AGENDA

For a Regular Meeting of the

Santa Clara County Health Authority
Pharmacy and Therapeutics Committee

Thursday, September 20, 2018, 6:00-8:00 PM
Santa Clara Family Health Plan, Boardroom Conference Room
6201 San Ignacio Blvd., San Jose, CA 95119

VIA TELECONFERENCE AT:
12340 Lakewood Blvd.
Downey, CA 92042

1.	**Introductions**	Dr. Robertson	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 public comment period to 30 minutes.	Dr. Robertson	6:05	5 min.
3.	**Meeting Minutes** Review SCFHP 2Q2018 P&T minutes. **Possible Action:** Approve minutes	Dr. Robertson	6:10	5 min.
4.	**Plan Updates**			
	a. CMO Health Plan Updates	Dr. Robertson	6:15	3 min.
	b. Appeals & Grievances	Mr. Breakbill	6:18	3 min.
	c. SCFHP Global DUR	Dr. Liu	6:21	1 min.
	d. Annual Charter Review		6:22	2 min.
	e. DHCS Hepatitis C Policy Update	Dr. Huynh	6:24	2 min.
	f. 2019 CMC Transition Fill Policy **Possible Action:** Approve 2019 CMC Transition Fill Policy		6:26	2 min.
	g. 2019 CMC Opioid Strategy		6:28	2 min.

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

5. **Metrics & Financial Updates**

a.	Membership Report	Dr. Robertson	6:30	3 min.
b.	Pharmacy Dashboard	Dr. Otomo	6:33	3 min.
c.	Drug Use Evaluation Results	Dr. McCarty	6:36	2 min.
d.	Drug Utilization & Spend	Dr. McCarty	6:38	10 min.

6. **Discussion and Recommendations for changes to SCFHP Cal MediConnect Formulary & Prior Authorization Criteria**

a.	MedImpact 2Q2018 P&T Meetings Minutes	Dr. Huynh	6:48	2 min.
b.	MedImpact 3Q2018 P&T Part D Actions		6:50	2 min.

Possible Action: Approve MedImpact Minutes & Actions

7. **Discussion and Recommendations for Changes to SCFHP Medi-Cal & Healthy Kids Formulary & Prior Authorization Criteria**

a.	Formulary Modifications	Dr. Otomo	6:52	8 min.

Possible Action: Approve formulary recommendations

b.	DHCS Medi-Cal CDL Updates & Comparibility	Dr. McCarty	7:00	5 min.

Possible Action: Approve formulary recommendations

c. Prior Authorization Criteria — Dr. Nguyen — 7:05 — 10 min.

i. New & Changes to Criteria
   1. Retacrit (New)
   2. Hepatitis C
   3. Humira
   4. Enbrel
   5. Myrbetriq
   6. Nicotrol

ii. Annual Review – No Changes — Dr. Nguyen — 7:15 — 2 min.
   1. Proventil
   2. Emend
   3. Penlac
   4. Duragesic
   5. Brand Name
   6. Compounded Medications
   7. Off-label
   8. Opioid Reauthorization

Possible Action: Approve prior authorization criteria

d. New Drugs and Class Reviews

i.	New drugs & line extension	Dr. McCarty	7:17	10 min.
ii.	Biosimilar Update – Retacrit & Fulphila		7:27	10 min.
iii.	HAE – Takhzyro		7:37	5 min.
iv.	hATTR – Onpattro		7:42	3 min.
v.	Continous Glucose Monitoring (CGM)		7:45	10 min.

Reconvene in Open Session

Discussion Items

8.	New Brand and Generic Pipeline	Dr. McCarty	7:55	5 min.

Adjournment

9. Next meeting Thursday, December 13, 2018

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.

- In compliance with the Americans with Disabilities Act, those requiring accommodations in this meeting should notify Caroline Alexander 48 hours prior to the meeting at 408-874-1835.

- To obtain a copy of any supporting document that is available, contact Caroline Alexander 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 Avenue, San Jose.

- This agenda and meeting documents are available at www.scfhp.com

Meeting Minutes

Santa Clara Family Health Plan

Regular Meeting of the
Santa Clara County Health Authority d.b.a. Santa Clara Family Health Plan
OPEN SESSION - **Pharmacy & Therapeutics Committee**
Thursday, June 21, 2018
6:00 PM - 8:00 PM
210 E. Hacienda Avenue Campbell, CA 95008

MINUTES

Voting Committee Members	Specialty	Present (Y or N)
Jimmy Lin, MD	Internal Medicine	Y
Hao Bui, BS, PharmD	Community Pharmacy (Walgreens)	N
Minh Thai, MD	Family Practice	N
Amara Balakrishnan, MD	Pediatrics	N
Peter Nguyen, MD	Family Practice	Y
Jesse Parashar-Rokicki, MD	Family Practice	Y
Narinder Singh, PharmD	Health System Pharmacy (SCVMC)	Y
Ali Alkoraishi, MD	Adult & Child Psychiatry	Y
Dolly Goel, MD	VHP Chief Medical Officer	Y
Xuan Cung, PharmD	Pharmacy Supervisor (VHP)	Y
Johanna Liu, PharmD, MBA	SCFHP Director of Quality and Pharmacy	Y
Jeff Robertson, MD	SCFHP Chief Medical Officer	Y

Non-Voting Committee Members	Specialty	Present (Y or N)
Lily Boris, MD	SCFHP Medical Director	N
Caroline Alexander	SCFHP Administrative Assistant, Medical Management	Y
Tami Otomo, PharmD	SCFHP Clinical Pharmacist	Y
Duyen Nguyen, PharmD	SCFHP Clinical Pharmacist	Y
Dang Huynh, PharmD	SCFHP Pharmacy Manager	Y
Amy McCarty, PharmD	MedImpact Clinical Program Manager	Y
Tiffanie Pham, CPhT	SCFHP Pharmacy Coordinator	Y

	Topic and Discussion	Follow-Up Action
1	**Introductions**	
	The meeting convened at 6:07 PM.	
2	**Public Comment**	
	No public comment.	
3	**Past Meeting Minutes**	
	The SCFHP 1Q2018 P&T Minutes from March 15, 2018 were reviewed by the Committee as submitted.	Upon motion duly made and seconded, the SCFHP 1Q2018 P&T Minutes from March 15, 2018 were approved as

		submitted and will be forwarded to the QI Committee and Board of Directors.
4	**Plan Updates**	
	Health Plan Updates Dr. Robertson presented the Health Plan Updates. Santa Clara Family Health Plan is moving to the new building on 50 Great Oaks in July. Discussion was had and a vote taken regarding Pharmacy Committee meeting time on a move forward basis in the new building. Proposed start meeting at 6:30 p.m. or continue to meet at 6 pm. Committee voted and it was unanimous to continue meeting at 6 p.m. Health Plan is busy working towards NCQA accreditation. Review period started June 1st. Site visit will take place in February.	
	Appeals & Grievances Dr. Huynh presented the Appeals & Grievances report Q1 2018. There was a spike in Medi-Cal appeals from December 2017 to January 2018. Q1 2018 58% overturn rate, 23% upheld, 11% partially favorable, 7% withdrawn, and 1% dismissed. For CalMediConnect (CMC), Q12018 Part C&D appeals slight increase from January 2018 to March 2018. Redeterminations Q1 2018, 70% overturned, 27% upheld, 3% partially favorable, 0% dismissed.	
	SCFHP Global DUR Dr. Liu presented and update on Global DUR. Streamlined requirements for managed Medi-Cal plans. Retrospective DUR of opioids. Concomitant use of anticholinergics and antipsychotics. Will present at Pharmacy Committee to share updates.	
	Adjourn to Closed Session Committee adjourned to closed session at 6:30 p.m. to discuss the following items: Membership Report, Pharmacy Dashboard, Drug Use Evaluation Results, Drug Utilization & Spend, Recommendations for Changes to SCFHP Cal MediConnect Formulary and Prior Authorization Criteria, Recommendations for changes to Medi-Cal and Healthy Kids Formulary and Prior Authorization Criteria, DHCS Medi-Cal CDL Updates & Comparability, Prior Authorization Criteria and New Drugs.	
5	**Metrics & Financial Updates**	
	Membership Report Dr. Robertson presented the membership report.	
	Pharmacy Dashboard Dr. Otomo presented the Pharmacy Dashboard.	

Santa Clara Family Health Plan

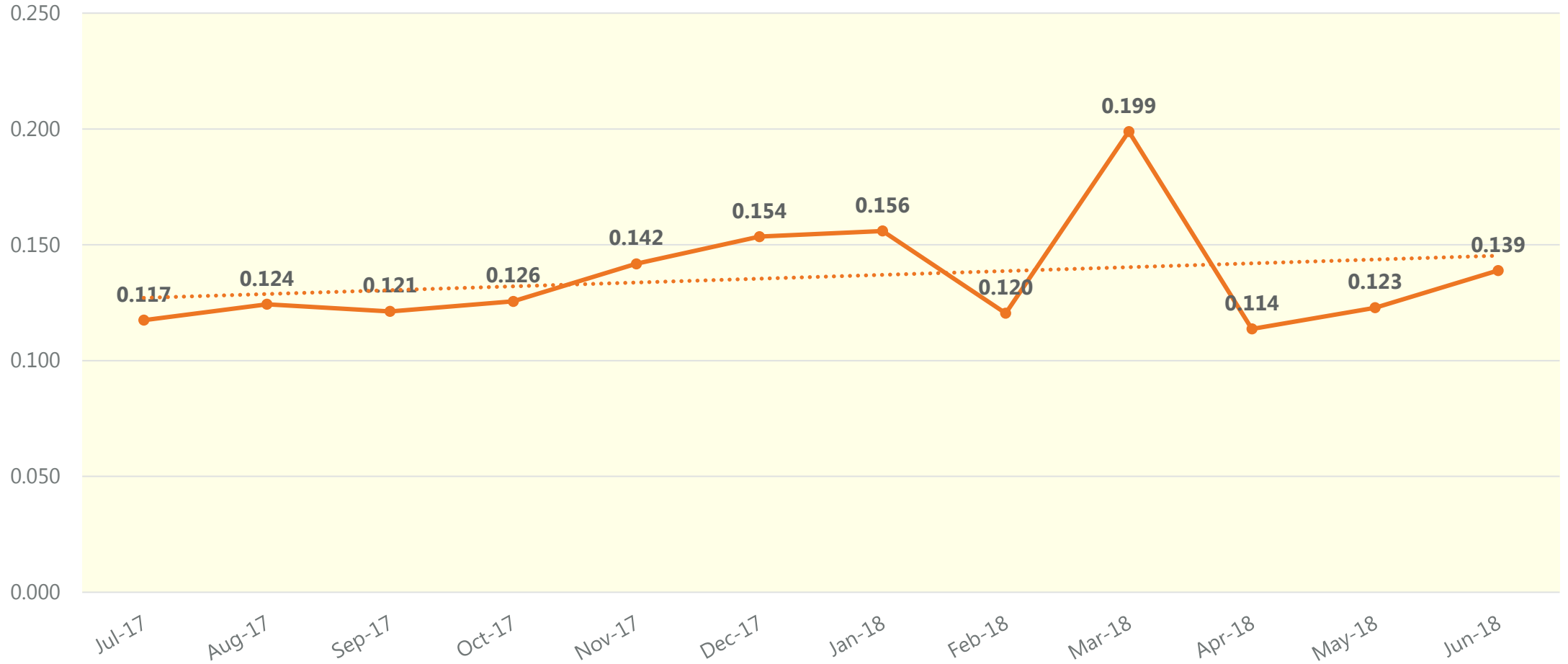
	Drug Utilization & Spend Review Dr. McCarty presented the Drug Use Evaluation Results.	
	Drug Utilization & Spend Review Dr. McCarty presented the Spend and Trend Overview.	
6	**Discussion and Recommendations for changes to SCFHP Cal MediConnect Formulary & Prior Authorization Criteria**	
	Dr. Huynh presented an overview of the MedImpact 1Q2018 P&T minutes as well as the MedImpact 2Q2018 P&T Part D Actions.	Upon motion duly made and seconded the MedImpact 1Q2018 P&T Minutes, and MedImpact 2Q2018 P&T Part D Actions were approved as submitted.
7	**Discussion and Recommendations for Changes to SCFHP Medi-Cal & Healthy Kids Formulary & Prior Authorization Criteria**	
	Formulary Modifications Dr. Otomo presented the formulary changes since the last P&T meeting.	Upon motion duly made and seconded, formulary modifications were approved as presented.
	DHCS Medi-Cal CDL Updates & Comparability Dr. McCarty presented DHCS Medi-Cal CDL Updates & Comparability.	
	Prior Authorization Criteria Dr. Duyen Nguyen presented the following PA criteria for approval by the committee: 1. Diabetic Supplies 2. Androgel 3. Humira 4. Enbrel	Upon motion duly made and seconded, prior authorization criteria were approved as presented.
	New Drugs and Class Reviews Dr. McCarty presented the following new drug reviews: 1. Aimovig 2. Erleada 3. PCSK9 Inhibitors Line Extensions: 1. Noctiva 2. Sinuva 3. Sublocade 4. Lonhala Magnair	Upon motion duly made and seconded, all recommendations were approved as presented.

	5. Firvanq 6. Bonjesta 7. Zypitamag	
	Reconvene in Open Session Committee reconvened to open session at 7:50 p.m.	
8	**Discussion Items**	
	Update on New Drugs and Generic Pipeline Dr. McCarty presented the generic pipeline for 1Q2018. High impact drugs: Symdeko, Erleada, Trogarzo, Ilumya, Andexxa, Aimovig, Epidiolex, baricitinib, lorlatinib, Nuvaring, Adcirca, Remodulin, Letairis, Ampyra, Cialis, Tracleer, Kaletra and medium/low impact drugs: Delzicol, Onexton, Zortress, Acanya, Levitra, Androgel, Moviprep, Flector, Proventil HFA, Rapaflo.	
9	**Adjournment at 7:55 PM**	

Plan Updates

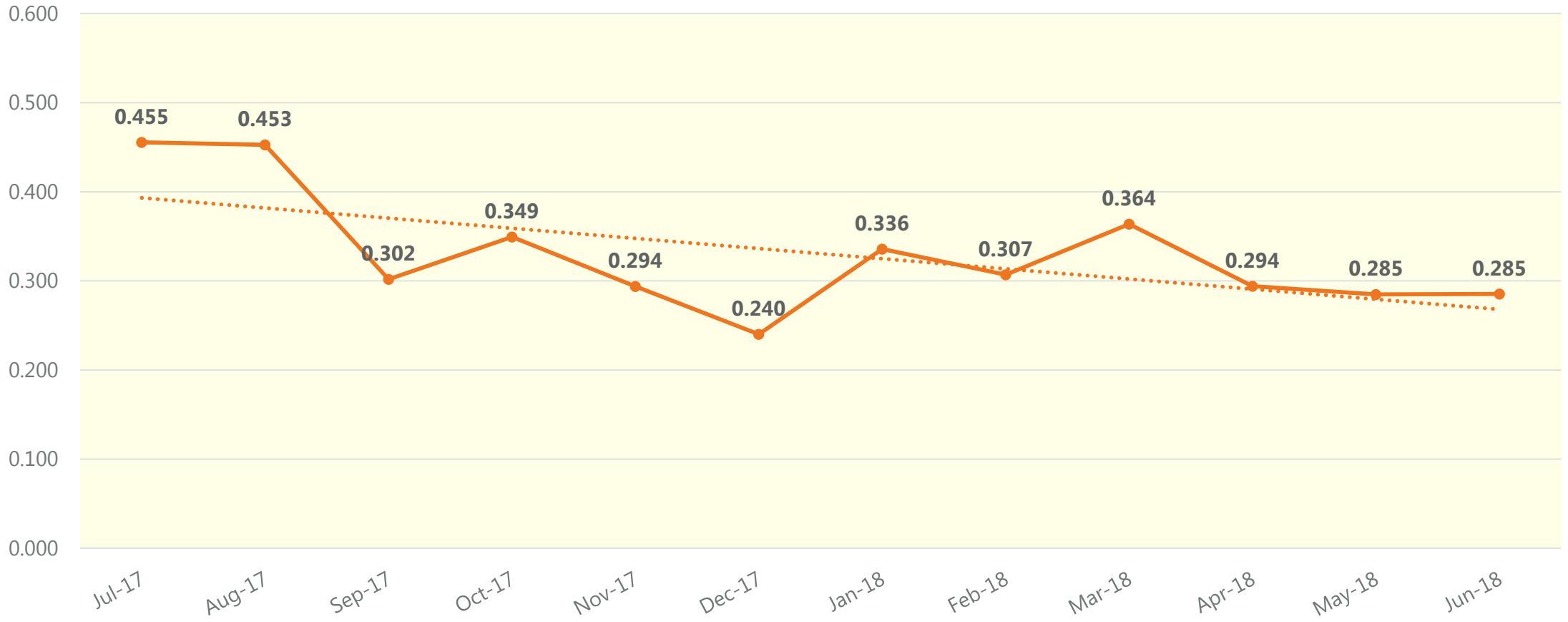
Q3 2017 – Q2 2018: Medi-Cal Appeals

Medical Appeals Per 1000 Members

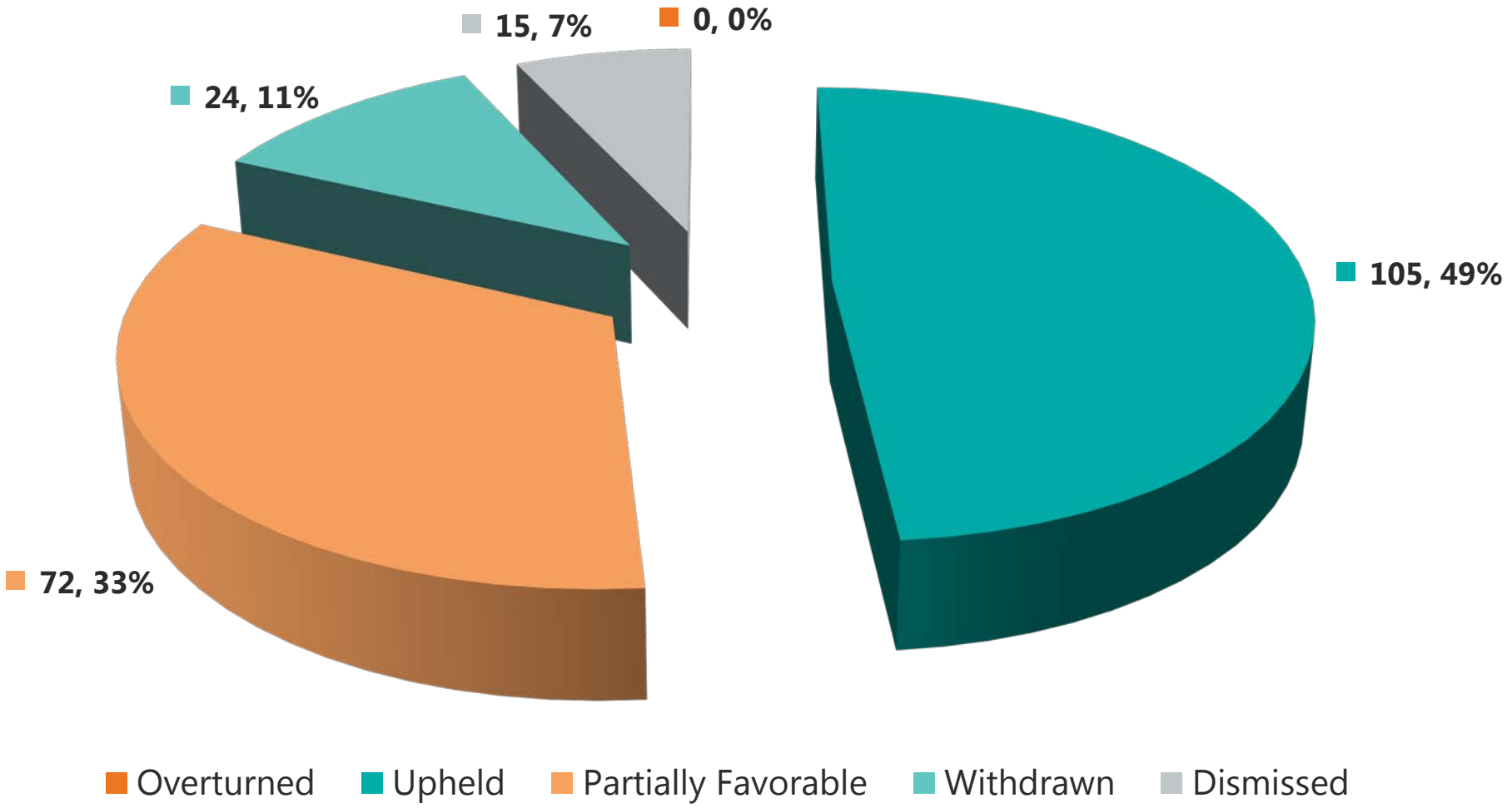


Q3 2017 – Q2 2018: Medi-Cal Appeals

Rx Appeals Per 1000 Members



Q2 2018 Pharmacy Appeals by Determinations



Santa Clara County Health Authority

Pharmacy and Therapeutics Committee Charter

Purpose

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

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

Members

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

All P&T members, including the Chairperson, shall be appointed by the Health Plan's Chief Executive Office (CEO). All P&T members, including the Chairperson, can serve up to three two-year terms. Additional terms may be appointed at the discretion of the CEO, provided that the member is in compliance with the requirements set forth in this charter.

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

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

Meetings

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

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

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

Responsibilities

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

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

Promote the delivery of quality patient care in an efficient and cost effective manner

Duration of Charter

The Director of Pharmacy, SCFHP, will review this charter annually from the date of approval.

CY Version	Change (Original/ Reviewed / Revised)	Reviewing Director of Pharmacy	Director of Pharmacy Review Date	Reviewing Committee (if applicable)	Committee Action/Date (Recommend or Approve)
2017	Revised	Johanna Liu, PharmD, MBA	09/05/2017	Pharmacy & Therapeutics Committee	09/21/2017
2018	Revised	Johanna Liu, PharmD, MBA	08/29/2018		

Treatment Policy for the Management of Chronic Hepatitis C

Effective July 1, 2018

This policy was developed by the California Department of Health Care Services (DHCS) based upon a review of the medical literature, the most recent guidelines, and reports published by the American Association for the Study of Liver Diseases (AASLD)/ Infectious Diseases Society of America (IDSA). This policy may be revised as new information becomes available.

1. Treatment considerations and choice of regimen for hepatitis C virus (HCV)-infected patients:
    A. Please refer to AASLD guidelines (hcvguidelines.org) for recommended treatment regimens and durations.

2. Identifying treatment candidates:
    A. Treatment is recommended for all patients with chronic HCV infection, except those with a short life expectancy who cannot be remediated by HCV therapy, liver transplantation, or another directed therapy.

    B. Patient readiness and adherence:
        i. Patients shall be evaluated for readiness to initiate treatment.
        ii. Patients selected for treatment shall be able and willing to strictly adhere to treatment protocols prescribed by their provider.
        iii. Caution shall be exercised with patients who have a history of treatment failure with prior HCV treatment due to non-adherence with treatment regimen and appointments.
        iv. Patients shall be educated regarding the potential risks and benefits of HCV therapy, as well as the potential for resistance and failed therapy if medication is not taken as prescribed.

C. Age requirements: Treatment candidate must be at least the minimum age approved by the FDA for use of the medication.

3. Other considerations
   A. Quantity limits:
      i. Prescription of HCV therapy will be dispensed in quantities up to 28 days at a time.

   B. Criteria for reauthorization/continuation of therapy:
      i. Initial authorization criteria have been met.
      ii. Evidence of lack of adherence may result in denial of treatment reauthorization.
      iii. Missed medical appointments related to HCV may result in the denial of treatment authorization.

   C. Laboratory testing:
      i. Documentation of baseline HCV-RNA level.
      ii. Documentation of HCV Genotype.
      iii. Laboratory testing and monitoring should be consistent with current AASLD/IDSA guidelines.

   D. Populations unlikely to benefit from HCV Treatment:
      According to AASLD/IDSA HCV guidelines, “patients with limited life expectancy for whom HCV therapy would not improve symptoms or prognosis do not require treatment. Chronic HCV is associated with a wide range of comorbid conditions. Little evidence exists to support initiation of HCV treatment in patients with limited life expectancy (less than 12 months) due to non–liver-related comorbid conditions. For these patients, the benefits of HCV treatment are unlikely to be realized, and palliative care strategies should take precedence.” In patients with a life expectancy less than 12 months, treatment is not recommended.

   E. Retreatment:
      Retreatment will be considered where there is evidence that such retreatment will improve patient outcomes. Please refer to AASLD guidelines for recommended retreatment regimens (hcvguidelines.org).

   F. Criteria for coverage of investigational services (Title 22 § 51303):
      i. Investigational services are not covered except when it is clearly documented that all of the following apply.

ii. Conventional therapy will not adequately treat the intended patient's condition.
iii. Conventional therapy will not prevent progressive disability or premature death.
iv. The provider of the proposed service has a record of safety and success with it equivalent or superior to that of other providers of the investigational service.
v. The investigational service is the lowest cost item or service that meets the patient's medical needs and is less costly than all conventional alternatives.
vi. The service is not being performed as a part of a research study protocol.
vii. There is a reasonable expectation that the investigational service will significantly prolong the intended patient's life or will maintain or restore a range of physical and social function suited to activities of daily living.
viii. All investigational services require prior authorization. Payment will not be authorized for investigational services that do not meet the above criteria or for associated inpatient care when a beneficiary needs to be in the hospital primarily because she/he is receiving such non-approved investigational services.

G. Unlabeled use of medication:
Authorization for unlabeled use of drugs shall not be granted unless the requested unlabeled use represents reasonable and current prescribing practices. The determination of reasonable and current prescribing practices shall be based upon:
i. Reference to current medical literature.
ii. Consultation with provider organizations and academic and professional specialists.

Santa Clara
Family Health Plan

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

I. Purpose

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

II. Policy

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

B. Transition of Care for State Covered Drugs
   1. The plan will apply transition of care logic to non-Part D drugs, drugs covered by the state. The logic is similar to the Part D functionality and allows new enrollees a transition fill for a defined period of time (e.g., 90 day minimum) for a specific day supply limit (e.g., 3~~10~~ day supply). These transition claims are also included in the daily notification files used for member and prescriber letter generation.

C. Transition Population

1. The plan will maintain an appropriate transition process consistent with 42 CFR §423.120(b)(3) that includes a written description of how, for enrollees whose current drug therapies may not be included in their new MMP plan's formulary, it will effectuate a meaningful transition for:
    a. new enrollees into prescription drug plans following the annual coordinated election period
    b. newly eligible Medicare Medicaid members from other coverage
    c. enrollees who switch from one plan to another after the start of a contract year
    d. enrollees residing in long-term care (LTC) facilities, and
    e. current enrollees affected by negative formulary changes across contract years.

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

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

point-of-sale overrides. The plan can also accommodate overrides at point-of-sale for emergency fills as described in section H.

F. Transition Fills for New Members in the Outpatient (Retail) Setting
   1. The plan will ensure that in the retail setting, the transition policy provides for up to a one-time, temporary ~~30~~1 month's supply- day fill (unless the enrollee presents with a prescription written for less than ~~30~~ 31 days in which case the Plan must allow multiple fills to provide up to a total of ~~30~~ 31 days of medication.) anytime during the first 90 days of a member's enrollment in a plan, beginning on the enrollee's effective date of coverage.
   2. If a brand medication is being filled under transition, the previous claim must also be brand (based on Comprehensive NDC SPL Data Elements File [NSDE] marketing status). If a generic medication is being filled under transition, the previous claim can be either brand or generic (based on NSDE marketing status)

G. Transition Fills for New Members in the LTC Setting
   1. The plan will ensure that in the long-term care setting:
      a. the transition policy provides for a ~~91 to 98~~ 1 month supply day fill consistent with the applicable dispensing increment in the long-term care setting (unless the enrollee presents with a prescription written for less), with refills provided if needed during the first 90 days of a member's enrollment in a plan, beginning on the enrollee's effective date of coverage;
      b. after the transition period has expired, the transition policy provides for a 31- day emergency supply of non-formulary Part D drugs (unless the enrollee presents with a prescription written for less than 31 days) while an exception or prior authorization is requested; and
      c. for enrollees being admitted to or discharged from a LTC facility, early refill edits are not used to limit appropriate and necessary access to their benefit, and such enrollees are allowed to access a refill upon admission or discharge.

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

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

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

K. Cost-sharing for Transition supplies

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

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

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

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

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

P. Exception Process
   1. The plan follows an overall transition plan for MMP members; a component of which includes the exception process. The plan's exception process integrates with the overall transition plan for these members in the following areas:
      a. The plan's exception process complements other processes and strategies to support the overall transition plan. The exception process follows the guidelines set forth by the transition plan when applicable.
      b. When evaluating an exception request for transitioning members, the plan's exception evaluation process considers the clinical aspects of the drug, including any risks involved in switching, when evaluating an exception request for transitioning members.

c. The exception policy includes a process for switching new MMP plan members to therapeutically appropriate formulary alternatives failing an affirmative medical necessity determination.

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

III. Responsibilities

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

IV. References

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

Discussion Items

Recently Approved Agents
&
Pipeline Agents

MedImpact

Independent, Trend-Focused
Pharmacy Benefit Manager™

Recently Approved - High Interest and Impact

May 2018 – August 2018

Entity	Disease State	FDA Approval	Route	Therapeutic Role	Net PMPM
Palynziq (pegvaliase)	Phenylketonuria (PKU)	May 24th, 2018	SQ	Additive	$0.010 – $0.015
Epidiolex (cannabidiol)	Dravet syndrome, Lennox-Gastaut syndrome	June 25th, 2018	Oral	Additive	$0.009 – $0.013
Orilissa (elagolix)	Endometriosis	July 24th, 2018	Oral	Competitor	$0.02 – $0.03
Onpattro (atisiran)	Hereditary ATTR Amyloidosis	August 10th, 2018	IV	Breakthrough Therapy	$0.03 – $0.05
Takhzyro (lanadelumab)	Hereditary angioedema (HAE)	August 23rd, 2018	SQ	Competitor	-$0.25 – $0.07

= Medical Cost

High Interest and Impact Pipeline Agents

FDA Decision Anticipated in 2018-2019

Entity	Disease State	Anticipated FDA Decision	Route	Therapeutic Role	Net PMPM
solriamfetol	Obstructive Sleep Apnea (OSA), Narcolepsy	December 20th, 2018	Oral	Competitor	$0.05 – 0.07
baloxavir marboxil	Influenza	December 24th, 2018	Oral	Competitor	$0.012 – $0.017
Roclatan (netarsudil/ latanoprost)	Glaucoma	March 14th, 2019	Ophth-almic	Competitor	$0.008 – $0.013
Zynquista (sotagliflozin)	Type 1 Diabetes	March 22nd, 2019	Oral	Additive Therapy	$0.01 – $0.02

= Medical Cost

Generic Pipeline

HIGH IMPACT

July 2018
Letairis

3Q 2018
Adcirca
Remodulin

Sept 2018
Cialis

2018
Tracleer*
Byetta
Kaletra
Nuvaring

3Q18 | **4Q18** | **1Q19**

July 2018
Acanya

3Q 2018
Abstral
Levitra

Sept 2018
Moviprep

2H 2018
Delzicol
Flector
Androgel
(1.62%)
Astagraf XL

Oct 2018
Onfi
Staxyn

Nov 2018
Finacea Gel*

4Q 2018
Rapaflo

Dec 2018
Canasa

Jan 2019
Zyclara
3.75%

Feb 2019
Ranexa
Solodyn 55mg
& 105mg

March 2019
Faslodex*
Tekturna

MEDIUM /LOW IMPACT

**NO exclusivity*