Regular Meeting of the

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

Thursday, December 16, 2021, 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: 879 4364 5193
Passcode: **SCFHP2021**
https://us06web.zoom.us/j/87943645193

AGENDA

1.	**Roll Call / Establish Quorum**	Dr. Lin	6:00	5 min
2.	**Public Comment** 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** Review Santa Clara Family Health Plan (SCFHP) 3Q 2021 P&T Open Session Minutes. **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	5 min
b.	Grievance & Appeals 2Q 2021 and 3Q 2021 Pharmacy Reports	Mr. Oliveira	6:17	3 min
c.	Medi-Cal Rx Update	Dr. Huynh	6:20	2 min
d.	Policy Review – PH.12 Drug Management Program	Dr. Huynh	6:22	2 min
e.	Plan/Global Medi-Cal Drug Use Review	Dr. Otomo	6:24	2 min
i.	Drug Utilization Evaluation Update			
f.	Emergency Supply Report – 3Q 2020, 4Q 2020	Dr. Nguyen	6:26	2 min

Adjourn to Closed Session

Pursuant to Welfare and Institutions Code Section 14087.36 (w)

5.	**Closed Meeting Minutes** Review SCFHP 3Q 2021 P&T Closed Session Minutes. **Possible Action:** Approve SCFHP P&T Closed Session Minutes	Dr. Lin	6:28	2 min
6.	**Metrics & Financial Updates**			
a.	Membership Report	Dr. Nakahira	6:30	1 min
b.	Pharmacy Dashboard	Dr. Otomo	6:31	2 min
c.	Drug Utilization & Spend – 3Q 2021	Dr. McCarty	6:33	5 min

7.	**Discussion and Recommendations for Changes to SCFHP's Cal MediConnect Formulary & Coverage Determination Criteria**	Dr. McCarty	6:38	3 min
	a. Pharmacy Benefit Manager 3Q 2021 P&T Minutes			
	b. Pharmacy Benefit Manager 4Q 2021 P&T Part D Actions **Possible Action:** Approve MedImpact Minutes & Actions			
	c. 2022 Medical Benefit Drug Prior Authorization Grid **Possible Action:** Approve 2022 Medical Benefit Drug Prior Authorization Grid for Cal MediConnect	Dr. Otomo	6:41	2 min
8.	**Discussion and Recommendations for Changes to SCFHP's Medi-Cal Formulary & Prior Authorization Criteria**			
	a. Old Business/Follow-Up			
	i. PCSK9 Inhibitors	Dr. McCarty	6:43	2 min
	ii. Trijardy XR	Dr. Le	6:45	2 min
	b. Formulary Modifications **Possible Action:** Approve Formulary Addition and Modification Recommendations	Dr. Otomo	6:47	2 min
	c. Fee-for-Service Contract Drug List Comparability **Possible Action:** Approve CDL Comparability Formulary Recommendations	Dr. McCarty	6:49	5 min
	d. 2022 Medical Benefit Drug Prior Authorization Grid **Possible Action:** Approve 2022 Medical Benefit Drug Prior Authorization Grid for Medi-Cal	Dr. Otomo	6:54	1 min
	e. Prior Authorization Criteria	Dr. Nguyen	6:55	5 min
	i. **New/Revised Criteria** 1. Stromectol 2. Zeposia			
	ii. **Annual Review** 1. Non-formulary 2. Norditropin Flexpro 3. Protopic ointment 4. Zarxio			
	Possible Action: Approve PA Criteria Recommendations			
9.	**New Drugs and Class Review**	Dr. McCarty	7:00	55 min
	a. COVID-19 Updates			
	b. Inhaled tobramycin			
	c. Dificid			
	d. New and Expanded Indications – Nucala, Fasenra, Xywav			
	e. New Entities, Derivatives & Formulations – Tyrvaya, Myrbetriq granules, Trudhesa			
	f. Informational only:			
	i. Myelofibrosis – pacritinib			
	ii. Presbyopia – presbysol			
	iii. Acute agitation – dexmedetomidine			
	iv. Pulmonary hypertension			
	v. Weight loss agents			
	vi. Continuous glucose monitors			
	vii. Drugs: Pennsaid, Santyl, Kuvan, Upneeq, Cosentyx, omidenepag isopropyl, maribavir, daridorexant, tezepelumab			
	Possible Action: Approve New Drug and Class Recommendations			

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 March 17, 2022			

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, September 16, 2021, 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
Xuan Cung, PharmD
Laurie Nakahira, DO, Chief Medical Officer
Judy Ngo, PharmD
Peter Nguyen, DO
Jesse Parashar-Rokicki, MD

Members Absent
Dang Huynh, PharmD, Director of Pharmacy and UM
Dolly Goel, MD

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

Others Present
Amy McCarty, PharmD, MedImpact

1. Roll Call

Jimmy Lin, MD, Chair, called the meeting to order at 6:04 pm. Roll call was taken and a quorum was established.

2. Public Comment

There were no public comments.

3. Open Meeting Minutes

The 2Q2021 P&T Committee open meeting minutes were reviewed.

It was moved, seconded and the open minutes of the 1Q2021 P&T meeting minutes were **unanimously approved.**

Motion: Dr. Nguyen
Second: Dr. Lin
Ayes: Dr. Lin, Dr. Alkoraishi, Dr. Nakahira, Dr. Cung, Dr. Nguyen, Dr. Parashar-Rokicki
Absent: Dr. Huynh, Dr. Goel, Dr. Ngo

4. Standing Agenda Items

a. Chief Medical Officer Health Plan Updates

Laurie Nakahira, DO, Chief Medical Officer (CMO), presented the CMO Health Plan Updates. Dr. Nakahira reported the current Plan membership is approximately 286,552 members, reflecting a 9.1% increase over the last year, September 2020. This increase is largely attributable to a hold on disenrollment of Medi-Cal members. When the Department of Health Care Services (DHCS) reactivates disenrollment, there will likely be a decrease in membership.

Dr. Nakahira announced the National Committee for Quality Assurance (NCQA) Cal MediConnect (CMC) Resurvey is coming up on January 31, 2022 to February 2, 2022. In addition, CalAIM, Enhanced Care Management (ECM), and In Lieu of Services (ILOS) will begin on January 1, 2022.

Currently, the Plan has placed a hold on returning to office due to concerns about the COVID-19 delta variant. All committee meetings will continue to be held via teleconference.

DHCS has initiated a COVID incentive program to address vaccine disparities. Out of SCFHP's Medi-Cal (MC) membership, approximately 56.9% are fully vaccinated and 5.7% are partially vaccinated. Out of SCFHP's CMC membership, approximately 75.8% are fully vaccinated and 4.5% are partially vaccinated. SCFHP will be participating in this incentive program to aid in closing gaps by offering MC members and providers incentives, partnering with community leaders, and conducting outreach to vulnerable populations. SCFHP will also be hosting COVID vaccine administration events at the Community Resource Center (CRC).

Dr. Nakahira noted that the CRC will be doing an opening kick-off on October 2, 2021.

Judy Ngo joined the meeting at 6:12p.m.

b. Medi-Cal Rx Update

Tami Otomo, PharmD, Clinical Pharmacist, noted the Medi-Cal Rx Carve Out will be implemented on January 1, 2022. Starting on this date, the pharmacy benefit for MC members will be carved back into the state. SCFHP will be identifying members who may require more assistance during this transition and work with pharmacy partners to ease the transition. DHCS will send a 60-day notice to members, and the Plan will send a 30-day notice to members. The Plan is also working on updating member and provider material and will be conducting additional provider communication. Provider training and portal enrollment is available on the Medi-Cal Rx website.

c. Plan/Global Medi-Cal Drug Use Review

i. Drug Utilization Evaluation Update

Dr. Otomo shared the results from SCFHP's quarterly retrospective Drug Use Evaluation (DUE) program. For Q3 2021, the focus was Asthma for both lines of business. This program identified members receiving four or more prescriptions for an asthma medication over a 12-month period and are not on a controller medication. For MC, there were 662 impacted members, and 324 providers were mailed letters on August 18, 2021. For CMC, there were 88 impacted members, and 68 providers were emailed letters on August 18, 2021.

Adjourned to Closed Session at 6:21p.m.
Pursuant to Welfare and Institutions Code Section 14087.36 (w)

5. Closed Meeting Minutes

The 2Q2021 P&T Committee closed meeting minutes were reviewed.

It was moved, seconded and the closed minutes of the 2Q2021 P&T meeting minutes were **unanimously approved**.

Motion: Dr. Nguyen
Second: Dr. Alkoraishi

Ayes: Dr. Lin, Dr. Alkoraishi, Dr. Nakahira, Dr. Cung, Dr. Nguyen, Dr. Parashar-Rokicki, Dr. Ngo
Absent: Dr. Huynh, Dr. Goel

6. Metrics and Financial Updates

a. Membership Report
The Membership Report was presented by Dr. Nakahira during the CMO Update.

b. Pharmacy Dashboard
Dr. Otomo reviewed the Pharmacy Dashboard from June to August 2021.

c. Pharmacy Member Portal Stats – 1H 2021
Dr. Otomo reviewed the Pharmacy Member Portal Stats for the first half of 2021.

d. Drug Utilization & Spend – 2Q 2021
Amy McCarty, PharmD, MedImpact, presented the Drug Utilization and Spend for 2Q2021.

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

a. Pharmacy Benefit Manager 2Q 2021 P&T Minutes
Dr. McCarty referenced the Pharmacy Benefit Manager 2Q 2021 P&T Minutes included in the meeting packet.

b. Pharmacy Benefit Manager 3Q 2021 P&T Part D Actions
Dr. McCarty reviewed the Pharmacy Benefit Manager 3Q 2021 P&T Part D Actions.

It was moved, seconded and the MedImpact Minutes and Actions were **unanimously approved**.

Motion: Dr. Nguyen
Second: Dr. Lin
Ayes: Dr. Lin, Dr. Alkoraishi, Dr. Nakahira, Dr. Cung, Dr. Nguyen, Dr. Parashar-Rokicki, Dr. Ngo
Absent: Dr. Huynh, Dr. Goel

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

a. Old Business/Follow-Up
Dr. Otomo provided a follow up to a question from the last meeting regarding available SGLT2 inhibitors and SGLT2 inhibitor combination products.

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

It was moved, seconded and the Formulary Modification were **unanimously approved**.

Motion: Dr. Nguyen
Second: Dr. Alkoraishi
Ayes: Dr. Lin, Dr. Alkoraishi, Dr. Nakahira, Dr. Cung, Dr. Nguyen, Dr. Parashar-Rokicki, Dr. Ngo
Absent: Dr. Huynh, Dr. Goel

c. Fee-for-Service Contract Drug List Comparability
Dr. McCarty reviewed the Fee-for-Service (FFS) Contract Drug List (CDL) Comparability for MC.

It was moved, seconded and the FFS Contract Drug List Comparability was **unanimously approved**.

Motion: Dr. Nguyen
Second: Dr. Alkoraishi
Ayes: Dr. Lin, Dr. Alkoraishi, Dr. Nakahira, Dr. Cung, Dr. Nguyen, Dr. Parashar-Rokicki, Dr. Ngo

Absent: Dr. Huynh, Dr. Goel

d. Prior Authorization Criteria
Dr. Nguyen reviewed the PA Criteria.

ii. <u>New or Revised Criteria</u>

1. Vfend – *new criteria*

iii. <u>Annual Review</u>

1. Compounded Medications – *no changes*
2. Duragesic – *no changes*
3. Emend – *no changes*
4. Enablex – *no changes*
5. Enbrel – *no changes*
6. Insulin Pens – *no changes*
7. Myrbetrig – *no changes*
8. Nicotrol – *no changes*
9. Off-label – *no changes*
10. Opioid Safety Edits – *no changes*
11. Penlac – *no changes*
12. Quantity Limit – *no changes*
13. Retacrit – *no changes*
14. Taltz – *no changes*
15. Trintellix – *no changes*
16. Xelpros – *no changes*
17. Zyvox – *no changes*

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

Motion: Dr. Nguyen
Second: Dr. Cung
Ayes: Dr. Lin, Dr. Alkoraishi, Dr. Nakahira, Dr. Cung, Dr. Nguyen, Dr. Parashar-Rokicki, Dr. Ngo
Absent: Dr. Huynh, Dr. Goel

9. New Drugs and Class Reviews

a. Pneumococcal vaccines
Dr. McCarty reviewed the current (Pneumovax 23 and Prevnar 13) and new (Prevnar 20 and Vaxneuvance) pneumococcal vaccines.

b. Heart Failure Update – Jardiance & Entresto
Dr. McCarty reviewed HFpEF for Entresto and Jardiance.

c. Granulocyte Colony-Stimulating Factors (GCSF)
Dr. McCarty reviewed all of the currently available long- and short-acting GCSFs, including biosimilars.

d. Xyrem & Xywav
Dr. McCarty reviewed Xyrem and Xywav.

e. Dupixent
Dr. McCarty reviewed Dupixent.

f. New Entities & Combinations – Brexafemme, Accrufer, Azstarys
Dr. McCarty presented information on Brexafemme, Accrufer, and Azstarys.

g. New Indications – Zeposia
Dr. McCarty presented Zeposia (first sphingosine-1 phosphate receptor modulator).

h. COVID-19 Treatment – Sotrovimab
Dr. McCarty presented sotrovimad.

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

Motion: Dr. Nguyen
Second: Dr. Cung
Ayes: Dr. Lin, Dr. Alkoraishi, Dr. Nakahira, Dr. Cung, Dr. Nguyen, Dr. Parashar-Rokicki, Dr. Ngo
Absent: Dr. Huynh, Dr. Goel

Reconvene in Open Session at 7:51 p.m.

10. Discussion Items

a. New and Generic Pipeline
Dr. McCarty reviewed the New and Generic Pipeline. There were no notable new or generic drugs.

11. Adjournment
The meeting adjourned at 7:54p.m. The next P&T Committee meeting will be on Thursday, December 16, 2021.

_____ _____
Jimmy Lin, MD, Chair Date

Santa Clara Family Health Plan™

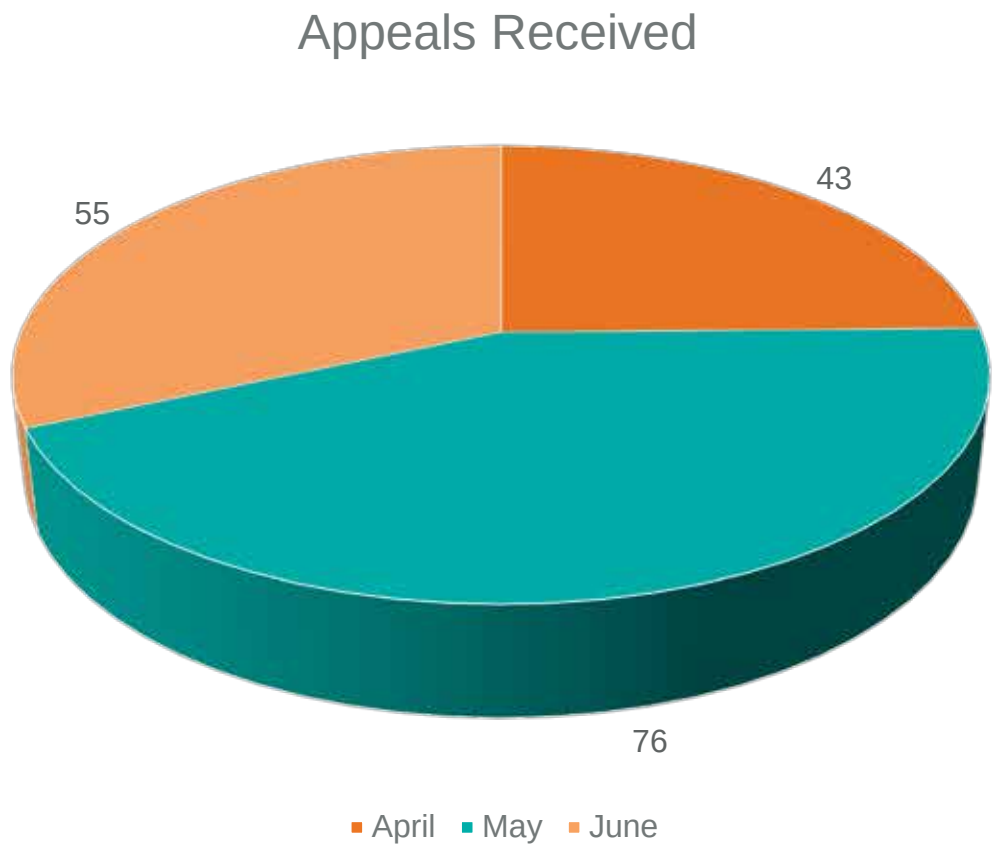
Pharmacy & Therapeutics Committee

STANDING AGENDA ITEMS

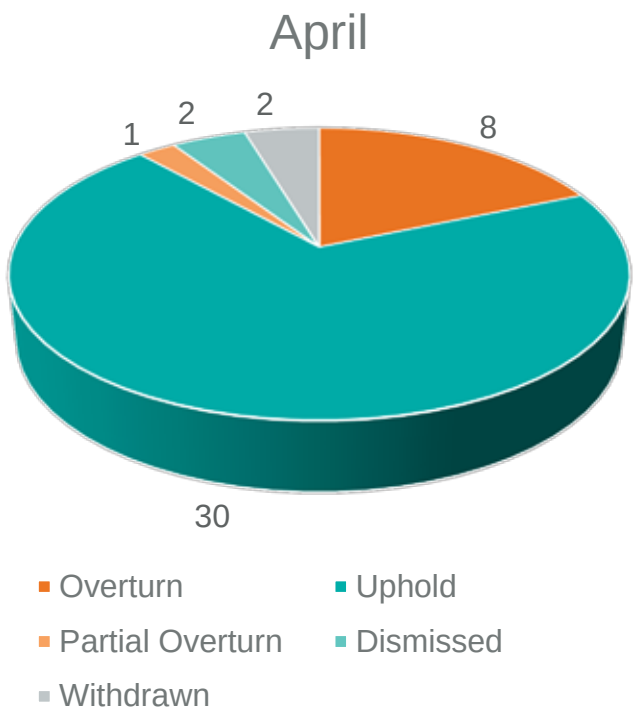
Santa Clara Family Health Plan™

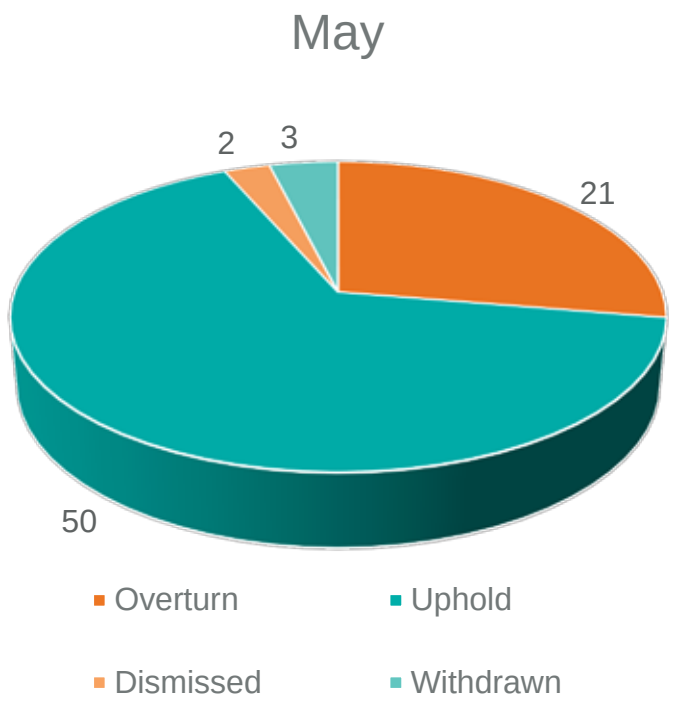
Grievance & Appeals Department
Q2 2021 Reporting

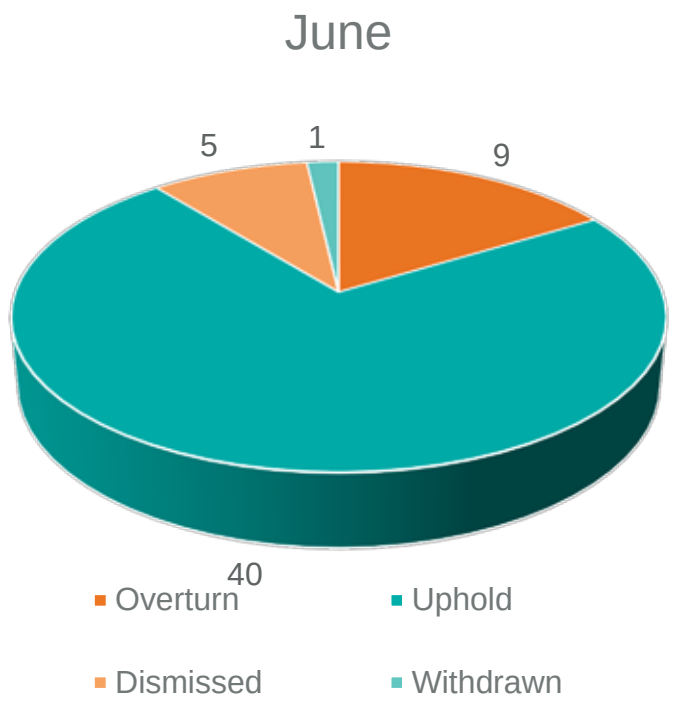
Q2 2021 Medi-Cal Appeals Volume



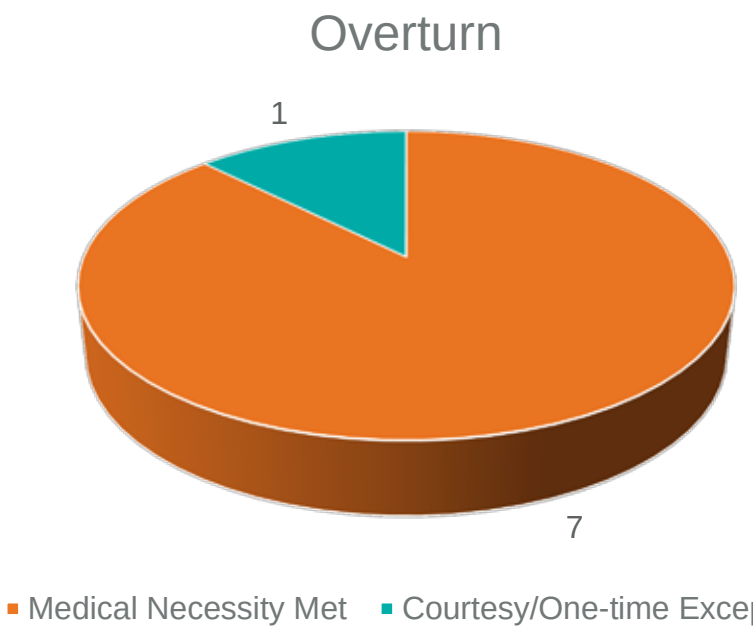
Q2 2021 MC Appeals by Decision

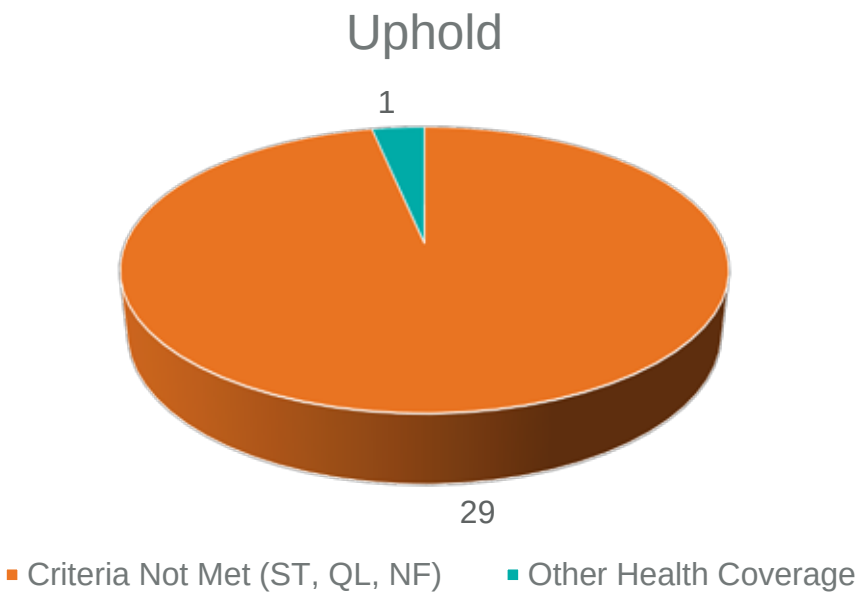




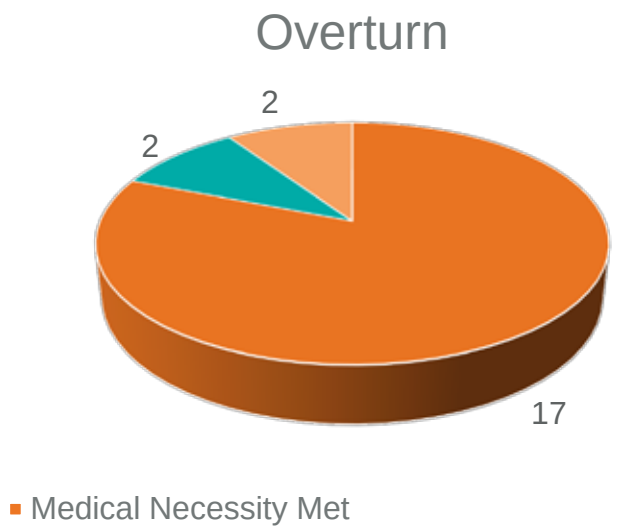


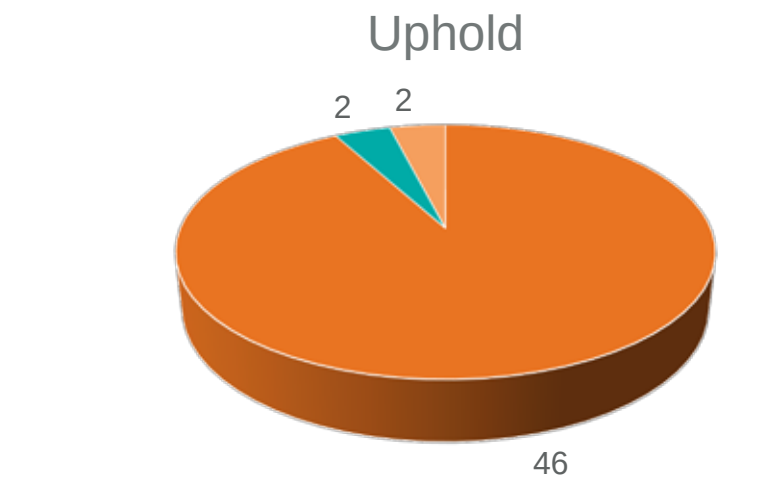
April 2021 MC Appeals by Rationale



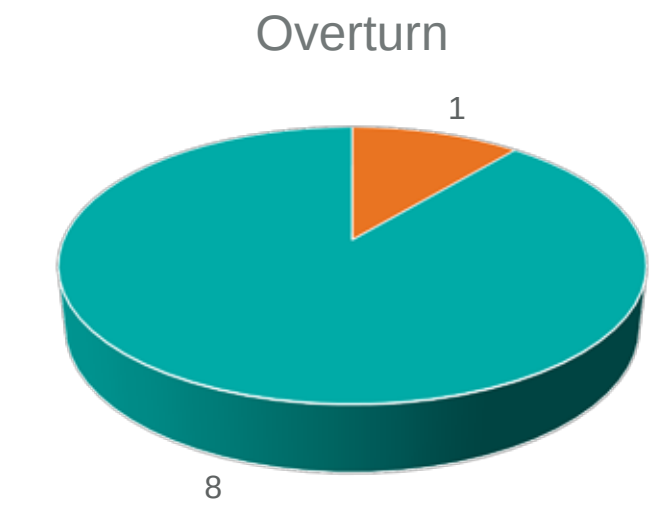


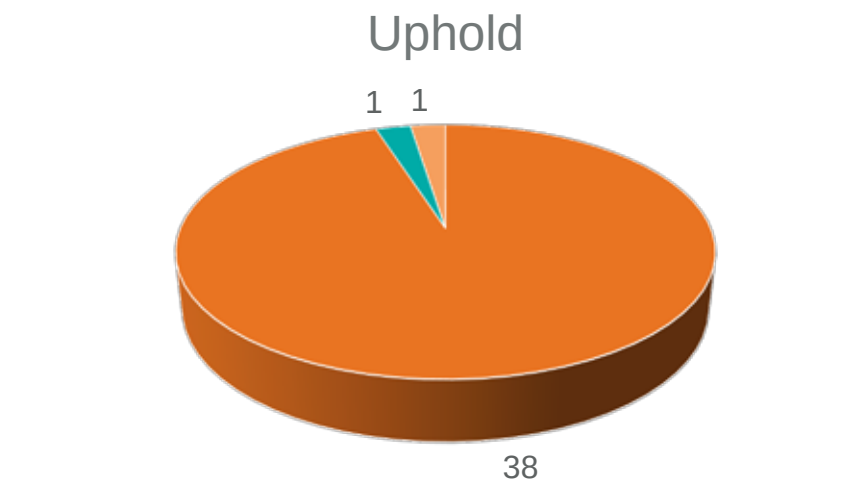
May 2021 MC Appeals by Rationale





June 2021 MC Appeals by Rationale





MC Top 3 Most Appealed Drugs

1

Vascepa – 10 cases

1 withdrawn

8 upheld

1 overturn

2

Trintellix – 4 cases

1 dismissed

3 overturn

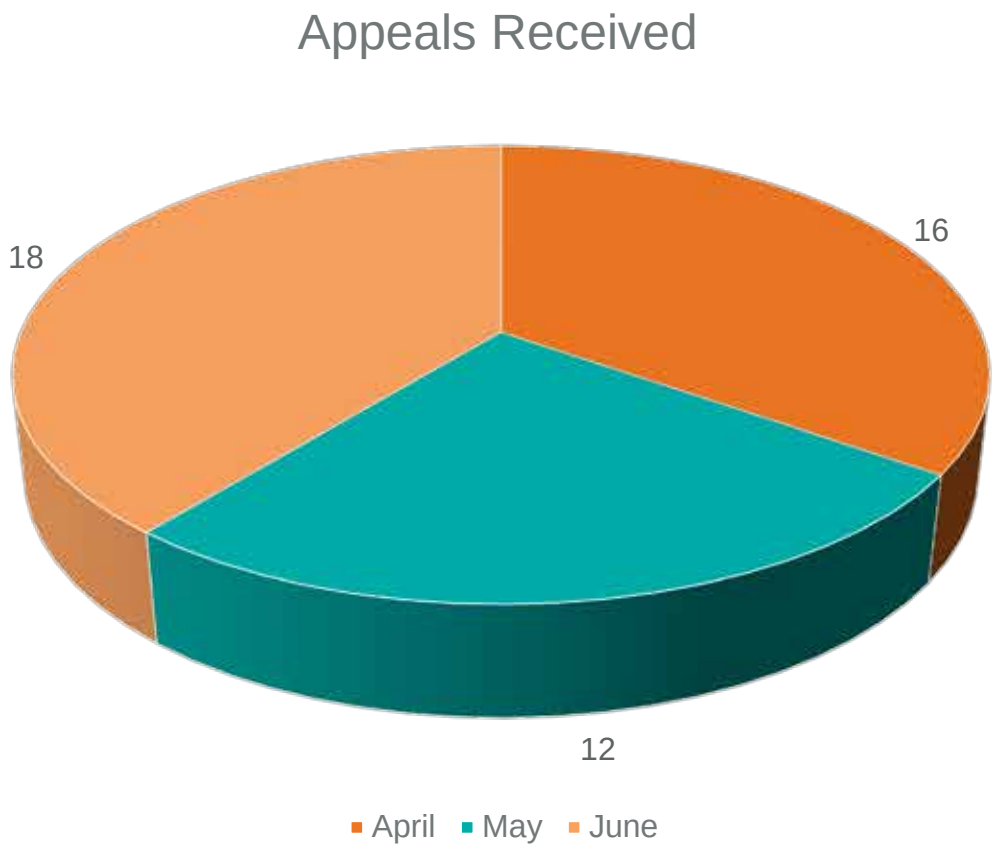
3

Azelastine – 4 cases

1 overturn

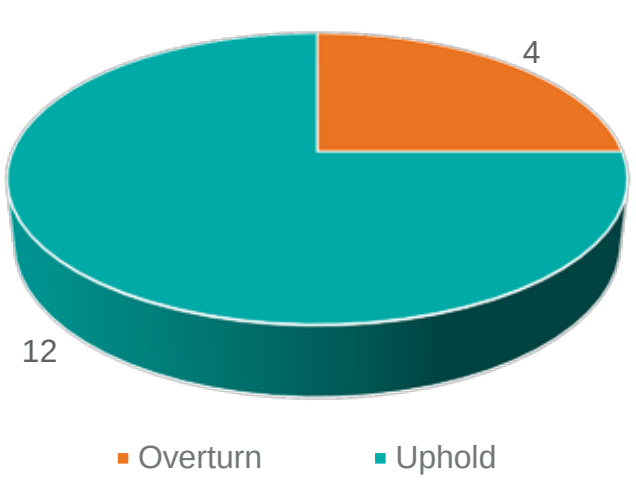
3 upheld

Q2 2021 Cal MediConnect Appeals Volume

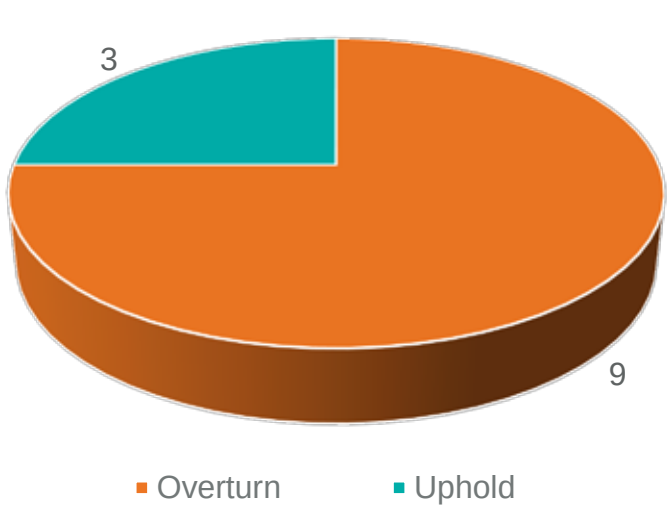


Q2 2021 CMC Appeals by Decision

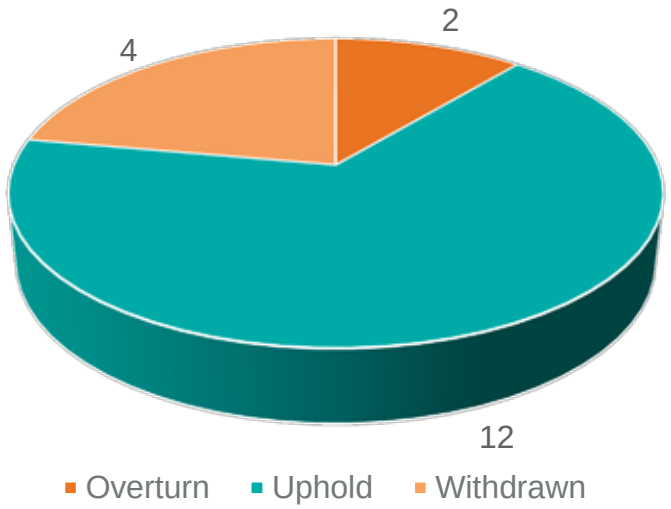
April



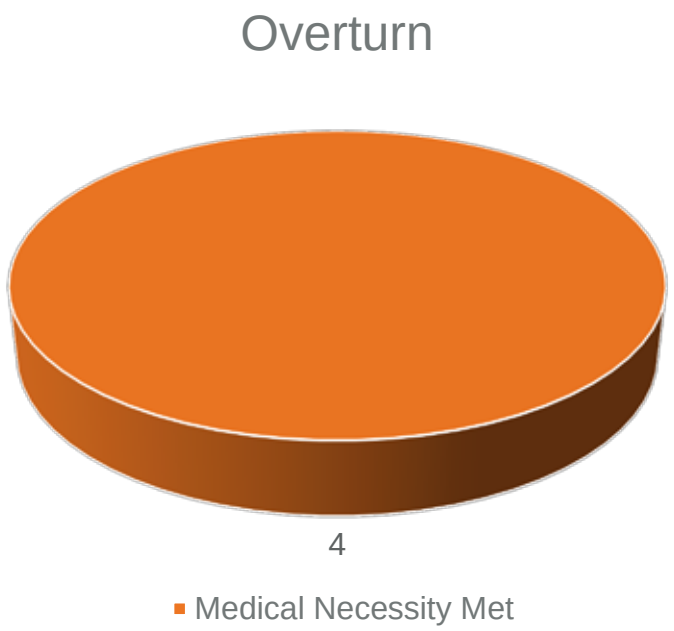
May

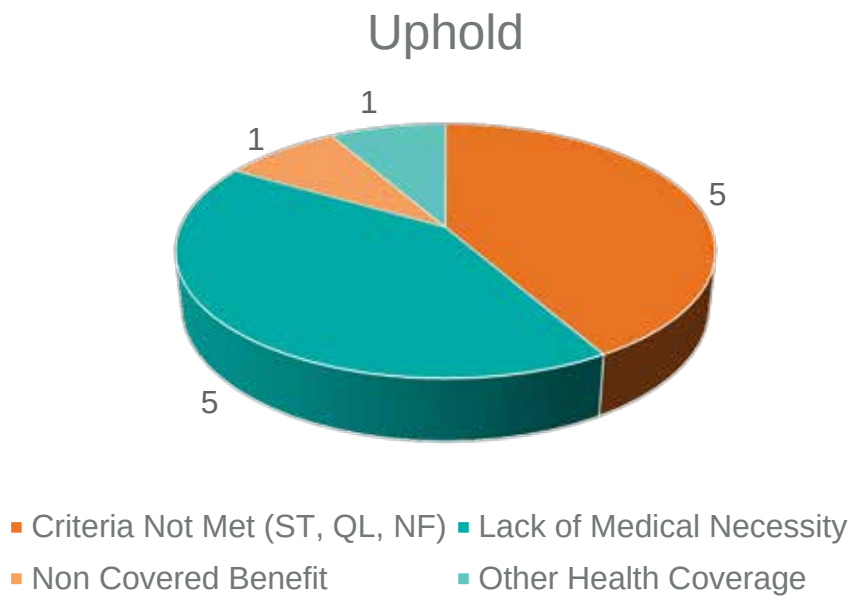


June



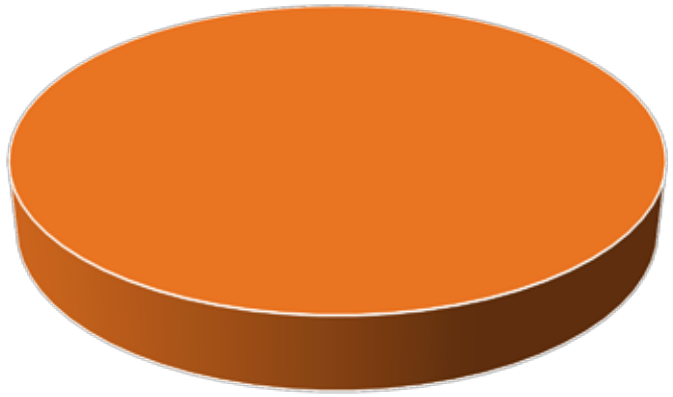
April 2021 CMC Appeals by Rationale





May 2021 CMC Appeals by Rationale

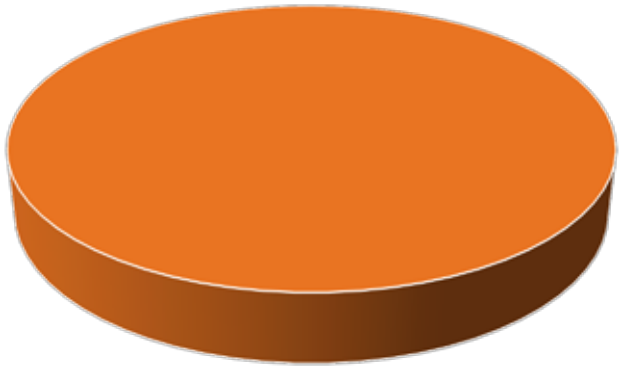
Overturn



9

Medical Necessity Met

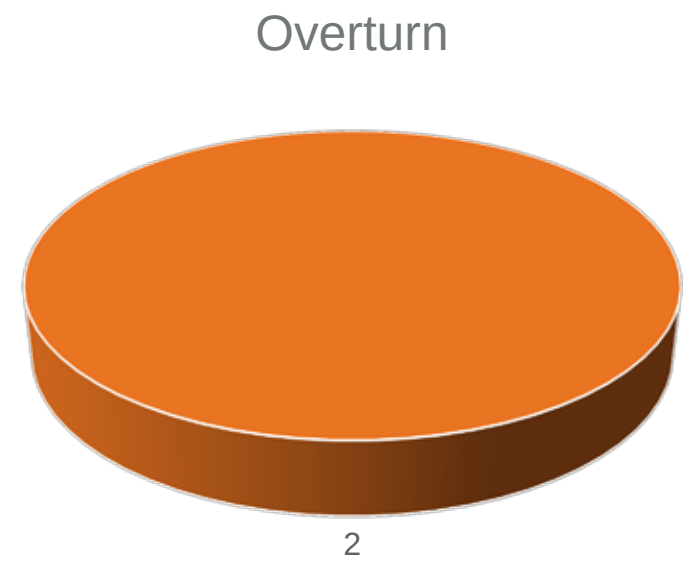
Uphold

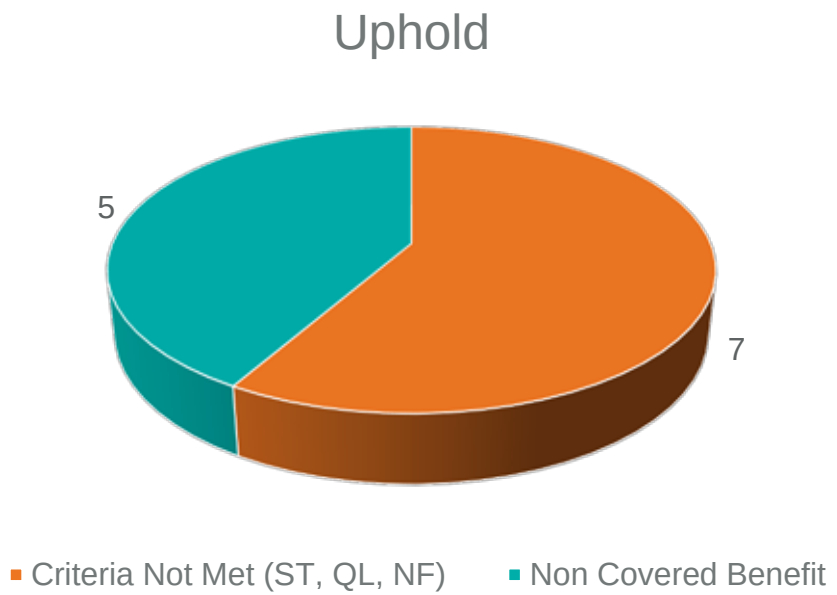


3

Criteria Not Met (ST, QL, NF)

June 2021 CMC Appeals by Rationale





CMC Top 3 Most Appealed Drugs

1

Lidocaine – 8 cases

1 withdrawn

7 upheld

2

Freestyle Libre – 4 cases

2 withdrawn

2 upheld

3

Cyclobenzaprine – 3 cases

1 withdrawn

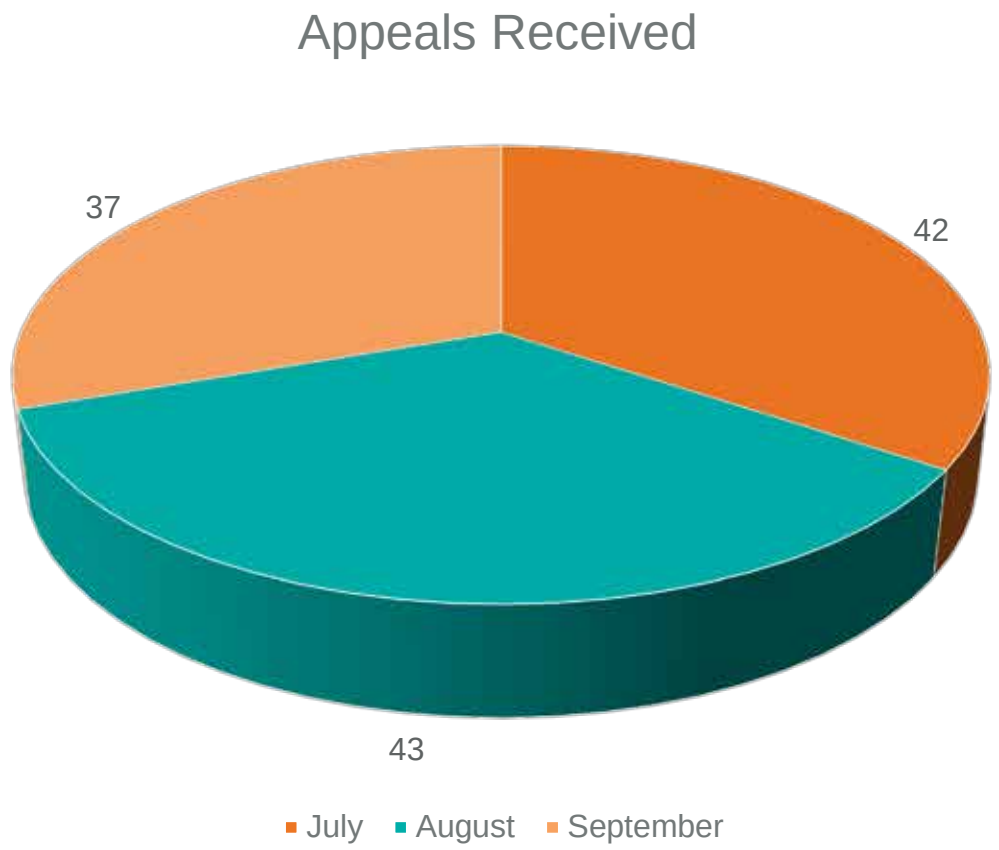
1 overturn

1 uphold

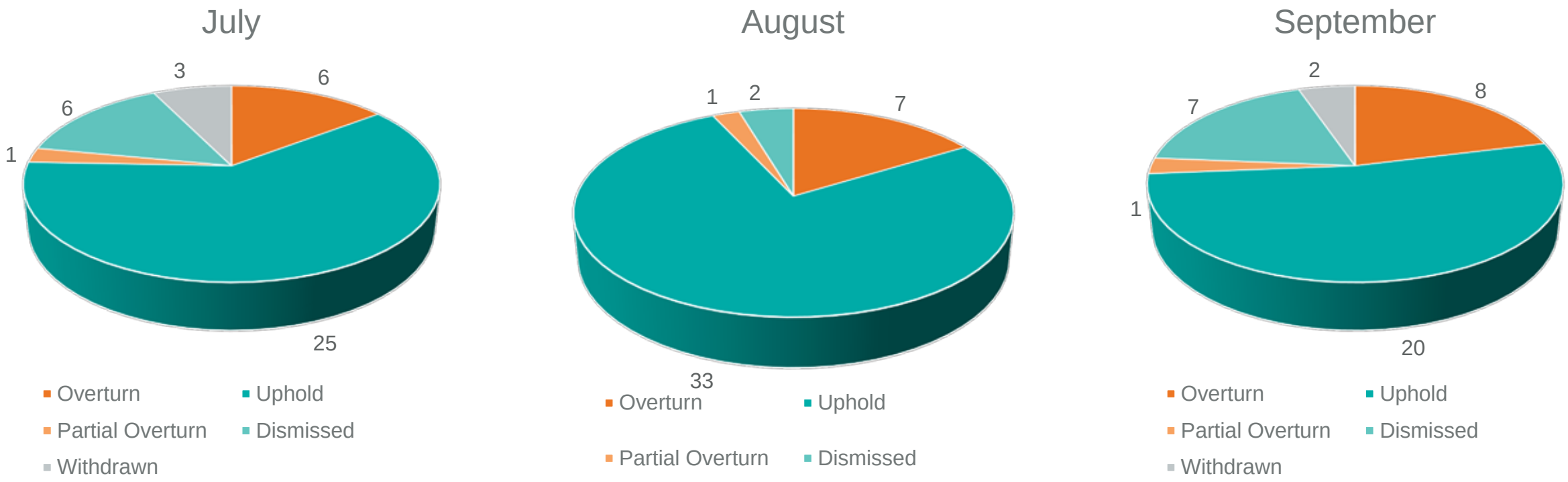
Santa Clara Family Health Plan™

Grievance & Appeals Department
Q3 2021 Reporting

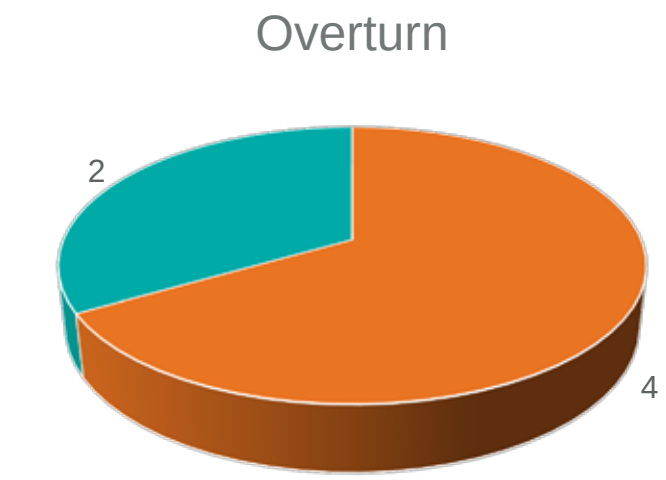
Q3 2021 Medi-Cal Appeals Volume

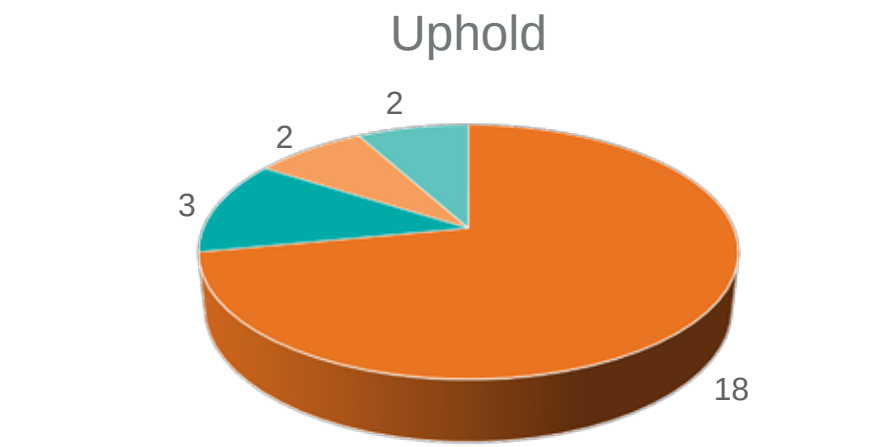


Q3 2021 MC Appeals by Decision

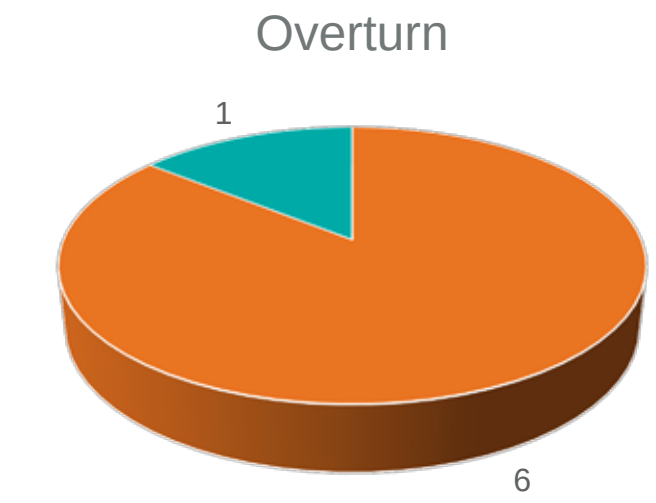


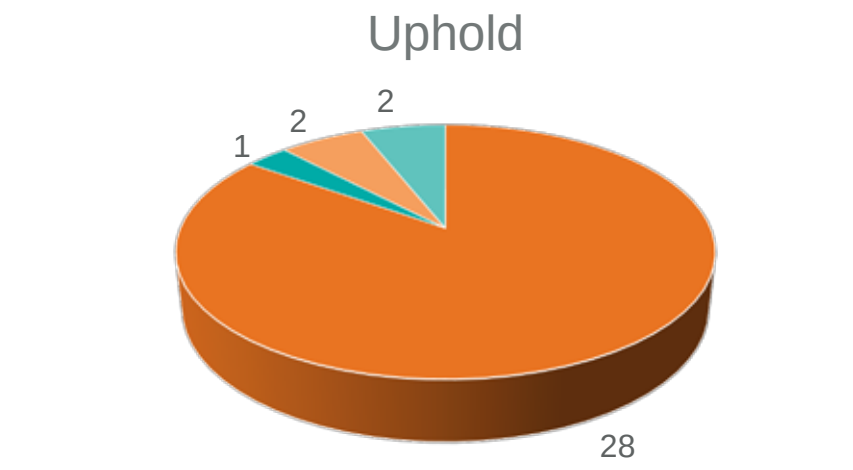
July 2021 MC Appeals by Rationale



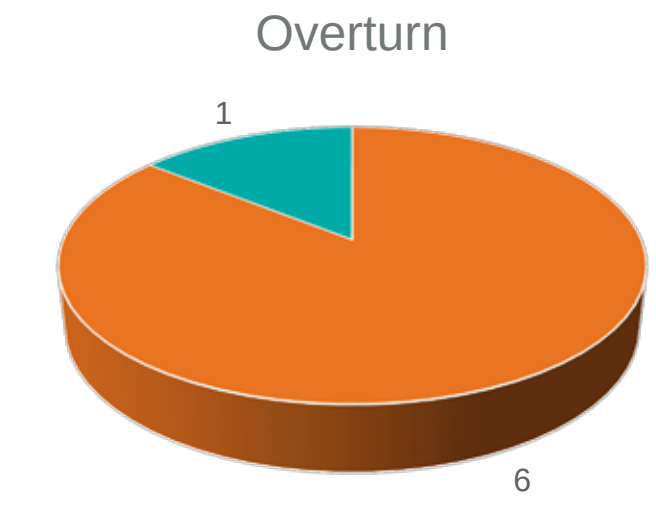


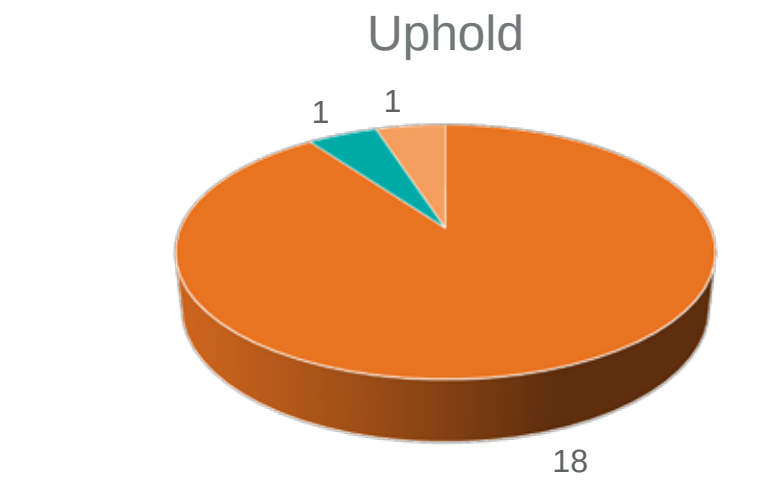
August 2021 MC Appeals by Rationale





September 2021 MC Appeals by Rationale

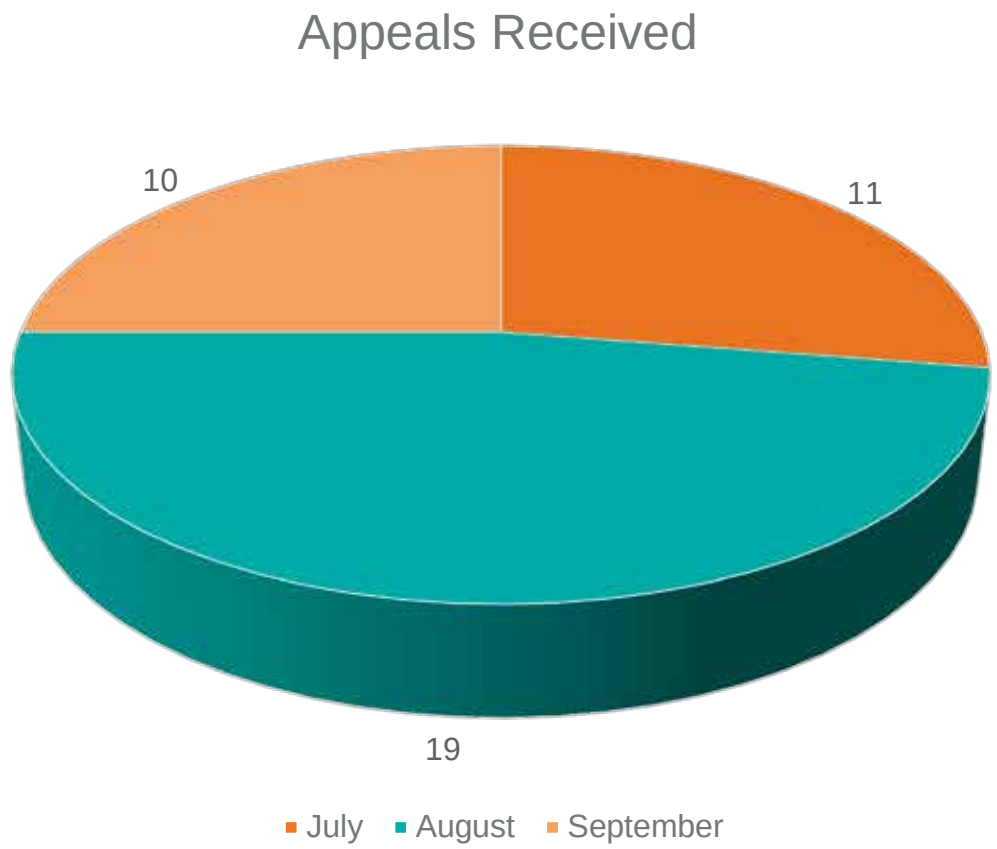




MC Top 3 Most Appealed Drugs

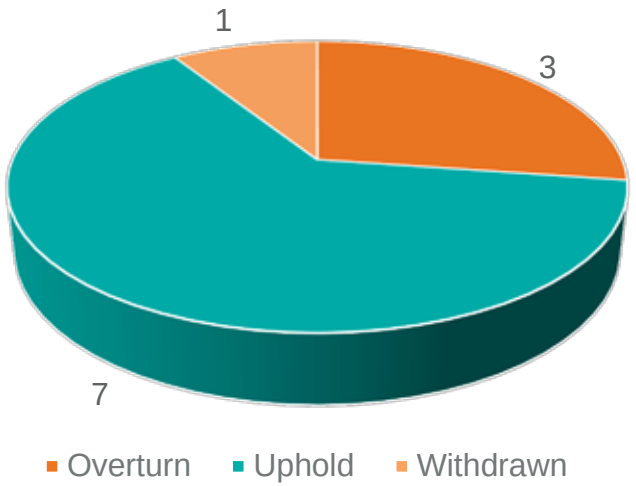
1	2	3
Restasis – 7 cases	Lidocaine – 4 cases	Tretinoin – 4 cases
7 upheld	1 dismissed 3 upheld	1 overturn 3 upheld

Q3 2021 Cal MediConnect Appeals Volume

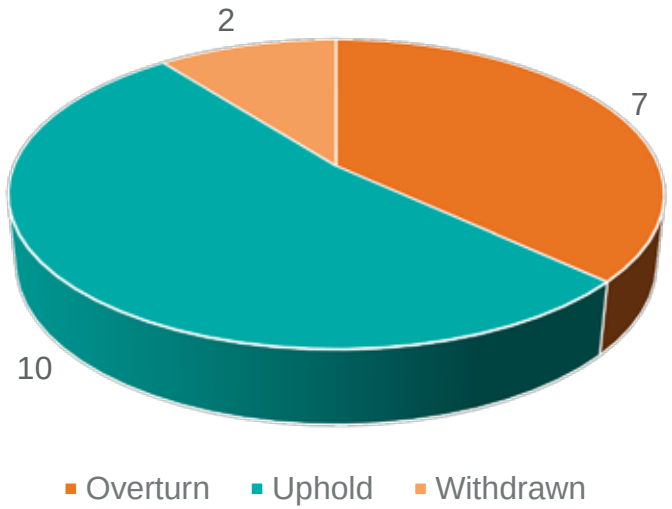


Q3 2021 CMC Appeals by Decision

July



August



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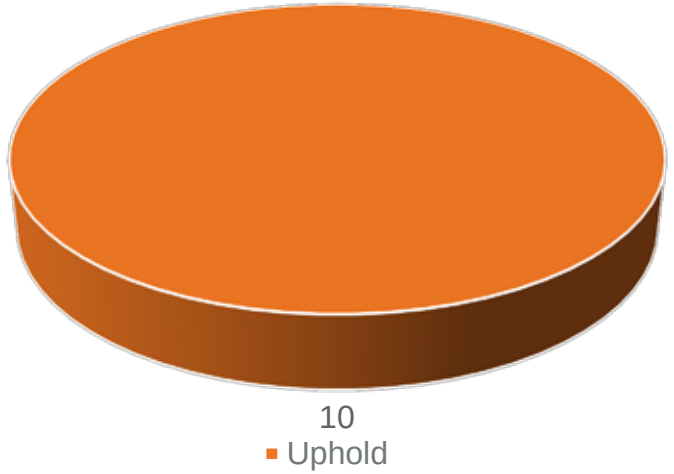

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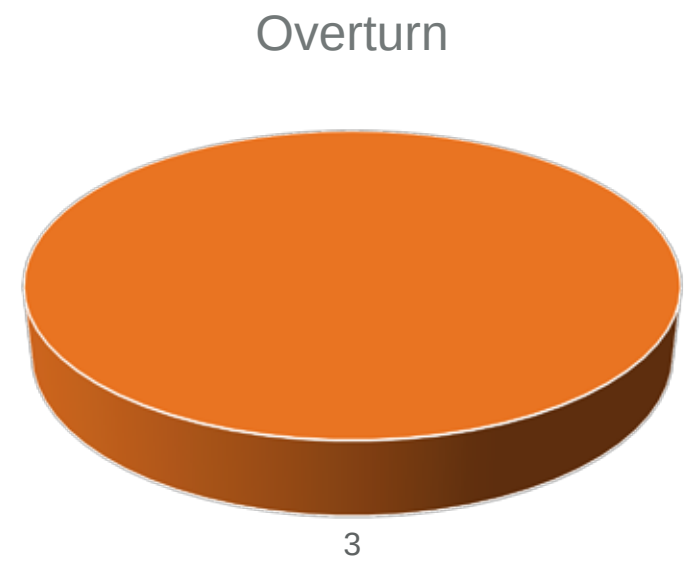
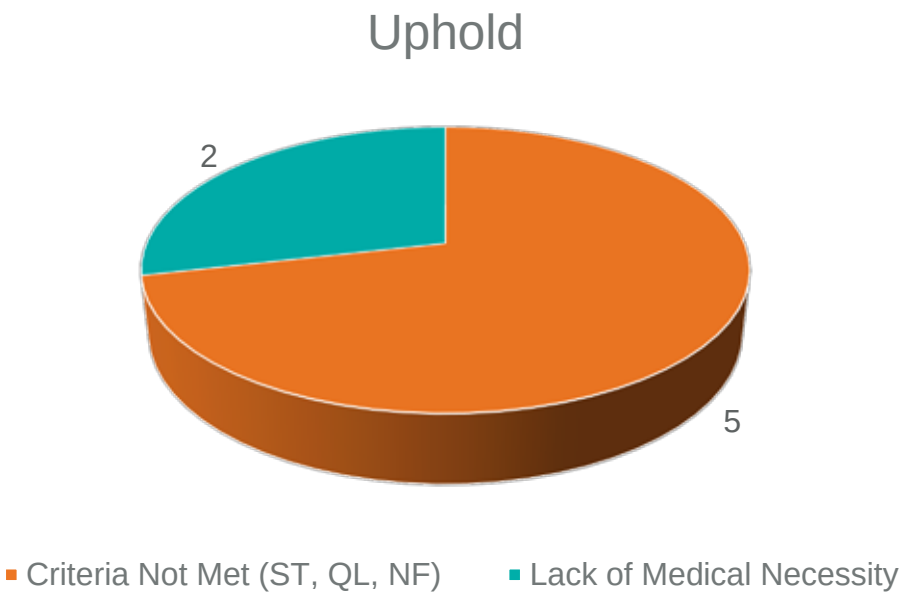
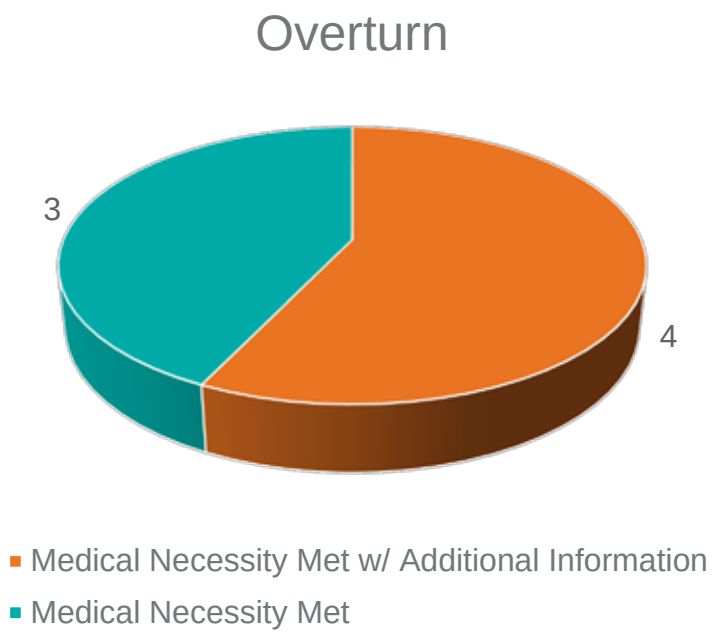
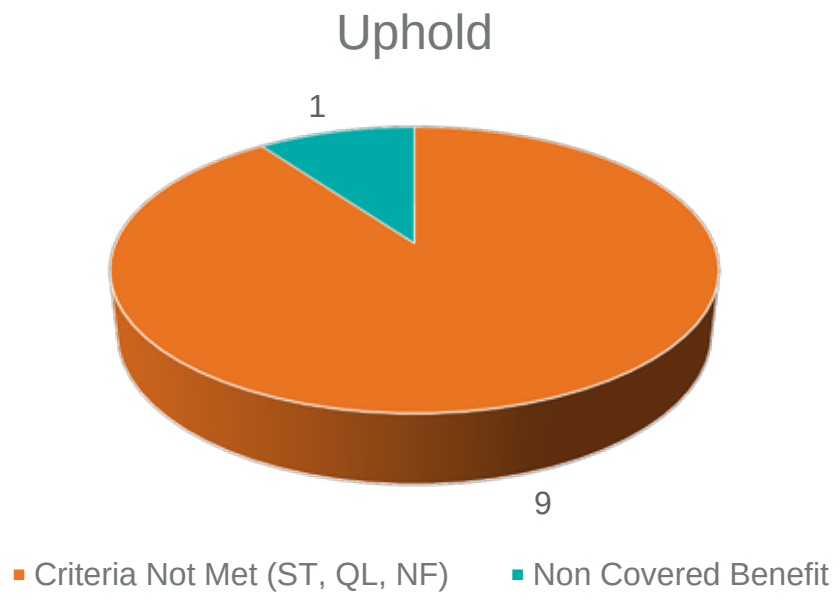


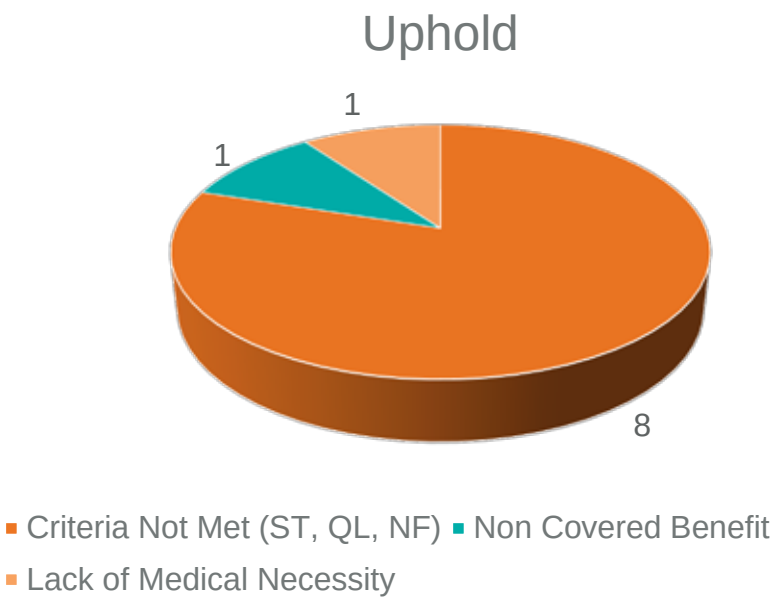


August 2021 CMC Appeals by Rationale





September 2021 CMC Appeals by Rationale



CMC Top 3 Most Appealed Drugs

1

Lidocaine – 11 cases

1 withdrawn

10 upheld

2

Colchicine – 3 cases

3 upheld

3

Nuplazid – 2 cases

1 withdrawn

1 overturn

Santa Clara Family Health Plan™

Grievance & Appeals Department

State of California—Health and Human Services Agency
Department of Health Care Services

MICHELLE BAASS
DIRECTOR

GAVIN NEWSOM
GOVERNOR

DATE: December 6, 2021

ALL PLAN LETTER 21-018
SUPERSEDES ALL PLAN LETTER 20-020

TO: ALL MEDI-CAL MANAGED CARE HEALTH PLANS

SUBJECT: GOVERNOR'S EXECUTIVE ORDER N-01-19, REGARDING TRANSITIONING MEDI-CAL PHARMACY BENEFITS FROM MANAGED CARE TO MEDI-CAL RX

PURPOSE:
The purpose of this All Plan Letter (APL) is to provide Medi-Cal managed care health plans (MCPs) with guidance on changes to the oversight and administration of the Medi-Cal pharmacy benefit. Governor Gavin Newsom's Executive Order (EO) N-01-19, requires the Department of Health Care Services (DHCS) to transition Medi-Cal pharmacy services from the managed care delivery system to the Fee-For-Service (FFS) delivery system known as Medi-Cal Rx, effective January 1, 2022.[1]

This APL is divided into DHCS' requirements for MCPs regarding pre- and post-Medi-Cal Rx transition requirements for oversight and administration of the Medi-Cal pharmacy benefit and related activities. To the extent any existing APLs have inconsistent provisions specific to the Medi-Cal pharmacy benefit, this APL supersedes all inconsistencies in prior APLs, and DHCS has included a table of affected APLs in this guidance.

BACKGROUND:
One of the primary goals of the Governor's EO is to achieve cost-savings for drug purchases made by the state. As a result, a major component of EO N-01-19 requires DHCS to transition Medi-Cal pharmacy services from the managed care delivery system to the FFS delivery system by January 2022. Transitioning pharmacy services from the managed care delivery system to the FFS delivery system will, among other things:

- Standardize the Medi-Cal pharmacy benefit statewide, under one delivery system.
- Improve access to pharmacy services with a pharmacy network that includes approximately 94 percent of the state's licensed outpatient pharmacies.
- Apply statewide utilization management protocols to all covered outpatient drugs.

[1] EO N-01-19 can be found at: https://www.gov.ca.gov/wp-content/uploads/2019/01/EO-N-01-19-Attested-01.07.19.pdf

- Strengthen California's ability to negotiate state supplemental drug rebates with drug manufacturers, thereby creating additional cost-savings for the state.

DHCS has contracted with Magellan Medicaid Administration, Inc. (Magellan) to provide administrative services and supports relative to the Medi-Cal pharmacy benefit as of January 1, 2022, which is collectively known as "Medi-Cal Rx". Magellan will provide administrative services, as directed by DHCS, which include claims management, prior authorization (PA) and utilization management, pharmacy drug rebate administration, provider and member support services, program integrity (PI) activities, and other ancillary and reporting services to support the administration of Medi-Cal Rx.

Change Overview

Most MCPs, including AIDS Healthcare Foundation (AHF) will be impacted by the Medi-Cal Rx transition. However, Medi-Cal Rx will not apply to:

- Programs of All-Inclusive Care for the Elderly plans
- Senior Care Action Network
- Cal MediConnect Medicare-Medicaid Plans (MMP) (MMPs retain existing responsibilities)
- Major Risk Medical Insurance Program

As of January 1, 2022, Medi-Cal Rx will be responsible for the following pharmacy benefits when billed by a pharmacy on a pharmacy claim:

- Covered Outpatient Drugs, including Physician Administered Drugs (PADs)
- Specific Medical Supplies
- Enteral Nutritional Products

For more granular information about pharmacy benefits under each of the categories identified above, please refer to the Medi-Cal Rx Scope Summary section of this APL.

DHCS recognizes the unique pharmacy needs of California Children's Services (CCS) members in Whole Child Model (WCM) programs. This APL does not alter the MCP's obligation to fully comply with the requirements of APL 21-005 or any superseding APL.[2] Current pharmacy policy embodied in CCS Numbered Letters will be integrated into Medi-Cal Rx policy by January 1, 2022 to ensure continuity of services to support

[2] All APLs and Policy Letters (PL) can be found on the DHCS webpage at: https://www.dhcs.ca.gov/formsandpubs/Pages/MgdCarePlanPolicyLtrs.aspx

WCM programs.[3]

DHCS recognizes that members may have emergency outpatient pharmacy service needs when traveling, and may not have access to a pharmacy enrolled in Medi-Cal. Medi-Cal Rx will provide a process to ensure timely and appropriate provision of emergency outpatient pharmacy services including payment to pharmacies that are not enrolled Medi-Cal pharmacy providers. MCPs are not responsible for the provision of, or payment for, such outpatient emergency pharmacy services.

With the transition to Medi-Cal Rx, all mental health medications including those currently carved-out (e.g., antipsychotics, lithium, monoamine oxidase inhibitors, and anticholinergics) and those currently covered by MCPs but carved-out under Medi-Cal Rx (e.g., antidepressants, psychostimulants, benzodiazepines) will be covered under one uniform Medi-Cal Rx policy regardless of where the member is receiving mental health services. Care coordination processes, roles, and responsibilities between specialty mental health services provided by County Mental Health Plans and non-specialty mental health services covered by MCPs will not be impacted by the transition.

Counties will also have access to pharmacy service information related to MCP members through the Medi-Cal Rx secure portal, which will enhance their support of care coordination as well as their support for grievances and appeals that may crossover delivery systems.

Please note that Medi-Cal Rx will not change the following:

- The scope of existing Medi-Cal pharmacy coverage for prescribed drugs, products, and services.
- The provision of pharmacy services that are billed on medical or institutional claims and/or as part of a bundled/all-inclusive billing structure in an inpatient or long-term care (LTC) setting, including Skilled Nursing Facilities (SNFs) and other Intermediate Care Facilities (ICFs), regardless of delivery system.
- Existing Medi-Cal managed care pharmacy carve-outs (e.g., blood factor, HIV/AIDS drugs, antipsychotics, or drugs used to treat a substance use disorder). For most MCPs, these are currently carved-out, with a few limited exceptions, and as of January 1, 2022, these drugs will be carved-out of all MCPs.
- Any pharmacy services that are billed as a medical and/or institutional claim instead of a pharmacy claim.

[3] CCS Numbered Letters can be found at:
https://www.dhcs.ca.gov/services/ccs/Pages/CCSNL.aspx

- DHCS' process for adding drugs to the Medi-Cal Contract Drug List (CDL) for which Medi-Cal Rx will be responsible for when billed by a pharmacy on a pharmacy claim, including drugs that may not be physician administered.[4]
- Reporting of fraud, waste, and abuse to DHCS.

Medi-Cal Rx Scope Summary

The following summary charts provide additional context and information related to DHCS' implementation scope for Medi-Cal Rx, effective January 1, 2022:

- **CHART #1, A pre- and post-transition view by delivery system -** providing a snapshot of what is changing and what is not in relation to pharmacy services in Medi-Cal's two delivery systems, managed care and FFS, in the current state (pre-transition) and future state (post-transition).

- **CHART #2: A post-transition view by pharmacy benefit categories -** providing a non-exhaustive inventory of the Medi-Cal pharmacy benefit, characterized as either not subject to (i.e., those pharmacy benefits that are billed on medical and institutional claims) versus those subject to the carve-out from managed care to FFS (i.e., all pharmacy benefits that are billed on pharmacy claims). MCPs should use this chart to better understand the overarching scope of Medi-Cal Rx.

- **CHART #3: A post-transition policy elaboration by targeted benefit categories** – providing additional benefit details where additional clarification is required.

CHART #1: A pre- and post-transition view by delivery system

	Current State (Pre-Transition)	Future State (Post-Transition)
Managed Care Delivery System		
• Pharmacy benefits that are billed on medical and institutional claims.	• MCPs are responsible for providing these benefits, and this is built into the capitated payment.	No change.

[4] The current process for adding drugs to the CDL may be viewed at: https://www.dhcs.ca.gov/provgovpart/pharmacy/Documents/DrugPolProc.pdf

	Current State (Pre-Transition)	Future State (Post-Transition)
• Pharmacy benefits that are billed on pharmacy claims.	• MCPs are responsible for providing these benefits, and this is built into the capitated payment.	• MCPs will no longer be responsible for those items identified in Chart #2 as being subject to the FFS carve-out; these benefits will be removed from the capitated payment. • All of these claims will process through Medi-Cal Rx, and be adjudicated by Magellan.
• Drugs currently "carved-out" of managed care delivery system (i.e., HIV/AIDS, Blood Factors, Anti-Psychotics, drugs used to treat substance use disorders).	• Most MCPs[5] are not currently responsible for covering these drugs and these costs are not built into the capitated payment. These drugs are reimbursed via the FFS delivery system only.	• No MCPs will be responsible for covering these drugs and the costs will not be built into the capitated payment.[6] • If billed on medical and institutional claims, these drugs will process and be adjudicated through California Medicaid Management Information System (CA-MMIS), a Medi-Cal FFS Fiscal Intermediary (FI). • If billed on pharmacy claims, these drugs will process through Medi-Cal Rx, and be adjudicated by Magellan.

[5] With the exception of AHF, Health Plan of San Mateo (HPSM) and CalOptima, which currently cover HIV/AIDS drugs, as well as AHF, HPSM, and a few counties under Partnership Health Plan, which cover psychotherapeutic drugs.
[6] This will be true as of January 1, 2022.

	Current State (Pre-Transition)	Future State (Post-Transition)
FFS Delivery System		
• Pharmacy benefits that are billed on medical and institutional claims.	• Are processed and adjudicated through CA-MMIS.	• No change.
• Pharmacy benefits that are billed on pharmacy claims.	• Are processed and adjudicated through CA-MMIS.	• All of these claims will process through Medi-Cal Rx and be adjudicated by Magellan.
• Drugs currently "carved-out" of managed care delivery system (i.e., HIV/AIDS, Blood Factors, Anti-Psychotics, drugs used to treat substance use disorders).	• Are processed and adjudicated through CA-MMIS.	• If billed on medical and institutional claims, then there will be no change. • If billed on pharmacy claims, then these claims will process through Medi-Cal Rx, and be adjudicated by Magellan.

CHART #2: A post-transition view by pharmacy benefit categories

Pharmacy Benefit Category	Sub-Category	Subject to Carve-out? Yes, No, Partially[7]	Medical Claim Not "Carved Out"	Pharmacy Claim "Carved Out" to Medi-Cal Rx	Billable on Both Claim Types? Yes or No
Outpatient Prescription Drugs[8]	General	Yes		✓	No
	Contraceptives	Partially	✓	✓	Yes

[7] Partial carve-out represents those products that can be billed by both a pharmacy claim and a medical claim, but are only carved-out when billed as a pharmacy claim.
[8] This includes prescription drugs, biological products, insulin, etc.

Pharmacy Benefit Category	**Sub-Category**	**Subject to Carve-out?** Yes, No, Partially[7]	**Medical Claim** Not "Carved Out"	**Pharmacy Claim** "Carved Out" to Medi-Cal Rx	**Billable on Both Claim Types?** Yes or No
PADs - including some oral medications	General	Partially	✓	✓	Yes
Vaccines	General	Partially	✓	✓	Yes
Over the Counter (OTC)[9, 10]	General	Yes		✓	No
Incontinence Supplies	General	No	✓		No
Medical Supplies[11, 12]	Syringes and Needles (non-insulin)	Partially	✓	✓	Yes
	Insulin Syringes, any size	Yes		✓	No
	Insulin Syringes, U-500	Yes		✓	No
	Pen Needles	Yes		✓	No
	Lancets	Yes		✓	No

[9] As allowed by law, and only when prescribed via a script from the physician.
[10] In order to be billable to DHCS as a covered Medi-Cal benefit, all OTC drugs must have a prescription, consistent with Social Security Act Section 1927 (Title 42 United States Code Section 1396r-8. US Code is searchable at: https://uscode.house.gov/)
[11] Medical supplies do not include benefits considered to be durable medical equipment (DME) as defined under applicable federal Medicaid statutes, regulations, and/or policies.
[12] With the exception of medical supplies subject to "partial" or "full" carve-out, as well as glucometers and related testing supplies, as identified on this chart – pursuant to footnote #10, DME, DME supplies, and disposable medical supplies will remain the responsibility of the MCPs in the managed care delivery system; or, in the FFS delivery system, billed to Medi-Cal's existing FFS FI on medical or institutional claims, as they are currently.

Pharmacy Benefit Category	**Sub-Category**	**Subject to Carve-out?** Yes, No, Partially[7]	**Medical Claim** Not "Carved Out"	**Pharmacy Claim** "Carved Out" to Medi-Cal Rx	**Billable on Both Claim Types?** Yes or No
	Diabetic Test Strips	Yes		✓	No
	Urine test or reagent strips	Yes		✓	No
	Cervical Cap; contraceptive use	Yes		✓	No
	Condoms, internal (female) and external (male); contraceptive use	Yes		✓	No
	Diaphragm, contoured or wide seal; contraceptive use	Yes		✓	No
	Disposable Insulin Delivery Devices	Yes		✓	No
	Therapeutic Continuous Glucose Monitoring (CGM) Systems	Yes		✓	No
	Self-Monitoring Blood Glucose Systems (Glucometers), Control Solutions, and Lancing Devices	Partially	✓	✓	Yes
	Heparin flush, 10 units/ml and 100 units per ml	Yes		✓	No
	Inhaler, assistive	Yes		✓	No

Pharmacy Benefit Category	**Sub-Category**	**Subject to Carve-out?** Yes, No, Partially[7]	**Medical Claim** Not "Carved Out"	**Pharmacy Claim** "Carved Out" to Medi-Cal Rx	**Billable on Both Claim Types?** Yes or No
	devices				
	Peak flow Meter	Yes		✓	No
	Syringe, Normal Saline/ 0.9% Sodium Chloride Flush	Yes		✓	No
	Tracheostomy	No	✓		No
	Ostomy	No	✓		No
	Urological	No	✓		No
	Wound Care	No	✓		No
	Infusion tubing	No	✓		No
	Infusion Pumps	No	✓		No
	Diaphragms/Cervical caps	Yes		✓	No
	Thermometer (oral or rectal)	No	✓		No
	Alcohol Pads	Partially	✓	✓	Yes
	70% isopropyl alcohol swab sticks, and Povidone-iodine swabsticks	No	✓		No
	Betadine or phisohex solution	No	✓		No
	Chlorhexidine containing antiseptic	No	✓		No
	Gloves (non-sterile or sterile)	No	✓		No

Pharmacy Benefit Category	**Sub-Category**	**Subject to Carve-out?** Yes, No, Partially[7]	**Medical Claim** Not "Carved Out"	**Pharmacy Claim** "Carved Out" to Medi-Cal Rx	**Billable on Both Claim Types?** Yes or No
	Sheeting, waterproof (protective underpad, reusable, bed size)	No	✓		No
Enteral Nutrition Products	Formula	Partially	✓	✓	Yes
	Pumps	No	✓		No
	Tubing	No	✓		No
	General	No	✓		No
Pharmacist Services	General	No	✓		No

CHART #3: A post-transition coverage clarification by targeted benefit categories

Diabetic Supplies – Diabetic Test Strips, Lancets, Glucometers, Control Solutions, and Lancing Devices

Diabetic test strips and lancets will be carved out and billable through the Medi-Cal Rx delivery system. Coverage is specific to products listed on the Medi-Cal List of Contracted Diabetic Test Strips and Lancets and the criteria currently published in Medical Supplies section of the Medi-Cal Provider Manual. Coverage criteria and contracted Lists will be updated on the Medi-Cal Rx website and the Medi-Cal Rx Provider Manual prior to January 1, 2022.

As of January 1, 2022, in addition to the existing policy for test strips and lancets, the policy for other specific diabetic supplies (insulin syringes, pen needles, glucometers, lancing devices and control solution) will be published in the Medi-Cal Rx Provider Manual.[13,14] Self-Monitoring Blood Glucose Systems (Glucometers), lancing devices and

[13] The List of Contracted Diabetic Test Strips and Lancets is available at: https://medi-calrx.dhcs.ca.gov/cms/medicalrx/static-assets/documents/provider/forms-and-information/Covered_Diabetic_Test_Strips_and_Lancets.xlsx
[14] The Medi-Cal Rx Provider Manual is available at: https://medi-calrx.dhcs.ca.gov/provider/

control solution compatible with the contracted test strips and lancets will be carved out and billable through Medi-Cal Rx delivery system as an National Drug Code (NDC)-billed pharmacy item. Coverage is specific to a contracted List of products, which will be published on the Medi-Cal Rx website prior to January 1, 2022. Non-contracted products can continue to be adjudicated through CA-MMIS as a medical claim, or through the MCP. NOTE: During the Medi-Cal Rx 180-day transition period, only glucometers, lancing devices, and control solutions compatible with the contracted test strips and lancets on the contracted List can be billed through the Medi-Cal Rx delivery system effective on or after January 1, 2022. Non-compatible glucometers will not be covered through Medi-Cal Rx during the transition period.
Therapeutic CGM Systems Effective January 1, 2022, therapeutic CGM systems will be a pharmacy-billed medical supply benefit with an approved pharmacy PA. Claims for covered products will process through Medi-Cal Rx, and be adjudicated by Magellan. During the Medi-Cal Rx 180-day transition period, a PA or paid claim within the past 90 days will allow a therapeutic CGM claim to pay. For patients new to therapeutic CGMs, all requests require a PA with documentation to demonstrate established criteria is met. MCPs may also provide and reimburse a therapeutic CGM billed on a medical claim.
Disposable Insulin Delivery Devices Effective January 1, 2022, Disposable Insulin Delivery Devices (DIDD) will be a pharmacy-billed medical supply benefit with an approved pharmacy PA and subject to a contracted List. All of these claims will process through Medi-Cal Rx, and be adjudicated by Magellan. During the Medi-Cal Rx 180-day transition period, a PA or paid claim within the past 90 days will allow a DIDD claim to pay. For patients new to DIDDs, all requests require a PA with required documentation to demonstrate the established criteria is met and must be a contracted product, listed on the List of Covered Disposable Insulin Delivery Devices. MCPs may also provide and reimburse DIDDs as a medical claim.

Alcohol Pads and Sterile Syringes with Needles (Non-Insulin) Medical Supplies

Effective January 1, 2022, alcohol pads and specific sterile syringes with needles (non-insulin) will be pharmacy-billed medical supply benefits through Medi-Cal Rx. Sterile syringes with needles will be subject to a List through Medi-Cal Rx. These items will be carved out and billable through Medi-Cal Rx as an NDC-billed pharmacy item. Non-contracted sterile syringes with needles and alcohol pads can continue to be adjudicated through CA-MMIS or a MCP as a medical claim.

Medi-Cal Rx Roles & Responsibilities Clarification Summary

DHCS expects MCPs to assist in the implementation efforts leading up to the transition to Medi-Cal Rx on January 1, 2022. Following the transition to Medi-Cal Rx on January 1, 2022, DHCS, Magellan and MCPs will be responsible (indicated by an "X") for activities, including but not limited to those listed in the table below. This table is provided to add clarity to areas of concerns related to activity responsibilities for DHCS, Magellan, and MCPs.

Activity	DHCS	Magellan	MCP
1. Developing, implementing, and maintaining all Medi-Cal pharmacy policy, including, but not limited to: o Drug coverage o State supplemental drug rebates o PA/utilization management	**X**		
2. Formulary updates including those based on regional needs, member specific segment risks, prior utilization, health outcome data, and other considerations.	**X**		
3. Providing a printed copy of the "formulary" (CDL) per a member request.		**X**	
4. Providing future member, provider, and pharmacy communications regarding pharmacy benefits/information.	**X**	**X**	
5. Negotiating and contracting for state supplemental drug rebates.	**X**		
6. Providing drug rebate administration services, in compliance with federal and state laws and DHCS' policies and guidance.		**X**	

Activity	DHCS	Magellan	MCP
7. Establishing and maintaining the Medi-Cal pharmacy provider network.	**X**		
8. Reviewing and issuing final determinations regarding all PA denials for pharmacy benefits (except administrative denials due to a 30-day non-response to a PA deferral).	**X**		
9. Contract management, inclusive of oversight and monitoring of all Medi-Cal Rx contract requirements and deliverables provided by Magellan.	**X**		
10. Processing and payment of all pharmacy services billed on medical and institutional claims.			**X**
11. Establishing Medi-Cal Rx pharmacy reimbursement methodologies, consistent with applicable state and federal requirements.	**X**		
12. Providing claims administration, processing, and payment functionalities for all pharmacy services billed on pharmacy claims.		**X**	
13. Processing coordination of pharmacy benefits with other health coverage, including Medicare.		**X**	
14. In partnership with the California Department of Social Services (CDSS), providing oversight of, and ensuring access to, the State Fair Hearing (SFH) process related to Medi-Cal Rx.	**X**		
15. Providing Medi-Cal Rx Customer Service Center (CSC) to support all pharmacy benefit related provider and member calls twenty-four (24) hours per day, seven (7) days per week, three hundred and sixty-five (365) days per year, inclusive of holidays and weekends unless otherwise directed by DHCS.		**X**	
16. Providing daily data feeds to MCPs, and other entities as designated by DHCS, to support their responsibilities of member care coordination, carrying out clinical aspects of pharmacy adherence, and disease and medication management.		**X**	

Activity	DHCS	Magellan	MCP
17. Providing real-time access into the Medi-Cal Rx electronic environment via a secure portal to all members, providers (prescribers and pharmacies), MCPs, and other entities as designated by DHCS.		**X**	
18. Providing dedicated Medi-Cal Rx Clinical Liaisons (CLs) for all MCPs to assist with care coordination and clinical issues, inclusive of members enrolled in WCM MCPs.		**X**	
19. Providing CLs supported by appropriate clinical staff, which will ensure MCP CLs, and by proxy MCPs, have twenty-four (24) hours per day, seven (7) days per week, three hundred and sixty-five (365) days per year access to these critical resources, including weekends and holidays unless otherwise directed by DHCS.		**X**	
20. Providing CLs to help resolve potential PA issues on the front end, with appropriate clinical staff support as needed, to ensure compliance with Medi-Cal Rx policy, which requires a decision to approve, defer, or recommend denial of a PA request within 24 hours.		**X**	
21. Providing CLs to facilitate intervention for urgent cases, such as after-hours hospital discharges where immediate access to medically necessary medication is required.		**X**	
22. Providing all CLs, Customer Service Representatives, and supportive clinical staff with training to understand and support the special needs and requirements of WCM MCPs and WCM MCP members.		**X**	
23. Overseeing and maintaining all activities necessary for member care management and coordination, and related activities consistent with legal and contractual obligations.			**X**
24. Providing oversight and management of all the clinical aspects of pharmacy adherence, including providing disease and medication management.			**X**
25. Maintaining policies related to notifying members if there is disruption in the supply chain or medication contamination for all Food and Drug Administration (FDA) consumer level notifications.		**X**	

Activity	DHCS	Magellan	MCP
26. Reviewing PAs for PADs, medical supplies, Enteral Nutritional Products, and covered outpatient drug claims billed on a pharmacy claim by an outpatient pharmacy.		**X**	
27. Providing utilization management functions and ensuring pharmacy PA decisions are made within 24 hours of receipt of the PA request.		**X**	
28. Providing prospective Drug Utilization Review (DUR) services.		**X**	
29. Providing retrospective DUR services.		**X**	**X**
30. Overseeing the Medi-Cal Global DUR Board and other DHCS organized pharmacy committees, in collaboration with Magellan.	**X**		
31. Participating in the Medi-Cal Global DUR Board and other DHCS organized pharmacy committee meetings.			**X**
32. Ensuring that DUR program meets or exceeds applicable provisions of Section 1004 requirements of the SUPPORT for Patient and Communities Act: A retrospective claims review process that monitors when an individual is concurrently prescribed opioids and benzodiazepines or opioids and antipsychotics.	**X**	**X**	**X**
33. Developing and implementing effective retrospective DUR and treatment outcome processes to assure that drug utilization is appropriate, medically necessary, and not likely to result in adverse events.[15]		**X**	**X**
34. Developing effective prospective DUR processes to assure that drug utilization is appropriate, medically necessary, and not likely to result in adverse events.	**X**		
35. Implementing effective prospective DUR processes to assure that drug utilization is appropriate, medically necessary, and not likely to result in adverse events.	**X**	**X**	

[15] For example, performing reviews of claims data to identify outlier prescribing trends, inappropriate dispensing activities by a provider/providers, patterns suggesting possible misuse/abuse of medications, etc.

Activity	DHCS	Magellan	MCP
36. Reimbursing for pharmacist professional services as required by Assembly Bill (AB) 1114 (Chapter 602, Statutes of 2016) in a community-based outpatient pharmacy setting.[16]	**X**		**X**
37. Processing and payment of all pharmacist professional services allowed by AB 1114 that are billed on medical and institutional claims.			**X**
38. Providing Non-Emergency Medical Transportation (NEMT) and Non-Medical Transportation (NMT) services required by Members to access pharmacy services for prescribed Medi-Cal covered drugs.			**X**
39. Providing fraud and abuse identification processes that identifies potential fraud or abuse of controlled substances by members, health care providers, and pharmacies.		**X**	**X**
40. Providing program integrity (PI) and oversight of Medi-Cal Rx and Medi-Cal's FFS outpatient pharmacy benefits and services.	**X**		
41. Administering the Medi-Cal Rx Program Integrity and Compliance Unit (PI/SIU) and providing support to DHCS through the application of best practices for identifying, sharing, reporting, preventing, or mitigating fraud, waste, and abuse schemes and risks.		**X**	
42. Providing fraud and abuse reporting, including prompt referral of any potential fraud, waste, or abuse the MCP identifies to the DHCS Audits and Investigations Intake Unit as well as conducting, completing, and reporting to DHCS the results of a preliminary investigation of the suspected fraud and/or abuse within 10 working days of the date the MCP first becomes aware of, or is on notice of, such activity.			**X**

[16] DHCS must reimburse for FFS-enrolled Medi-Cal beneficiaries.

PRE AND POST TRANSITION POLICIES:

I. PRE-TRANSITION RESPONSIBILITIES

Pharmacy Transition Policy

To help support the Medi-Cal Rx transition and ensure continued and uninterrupted access to medically necessary medications, DHCS has developed a pharmacy transition policy. For purposes of that policy, Magellan will load at least 12 months of encounters/paid claims and PA history received from the MCPs and CA-MMIS into Magellan's claims processing system to support edits that may "grandfather" and/or "look-back" to see if a product has been previously dispensed to a Medi-Cal beneficiary whether in managed care or FFS.

The transition period also includes a 180-day period where DHCS will not require PA for existing prescriptions, including controlled substances (e.g., opioids, benzodiazepines) and antibiotics, without previously approved PAs from their applicable MCPs (or for prescriptions that have a previously approved PA that expires prior to the end of the transition period), for drugs not on the Medi-Cal Contract Drug List (CDL), or that otherwise have PA requirements under Medi-Cal Rx. This policy does not apply to new prescriptions or drugs that do not have PA requirements under Medi-Cal Rx.

During this transition period, Magellan will provide system messaging, reporting, and outreach to ensure a smooth transition to Medi-Cal Rx. For more information including related MCP transition responsibilities, please see the complete pharmacy transition policy.[17]

For all Medi-Cal beneficiaries with an existing prescription that did not require PA as of December 31, 2021, but will otherwise require PA per Medi-Cal Rx policy on or after January 1, 2022, DHCS/Magellan will use encounters/paid claims data received from the MCPs and CA-MMIS to "look back" and validate that a prior prescription existed for the applicable medication. Based upon this "look back", DHCS will not require any PA during the 180-day period for covered Medi-Cal pharmacy benefits billed on pharmacy claims, with the exception of off-label use pursuant to federal Medicaid requirements. DHCS/Magellan will also use the "look back" functionality pertaining to encounter/claims history and medical profile for purposes of facilitating systems edits and audits designed to alert providers to potential safety considerations such as contraindications, duplication, or overuse of the medication. MCPs should review the pharmacy transition policy for additional details.

[17] The complete pharmacy transition policy is available at: https://www.dhcs.ca.gov/provgovpart/pharmacy/Documents/MRX-Pharmacy-Transition-Policy-Ver%208.0-08-14-2020.pdf

For existing prescriptions for covered Medi-Cal pharmacy benefits with a previously approved PA on or before December 31, 2021, DHCS/Magellan will use PA and encounter/claims history data to "grandfather" those prescriptions to allow continuation of the PA through its stated duration, (i.e. three months, six months, etc.), but not to exceed one (1) full year from the approval date of the PA. Please note that certain drug classes/categories described in the Pharmacy Transition Policy, such as maintenance medications used to treat chronic conditions, may be "grandfathered" pursuant to DHCS' extended/multi-year PA policy, which allows for continuation of the PA through its stated duration, but not to exceed five (5) years from the approval date of the PA. DHCS/Magellan will also use encounters/paid claims and PA data to "look back" for purposes of facilitating edits and audits designed to alert providers to potential safety considerations such as contraindications, duplication, or overuse of the medication. MCPs should review the pharmacy transition policy for additional details.

For new prescriptions (i.e., drugs/therapies not previously prescribed to the Medi-Cal beneficiary in either Medi-Cal managed care or FFS) requiring PA under Medi-Cal Rx, the "grandfather" component will not apply, and the submitting provider will need to submit a PA for review/approval consistent with Medi-Cal Rx policy and based upon medical necessity for each individual patient. DHCS/Magellan will still use the "look back" information for purposes of facilitating systems edits and audits designed to alert providers to potential safety considerations such as contraindications, duplication, or overuse of the medication. MCPs should review the pharmacy transition policy for additional details.

For new prescriptions not requiring PA under Medi-Cal Rx, these claims are not impacted by this policy, and will be processed and paid by Magellan per Medi-Cal Rx policy, as of January 1, 2022.

Medi-Cal Pharmacy Financial Responsibility

For pharmacy-related services provided on or before December 31, 2021, by MCPs, the MCPs remain contractually responsible for all aspects of administration of the pharmacy benefit, as set forth in the applicable MCP contracts executed with DHCS.[18]

In anticipation of the Medi-Cal Rx transition on January 1, 2022, and in compliance with the Pharmacy Transition Policy described and referenced above, MCPs must not discontinue and/or void previously approved PAs for pharmacy-related services. MCPs must also ensure that PAs for pharmacy-related services do not automatically expire on December 31, 2021. DHCS requires MCPs to take all necessary steps to ensure their

[18] MCP boilerplate contracts can be found on the DHCS website at: https://www.dhcs.ca.gov/provgovpart/Pages/MMCDBoilerplateContracts.aspx

members continue to have uninterrupted access to medically necessary pharmacy benefits and services during the transition to Medi-Cal Rx.

To help effectuate and facilitate a smooth transition through December 31, 2021, MCPs must act as follows:

- For all pharmacy services rendered on or before December 31, 2021, MCPs must continue to process and address related calls, grievances, and appeals to their final disposition.

- For calls about pharmacy issues unrelated to the Medi-Cal Rx transition, such as coverage of certain medications, grievances, appeals, etc., MCPs must continue to process and address these calls, resolve all grievances and appeals and not refer questions to DHCS or Magellan.

- For calls about the Medi-Cal Rx transition, such as questions about the Medi-Cal Rx outreach letters or general Medi-Cal Rx questions, MCPs must utilize the call center scripts provided by DHCS to answer any general questions.

- If unable to answer an inquiry, MCPs may refer calls about the Medi-Cal Rx transition to DHCS' existing CSC through the MCP Member Help Line (1-800-541-5555), which is available Monday through Friday, 8:00 a.m. to 5:00 p.m. MCPs may also direct callers to contact DHCS by email at: RxCarveOut@dhcs.ca.gov.

    - Note: When MCPs direct a caller to contact DHCS by email, the MCP must instruct the caller to not include any personal information in their initial email. DHCS staff will reply with a secure email asking for further information, if needed, to assist.

- For information about Medi-Cal pharmacy policy on or before December 31, 2021, MCPs should refer to DHCS' existing website for APLs and Policy Letters, Medi-Cal Provider Manual pharmacy sections, published CDL, and provider bulletins.[19] Leading up to the transition, DHCS has been posting, and will continue to post provider bulletin articles with helpful information and resources. Moreover, DHCS encourages MCPs and their affiliates to subscribe to the Medi-Cal Rx Subscription Service (MCRxSS), which is available on the Medi-Cal Rx website as it allows interested parties to sign up and receive regular Medi-Cal Rx updates by email.[20]

[19] Medi-Cal coverage policy is outlined in the Medi-Cal Provider Manual and associated provider bulletins, which can be found at: https://files.medi-cal.ca.gov/pubsdoco/Manuals_menu.aspx.
[20] MCRxSS is available at the Medi-Cal Rx website here: https://mcrxsspages.dhcs.ca.gov/Medi-CalRxDHCScagov-Subscription-Sign-Up.

- Provide needed data for a safe, smooth, and effective transition, in the manner and format previously discussed and agreed upon between DHCS and the MCPs as part of Medi-Cal Rx transition planning.

To help effectuate and facilitate a smooth transition from January 1, 2022, and forward, MCPs must act as follows:

- For all pharmacy services rendered on or after January 1, 2022, MCPs must refer all pharmacy-related calls to the Medi-Cal Rx CSC Line (1-800-977-2273), which is available twenty-four (24) hours a day, seven (7) days a week, or 711 for TDD Monday thru Friday, 8:00 a.m. to 5:00 p.m.

- MCPs must continue to track all pharmacy-related calls including those that are referred to, or transferred directly to, Medi-Cal Rx for at least sixty (60) days starting January 1, 2022. Call tracking information may be used during the sixty day period to identify and resolve problems that may arise in referring or transferring callers appropriately to Medi-Cal Rx. Tracking information must be maintained for at least ninety (90) days starting January 1, 2022, or thirty (30) days following the cessation of tracking, whichever is longer.

Member Noticing and Outreach

DHCS has created noticing and outreach strategies to ensure Medi-Cal beneficiaries have the necessary information and access to helpful resources/tools to prepare them for a successful transition to Medi-Cal Rx on January 1, 2022. These noticing and outreach strategies include, but are not limited to:

- Medi-Cal beneficiary notices, which will be used for the 60-, and 30-day written outreach campaign. DHCS/Magellan will send the 60-day notices to all Medi-Cal beneficiaries regardless of delivery system. MCPs are required to mail the DHCS-approved 30-day beneficiary notice and must submit a template to DHCS for review and approval prior to mailing to their members if any changes have been made since the initial submission and approval by DHCS. The DHCS-approved 30-day beneficiary notice will also need to be filed with the Department of Managed Health Care (DMHC).[21]

- Call center scripts, which will be provided by DHCS to all affected CSCs, including those within MCPs, DHCS, DMHC, CDSS, and others to respond to potential

[21] DMHC's Medi-Cal Rx Transition APL 20-035 is available on DMHC's website at: https://www.dmhc.ca.gov/Portals/0/Docs/OPL/APL%2020-035%20-%20Medi-Cal%20Pharmacy%20Benefit%20Carve%20Out%20-%20Medi-Cal%20Rx%20(10_6_2020).pdf?ver=2020-10-06-165704-497

questions resulting from the outreach notices. DHCS will provide the call script in advance for distribution to call center staff and to allow for adequate training.

- MCPs must utilize the DHCS generated outreach campaign template/script to complete the corresponding Medi-Cal Rx outreach campaign, which can be either a traditional outbound call campaign or an alternative communication strategy. This Medi-Cal Rx outreach campaign can be carried out over the full 90-day period corresponding to written notices and leading up to January 1, 2022.

- While DHCS still expects that all MCPs implement a Medi-Cal Rx outreach campaign, consistent with federal and state law, to inform their respective members of the Medi-Cal Rx transition, DHCS does not explicitly prescribe how MCPs achieve this outreach and supports MCPs in finding innovative, alternative solutions relative to the Medi-Cal Rx outreach campaign. Below is a non-exhaustive list of traditional communication modalities as well as alternative communication modalities and/or options that MCPs may choose to utilize. Please note that despite selecting an alternative communication modality or modalities in lieu of a traditional outbound call campaign, DHCS still requires that MCPs make all necessary efforts to ensure that the Medi-Cal Rx outreach campaign provides the same information and overall level of awareness.

    - Outbound call campaign, utilizing in-person calls, robocalls, or both. This could include calls to both landlines as well as cell phones.
    - Leveraging existing MCP provider networks and contractual relationships to help disseminate important information by encouraging providers to share information when members come in for visits, posting flyers in their offices, etc.
    - Direct mailings, such as those being utilized for the 30-day notice, and related member newsletters.
    - Social media outreach through one or more outlets, e.g., Facebook, Twitter, Instagram, etc.
    - MCP website updates, inclusive of banners, videos, interactive modules, etc.
    - Member portal updates and communications, inclusive of push-notifications (if members have signed up), banners, videos, interactive modules, etc.
    - Other media, such as radio or television campaigns, as well as billboards, newspaper/print, etc.

- Relative to the Medi-Cal Rx outreach campaign, given that MCPs will have an option as to whether to effectuate a traditional outbound call campaign and/or utilize one or more alternative communication modalities, such as those listed above, DHCS previously required that all MCPs report to DHCS via the RxCarveOut@dhcs.ca.gov mailbox how they intend to satisfy the Medi-Cal Rx outreach campaign component. To ensure compliance with this guidance, DHCS will collect, track, and approve each MCP submission, which must include the following information:
    - **Submitter Information** – Full name, phone number, and email address.
    - **MCP Information** – Legal name of the MCP.
    - **Timeline** – Start and end date anticipated for the Medi-Cal Rx outreach campaign.
    - **Modality (ies)** – Selected modality or modalities for satisfying the Medi-Cal Rx outreach campaign requirements and proposed content for each modality based on approved language in beneficiary notice letters and outreach script templates.

  For MCPs not utilizing a traditional outbound call campaign, DHCS' review and approval was aimed at ensuring that the selected alternative communication modality or modalities provide the same information and overall level of awareness. DHCS will retain this information future forward for documentation purposes. As a reminder, DHCS requires all MCPs to utilize only the previously approved call campaign scripts and/or notice language to effectuate this outreach campaign. Any requested changes to those template materials must be approved by DHCS.

Medi-Cal Beneficiary Identification Cards and MCP Member Identification Cards

In the managed care delivery system, Medi-Cal Beneficiary Identification Cards (BIC) are used to verify member eligibility for carved-out services, and allow Medi-Cal providers to bill for any carved-out services rendered. As part of the transition to Medi-Cal Rx on January 1, 2022, and in the same manner as for other carved-out benefits and services, Medi-Cal beneficiaries should carry their plastic BIC card and have it available whenever they are going to the pharmacy. Once Medi-Cal beneficiaries are enrolled in an MCP, they must always keep their Member Identification (ID) Card and their Medi-Cal BIC with them. Members should take both cards to office visits, x-rays, pharmacies, and all other medical services.

Please note that DHCS will not be changing and/or reissuing all Medi-Cal BICs as a result of the transition to Medi-Cal Rx. Today, Medi-Cal BICs contain information on the front, including unique identification number, full name, gender, date of birth, and issue

date; on the back, the card has a magnetic slider strip and signature block. To the extent MCP members lose or misplace their BIC cards, they can request a replacement BIC from their local county social services office.[22] If a member's BIC is stolen, they should inform their local police department and county social services office. MCP members should give as much information about the theft as possible. Once MCP members are issued a new BIC, their old BIC card will no longer be valid.

For MCP Member ID cards, MCPs must have a procedure in place to notify members of the Medi-Cal Rx CSC phone number and website. This can be accomplished by updating Member ID cards, as part of the corresponding mandatory update to the Member Handbook, sending out notices to members, and including information in an Interactive Voice Response (IVR) system, or some combination of one or more of these options.

To help facilitate the MCP decision-making process relative to Member ID card updates, DHCS has identified two overarching scenarios, as follows:

- **Changing/Reissuing MCP Member IDs NOT Required:** This would apply to MCPs that use a single CSC phone number for all issues, which includes an IVR menu where the member selects a specific number (e.g., "select 4") for pharmacy issues. MCPs can set up their IVR to automatically roll over to the Medi-Cal Rx CSC phone number upon the applicable selection. Given that users will often select the initial menu options for any issue, we suggest placing the pharmacy selection towards the end of the IVR menu selections.
- **Changing/Reissuing MCP Member IDs Required:** This would apply to MCPs that either use a standalone pharmacy customer service phone number or that issue a separate pharmacy services ID card (e.g., issued by their pharmacy benefits manager, and in addition to the MCP Member ID for other services).

To avoid confusion and ensure the phone number on the cards aligns with the Medi-Cal Rx CSC phone number in the Member Handbook and various notices, MCPs must change/reissue Member ID cards (or rescind and issue notices in the case of standalone pharmacy services ID cards) to either remove the old phone number or replace the old phone number with the Medi-Cal Rx CSC phone number.

MCPs must reissue Member ID cards if Member ID cards have specific billing information or identifiers (e.g., Bank Identification Number (BIN), Processor Control Number (PCN), etc.), printed on the cards that conflict with Medi-Cal Rx. MCPs may print the Medi-Cal Rx BIN, PCN, and other information or identifiers specific to Medi-Cal

[22] A listing of local county social services offices can be found here: https://www.dhcs.ca.gov/services/medi-cal/Pages/CountyOffices.aspx

Rx on reissued Member ID cards if desired.

DHCS will allow MCPs to use a member applied adhesive label to cover or replace member card information that conflicts with Medi-Cal Rx pharmacy services information as a temporary method of card information correction for January 1, 2022, compliance. The label must reflect the member card content changes that are submitted to DHCS on the updated Member ID deliverable. DHCS does not require submission of label layouts in the updated Member ID Card deliverable.

For MCPs that use this temporary correction method for existing member cards, DHCS requires those MCPs to replace all existing cards with corrected cards by April 1, 2022, including those with temporary labels. DHCS also requires all MCPs to provide new members enrolled in their Plan with a member ID card containing correct information (without temporary labels) beginning January 1, 2022.

Quality Monitoring & Reporting Requirements

MCPs are expected to submit complete, accurate, and timely pharmacy encounter data for all dates of service prior to January 1, 2022, as required by APL 14-019, APL 14-020, and the most recent publication of the Quality Measures for Encounter Data.[23] MCPs must also correct all encounter data errors identified by DHCS and sent to the MCPs through response files. For dates of service on or after January 1, 2022, MCPs will no longer be responsible for submitting any pharmacy encounter data for pharmacy-related services covered by Medi-Cal Rx, i.e., those services billed by a pharmacy on a pharmacy claim. MCPs will still be responsible for submitting encounter data for pharmacy-related services that are not within the scope of Medi-Cal Rx, i.e., those services billed on a medical or institutional claim and/or as part of a bundled/all-inclusive billing structure in an inpatient or LTC setting (including SNFs and other ICFs).

Note, MCPs are still expected to incorporate pharmacy data to meet MCP obligations for aspects of member care management including care coordination, medication management and adherence, and complex care management for high risk members.

DHCS will provide updates to performance measures known as the Managed Care Accountability Set, applicable for the 2022 Reporting Year (RY) and forward, through its

[23] See APL 14-019, available at: https://www.dhcs.ca.gov/formsandpubs/Documents/MMCDAPLsandPolicyLetters/APL2014/APL14-019.pdf, APL 14-020, available at: https://www.dhcs.ca.gov/formsandpubs/Documents/MMCDAPLsandPolicyLetters/APL2014/APL14-020.pdf, as well as the attachment to APL 14-020, available at: https://www.dhcs.ca.gov/formsandpubs/Documents/MMCDAPLsandPolicyLetters/APL2014/DHCSQualityMeasuresforEncounterData.pdf.

Quality and Performance Improvement Requirements APL that it releases prior to each RY.[24]

National Committee for Quality Assurance Accreditation & Healthcare Effectiveness Data and Information Set Measures

DHCS will not hold MCPs to the National Committee for Quality Assurance (NCQA) standards for carved-out Medi-Cal Rx services, as of January 1, 2022.

As for the Healthcare Effectiveness Data and Information Set (HEDIS) pharmacy data measures that accredited MCPs are required to report on, MCPs can use the pharmacy daily data feeds and real-time pharmacy portal information provided by Medi-Cal Rx for HEDIS reporting purposes, as of January 1, 2022. Similarly, as of January 1, 2022, MCPs can also choose to report "no benefit" meaning that service is not a benefit provided by the MCP. Therefore, HEDIS measures for pharmacy claims will be removed from the MCP's star rating and will not impact the MCP's accreditation status (accredited vs. not accredited).

DHCS will identify specific standards that MCPs will be held to in 2022 and forward in its Quality and Performance Improvement Requirements APL that it releases prior to each RY.

II. POST-TRANSITION RESPONSIBILITIES

The following section outlines and provides details relative to key post-transition programmatic, operational, contractual, and policy requirements that are critical to ensuring MCPs meet expectations for the January 1, 2022, Medi-Cal Rx transition.[25]

Magellan Daily Data Feeds

For pharmacy services on or after January 1, 2022, Medi-Cal Rx will provide daily data feeds, in a file format agreed upon with the MCPs, to support MCP obligations for all aspects of member care management including care coordination, medication management and adherence, and complex care management for high risk members.

For the Medi-Cal Rx daily data feeds, DHCS will build upon existing data feeds to MCPs for existing carved-out drugs. Under the pre-transition policy, these data feeds are sent monthly and only to the DHCS-contracted MCPs using the applicable Health Care Plan

[24] The current Quality and Performance and Improvement Requirements APL (APL 19-017) and Supplement to APL 19-017 can be found on the DHCS webpage.
[25] For information about Medi-Cal Rx coverage policy on or after January 1, 2022, MCPs should refer to the dedicated Medi-Cal Rx website and associated Medi-Cal Provider Manuals. The dedicated Medi-Cal Rx website can be found at: https://medi-calrx.dhcs.ca.gov/home/.

(HCP) Code to identify membership in the contracted MCP. Under the post-transition policy, these data feeds will be sent daily and will continue only to be sent to the DHCS-contract MCPs using the applicable HCP Code to identify membership in the contracted MCP.

DHCS recognizes that many MCPs have Network Provider Agreements and Subcontractor Agreements with other MCPs. As a result, DHCS anticipates that most DHCS-contracted MCPs already have some type of interface or arrangement with their Network Providers and Subcontractors for data sharing purposes. However, if not, DHCS requires that those DHCS-contracted MCPs will work to establish and implement data sharing arrangements with their Network Providers and Subcontractors for purposes of sharing the daily data feeds.

Ultimately, all DHCS-contracted MCPs are required to implement appropriate interfaces or arrangements with each of their Subcontractors and Network Providers to ensure timely access to information to support clinical aspects of pharmacy adherence, and disease and medication management for applicable sub-delegated populations.

Medi-Cal Rx Website/Pharmacy Portals & Clinical Liaison Access

Medi-Cal Rx Website/Pharmacy Portals: DHCS, in partnership with Magellan, has created a comprehensive Medi-Cal Rx website.[26] This dedicated website will offer content on a public platform that is accessible to the general public, MCP members and all Medi-Cal beneficiaries, providers (pharmacies and prescribing physicians), MCPs, and other entities as designed by DHCS. Additionally, secure pharmacy portals will be available to MCP members and all Medi-Cal beneficiaries, providers (pharmacies and prescribing physicians), MCPs, and other entities as designated by DHCS, to ensure they can access appropriate tools for services that require access to protected health information.

The MCRxSS is also available at the Medi-Cal Rx website and allows interested parties to sign up and receive regular Medi-Cal Rx updates by email. Additional information will be posted on the Medi-Cal Rx website, which will be fully operational by January 1, 2022. For more information, please refer to the Medi-Cal Rx Website/Pharmacy Portal policy, which is available on the DHCS website.[27]

[26] The Medi-Cal Rx website is available at: https://medi-calrx.dhcs.ca.gov/home/
[27] The Medi-Cal Rx Website/Pharmacy Portal Policy is available at: https://www.dhcs.ca.gov/provgovpart/pharmacy/Documents/MRX-Website-and-PharmacY-Portal-Policy-081420.pdf

MCP Clinical Liaisons: The primary responsibility of MCP CLs is to work directly with the MCPs on clinical pharmacy-related issues to ensure Medi-Cal beneficiaries receive medically necessary medications in a timely fashion and based upon the established DHCS Medi-Cal Rx policy.

Medi-Cal Rx will provide a dedicated Medi-Cal Rx CL team to support MCPs in complying with contractual obligations relating to member care coordination, medication adherence, and other responsibilities related to medication requirements, in accordance with applicable state and federal law. The Medi-Cal Rx MCP CLs will be a Certified Pharmacy Technician (CPhT) and expert user of the FirstTrax℠ contact center system. The Medi-Cal Rx MCP CLs will:

- Have in-depth knowledge of the CDL and related PA processes.
- Have access to a Magellan Medi-Cal Rx pharmacist twenty-four (24) hours per day, seven (7) days per week, including weekends and holidays to assist MCPs.
- Assist with any clinical, pharmacy-related matter, including but not limited to urgent or time-sensitive requests, PA statuses, and claims issues.
- Have direct access to appropriate clinical staff including Registered Pharmacists and other Medi-Cal clinicians as well as a CPhT Supervisor and the CSC Director.

Please note that Medi-Cal Rx CLs should not be utilized for non-clinical and/or non-emergent issues, or general administrative issues, that could otherwise be resolved through the Medi-Cal Rx CSC.

The Medi-Cal Rx MCP CLs will have an understanding of the MCP population by developing profiles for each MCP, based on the population the MCP serves, key areas of interest and/or challenges, and other nuances that are necessary to ensure quality customer service and timely access to medically necessary prescriptions.

To this end, MCP CLs will be able to better understand anything that is unique about the MCP's population and intervene in urgent cases that cannot be resolved by the normal pharmacy call center and are escalated by the MCP's designated contact(s).[28] The MCP CLs will also develop and own the relationship with particular MCPs**,** and will be trained to address all MCP inquiries.

Designated Users (DUs): DHCS allows DUs for each DHCS-contracted MCP, which can be utilized both at the DHCS-contracted plan level as well as for any Network

[28] For more information, please refer to the MCP CL policy, which is available at: https://www.dhcs.ca.gov/provgovpart/pharmacy/Documents/MRX-MCP-Clinical-Liaison-Policy-081420.pdf

Providers and Subcontractors. The DU access takes into consideration key MCP roles, including but not limited to pharmacy staff, care managers and behavioral health staff, etc., that require access to the Medi-Cal Rx secure MCP Pharmacy Portal and the MCP CL.

DUs with CL access privileges are those individuals identified by the MCPs as needing CL access for critical functionalities including but not limited to clinical and care coordination, medication adherence, and other responsibilities related to medication requirements. DUs with CL access privileges will be provided access to the MCP CLs through Medi-Cal Rx's dedicated IVR system to assist and resolve clinical pharmacy-related issues.

Please note that existing contractual requirements between DHCS and MCPs, including requirements to comply with the Health Insurance Portability and Accountability Act (HIPAA) and all Business Service Agreements/Business Use Agreements (BSAs/BUAs), provide sufficient coverage from a sensitive data and privacy perspective. To that end, MCPs will be responsible for ensuring that DUs only access or interact with data and information reasonably necessary to resolve a pharmacy benefit issue for a specific member or population served, versus all contracted MCP lives. Each DU will have a password and User ID associated with the user's name and MCP. All DUs will have access to the Medi-Cal Rx secure MCP Pharmacy Portal using their User ID and password. MCPs can determine whether they want all DUs, or a subset of DUs, to have access to MCP CLs. DUs identified by an MCP to have access to MCP CLs will receive a Personal Identification Number (PIN) to access MCP CLs through the Medi-Cal Rx CSC IVR system.

Magellan will provide each contracted MCP with a Monthly DU Access Report (MDUAR). Each MDUAR will capture the following information for each DU:

- User Identity;
- Login/out date/time; and
- Beneficiary Client Identification Numbers (CINs) whose records were accessed by the DU**
  (**reported when a DU selects and goes into that member record)

Magellan will deliver the reports to the MCPs monthly via a secure file transfer protocol or other secure method. These MCP specific MDUARs will be created in an Excel file format for consumption and utilization by the respective MCP to audit and verify DU lists and appropriate DU access. Magellan will provide the reports by the 5th business day of each month for the prior month.

MCPs who require Medi-Cal Rx to take action regarding access privileges for any DU must provide that request in accordance with the Medi-Cal Rx Designated User Access Request Form.

DHCS, in partnership with Magellan, has worked and will continue to work collaboratively with MCPs to identify the list of MCP DUs that will have immediate access to the secure MCP Pharmacy Portal and/or Medi-Cal Rx MCP CLs, based upon direction of the MCP, as of January 1, 2022. Going forward, and to facilitate changes to that initial DU list, DHCS, in partnership with Magellan, has established the following process for receiving and reviewing DU access requests for the Medi-Cal Rx secure MCP Pharmacy Portal and Medi-Cal Rx MCP CLs:

- MCPs will establish DU Access Request Contact(s) for MCPs to request authorized access to the Medi-Cal Rx secure MCP Pharmacy Portal and MCP CLs.

- Magellan will establish a DU Access Request Agent via an established email inbox that will be responsible for receiving and controlling DU Access Requests only from the DU Access Request Contact(s) for each MCP. Magellan will ensure access is granted only to MCP authorized individuals. In order to establish credentials, the DU Access Request Contact(s) for each MCP must submit a DU Access Request that includes the following DU information:
    - Individual's name, title, MCP, and MCP generated email address;
    - If the individual is a new incremental add or replacing someone who no longer needs access; and
    - If the individual shall have access to MCP CLs and MCP attestation that the individual meets MCP CL access requirements.
- Magellan will process MCP DU Access Requests following receipt of a completed DU Access Request from an MCP DU Access Request Contact.
- Magellan will provide approved DUs with a User ID and Temporary Password. DUs authorized to have MCP CL access will also receive a PIN upon completion of registration and training.
    - If a Password needs to be reset, the user can do this through Magellan's portal system.
    - If the PIN has been lost, the user must contact the Medi-Cal Rx CSC and request a new PIN.
- Magellan will complete processing of approved DU Access Requests no later than seven (7) business days from receipt of a completed DU Access Request to

providing credentials to the approved DU as well as an approval response to the MCP DU Access Request Contact.

- Magellan will complete processing of disapproved DU Access Requests no later than seven (7) business days from receipt of a completed DU Access Request to providing a disapproval response to the MCP DU Access Request Contact.

MCPs must report all MCP DU changes (such as resignations or terminations) to DHCS and Magellan via the Medi-Cal Rx CSC within 24 hours so that the DU's access can be terminated.

MCP DUR Requirements:
The following outlines DUR related responsibilities and supports for MCPs.

- **Prospective DUR**– This is not required of MCPs as of January 1, 2022. MCPs will be able to review pro DUR alerts and overrides for their members and use this information for provider (prescriber) education and interventions, which is a part of retrospective DUR.

- **Retrospective DUR** – This is still required of MCPs January 1, 2022, and forward. MCPs will receive comprehensive claims and PA history for their members and can use claims data for their own quality improvement and retrospective DUR activities. In addition to that, as part of Global Medi-Cal DUR program, administered by DHCS in collaboration with Magellan and the University of California San Francisco (UCSF), retrospective DUR analyses will be conducted for the entire Medi-Cal population, and results shared in aggregate, with the DUR Board, and by MCP, via the Medi-Cal Rx MCP secure portal, for their populations only.

  Any provider outreach needed as part of retrospective DUR interventions, will be recommended to MCPs for their members. UCSF will be responsible for FFS-enrolled beneficiaries, and MCPs will be able to use FFS developed communications (e.g., provider letter templates) or use their preferred method of provider communication.

  MCPs must continue to provide retrospective DUR (Retro DUR) activities designed to manage care including but not limited to identifying patterns of:

  - Therapeutic appropriateness
  - Adverse events
  - Incorrect duration of treatment

  - Over or under utilization
  - Inappropriate or medically unnecessary prescribing
  - Gross overprescribing and use
  - Fraud, waste, or abuse
  - Assessing medication adherence and identifying opportunities for care management interventions / outreach

- **Educational Outreach** – This is still required of MCPs January 1, 2022, and forward. UCSF will develop and publish educational bulletins and alerts throughout each year on a variety of topics. MCPs are currently required to disseminate DUR educational articles via their preferred method of provider communication, which may include posting them on their provider web page.

  MCPs will continue to provide active and ongoing outreach to educate providers on common drug therapy problems (e.g., asthma medication ratio monitoring, opioid and naloxone co-prescribing, new prescribing guidelines and advisories) with the goals of improving prescribing and dispensing practices, increasing medication compliance, and improvement of over-all beneficiary health.

- **Annual DUR Report** – This is still required of MCPs January 1, 2022, and forward. Annual submission of the modified annual report will be required from the MCPs and will need to include descriptions of any retro DUR activities and any innovative practices implemented by the MCP in the prior federal Fiscal Year.

- **Global Medi-Cal DUR Board Participation** – This is still required of MCPs January 1, 2022, and forward. MCPs are currently required to participate in the activities of the Global Medi-Cal DUR Board, including but not limited to:
  - Providing advice and feedback related to the nature and scope of the prospective and retrospective DUR programs.
  - Recommendations for DUR interventions.
  - Input regarding innovative DUR practices.
  - Board meeting attendance and Board membership.

  Going forward, to encourage more widespread participation and diversify representation on the DUR Board, DHCS may consider a revision of the bylaws in order to introduce term limits and rotation of the MCPs represented in the DUR Board membership. DHCS may also consider including other stakeholder entities in the DUR Board membership rotation.

- **DHCS Organized Pharmacy Committee Meetings –** This is still required of MCPs January 1, 2022, and forward. An example of this type of meeting would be the Pharmacy Directors' Meeting.

Pharmacy Directors' Meeting
Post-transition on January 1, 2022, MCPs will still be required to attend the Pharmacy Directors' Meetings hosted by DHCS. These meetings provide a platform where MCPs can engage in discussion on pharmacy benefit-related topics, including, utilization management, changes to the Medi-Cal CDL, care coordination, quality improvement, etc. This can also serve as a forum for reporting out on experiences and challenges, if any, relative to the transition to Medi-Cal Rx.

H.R. 6, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act
As an active member of the Statewide Opioid Safety Workgroup, the issue of opioid safety is of primary importance to DHCS. As of the transition to Medi-Cal Rx on January 1, 2022, there will be no pharmacy lock-in programs for Medi-Cal beneficiaries in connection with any aspect of their pharmacy benefit, including opioids. This issue is addressed in the Frequently Asked Questions (FAQs) for Medi-Cal Rx and is summarized below.[29]

DHCS will not implement a lock-in program as part of its January 1, 2022, implementation but will be evaluating options with the Medi-Cal Rx Contractor future forward. As part of the Medi-Cal Rx Request for Proposal #19-96125, DHCS solicited Proposals to explore further pharmacy lock-in program options, including, but not limited to, things such as: use of multiple pharmacies, different prescribers of controlled substances, and number of controlled substances. In addition, DHCS is aware that approximately 50 percent of MCPs utilize pharmacy lock-in programs today, so through stakeholder engagement efforts, DHCS will be looking to learn more and utilize best practices for Medi-Cal Rx.

As of January 1, 2022, MCPs will not be contractually responsible for the pharmacy benefit and MCPs will not be able to continue lock-in programs through the use of the resources available through the DHCS Medi-Cal Rx Contractor. However, DHCS has adopted a number of measures designed to limit abuse, misuse, and fraudulent activities related to opioid medications. These measures include:

[29] The Medi-Cal Rx FAQ is available at:
https://www.dhcs.ca.gov/provgovpart/pharmacy/Documents/MRX-FAQ-V3-6-30-20.pdf

- Limitations on maximum day supply.
- Limitations on maximum quantity per dispensing.
- Limitations on number of refills and duration of therapy.
- Limitations on early refills.
- Improved access to Medication Assisted Treatment (MAT) medications used in the treatment of substance use disorders (SUDs).
- Restrictions based on Morphine Equivalent Dose (MED), using CDC guidelines.
- Working with prescribers to implement reasonable tapering of high dose opioids as appropriate.
- Limitations on concurrent use of opioids and benzodiazepines, muscle relaxants, and/or psychotropic medications.

Member Complaints and Grievances

As of January 1, 2022, Medi-Cal Rx will be responsible for managing the resolution of complaints and grievances raised by MCP members, their Authorized Representatives, or other interested parties, regarding a Medi-Cal Rx complaint or grievance.

Medi-Cal Rx complaints and grievances may be filed at any time, and are not subject to any specific codified timeframes, relative to the incident or action that is the subject of the Complainant's dissatisfaction. Complaints or grievances may be made orally or in writing, consistent with all applicable state and federal law requirements and DHCS policies and procedures.

DHCS will oversee the Medi-Cal Rx complaint and grievance process to ensure appropriate and timely handling and resolution occurs. For more information, please refer to the Medi-Cal Rx Complaints and Grievances policy, which is available on the Medi-Cal Rx website as well as in DMHC's APL 20-035 (OPL): Medi-Cal Pharmacy Benefit Carve Out - Medi-Cal Rx.[30]

The following outlines Medi-Cal Rx complaint and grievance processing requirements, which are intended to help manage transitional responsibilities for pharmacy-related complaints and grievances:

[30] The Medi-Cal Rx Complaints and Grievances policy document is available on DHCS' website at: https://www.dhcs.ca.gov/provgovpart/pharmacy/Documents/MRX-Complaints-and-Grievances-08-25-2020.pdf.

- Pharmacy-related complaints and grievances for services rendered or requested on or before December 31, 2021, by an MCP, which are services the MCP was at risk for, must be fully adjudicated by the MCP in accordance with APL 21-011 or any superseding APL.
- Pharmacy-related complaints and grievances received on or after January 1, 2022, by the Medi-Cal Rx CSC for services provided by an MCP on or before December 31, 2021, will be transferred by the Medi-Cal Rx CSC to the appropriate MCP CSC for full resolution. The Medi-Cal Rx CSC will advise MCP members that they should contact their MCP for such pharmacy-related complaints and grievances. Complaints and grievances received via phone or secure chat will be appropriately triaged and referred by the Medi-Cal Rx CSC to the MCP via phone once they are determined to be an MCP complaint or grievance. The Medi-Cal Rx will make best efforts to immediately forward complaints and grievances for timely and accurate resolution by the appropriate MCP. Complaints and grievances received in writing, will be appropriately triaged and mailed or faxed within three (3) calendar days.
- The right of MCP members to submit complaints and grievances to their MCPs for pharmacy-related services rendered on or before December 31, 2021, are not impacted by Medi-Cal Rx.
- Pharmacy-related complaints and grievances, received by an MCP for Medi-Cal Rx services provided on or after January 1, 2022, must be transferred by the MCP to the Medi-Cal Rx CSC for resolution. Complaints and grievances coming in via phone or secure chat must be appropriately triaged and referred to the Medi-Cal Rx CSC via phone once they are determined to be an MCP complaint or grievance. MCPs must make best efforts to immediately forward complaints and grievances for timely and accurate resolution by the Medi-Cal Rx CSC. Complaints and grievances received in writing must be appropriately triaged and mailed or faxed to the Medi-Cal Rx CSC within three (3) calendar days.

Medi-Cal Rx Member Appeals

For pharmacy-related services covered under Medi-Cal Rx requested on or after January 1, 2022, all MCP member appeals involving disagreement with benefit-related decisions, such as coverage disputes, disagreeing with and seeking reversal of a request for PA involving medical necessity, etc., that are associated with a Notice of Action (NOA) will be adjudicated through the existing SFH process. Although the Medi-Cal Rx CSC will not be involved in resolving member appeals issues, please note that contacting the Medi-Cal Rx CSC to ask questions, seek clarification on the NOA contents, or provide additional information will not impact the member’s right to pursue a fair hearing.

For more information about the Medi-Cal Rx SFH appeals process, please see DHCS' existing SFH policy and processes which are available on the DHCS and California Department of Social Services' (CDSS) websites, respectively.[31, 32] Please refer to DMHC's APL 20-035 (OPL): Medi-Cal Pharmacy Benefit Carve Out - Medi-Cal Rx for additional information related to member appeals.

MCPs must resolve all MCP member appeals that originated as a result of an MCP decision relative to pharmacy-related services for which the MCP was at risk on or before December 31, 2021, in accordance with APL 21-011 or any superseding APL. The right of MCP members to submit appeals to DMHC, including but not limited to the right to Independent Medical Review (IMR), for MCP services rendered on or before December 31, 2021, are not impacted by Medi-Cal Rx.

Provider Claim Appeals

Provider claim appeals are a method to resolve claim payment problems (e.g., resubmission, non-payment, underpayment, overpayment, etc.). Post-transition on January 1, 2022, DHCS' Medi-Cal Rx Provider Claim Appeals policy aligns with and builds upon existing Medi-Cal FFS processes and protocols for the Medi-Cal program. Providers will complete the Medi-Cal Rx Provider Appeal form and submit the completed form to:

Medi-Cal Rx CSC, Provider Claims Appeals Unit
P.O. Box 610
Rancho Cordova, CA, 95741-0610.

Once the Medi-Cal Rx Provider Appeal form is submitted, Medi-Cal Rx will acknowledge each appeal within 15 days of receipt and make a decision within 45 days of receipt. If Medi-Cal Rx is unable to make a decision within this time period, the appeal is referred to the professional review unit for an additional 30 days. If the appealed claim is approved for reprocessing, it will appear on a future Remittance Advice Details. The reprocessed claim will continue to be subject to Medi-Cal policy and claims processing criteria and could be denied for a separate reason.

Medi-Cal Rx will send a letter of explanation in response to each appeal. Providers who are dissatisfied with the decision may submit subsequent appeals, as stated in the

[31] DHCS' SFH webpage is available at: https://www.dhcs.ca.gov/services/medi-cal/Pages/Medi-CalFairHearing.aspx
[32] CDSS' Hearing page is available at: https://www.cdss.ca.gov/hearing-requests

Provider Appeals policy, to be published not later than December 31, 2021.[33] Medi-Cal Providers also retain their right to seek judicial review of an appeal determination, as authorized under state law.[34]

More information about the Medi-Cal Rx Provider Appeal process, including to access the Medi-Cal Rx Provider Appeal form, will be provided before December 31, 2021, on the Medi-Cal Rx website.

For provider claim appeals that originated pre-transition as a result of an MCP decision, but were delayed until post-transition to Medi-Cal Rx (e.g., they were in process but not fully resolved, delayed filing, etc.), the following outlines how those issues are to be handled:

- MCPs will be responsible for resolving all provider claim appeals for claims with dates of service prior to January 1, 2022. To help ensure a smooth transition and reduce administrative burden, MCPs should attempt to adjudicate and close all open pre-transition provider claim appeals prior to January 1, 2022.
- MCPs must resolve all remaining open pre-transition provider claims appeals.
- Any provider claim appeal received by Medi-Cal Rx for a pharmacy claim adjudicated by the MCP prior to January 1, 2022, will be routed to the MCP for resolution.

Provider PA Appeals

Providers can appeal Medi-Cal Rx PA denials, delays and modifications.[35] Providers will submit appeals of PA adjudication results, clearly identified as appeals, to:

Medi-Cal Rx CSC, Provider Claims Appeals Unit
P.O. Box 610
Rancho Cordova, CA, 95741-0610.

Medi-Cal Rx will acknowledge each submitted PA appeal within three (3) days of receipt and make a decision within 60 days of receipt. Medi-Cal Rx will send a letter of explanation in response to each PA appeal. Providers who are dissatisfied with the decision may submit subsequent appeals. Medi-Cal providers may seek a judicial

[33] See the Medi-Cal Rx webpage for more information, available at: https://medi-calrx.dhcs.ca.gov/home/
[34] Welfare and Institutions Code (WIC) section 14104.5. WIC is searchable at: http://leginfo.legislature.ca.gov/.
[35] WIC section 14133.05.

review of the appeal decision, as authorized under state law.[36] For more information about the Medi-Cal Rx provider PA appeal process, please visit the Medi-Cal Rx website.

Provider PA appeals that originated pre-transition as a result of an MCP decision, but were delayed until post-transition to Medi-Cal Rx (e.g., they were in process but not fully resolved, delayed filing, etc.), will be handled as follows:

- MCPs will be responsible for resolving all provider PA appeals for PAs with dates of submission on or before December 31, 2021, in accordance with APL 21-011 or any superseding APL.
- To help ensure a smooth transition and reduce administrative burden, MCPs must attempt to adjudicate and close all open pre-transition provider PA appeals prior to January 1, 2022.
- MCPs must resolve all remaining open pre-transition provider PA appeals.
- Any provider PA appeal received by Medi-Cal Rx for a pharmacy PA adjudicated by the MCP prior to January 1, 2022, will be routed to the MCP for resolution.

Post-Transition Monitoring

DHCS will prepare a Post-Transition Monitoring Plan in collaboration with Magellan and MCPs to identify a phased approach to monitoring Medi-Cal Rx transition performance. This plan will focus on available data and tools to monitor key operational and clinical performance measures, related to Medi-Cal Rx and MCP operations. This will allow for timely and effective actions focused on optimizing member care, member experience, and operational effectiveness during the transition.

MCPs are encouraged to participate in the development and execution of the plan, to the extent possible and reasonable, to the benefit of their members as well as prescribers, pharmacies, and others impacted by Medi-Cal Rx.

DHCS and DMHC APL Guidance

On October 6, 2020, DMHC issued an APL on Medi-Cal Rx (APL 20-035 (OPL): Medi-Cal Pharmacy Benefit Carve Out - Medi-Cal Rx) specific to various MCP regulatory and compliance requirements for the transition. This DHCS Medi-Cal Transition APL 21-018 incorporates all of those provisions by reference. For more information, please see DMHC's APL[37].

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[36] WIC section 14133.05.

[37] DMHC's Medi-Cal Rx Transition APL 20-035 is available on DMHC's website at: https://www.dmhc.ca.gov/Portals/0/Docs/OPL/APL%2020-035%20-%20Medi-

Existing DHCS APL/PL Policy

To assist MCPs in understanding Medi-Cal Rx considerations related to existing APL and PL guidance, the following table provides supplementary guidance to assist with the Medi-Cal Rx transition. To the extent any existing APLs or PLs have inconsistent provisions specific to the Medi-Cal pharmacy benefit, this APL supersedes all inconsistencies in prior APLs or PLs. For more information, please see DHCS' APL and PL websites as well as the Medi-Cal Rx Scope Summary section of this APL.

APL / PL	Summary
APL 21-006 Network Certification Requirements	DHCS is currently updating the requirements for Annual Network Certifications to exclude pharmacies from the assessment; therefore, MCPs will not be required to contract with pharmacies for network certification purposes. Refer to APL 20-035 (OPL): Medi-Cal Pharmacy Benefit Carve Out - Medi-Cal Rx "Network Adequacy" section for additional guidance.
APL 19-017 Quality and Performance Improvement Requirements	DHCS will provide further instruction regarding Quality and Performance Improvement Requirements in the form of annual updates to this APL that DHCS will release prior to each RY.
APL 17-018 Medi-Cal Managed Care Health Plan Responsibilities for Outpatient Mental Health Services	Refer to the Medi-Cal Rx Scope Summary section of this APL to determine carved-out pharmacy services in support of outpatient mental health services. Per existing guidance to MCPs, DHCS is responsible for ensuring compliance with mental health parity provisions for drugs carved-out through specific contract agreements between MCPs and DHCS. Provider manual updates related to APL 17-018 are also underway.
APL 17-010 Non-Emergency Medical and Non-Medical Transportation Services	NMT Prior to the Medi-Cal Rx transition, MCPs are required to provide NMT services for members to access all Medi-Cal covered services, including those services that are carved-out of the MCP's contract. Post-transition, MCPs must continue to provide NMT services for members to access all Medi-Cal covered

Cal%20Pharmacy%20Benefit%20Carve%20Out%20-%20Medi-Cal%20Rx%20(10_6_2020).pdf?ver=2020-10-06-165704-497

APL / PL	Summary
	services, including those services that are carved-out of the MCP's contract. This includes pharmacy trips for medications that are carved-out under Medi-Cal Rx. NEMT Prior to the Medi-Cal Rx transition, MCPs are only required to provide clinically appropriate NEMT services for members to access Medi-Cal covered services that are carved-in to the MCP's contract. For carved-out services, MCPs are generally only required make a best effort to refer for and coordinate NEMT. Post-transition and ongoing thereafter, in an effort to ensure a smooth and effective transition and prevent against any disruption to care and/or access issues, DHCS is requiring MCPs to continue to provide NEMT services for pharmacy trips for medications that are carved-out under Medi-Cal Rx. DHCS is in the process of updating APL 17-010 to include this updated policy. MCPs will continue to be capitated for NEMT services for pharmacy trips for medications that are carved-out under Medi-Cal Rx, and DHCS will make any necessary rate adjustments as part of its standard processes. MCPs will have access to real-time claims and PA data through the Medi-Cal Rx portal that will identify the dispensing pharmacy.
APL 17-008 Requirement to Participate in the Medi-Cal Drug Utilization Review Program	Refer to DMHC's APL 20-035 (OPL): Medi-Cal Pharmacy Benefit Carve Out - Medi-Cal Rx "Utilization Management" and "Medi-Cal Rx Contractor Roles and Responsibilities" for guidance regarding the DUR. Also refer to DUR participation information in the Post-Transition section of this APL.
APL 21-011 Grievance and Appeal Requirements and Revised Notice Templates and "Your Rights" Attachments	Refer to DMHC's APL 20-035 (OPL): Medi-Cal Pharmacy Benefit Carve Out - Medi-Cal Rx "Grievances & Appeals" section for guidance regarding Grievances and Appeals.

APL / PL	Summary
	Also refer to the “Complaints & Grievances”, “Member Appeals”, and “Provider Appeals” guidance in the Post-Transition section of this APL.
APL 16-014 Comprehensive Tobacco Prevention and Cessation Services for Medi-Cal Beneficiaries	The Medi-Cal pharmacy benefit covers all FDA-approved products for smoking cessation. They will all be carved-out to Medi-Cal Rx when dispensed and billed by an enrolled Medi-Cal pharmacy provider. Medical providers can also legally provide them to their patients. MCPs will be responsible for these medical claims just as they would be for any other claim billed by a non-pharmacy provider.
APL 16-010 Medi-Cal Managed Care Health Plan Pharmaceutical Formulary Comparability Requirement	Refer to DMHC’s APL 20-035 (OPL): Medi-Cal Pharmacy Benefit Carve Out - Medi-Cal Rx “Standard Formulary Template" section for additional guidance regarding formularies. APL 16-010 will be retired by DHCS on December 31, 2021.
APL 16-009 Adult Immunizations as a Pharmacy Benefit	Adult immunizations billed on pharmacy claims by an enrolled Medi-Cal pharmacy provider are in scope for Medi-Cal Rx. The professional services provided by a pharmacist pursuant to AB 1114, including the consultation, assessment of need, and the administration of the injection will all remain the responsibility of the MCP when provided in an outpatient pharmacy setting.
APL 16-004 Medi-Cal Managed Care Health Plans Carved-Out Drugs	APL 16-004 will be superseded by DHCS to align with the current Medi-Cal Rx Scope Summary section of this APL.
APL 15-012 Dental Services - Intravenous Sedation and General Anesthesia Coverage	In response to related questions by MCPs, intravenous sedation and general anesthesia must be administered by a doctor and are never self-administered. These drugs are not currently part of the pharmacy benefit and will not be covered under Medi-Cal Rx.
APL 07-002 Conlan v. Bonta; Conlan v. Shewry: Court Ordered Medi-Cal Beneficiary	All initial claim requests for Beneficiary Reimbursement (“Conlan claims”) are currently received by DHCS’ California Medicaid Management Information Systems (CA-MMIS) division. CA-MMIS triages and refers these claim requests to the DHCS

APL / PL	Summary
Reimbursement Process APL	program and/or external organization responsible for processing (e.g., individual MCPs, other fiscal intermediaries, etc.). Starting January 1, 2022, CA-MMIS will continue its intake responsibilities to triage and refer initial claim requests for pharmacy services administered by Medi-Cal Rx to the Medi-Cal Rx CSC for processing and final disposition. All initial claim requests for beneficiary reimbursement for pharmacy services rendered on or before December 31, 2021, that are received on or after January 1, 2022, will be triaged and referred by CA-MMIS to the DHCS program and/or external organization responsible on the date of service, which can and will include MCPs.
APL 06-010 Quality and Performance Improvement Program Requirements for 2007	HEDIS rates for Outpatient Drug Utilization services are not required since these services are carved-out to Medi-Cal Rx. Also, this APL was specific to the Quality and Performance Improvement Program Requirements for 2007.
APL 06-008 Contraceptive Devices	The APL 06-008 Standard of Care Policy is not in conflict with Medi-Cal Rx as APL 06-008 cites state law that allows for carve-out of outpatient prescription drug benefits while also providing requirements for MCPs who may pursue a partial carve-out as Medi-Cal Rx scope allows.
PL 14-003 Enteral Nutrition Products	Refer to the Medi-Cal Rx Scope Summary section of this APL for carve-out guidance to address MCP responsibilities for authorizing and paying for the formula, pumps, and tubing identified in PL 14-003.
PL 12-005 Enteral Nutrition Products (supersedes PL 07-006 and PL 07-016) PL 12-005	PL 12-005 is written in a manner where provision of formula through Medi-Cal Rx would comport with the PL as written. Refer to the Medi-Cal Rx Scope Summary section of this APL for carve-out guidance to address MCP responsibilities for authorizing and paying for formula.

In addition to the impacts described for the APLs and PLs in the prior table, additional APLs and PLs have been targeted for retirement by December 31, 2021. These APLs and PLs are listed below:

APL 18-013	Hepatitis C Virus Treatment
APL 16-010	Medi-Cal Managed Care Health Plan Pharmaceutical Formulary Comparability Requirement
APL 08-013	Pharmacy Prior Authorization Requests by California Licensed Pharmacists
APL 06-008	Contraceptive Devices
APL 05-012	Medicare Modernization Act; Medicare Part D Prescription Drug
APL 03-010	Medi-Cal Managed Care Plan Requirements for Provision of Contraceptive Drug Services and Supplies
APL 03-004	Medi-Cal Managed Care Health Plan Capitated and Non-Capitated Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome (HIV/AIDS) and Antipsychotic Drugs

If the requirements contained in this APL, including any updates or revisions to this APL, necessitate a change in an MCP's policies and procedures (P&Ps), the MCP must submit its updated P&Ps to its Managed Care Operations Division (MCOD) contract manager by April 1, 2022. If an MCP determines that no changes to its P&Ps are necessary, the MCP must submit an email confirmation to its MCOD contract manager by April 21, 2022, stating that the MCP's P&Ps have been reviewed and no changes are necessary. The email confirmation must include the title of this APL as well as the applicable APL release date in the subject line.

MCPs are responsible for ensuring that their Subcontractors and Network Providers comply with all applicable state and federal laws and regulations, contract requirements, and other DHCS guidance, including APLs and PLs. These requirements must be communicated by each MCP to all Subcontractors and Network Providers.

If you have any questions regarding this APL, please contact your MCOD Contract Manager.

Sincerely,

Original Signed by Dana Durham

Dana Durham, Chief
Managed Care Quality and Monitoring Division

POLICY

Santa Clara Family Health Plan

Policy Title:	**Drug Management Program**	**Policy No.:**	PH.12
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 framework of the Plan's Drug Management Program (DMP)

II. Policy

A. SCFHP maintains written procedures on how the DMP addresses overutilization of frequently abused drugs while maintaining access to such drugs as medically necessary
B. SCFHP defines how members are identified as potential at-risk beneficiaries (PARB) and at-risk beneficiaries (ARB)
C. SCFHP ensures that all ARBs are included in medication therapy management (MTM) program targeting
D. SCFHP ensures that the clinical staff conducting case management services for DMP members have appropriate credentials with a current and unrestricted license to practice within the scope of their profession in California
E. SCFHP defines all written and oral communications with members and their prescribers regarding the DMP and any coverage limitations, including appropriate and accurate documentation of all outreach conducted
F. SCFHP shall report all decisions to impose coverage limitation(s) to the Centers for Medicare and Medicaid Services (CMS)
G. SCFHP shall respond to requests from other Part D sponsors for information about PARBs and ARBs who recently disenrolled from SCFHP and will document such communications and transfers of information.

III. Responsibilities

A. Director of Pharmacy, or designee, will ensure continuous quality improvement for pharmacy services.

IV. References

A. CMS 2021 Part D Drug Management Program Guidance
B. Announcement of Calendar Year (CY) 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter, April 1, 2019
C. Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance, January 1, 2020

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)**	
1	Original	Pharmacy & Therapeutics Committee	Pending 3Q21	

Drug Utilization Evaluation (DUE) Outcomes

Polypharmacy DUE

Polypharmacy: Identify members receiving more than 10 unique, chronic mediations from 3 or more prescribers over a 3-month time period.

Cal MediConnect =

- 511 members identified (1/1/2021 to 3/31/2021)
- 247 prescriber letters sent (5/21/21)
- 504 members still active in follow up period (7/1/2021 to 9/30/2021)
- 194 members no longer identified in follow up period
- **Polypharmacy DUE = 38% success rate**

Emergency Prescription Access Report
3rd 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 Q3 2020, SCFHP had total 15,834 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	754	158	872	1030
Non-Delegated	1207	873	871	1,744
Valley Health Plan	6939	4,429	5,443	9,872
Palo Alto Medical Foundation	260	131	217	348
Physician Medical Group	1,859	1,130	1309	2,439
Premier Care	330	216	185	401
Grand Total	11/349	6,937	8,897	15,834

Section 2 – Diagnosis

Table 2: Key Diagnosis

		3Q2020		
Code	Diagnosis	Rx	No Rx	% Rx
N390	UTI, SITE NOT SPEC	196	88	69%

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**	Regional Medical Center of SJ	**1**
Grand Total			**1**

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

Denied Claims

We excluded those members who had primary insurance coverage outside of SCFHP. There were no inappropriate denied claims.

No Claims

88 unique members diagnosed with UTI ER claims did not result in a prescription processed within 72 hours. We initially excluded 33 members with primary insurance coverage outside of SCFHP from this analysis. We subsequently randomly chose a sample of approximately 20% of 55 members, which is 11 total members, using Excel. We requested 10 chart notes from different hospitals. We received and reviewed 4 charts. Findings are presented below.

Mbr	Hospital	DOS	Findings
1	O'connor Hospital	09/10/2020	Chart reviewed - RX for Cephalexin 500mg cap, #28 per 7 days
2	SCVMC	08/25/2020	Chart reviewed- Ceftriaxone 1 gram IV x1 ED. Sulfamethoxazole-TMP DS tab filled #14/7 on 09/02/2020
3	SCVMC	07/07/2020	Chart reviewed – Per Nurse Practitioner, pt on Bactrim which is resistant, called in new prescription. Reversed claim for Cephalexin 500mg cap #40/10 on 7/13/2020
4	SCVMC	07/28/2020	Chart reviewed - incomplete
5	Good Samaritan Hospital	07/04/2020	Cefdinir 300mg cap filled #20/10 on 7/12/2020. No chart received.
6	Regional Medical Center of SJ	08/03/2020	Ciprofloxacin 500mg tab, #14/7 on 9/10/2020. No chart received.

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. Approved claims were appropriate. There were no inappropriate denied claims. For no claims, there were no issues with the completed charts that were reviewed.

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.

Emergency Prescription Access Report
4th 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 Q4 2020, SCFHP had total 15,980 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	830	152	979	1131
Non-Delegated	1346	915	969	1,884
Valley Health Plan	6,964	4,042	5,357	9,399
Palo Alto Medical Foundation	283	134	243	377
Physician Medical Group	2,061	1176	1,498	2,674
Premier Care	422	230	285	515
Admin-Medi-Cal Only	38	30	25	55
Grand Total	11,906	6,031	6,834	15,980

Section 2 – Diagnosis

Table 2: Key Diagnosis

		4Q2020		
Code	Diagnosis			
N390	UTI, SITE NOT SPEC	165	64	72%

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**	Memorial Hospital Los Banos	**1**
	1	Regional Medical Center of SJ	**1**
	1	El Camino Hospital-Mountain View	**1**
Nitrofurantoin 25mg/5mL suspension	**1**	SCVMC Acute Care Hospital	**1**
Grand Total			**4**

We did not identify any issues with approved claims. Fluconazole was appropriately written for a 1 day supply for 3 prescriptions. 1 patient had an approved claim for nitrofurantoin 25mg/5mL suspension, #40 mL for 1 day (200mg/day). Per chart note, patient with UTI, given nitrofurantoin monohydrate 100mg capsule x1 in the ED. Per Nurse Practitioner's conversation with the patient, patient has been taking Macrobid outpatient but wanted to switch to liquid form, hence, Macrobid liquid prescription was given.

Denied Claims

We excluded those members who had primary insurance coverage outside of SCFHP. There were no inappropriate denied claims.

No Claims

64 unique members diagnosed with UTI ER claims did not result in a prescription processed within 72 hours. We initially excluded 36 members with primary insurance coverage outside of SCFHP from this analysis. We subsequently randomly chose a sample of approximately 20% of 28 members, which is 6 total members, using Excel. We requested 6 chart notes from different hospitals. We received and reviewed 2 charts. 1 chart for a member with primary Medicare part D states levofloxacin 750mg IV x1 given in ED, and Rx for ciprofloxacin 500mg, #20/10 days. Findings for the Medi-Cal members are presented below.

Mbr	Hospital	DOS	Findings
1	Regional Medical Center of SJ	11/04/2020	Nitrofurantoin 100mg cap filled for #6/3 days on 10/26/2020
2	SCVMC	10/02/2020	Chart note reviewed. Urinalysis result negative for UTI

Section 4 – Pharmacies

Pharmacy Locations

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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. Approved claims were appropriate. There were no inappropriate denied claims. For no claims, we did not receive all the chart notes we requested. For the ones that were received, they were appropriate.

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.

3rd Quarter 2021

Qulipta (migraine prevention) –C
Comirnaty (COVID prevention) –BT
Korsuva (pruritus with HD) -BT
Livmarli (Alagille syndrome) –BT
Rolontis*
roxadustat*

1st Quarter 2022

cabotegravir (HIV PrEP) –BT†
Cilta-cel (multiple myeloma)-BT†
lenacapavir (HIV Tx) –C
inclisiran (hypercholesterolemia)–C
mavacamten (obstructive cardiomyopathy) –BT
tezepelumab (severe asthma) –BT

3rd Quarter 2022

tirzepatide (DMT2) –C
adagrasib (NSCLC) –C

3Q21 | 4Q21 | 1Q22 | 2Q22 | 3Q22+

4th Quarter 2021

Tavneos (ANCA vasculitis) -BT
bimekizumab (plaque psoriasis) -C
Cibinqo, Olumiant & Rinvoq (atopic derm.) –C
efgartigimod (myasthenia gravis)-BT†
Scemblix (chronic myelogenous leukemia) –C
Verzenio (breast cancer) –NI
vosoritide (achondroplasia) -BT

2nd Quarter 2022

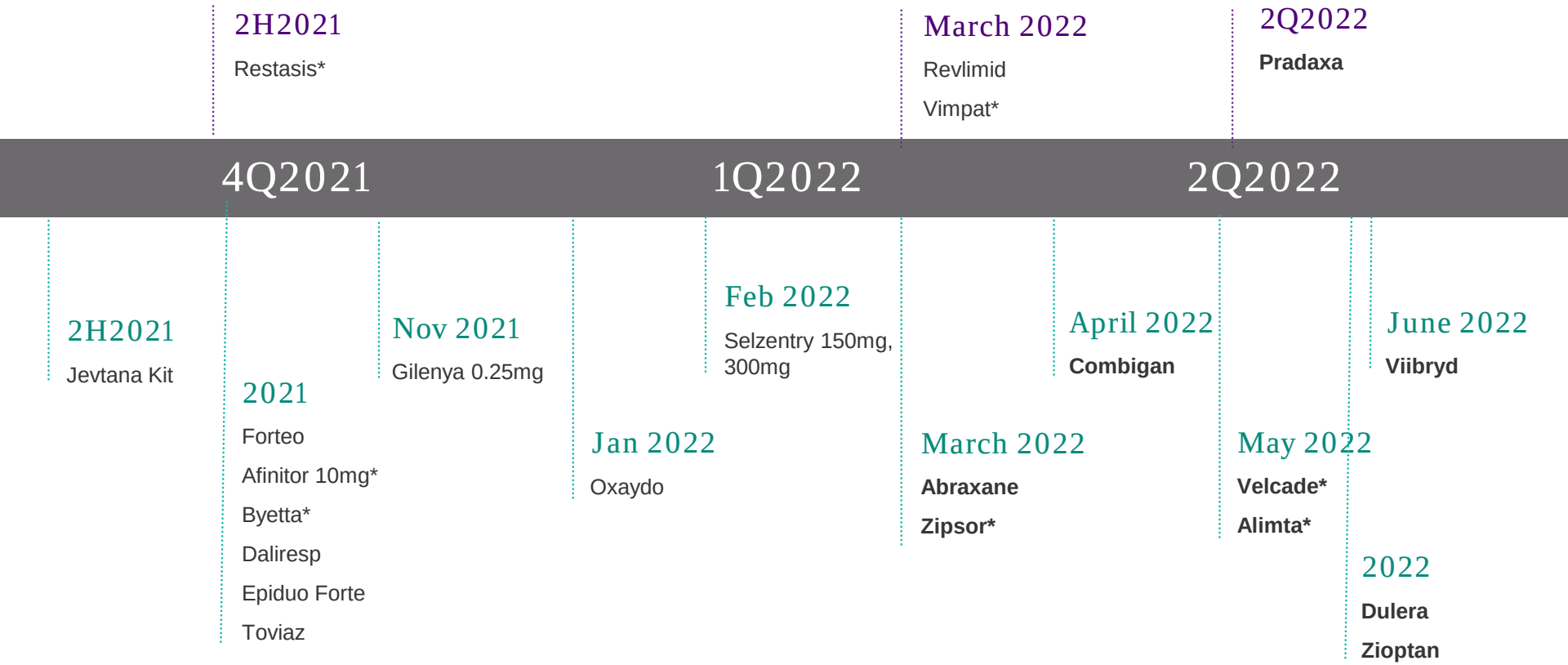
NOT YET FILED
adagrasib (KRAS G12C NSCLC) –C

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
# = Emergency Use Authorization

Generic pipeline.

High impact



Medium/Low impact

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