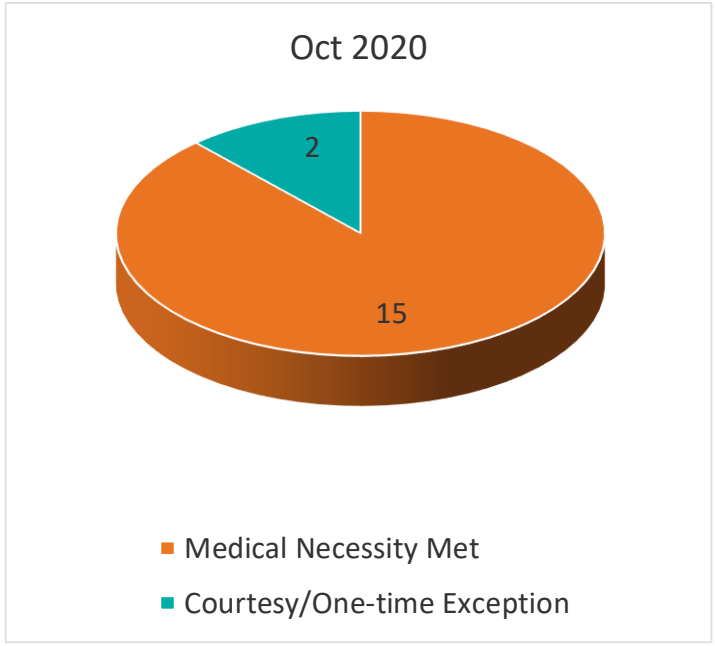
# Q4 2020 MC Appeals by Disposition

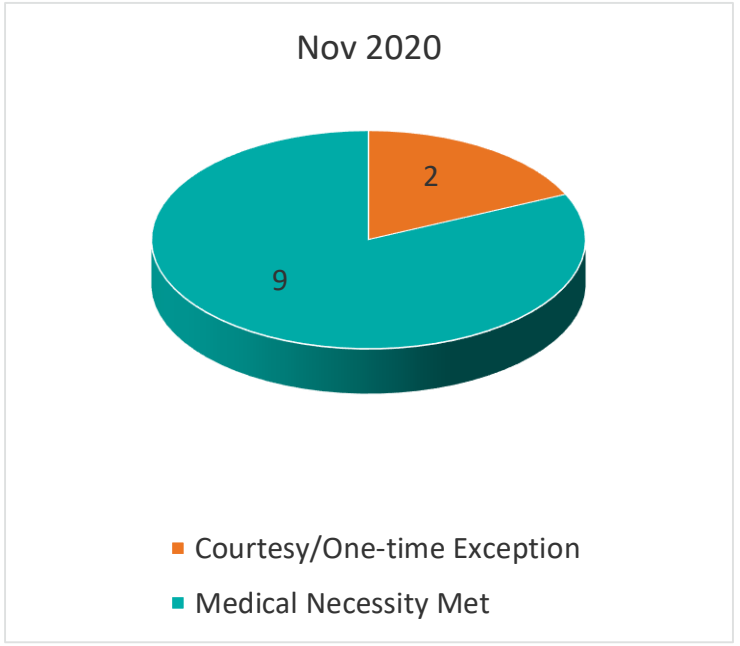


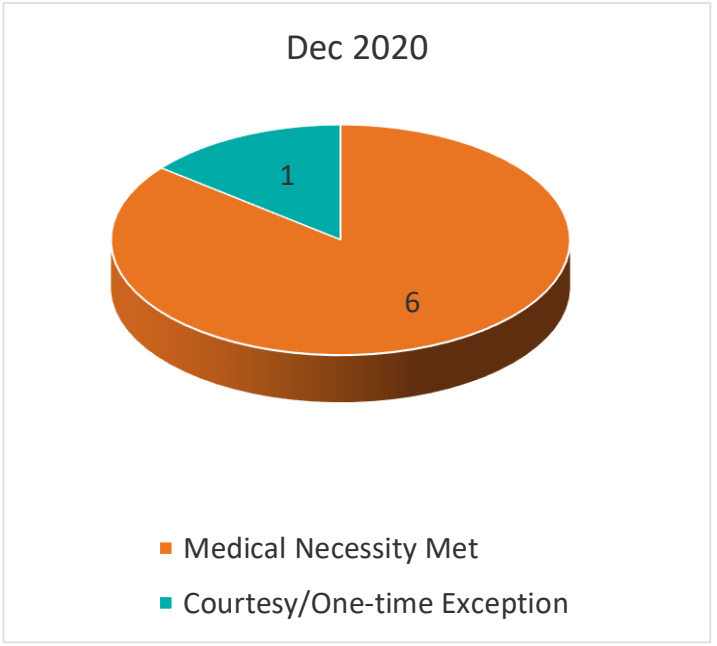



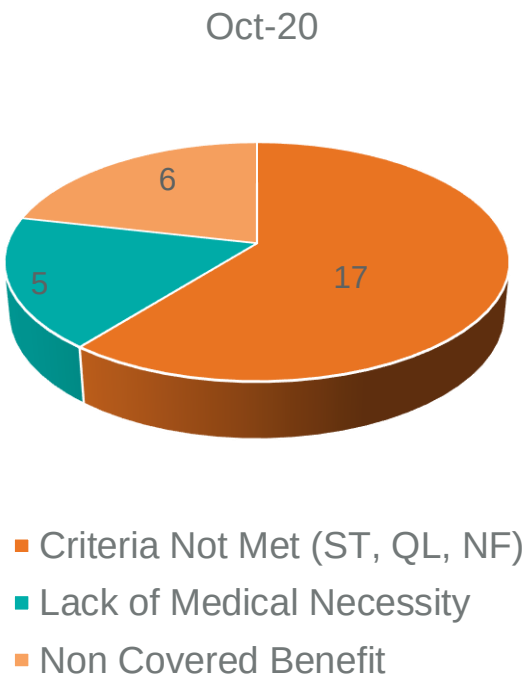
# Q4 2020 MC Appeals: Overturn Rationale

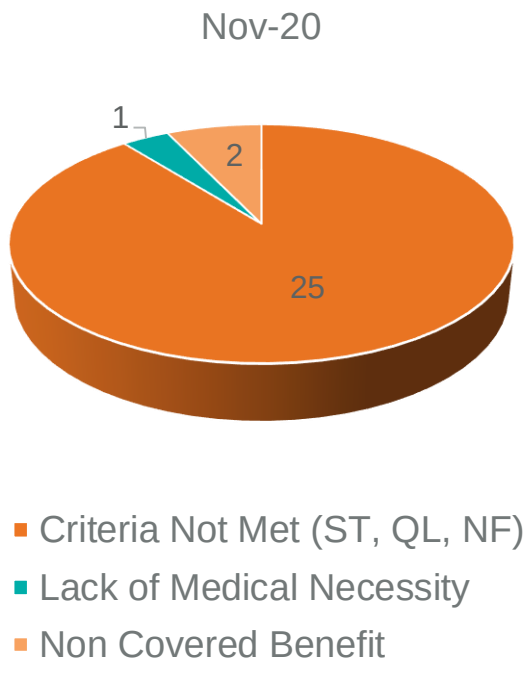


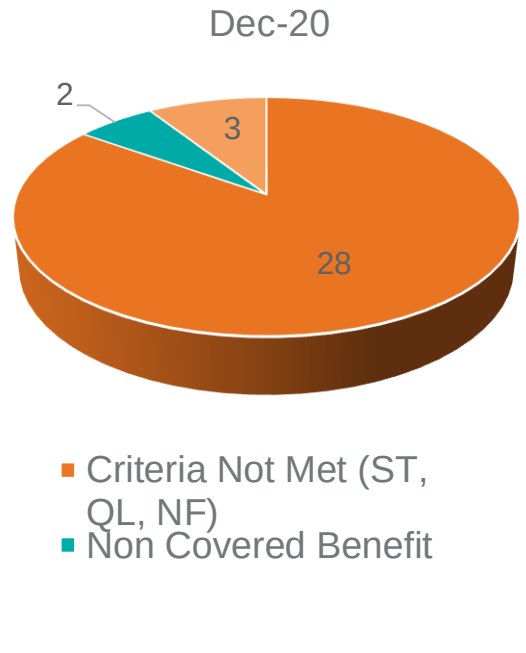



# Q4 2020 MC Appeals: Uphold Rationale



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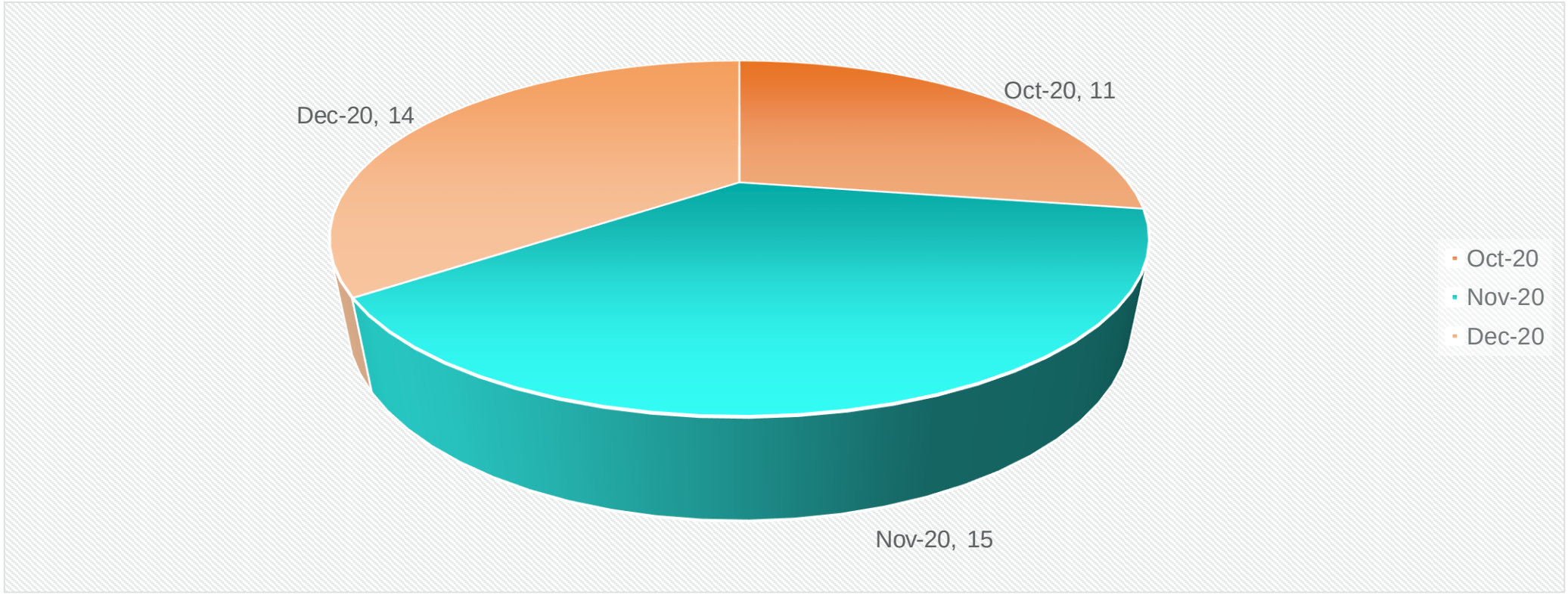
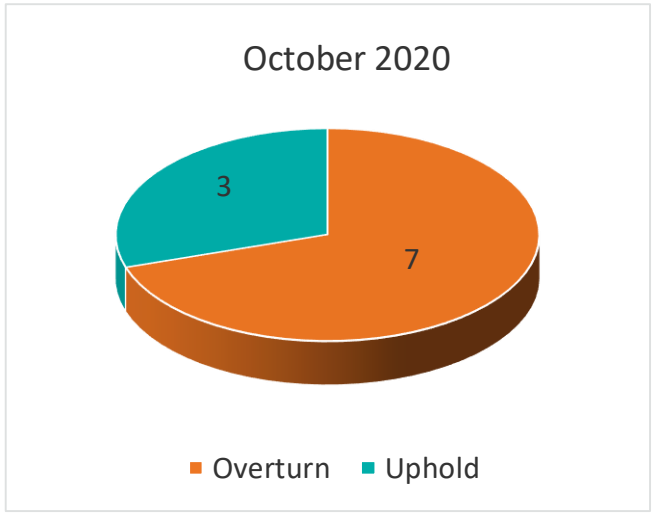
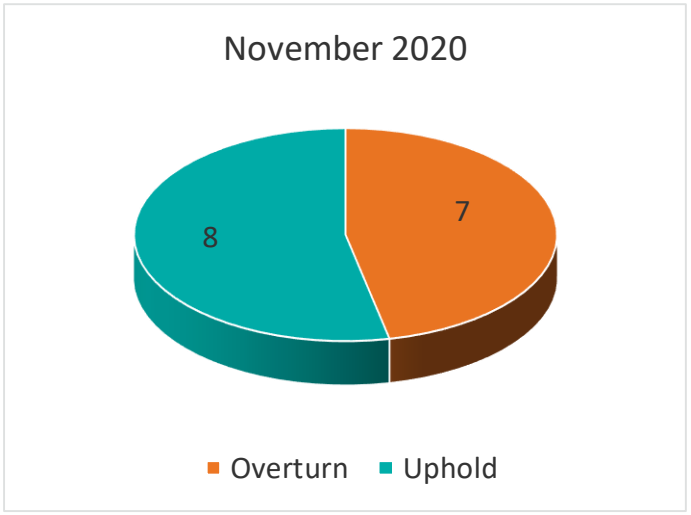
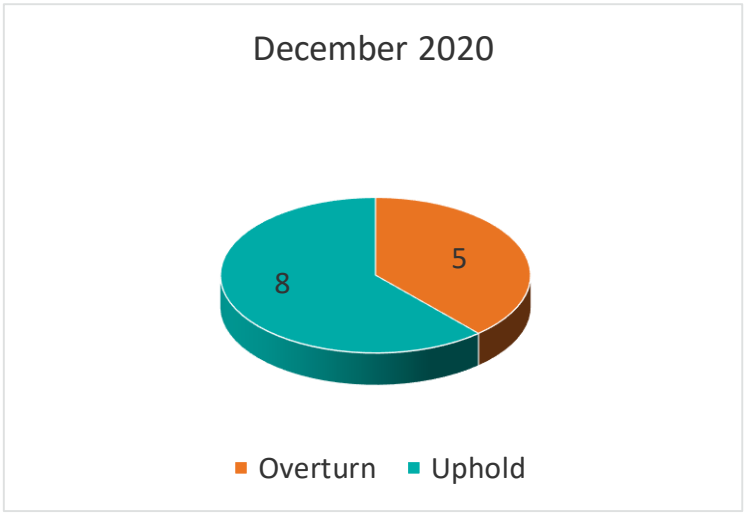


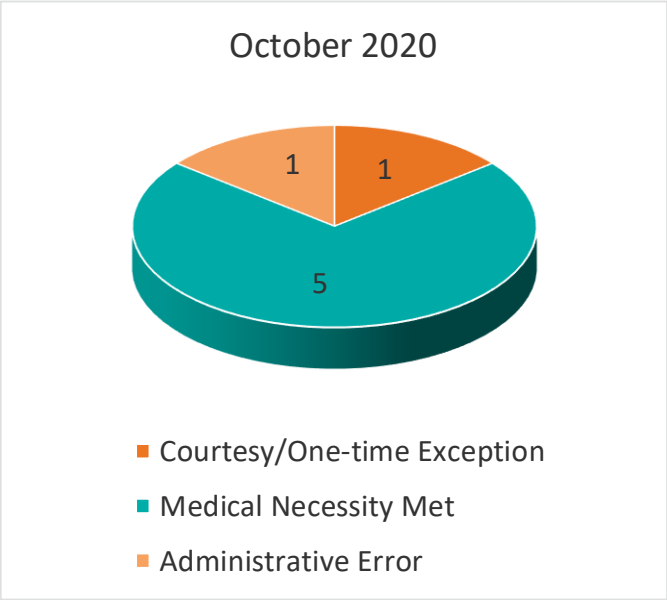
# Q4 2020 CMC Appeals by Disposition

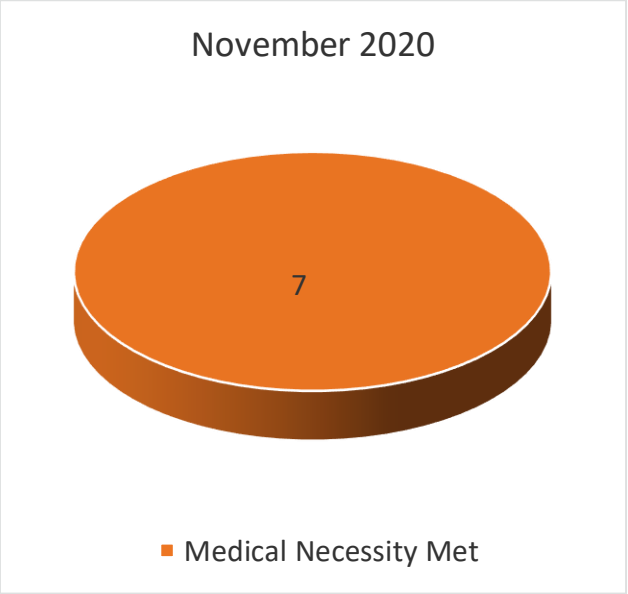


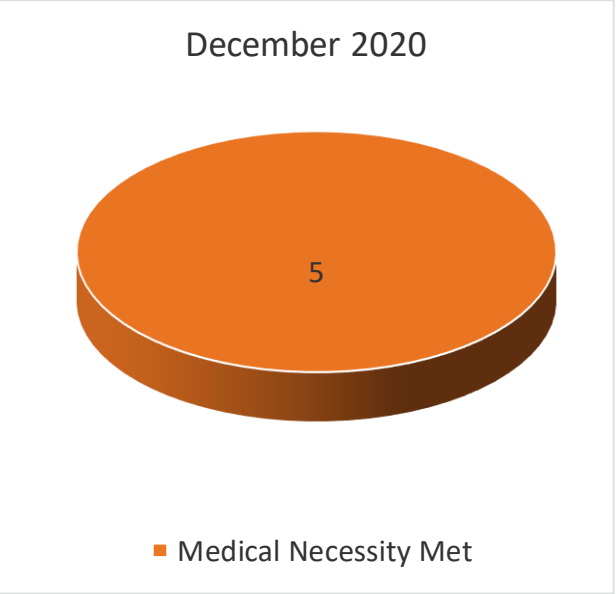



# Q4 2020 CMC Appeals: Overturn Rationale

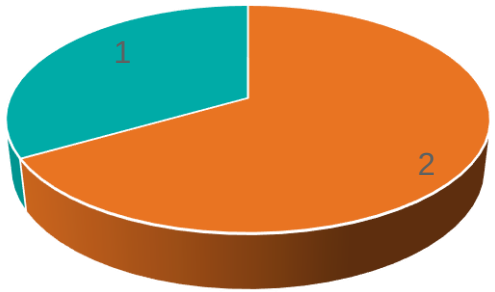


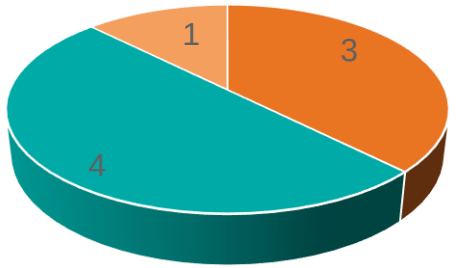



# Q4 2020 CMC Appeals: Uphold Rationale

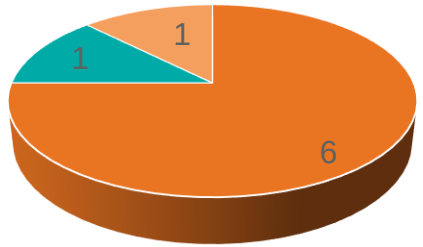
Oct-20




Nov-20




Dec-20



Santa Clara Family Health Plan™

# Grievance & Appeals Department

# 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 | | ☒ 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 |
|---|---|
| | |

| 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 | |
| 1 | Reviewed | Pharmacy & Therapeutics Committee | Approved 3/15/2018 | |
| 1 | Reviewed | Pharmacy & Therapeutics Committee | Approved 3/21/2019 | |
| 2 | Revised | Pharmacy & Therapeutics Committee | Approved 4/30/2020 | |

# 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 | | ☒ 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** | |
| **1** | **Reviewed** | **Pharmacy & Therapeutics Committee** | **Approved 3/16/2017** | |
| **1** | **Reviewed** | **Pharmacy & Therapeutics Committee** | **Approved 3/15/2018** | |
| **1** | **Reviewed** | **Pharmacy & Therapeutics Committee** | **Approved 3/21/2019** | |
| **2** | **Revised** | **Pharmacy & Therapeutics Committee** | **Approved 4/30/2020** | |

# POLICY

Santa Clara Family Health Plan

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|---|---|---|---|
| **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>Prior Authorization<br>Member Notification Regarding Drug PA Determinations | **Replaces Policy No. (if applicable):** | PM 102<br>PM 106<br>PM 125 |
| **Issuing Department:** | Pharmacy | **Policy Review Frequency:** | Annually |
| **Lines of Business (check all that apply):** | ☒ Medi-Cal | | ☒ 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 | |
|---|---|---|---|---|
| | | | | |
| **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** | |
| **1** | **Reviewed** | **Pharmacy & Therapeutics Committee** | **Approved 3/16/2017** | |
| **1** | **Reviewed** | **Pharmacy & Therapeutics Committee** | **Approved 3/15/2018** | |
| **1** | **Reviewed** | **Pharmacy & Therapeutics Committee** | **Approved 3/21/2019** | |
| **2** | **Revised** | **Pharmacy & Therapeutics Committee** | **Approved 4/30/2020** | |

# 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 | | ☒ 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 | |
|---|---|---|---|---|
| | | | | |
| **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 6/15/2017** | |
| **2** | **Reviewed** | **Pharmacy & Therapeutics Committee** | **Approved 3/15/2018** | |
| **2** | **Reviewed** | **Pharmacy & Therapeutics Committee** | **Approved 3/21/2019** | |
| **3** | **Revised** | **Pharmacy & Therapeutics Committee** | **Approved 4/30/2020** | |

# 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 | | ☒ 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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| **1** | **Original** | **Pharmacy & Therapeutics Committee** | **Approved 3/24/2016** | |
| **1** | **Reviewed** | **Pharmacy & Therapeutics Committee** | **Approved 3/16/2017** | |
| **1** | **Reviewed** | **Pharmacy & Therapeutics Committee** | **Approved 3/15/2018** | |
| **1** | **Reviewed** | **Pharmacy & Therapeutics Committee** | **Approved 3/21/2019** | |
| **2** | **Revised** | **Pharmacy & Therapeutics Committee** | **Approved 4/30/2020** | |

# 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 | | ☒ 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 | |
| 1 | Reviewed | Pharmacy & Therapeutics Committee | Approved 3/16/2017 | |
| 1 | Reviewed | Pharmacy & Therapeutics Committee | Approved 3/15/2018 | |
| 1 | Reviewed | Pharmacy & Therapeutics Committee | Approved 3/21/2019 | |
| 2 | Revised | Pharmacy & Therapeutics Committee | Approved 4/30/2020 | |

# POLICY

Santa Clara Family Health Plan

| | | | |
|---|---|---|---|
| **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 | ☐ | ☒ 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 |
|---|---|
| | |

| 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 | |
| 1 | Reviewed | Pharmacy & Therapeutics Committee | Approved 3/16/2017 | |
| 1 | Reviewed | Pharmacy & Therapeutics Committee | Approved 3/15/2018 | |
| 1 | Reviewed | Pharmacy & Therapeutics Committee | Approved 3/21/2019 | |
| 2 | Revised | Pharmacy & Therapeutics Committee | Approved 4/30/2020 | |

# 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 | | ☐ 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

| | |
|---|---|
| Dang Huynh, PharmD<br>Director, Pharmacy & Utilization Management | Laurie Nakahira, DO<br>Chief Medical Officer |

| 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 | |
| 2 | Revised | Pharmacy & Therapeutics Committee | Approved 3/16/2017 | |
| 2 | Reviewed | Pharmacy & Therapeutics Committee | Approved 3/15/2018 | |
| 2 | Reviewed | Pharmacy & Therapeutics Committee | Approved 3/21/2019 | |
| 3 | Revised | Pharmacy & Therapeutics Committee | Approved 4/30/2020 | |

# POLICY

Santa Clara Family Health Plan

| | | | |
|---|---|---|---|
| **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 | | ☒ 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 | Approved 4/30/2020 | |

# 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 | | ☐ 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 | Approved 4/30/2020 | |

# 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 | | ☐ 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** | **Approved 4/30/2020** | |

# Emergency Prescription Access Report

1st Quarter 2020

Santa Clara Family Health Plan

**Analysis Goal:** Evaluate access to medications prescribed pursuant to an emergency room (ER) visit and determine whether any barriers to care exist.

**Methodology:** Claims and encounter records for an emergency room visit during a calendar quarter will be evaluated and analyzed by network, primary diagnosis, and claims status. Prescription claims history will be evaluated to assess if any prescriptions were filled by the member within 72 hours of the ER visit date. Key diagnosis used will be urinary tract infection (UTI) due to clinical determination that such a diagnosis will require a prescription, particularly for antibiotic. Analysis includes: 1. Approved antibiotic claims: sampling of cases to evaluate for sufficient quantity based on diagnosis and medication per nationally recognized drug compendia and the Infectious Disease Society of America (IDSA) guidelines; 2. Denied antibiotic claims: sampling of cases to evaluate sufficient quantity based on diagnosis and medication as well as denial reasons; 3. No claims history: sampling of cases through claims history review as well as chart review of no related prescription claims history following an emergency room visit to identify non-pharmacy point-of-sale in-hospital dispensing or completion of in-house antibiotics regimen.

**Summary of Findings:**

## Section 1 – ER Visits

In 2020Q1, SCFHP had total 21,494 ER visits from claims and encounter data.

**Table 1: Members by Provider Network**

| Network | Unique Members | ER Visit Rx | ER Visit w/o Rx | Total ER Visits |
|---|---|---|---|---|
| No Network | 939 | 295 | 1,005 | 1,283 |
| Non-Delegated | 1,828 | 1,089 | 1,156 | 2,532 |
| Valley Health Plan | 9,423 | 5,248 | 6,071 | 12,404 |
| Palo Alto Medical Foundation | 313 | 149 | 222 | 404 |
| Physician Medical Group | 3,107 | 1,832 | 1,836 | 4,019 |
| Premier Care | 689 | 430 | 363 | 852 |
| **Grand Total** | 16,299 | 10,841 | 10,653 | 21,494 |

## Section 2 – Diagnosis

**Table 2: Key Diagnosis**

| | | 1Q2020 | | |
|---|---|---|---|---|
| **Code** | Diagnosis | Rx | No Rx | % Rx |
| **N390** | UTI, SITE NOT SPEC | 241 | 103 | 70% |

## Section 3 – Claims Analysis

### Approved Claims

Treatment guidelines for urinary tract infection/uncomplicated cystitis treatment are typically for at least 3 days, with the exception of fluconazole, fosfomycin, and ofloxacin that are administered as a single dose. Of prescriptions processed, we evaluated quantity per day supply and total day supply. There were no prescriptions filled inappropriately for less than a quantity of 1 per day. In this section we will focus on approved prescriptions with 2 day supply or less to evaluate if sufficient quantity and day supplies were written.

**Table 3: Approved Antibiotics Prescribed for UTI 2-Day Supply or Less**

| DRUG | Day Supply | Svc Prov Name | Approved |
|---|---|---|---|
| **FLUCONAZOLE** | **1** | Good Samaritan Hospital | **2** |
| **Grand Total** | | | **2** |

We did not identify any issues with approved claims. Fluconazole was appropriately written for a 1 day supply for 2 prescriptions.

### Denied Claims

We excluded those members who had primary insurance coverage outside of SCFHP. 1 member had a denied claim for Cefixime 400mg capsule. We called the pharmacy and verified that member did not pay out of pocket. We identified this as a gap, therefore, we will implement point of sale (POS) message for Cefdinir oral as formulary alternative since they are both 3rd generation cephalosporin with similar indications.

### No Claims

103 unique members diagnosed with UTI ER claims did not result in a prescription processed within 72 hours. We initially excluded 45 members with primary insurance coverage outside of SCFHP from this analysis. We subsequently randomly chose a sample of approximately 20% of 45 members, which is 9 total members, using Excel. We requested 5 chart notes from different hospitals. Findings are presented below.

| Mbr | Hospital | DOS | Findings |
|---|---|---|---|
| 1 | Santa Clara Valley Medical Center | 01/23/2020 | Cephalexin 500mg cap filled #14/7 on 1/27/2019 |
| 2 | Good Samaritan Hospital | 01/09/2020 | Levofloxacin 500mg tab filled #10/10 on 1/13/2020 |
| 3 | O'connor Hospital | 01/27/2020 | Cephalexin 500mg cap filled #24/6 on 1/1/2020 and #40/10 on 2/3/2020 |
| 4 | Regional Medical Center of SJ | 03/12/2020 | Cefpodoxime 100mg tab denied on 3/20/2020 |
| 5 | Regional Medical Center of SJ | 03/04/2020 | Chart note reviewed. Cephalexin 500mg x1 in ER. Prescription given, drug not mentioned. |
| 6 | Santa Clara Valley Medical Center | 01/30/2020 | Chart note reviewed. Cephalexin 500mg x1 in ER. Rx for Cephalexin 500mg, #40/10 days. |
| 7 | Regional Medical Center of SJ | 02/15/2020 | Chart note reviewed. Primary impression: UTI. Discharge/care plan: no primary or family physician. No Rx mentioned. Will forward case to Quality Department for review. |
| 8 | Regional Medical Center of SJ | 02/10/2020 | Chart note reviewed. UTI, will treat with Keflex. |

| | | | |
|---|---|---|---|
| 9 | O'Connor Hospital | 02/22/2020 | Chart note reviewed. UTI, antibiotics given, will be treated outpatient (not specified name of antibiotics) |

## Section 4 – Pharmacies

*Pharmacy Locations*

SCFHP has four 24-hour in-network pharmacies within Santa Clara County for members to access. In addition, the majority of retail chain pharmacies are opened until 9 P.M.

**Table 4: 24-Hour In-Network Pharmacies in Santa Clara County**

| NABP | NPI | Pharmacy Name | Address | City | Zip |
|---|---|---|---|---|---|
| 501507 | 1962417238 | WALGREENS | 121 E. EL CAMINO REAL | MT. VIEW | 94040 |
| 514667 | 1730194002 | WALGREENS | 350 NORTH CAPITOL AVE. | SAN JOSE | 95133 |
| 533011 | 1255346532 | WALGREENS | 440 BLOSSOM HILL ROAD | SAN JOSE | 95123 |
| 552287 | 1710921549 | CVS PHARMACY | 2514 BERRYESSA RD | SAN JOSE | 95132 |

**Summary:** Members with a diagnosis of UTI who do not have access to medications after an ER visit are at high risk for complications or readmissions. 1 member had a denied claim for Cefixime 400mg capsule. We identified this as a gap, therefore, we will implement point of sale (POS) message for Cefdinir oral as formulary alternative since they are both 3rd generation cephalosporin with similar indications. For members with no antibiotic claims after an ER visit for UTI, we continue to find members who were given prescriptions who did not fill them. Chart notes for 1 member did not mention discharge antibiotic, in addition, patient did not have primary or family physician. Case will be forwarded to Quality Department for further review. No readmissions for the same diagnosis were found within this quarter.

**Next Steps:** Continue quarterly assessment of emergency prescription access with medical and pharmacy data. Follow up on members who did not have prescription claims to identify any trends and readmissions. Cases with potential barriers of care will be forwarded to SCFHP Quality Department.

Santa Clara Family Health Plan™

# Pharmacy & Therapeutics Committee

# DISCUSSION ITEMS

# Pipeline Agents

Santa Clara Family Health Plan™

SANTA CLARA FAMILY HEALTH PLAN

# High Impact/Interest Pipeline

## 4th Quarter 2020

mRNA vaccines (Covid-19)–BT #
bamlanivimab (Covid-19) –BT # †
casirivimab/imdevimab (Covid-19) –BT # †
Olumiant (Covid-19)-A # †
Orladeyo (HAE)-C
inclisiran (hypercholesterolemia)-C
Trikafta (cystic fibrosis-rare mutations)-NI
Veklury (Covid-19)–BT

## 1st Quarter 2021

bamlanivimab/etesavimab (Covid-19) –BT #†
Cabenuva (HIV)-C†
Entresto (HF)-NI
Lupkynis (lupus nephritis)–BT
ide-cel (multiple myeloma)-BT†
roxadustat (anemia of CKD)-C
Ukoniq (lymphoma)-C

## 2nd Quarter 2021

abrocitinib, Olumiant & Rinvoq (atopic dermatitis)-C
aducanumab (Alzheimer's)-BT†
Farxiga (CKD) –NI
Nurtec ODT (migraine prevention) –NI
Nuplazid (dementia-related psychosis)-NI
relugolix/E2/NE (fibroids)-C
Rolontis (neutropenia)-C

## 3rd Quarter 2021

atogepant (migraine prevention) -C
avacopan (ANCA vasculitis) -BT
bimekizumab (plaque psoriasis)-C
sotorasib (lung cancer)-BT
teplizumab (diabetes type 1, prevention)-BT

## 4th Quarter 2021

Cilta-cel (multiple myeloma)-BT†
*(rolling NDA initiated)*
efgartigimod (myas. gravis)-BT†

4Q20 | 1Q21 | 2Q21 | 3Q21 | 4Q21 →

## 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
# = Emergency Use Authorization

# Generic Pipeline

## High impact


## Medium /Low impact

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