



Santa Clara
Family Health Plan

Santa Clara Family Health Plan

Pharmacy & Therapeutics Committee

March 15, 2018
P&T Committee Member Materials



Regular Meeting of the
Santa Clara County Health Authority d.b.a. Santa Clara Family Health Plan
Pharmacy & Therapeutics Committee

Thursday, March 15, 2018

6:00 PM - 8:00 PM

210 E. Hacienda Avenue Campbell, CA 95008

AGENDA

- | | | | |
|--|---|----------------------|----------------------------|
| 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. Lin | 6:05 | 5 min. |
| 3. Meeting Minutes
Review SCFHP 4Q2017 P&T minutes
Possible Action: Approve minutes | Dr. Lin | 6:10 | 3 min. |
| 4. Plan Updates <ul style="list-style-type: none">a. CMO Health Plan Updatesb. Appeals & Grievancesc. SCFHP Pharmacy Dept. Policies<ul style="list-style-type: none">1. PH01 Pharmacy and Therapeutics Committee2. PH02 Formulary Development and Guideline Management3. PH03 Prior Authorization4. PH04 Pharmacy Clinical Programs and Quality Monitoring5. PH05 Continuity of Care for Pharmacy Services6. PH06 Pharmacy Communications7. PH07 Drug Recalls8. PH08 Pain Management Drugs for Terminally Ill9. PH09 Medications for Members with Behavioral Health Conditions – <i>Revised</i>10. PH10 Cal MediConnect Part D Transition11. PH11 340B Program Compliance12. PH14 Medications for Cancer Clinical Trial Possible Action: Approve Policies | Dr. Robertson
Mr. Breakbill
Dr. Huynh | 6:13
6:16
6:21 | 3 min.
5 min.
4 min. |
| Adjourn to Closed Session
Pursuant to Welfare and Institutions Code Section 14087.36 (w) | | | |
| 5. Metric & Financial Updates <ul style="list-style-type: none">a. Membership Report | Dr. Robertson | 6:25 | 2 min. |



b. Pharmacy Dashboard	Dr. Otomo	6:27	5 min.
c. Drug Use Evaluation Results	Dr. McCarty	6:32	3 min.
d. Drug Utilization & Spend	Dr. McCarty	6:35	10 min.
6. Discussion and Recommendations for changes to SCFHP Cal MediConnect Formulary & Prior Authorization Criteria			
a. MedImpact 4Q2017 P&T Meetings Minutes	Dr. Huynh	6:45	5 min.
b. MedImpact 1Q2018 P&T Part D Actions			
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	6:50	5 min.
Possible Action: Approve formulary recommendations			
b. DHCS Medi-Cal CDL Updates & Comparability	Dr. McCarty	6:55	5 min.
Possible Action: Approve formulary recommendations			
c. Prior Authorization Criteria	Dr. Nguyen	7:00	20 min.
1. Zetia			
2. Glatiramer acetate			
3. Oncology			
4. Quantity Limit – <i>Revised</i>			
Possible Action: Approve prior authorization criteria			
d. New Drugs and Class Reviews	Dr. McCarty	7:20	30 min.
1. Diabetes Update: SGLT-2 inhibitors, Rapid Acting Insulin			
2. Hemlibra			
3. Psoriasis Update			
4. Cystic Fibrosis Update – <i>informational only</i>			
5. HIV Update – <i>informational only</i>			
6. Biosimilar Update – <i>informational only</i>			
Possible Action: Approve formulary recommendations			
Reconvene in Open Session			
Discussion Items			
8. Update on New Drugs and Generic Pipeline	Dr. McCarty	7:50	10 min.
Adjournment			
9. Next Meeting Thursday June 21, 2018	Dr. Lin	8:00	



CONFIDENTIALITY, CONFLICT OF INTEREST, AND NON-DISCRIMINATION AGREEMENT

Applicability

All Santa Clara Family Health Plan (SCFHP) employees and affiliates, including consultants; peer reviewers; members of the following committees: Quality Improvement, Pharmacy and Therapeutics, Utilization Management, Peer Review, and Credentialing.

Confidentiality Statement

Persons involved in the evaluation of quality of care must recognize that confidentiality is vital to the free and candid discussion necessary for effective peer review and quality improvement activities. Therefore, all persons are required to respect and maintain the confidentiality of all review discussions, deliberations, records, and other information generated in connection with these activities, and to make no voluntary disclosures of such information, except to persons authorized to receive it in the conduct of business.

Furthermore, participation in quality management activities is based upon the premise that every other SCFHP employee and affiliates will similarly preserve the confidentiality of these activities. All employees and affiliates are entitled to undertake such action as is deemed appropriate to ensure that this confidentiality is maintained, including actions necessitated by any breach or threatened breach of this agreement.

Conflict of Interest Statement

Any employee or affiliate, as defined above, who has a conflict of interest with respect to any matter being reviewed, shall report the conflict of interest either to the Department Manager or to the person requesting the peer review. An employee or affiliate shall be deemed to have a conflict of interest if he/she has 1) any involvement in the care of the plan member whose case is under review; 2) any fiduciary interest in or fiduciary relationship with the provider in question; or 3) any other involvement in the case which impairs his/her objectivity in performing the review.

All Committee members and affiliates with a conflict of interest shall refrain from participating in the peer review process and shall abstain from any proceeding of the committee in which such issues are raised for consideration. Committee members shall report conflict of interest to the committee chairperson and shall refrain from casting a committee vote on any issue related to a conflict of interest.

Non-Discrimination Statement

SCFHP employees and affiliates agree not to make credentialing and recredentialing decisions based solely on a practitioner's race, ethnic/national identity, gender, age, sexual orientation or the type of procedure or patient in which the practitioner specializes.

Agreement

I, the undersigned, have read and understand the above Confidentiality, Conflict of Interest, and Non-Discrimination Statements and agree to abide by these standards and requirements in the conduct of my responsibilities at/with Santa Clara Family Health Plan.

Name (print)

Name (signature)

Date

SCFHP 4Q2017 P&T
MINUTES



Regular Meeting of the
Santa Clara County Health Authority d.b.a. Santa Clara Family Health Plan
Pharmacy & Therapeutics Committee

Thursday, December 14, 2017
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)	Y
Minh Thai, MD	Family Practice	N
Amara Balakrishnan, MD	Pediatrics	Y
Peter Nguyen, MD	Family Practice	N
Jesse Parashar-Rokicki, MD	Family Practice	N
Narinder Singh, PharmD	Health System Pharmacy (SCVMC)	Y
Ali Alkoraishi, MD	Adult & Child Psychiatry	Y
Dolly Goel, MD	VHP Chief Medical Officer	N
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	N

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	N
Duyen Nguyen, PharmD	SCFHP Clinical Pharmacist	Y
Dang Huynh, PharmD	SCFHP Pharmacy Manager	Y
Amy McCarty, PharmD	MedImpact Clinical Program Manager	Y
Dawn Davis	SCFHP Grievance and Appeals Consultant	Y (via telephone)
Tiffanie Pham, CPHT	SCFHP Pharmacy Coordinator	Y
Guests	Specialty	Present (Y or N)
Jade Vitug, PharmD	VHP Pharmacy Resident	Y

	Topic and Discussion	Follow-Up Action
1	Introductions The meeting convened at 6:10 PM. Introduced Duyen Nguyen, SCFHP Clinical Pharmacist, Tiffanie Pham, SCFHP Pharmacy Coordinator and guest Jade Vitug, Pharmacy Resident at Valley Health Plan.	
2	Past Meeting Minutes The SCFHP 3Q2017 P&T Minutes from September 21, 2017 were reviewed by the Committee as submitted.	Upon motion duly made and seconded, the SCFHP 3Q2017



		P&T Minutes from September 21, 2017 were approved as submitted and will be forwarded to the QI Committee and Board of Directors.
3	Public Comment	
	No public comment.	
4	Informational Updates	
	<p>Health Plan Updates Deferred until next committee meeting.</p> <p>Prescription Drug Prior Authorization or Step Therapy Exception Request Form (Revised Form 61-211) Dr. Huynh presented the update on Form 61-211. A memo was sent to providers via FAX blast and will be attached to prior authorization decisions in the next few weeks. DHCS requires form 61-211 which was revised December 2016 and became effective July 1, 2017. Effective January 1, 2018, the plan will no longer accept the old form.</p>	
	<p>Appeals & Grievances Ms. Davis presented the Appeals and Grievances report for Pharmacy and Part D. There was an increase in Medi-Cal appeals. Change in process, data is being collected through appeals department. Q2 2017 41% overturn rate, 55% upheld. Q3 2017 56% overturn rate, 20% upheld, 11% withdrawn. For Cal MediConnect Q3 Part C&D redeterminations have remained steady. Low during Q3: 4 in July, 8 in August, 7 in September. Part D redeterminations Q2: 50% overturned, 34% upheld, 8% withdrawn. Q3: 20% upheld, 30% overturned, 40% withdrawn.</p>	
	<p>Adjourn to Closed Session Committee adjourned to closed session at 6:42 p.m. to discuss the following items: Membership, Pharmacy Dashboard, Drug Utilization & Spend, Recommendations for Changes to SCFHP Cal MediConnect, Medi-Cal, Healthy Kids Formulary and Prior Authorization Criteria, Medical Pharmacy Prior Authorization Grid, DHCS Medi-Cal CDL Updates & Comparability, and New Drugs and Class Reviews.</p>	
5	Metrics & Financial Updates	
	<p>Membership Report Dr. Liu presented the membership report. Slight decline in Medi-Cal line of business membership. Slight increases in Cal MediConnect (CMC). Attribute the growth in CMC to more fully developing Medi-Care Outreach department. Outreach to our existing Medi-Cal population that are also full dual and may be eligible for CMC.</p>	
	Pharmacy Dashboard	



	<p>Dr. Huynh presented the Pharmacy Dashboard. For Medi-Cal line of business, prior authorization approval rate increased from 55% to 70% during the timeframe of September to October. 24 hour turnaround time is compliant at 100%. Expedited 24 hour turnaround time approval rate is from 62 to 77%. Interrater reliability done 10/19/2017. For Cal MediConnect line of business, prior authorization volume increased in the previous quarter. 72 hour turnaround time is 100%. Expedited increased from 58% to 68%. Met goal of CMR completion rate of 20% earlier than the previous calendar year. Percent shifted slightly, still on track to meet goal. Denied claims reviewed: 96%, on track with formulary submission to CMS.</p>	
	<p>Discussion and Recommendations for changes to SCFHP Cal MediConnect Formulary & Prior Authorization Criteria</p> <p>Dr. Huynh presented an overview of the MedImpact 3Q2017 P&T minutes as well as the MedImpact 4Q2017 P&T Part D Actions.</p>	<p>Upon motion duly made and seconded the MedImpact 3Q2017 P&T Minutes, and MedImpact 4Q2017 P&T Part D Actions were approved as submitted.</p>
	<p>Discussion and Recommendations for Changes to SCFHP Medi-Cal & Healthy Kids Formulary & Prior Authorization Criteria</p> <p>Formulary Modifications Dr. Huynh presented the formulary changes since the last P&T meeting. Of note: added Mavyret to formulary with prior authorization and quantity limit of 3/day. Added Vitamin D3 50,000 unit capsule to formulary. Added Tears Again, Lubrifresh PM, and Tears Naturale PM ophthalmic ointment products to formulary. Added Shingrix with age limit of greater than or equal to 50 years old and quantity limit. Remove Glatopa 20mg/ml from formulary. Added Makena 250mg/ml (1 ml vial) to formulary with prior authorization. Recommend: Add Leucovorin 25mg tablet to formulary. Remove Triamex ointment to formulary. Remove Zepatier from formulary.</p>	<p>Upon motion duly made and seconded, formulary modifications were approved as presented.</p>
	<p>Prior Authorization Criteria</p> <ul style="list-style-type: none"> - Dr. Nguyen presented the following PA criteria for approval by the committee: <ul style="list-style-type: none"> - Hepatitis C - Ciclopirox 8% - Non-formulary - Brand Name - Off-Label - Compounded Medications - General Criteria-UM Medical Drugs - Eosinophilic Asthma 	<p>Upon motion duly made and seconded, prior authorization criteria were approved as requested.</p>



	<ul style="list-style-type: none"> - Cotellic - Duragesic - Emend - Exelon - Farydak - Iressa - Keytruda - Lyrica - Marinol - Myrbetriq - Nebupent - Nexavar - Odomzo - Restasis - Revatio - Targretin - Temodar - Tymlos - Xarelto - Xolair - Zarxio 	
	<p>DHCS Medi-Cal CDL Updates & Comparability</p> <p>Dr. McCarty presented the DHCS Medi-Cal Updates and Comparability. For September 2017, two drugs added and one dosage form added. No proposed action for September 2017. For October 2017, one drug with strength removed. No proposed action for October 2017. For November 2017, one drug with quantity limit and fill limit. November 2017 propose add quantity limit and match CDL for Promethazine w/Phenylephrine and Codeine.</p>	<p>Upon motion duly made and seconded, all recommendations were approved and presented.</p>
	<p>New Drugs and Class Reviews</p> <p>New Drug Reviews</p> <p>Dr. McCarty presented the following new drug reviews:</p> <ul style="list-style-type: none"> - Shingrix –Add age limit to allow in 50 and older; add quantity limit of 2 doses per lifetime. Remove Zostavax from formulary. - Diabetes – Jardiance/Synjardy/Synjardy XR-Add to formulary, add step therapy (required trial of Metformin + oral/GLP-1RA), add quantity limit Jardiance & Synjardy XR 1/day, Synjardy 2/day - Diabetes-Januvia/Janumet/Janumet XR-remove from formulary - Car T Cell Therapies –Kymriah for pediatric, Yescarta for Adults; administered via single IV infusion bag 	<p>Upon motion duly made and seconded, all recommendations were approved as presented.</p>



	Drug Utilization and Spend Review Dr. McCarty presented the Drug Utilization and Spend Review report. Diabetes remains the top spend. Drop in infectious disease. Pulmonary arterial hypertension has doubled. A lot more utilization of calcium by members of Santa Clara Family Health Plan.	
	Reconvene in Open Session Committee reconvened to open session at 7:35 p.m.	
6	Discussion Items	
	Update on New Drugs and Generic Pipeline Informational Only	
7	Adjournment at 8:02 PM	

APPEALS &
GRIEVANCES
REPORT



Santa Clara
Family Health Plan

The Spirit of Care

P&T Committee

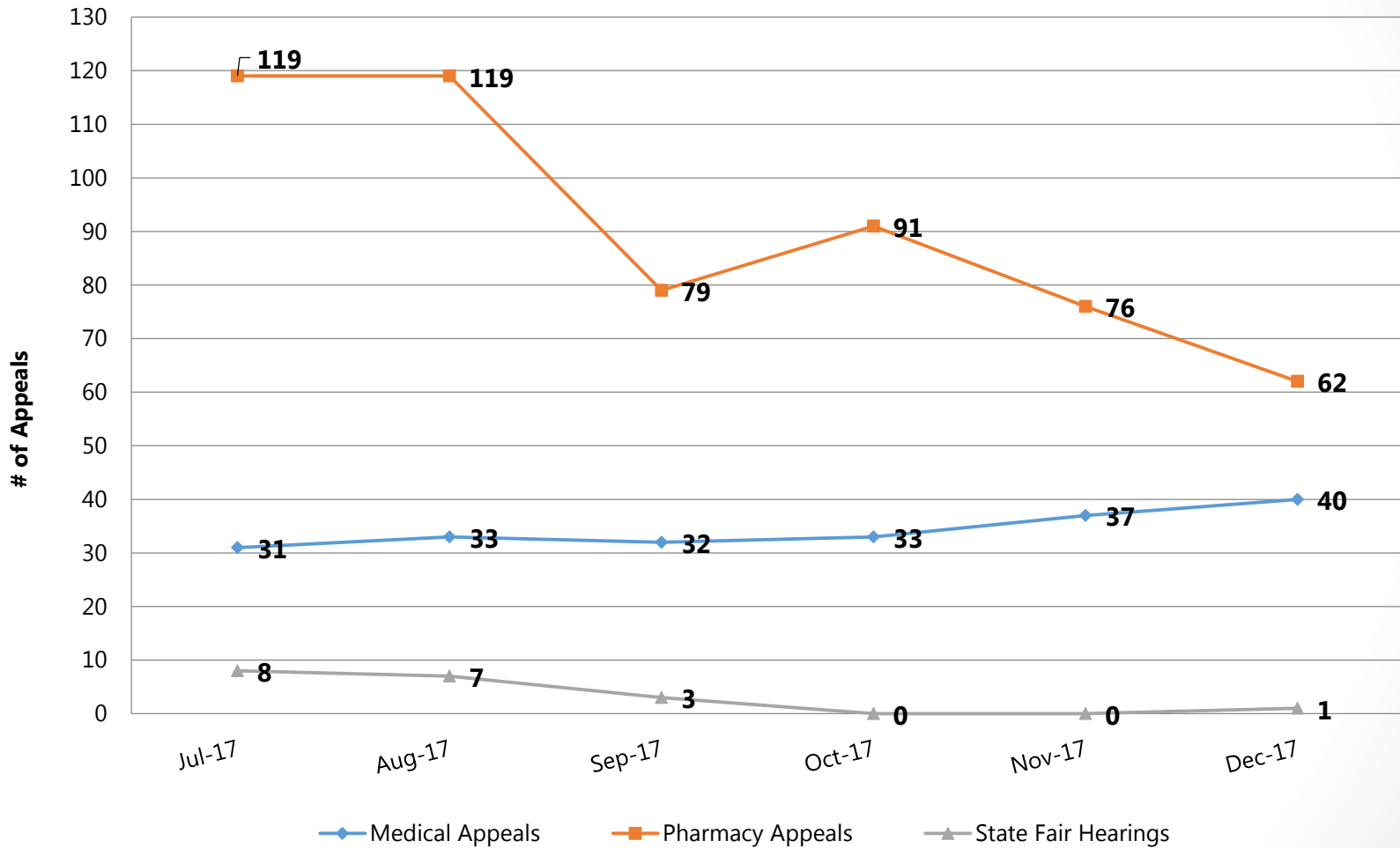
Grievance and Appeals Q4 2017 Report

March 15, 2018

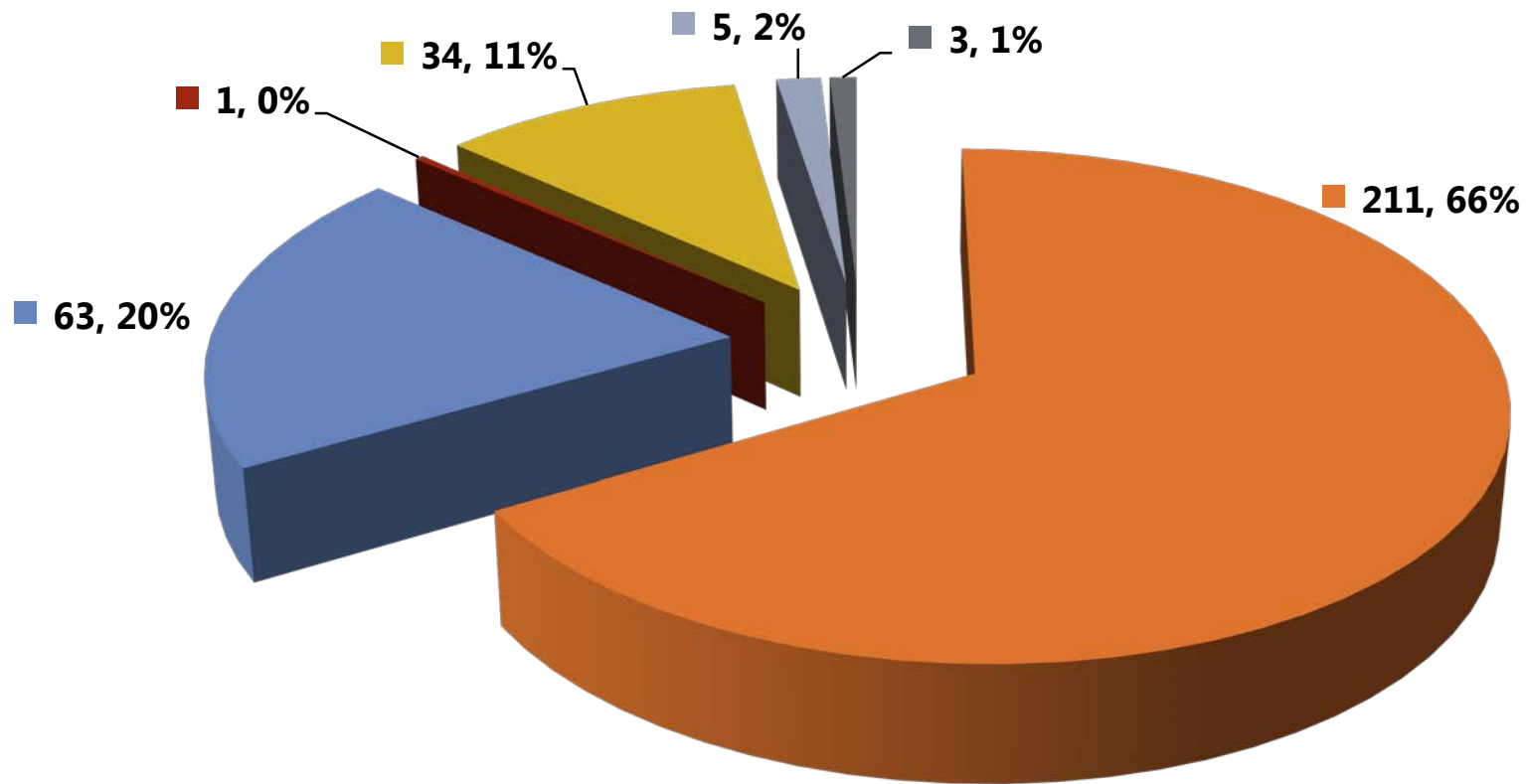
3/15/2018



Q3-Q4 2017: Medi-Cal Appeals



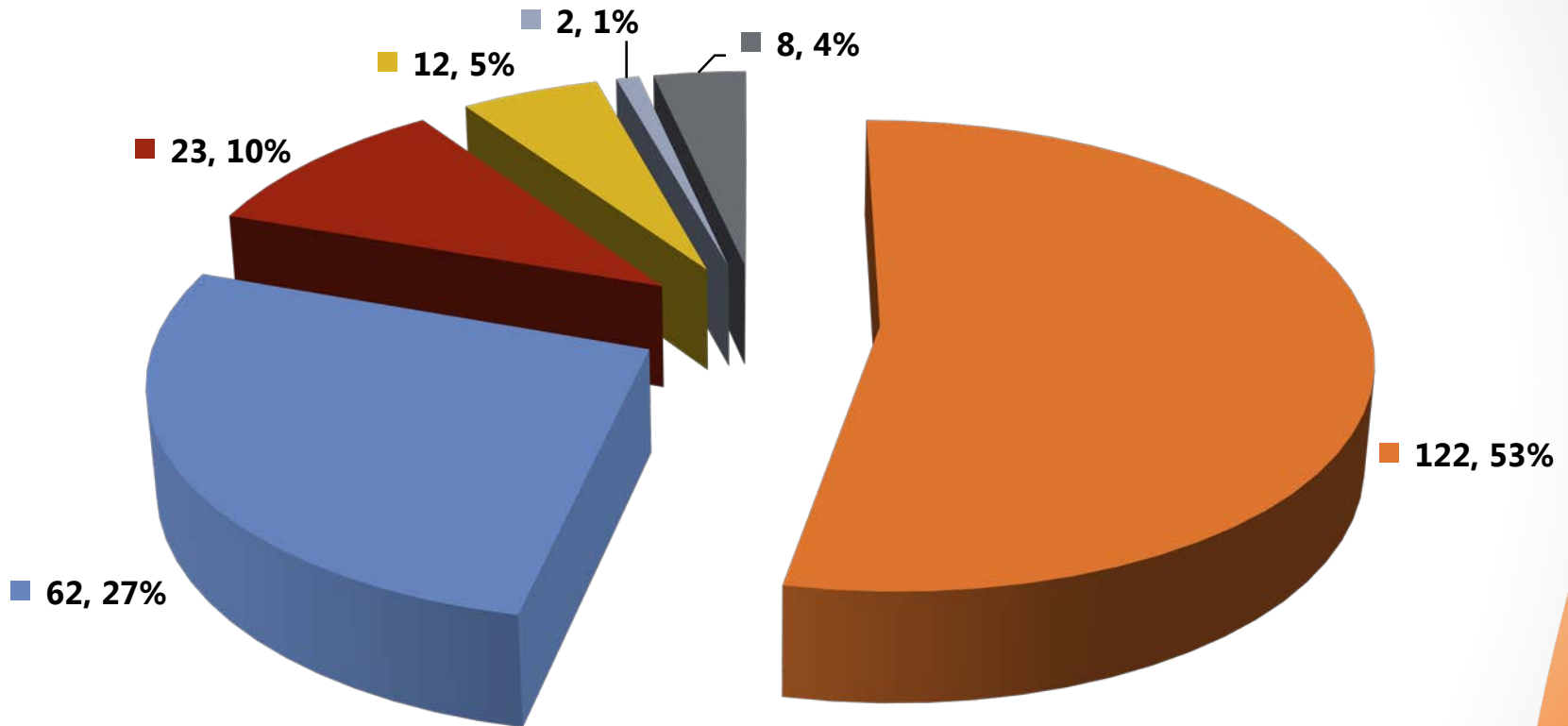
Q3 2017 Medi-Cal Pharmacy Appeals



Overturned Upheld Partially Favorable Withdrawn Dismissed In Process



Q4 2017 Medi-Cal Pharmacy Appeals

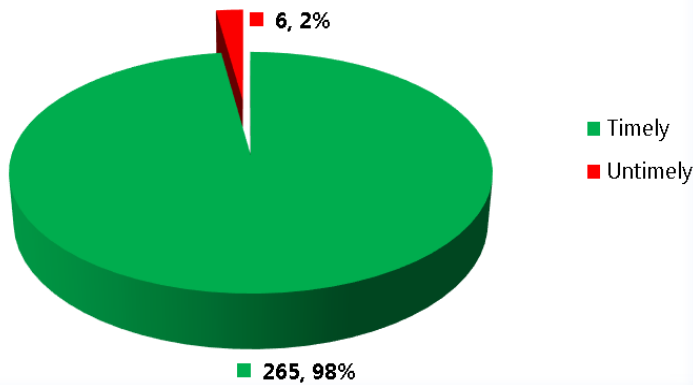


Overturned Upheld Partially Favorable Withdrawn Dismissed In Process

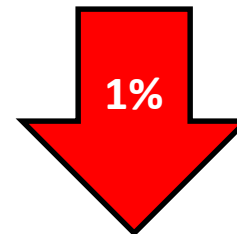
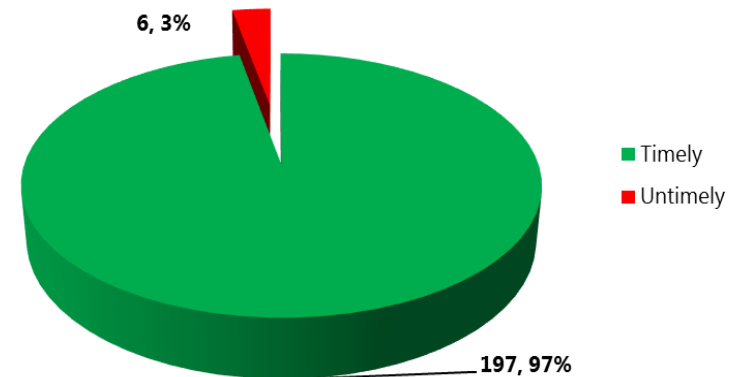
Q3-Q4 2017: Medi-Cal Timeliness



Q3 Pharmacy Appeals Timeliness
Standard Requests



Q4 Pharmacy Appeals Timeliness
Standard Requests



STANDARD: 30 calendar days or as quickly as the member's health condition requires.

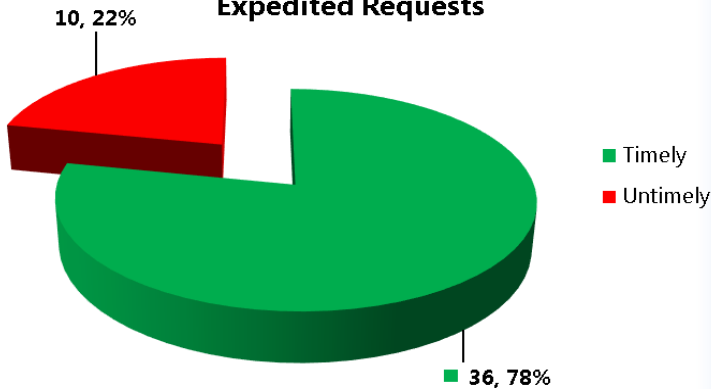


Q3-Q4 2017: Medi-Cal Timeliness



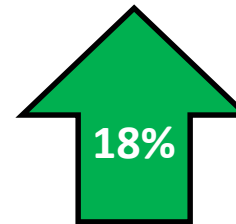
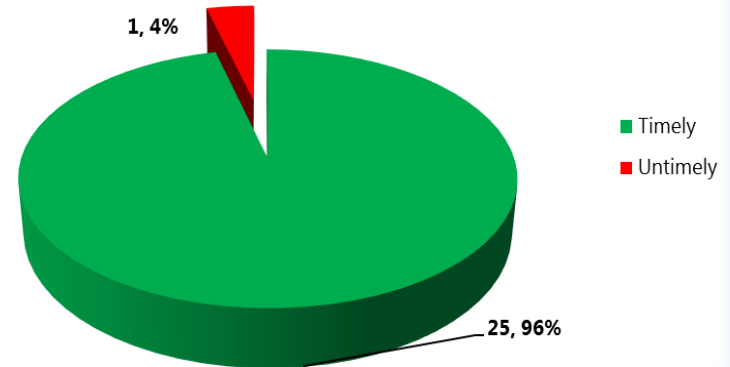
Q3 Pharmacy Appeals Timeliness

Expedited Requests



Q4 Pharmacy Appeals Timeliness

Expedited Requests

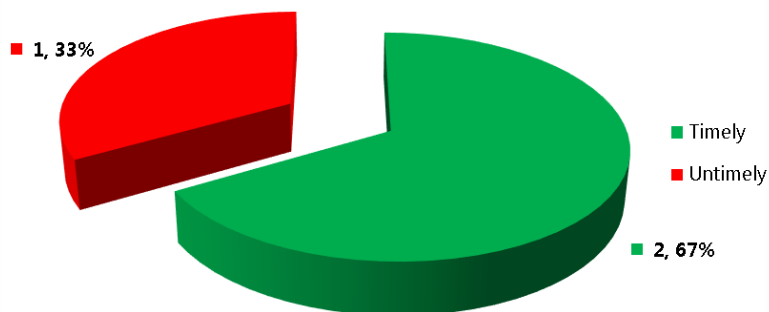


STANDARD: Within **72 hours** from the date that the appeal is received ,or as quickly as the member's health condition requires.

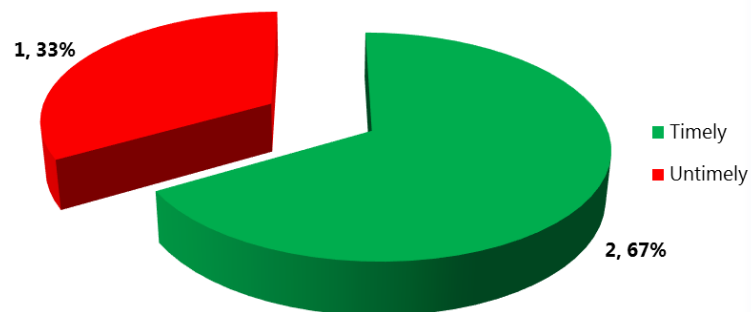
Q2-Q3 2017: Medi-Cal Timeliness



Q3 Grievances Timeliness
Expedited Requests



Q4 Grievances Timeliness
Expedited Requests



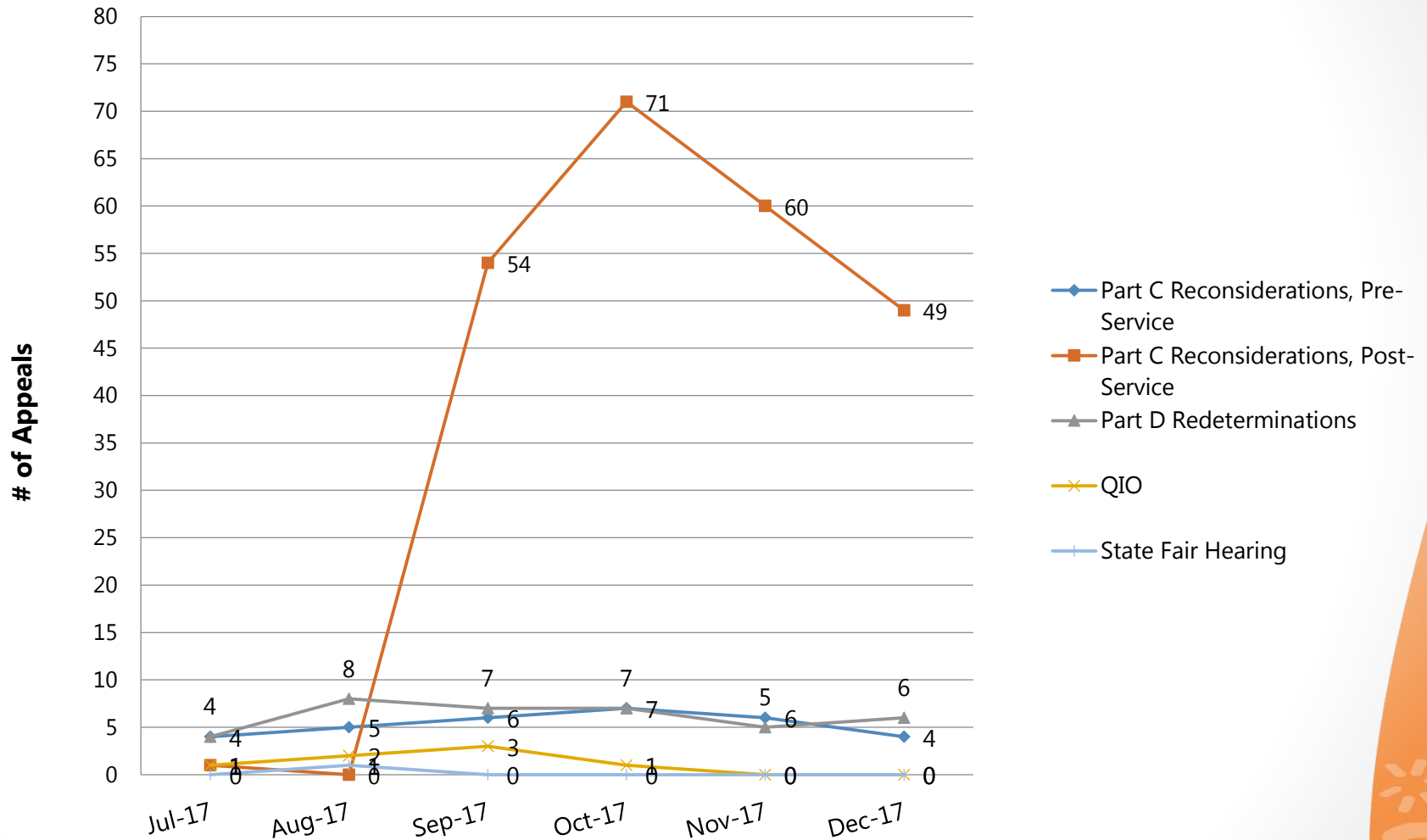
STANDARD: Within **72 hours** from the date that the appeal is received ,or as quickly as the member's health condition requires.



Medi-Cal Rates per 1000: CY 2017

	Jan-17	Feb-17	Mar-17	Apr-17	May-17	Jun-17	Jul-17	Aug-17	Sep-17	Oct-17	Nov-17	Dec-17
<i>Total Medical Appeals</i>	23	16	32	36	35	44	31	33	32	33	37	40
<i>Healthy Kids Membership</i>	2,585	2,780	2,752	2,794	2,757	2,732	2,633	2,618	2,243	2,288	2,321	2,447
<i>Medi-Cal Membership</i>	268,008	268,360	267,437	267,199	265,711	265,649	261,287	262,871	261,702	260,518	258,633	258,106
<i>TOTAL Membership</i>	270,593	271,140	270,189	269,993	268,468	268,381	263,920	265,489	263,945	262,806	260,954	260,553
<i>Rate per 1000</i>	0.086	0.060	0.120	0.135	0.132	0.166	0.119	0.126	0.122	0.127	0.143	0.155
	Jan-17	Feb-17	Mar-17	Apr-17	May-17	Jun-17	Jul-17	Aug-17	Sep-17	Oct-17	Nov-17	Dec-17
<i>Total Fix Appeals</i>	12	13	14	11	19	16	119	119	79	91	76	62
<i>Healthy Kids Membership</i>	2,585	2,780	2,752	2,794	2,757	2,732	2,633	2,618	2,243	2,288	2,321	2,447
<i>Medi-Cal Membership</i>	268,008	268,360	267,437	267,199	265,711	265,649	261,287	262,871	261,702	260,518	258,633	258,106
<i>TOTAL Membership</i>	270,593	271,140	270,189	269,993	268,468	268,381	263,920	265,489	263,945	262,806	260,954	260,553
<i>Rate per 1000</i>	0.045	0.048	0.052	0.041	0.072	0.060	0.455	0.453	0.302	0.349	0.294	0.240
	Jan-17	Feb-17	Mar-17	Apr-17	May-17	Jun-17	Jul-17	Aug-17	Sep-17	Oct-17	Nov-17	Dec-17
<i>Total Grievances</i>	57	48	55	53	102	97	85	118	94	87	92	73
<i>Healthy Kids Membership</i>	2,585	2,780	2,752	2,794	2,757	2,732	2,633	2,618	2,243	2,288	2,321	2,447
<i>Medi-Cal Membership</i>	268,008	268,360	267,437	267,199	265,711	265,649	261,287	262,871	261,702	260,518	258,633	258,106
<i>TOTAL Membership</i>	270,593	271,140	270,189	269,993	268,468	268,381	263,920	265,489	263,945	262,806	260,954	260,553
<i>Rate per 1000</i>	0.213	0.179	0.206	0.198	0.384	0.365	0.325	0.449	0.359	0.334	0.356	0.283

Q3-Q4 2017: Part C&D Appeals

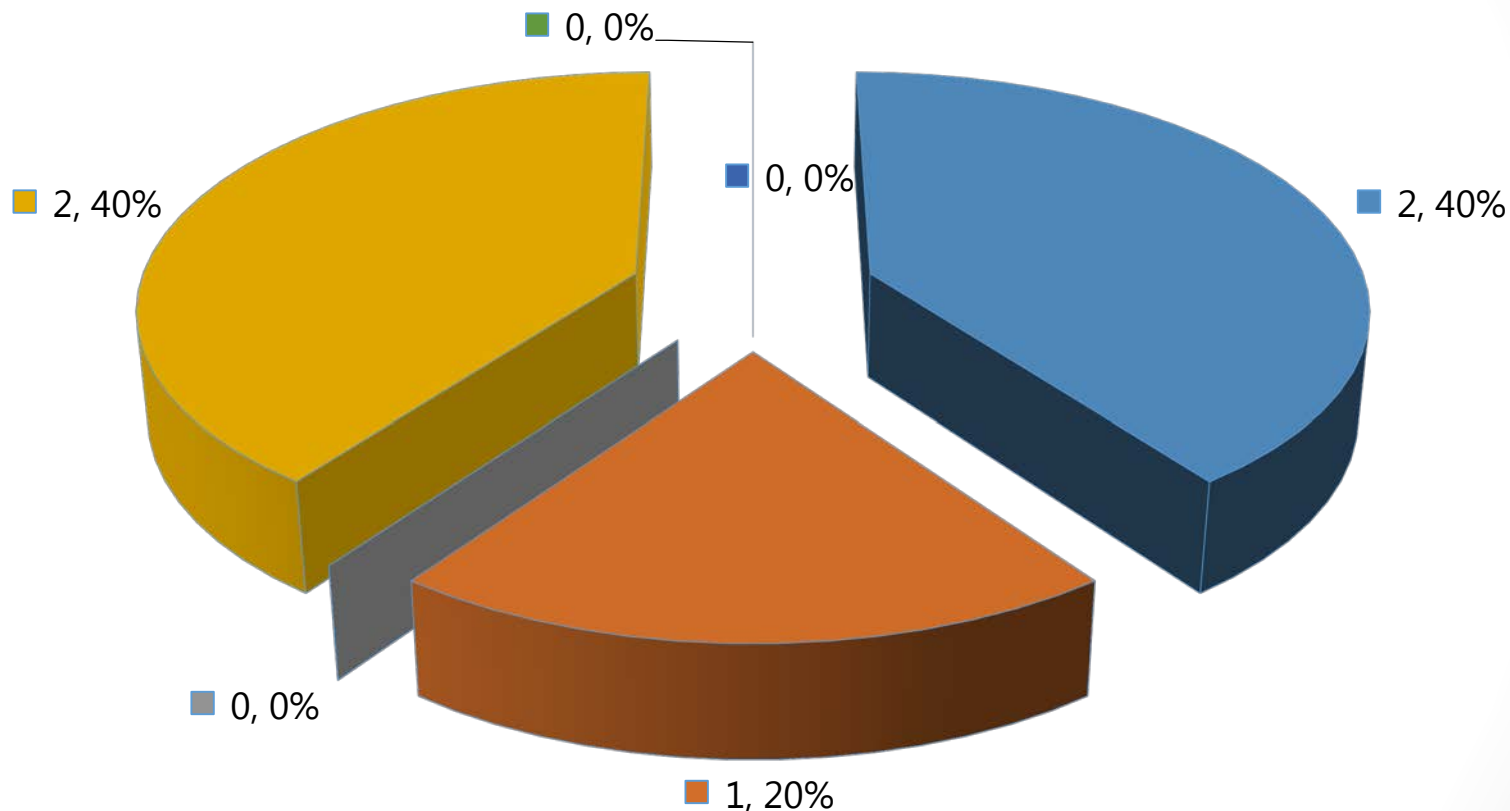


Q3-Q4 2017: Part C&D Appeals

TYPE	Jul-17	Aug-17	Sep-17	Oct-17	Nov-17	Dec-17
Part D Redeterminations	4	8	7	7	5	6
QIO (Livanta)	1	2	3	1	0	0
IMR (Maximus)	0	0	0	0	0	0
Administrative Law Judge (ALJ)	0	0	0	0	0	0
State Fair Hearing	0	1	0	0	0	0



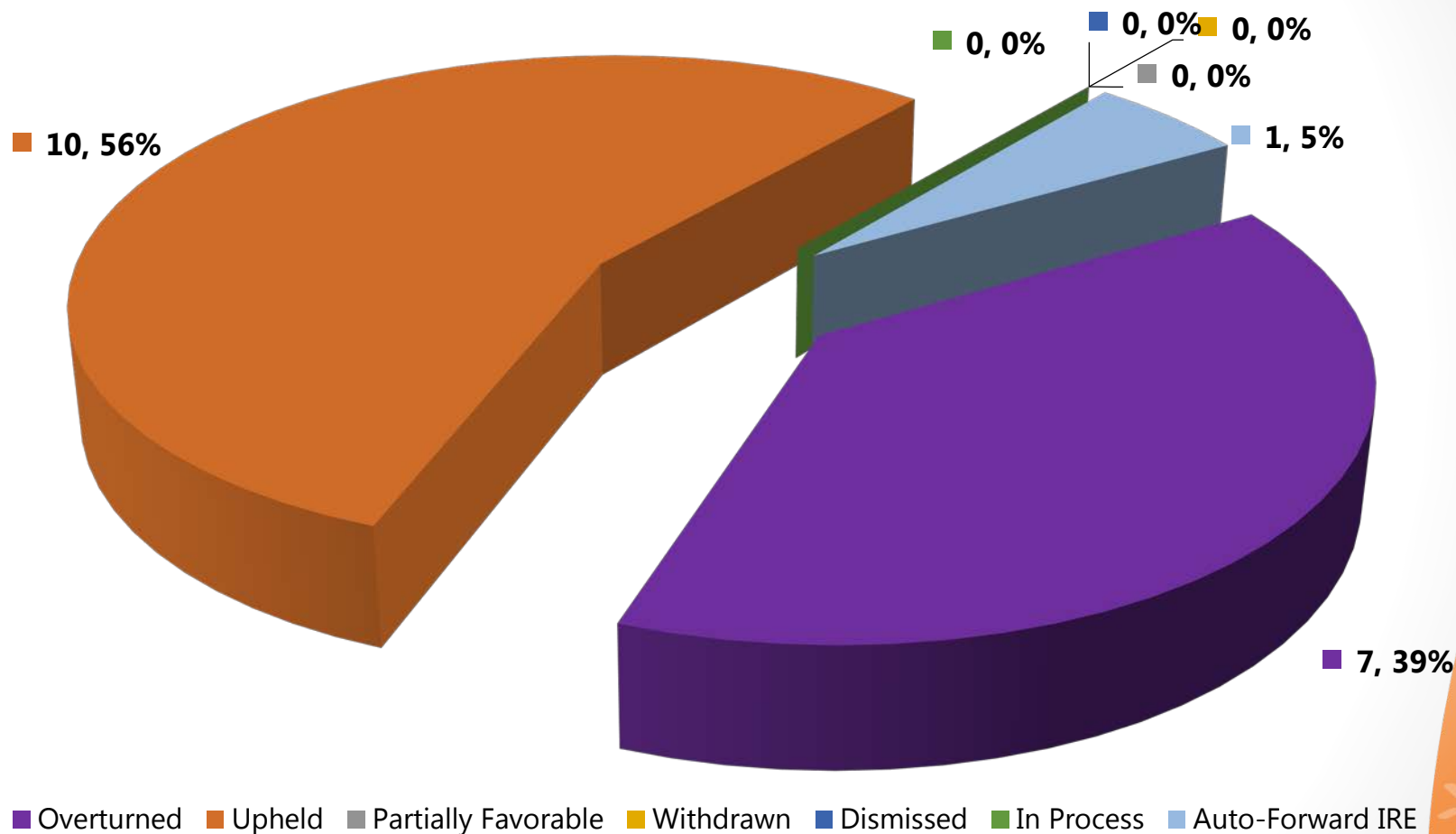
CMC Part D Redeterminations by Determination Q3 2017



■ Overturned ■ Upheld ■ Partially Favorable ■ Withdrawn ■ Dismissed ■ In Process



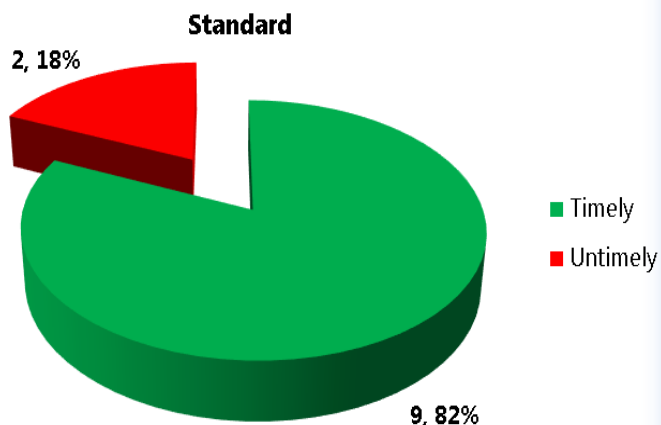
CMC Part D Redeterminations by Determination Q4 2017



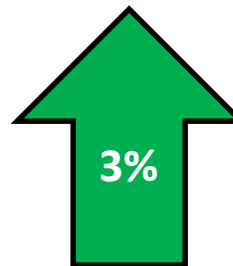
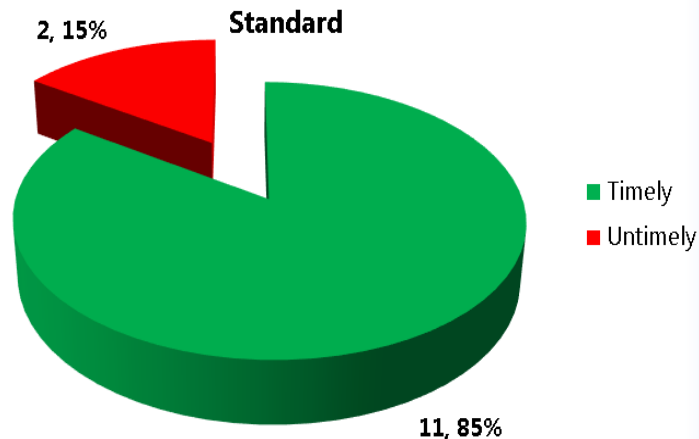
Q3-Q4 2017: CMC Timeliness



Q3 Part D Redeterminations Timeliness



Q4 Part D Redeterminations Timeliness



Standard Requests = 7 calendar days

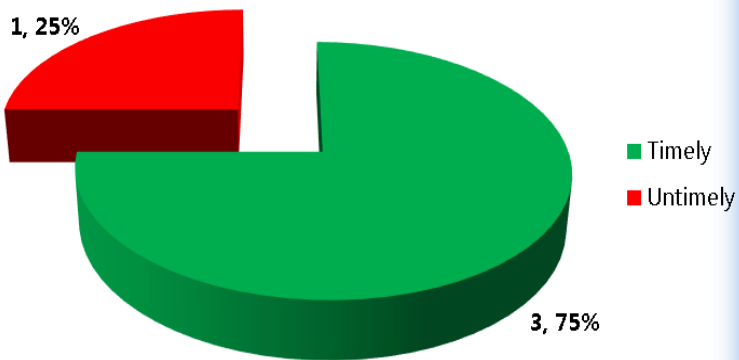


Q3-Q4 2017: CMC Timeliness



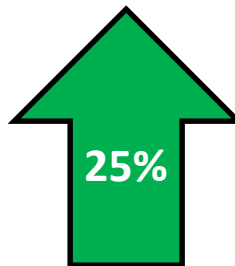
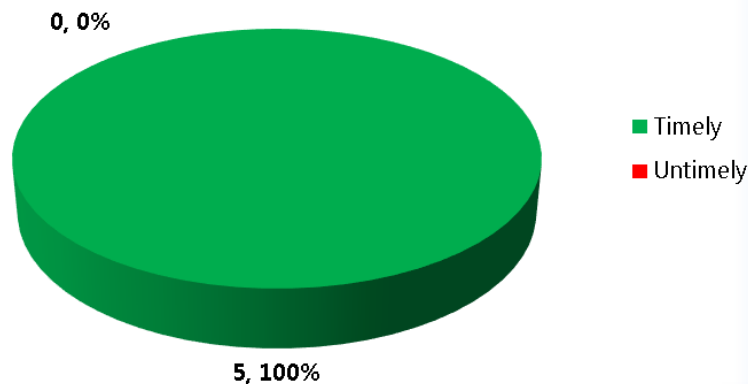
Q3 Part D Redeterminations Timeliness

Expedited



Q4 Part D Redeterminations Timeliness

Expedited



Expedited Requests = 72 hours



Cal Medi-Connect Rates per 1000: CY 2017

	Jan-17	Feb-17	Mar-17	Apr-17	May-17	Jun-17	Jul-17	Aug-17	Sep-17	Oct-17	Nov-17	Dec-17
<i>Total Appeals</i>	21	29	21	18	15	16	9	13	67	62	91	59
<i>CMC Membership</i>	7,527	7,598	7,622	7,567	7,545	7,543	7,525	7,405	7,383	7,326	7,349	7,389
<i>Rate per 1000</i>	2.790	3.817	2.755	2.379	1.988	2.121	1.196	1.756	9.075	8.463	12.383	7.985

	Jan-17	Feb-17	Mar-17	Apr-17	May-17	Jun-17	Jul-17	Aug-17	Sep-17	Oct-17	Nov-17	Dec-17
<i>Total Grievances</i>	39	27	31	22	16	22	20	29	31	43	38	43
<i>CMC Membership</i>	7,527	7,598	7,622	7,567	7,545	7,543	7,525	7,405	7,383	7,326	7,349	7,389
<i>Rate per 1000</i>	5.181	3.554	4.067	2.907	2.121	2.917	2.658	3.916	4.199	5.870	5.171	5.819



PHARMACY
DEPARTMENT
POLICIES

POLICY



Santa Clara
Family Health Plan

Policy Title:	Pharmacy and Therapeutics Committee	Policy No.:	PH01
Replaces Policy Title (if applicable):	Pharmaceutical and Therapeutics Committee	Replaces Policy No. (if applicable):	PM 114
Issuing Department:	Pharmacy	Policy Review Frequency:	Annually
Lines of Business (check all that apply):	<input checked="" type="checkbox"/> Medi-Cal	<input checked="" type="checkbox"/> Healthy Kids	<input checked="" type="checkbox"/> CMC

I. Purpose

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

II. Policy

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

III. Responsibilities

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

IV. References

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

POLICY

V. Approval/Revision History

First Level Approval		Second Level Approval		
				
Signature Johanna Liu, PharmD		Signature Jeff Robertson, MD		
Name Director of Quality and Pharmacy		Name Chief Medical Officer		
Title March 17, 2017		Title March 17, 2017		
Date		Date		
Version Number	Change (Original/ Reviewed/ Revised)	Reviewing Committee (if applicable)	Committee Action/Date (Recommend or Approve)	Board Action/Date (Approve or Ratify)
1	Original	Pharmacy & Therapeutics Committee	Approved 3/24/2016	
1	Reviewed	Pharmacy & Therapeutics Committee	Approved 3/16/2017	

POLICY



Santa Clara
Family Health Plan

Policy Title:	Formulary Development and Guideline Management	Policy No.:	PH02
Replaces Policy Title (if applicable):	Provider Non-Formulary Drug Review Requests	Replaces Policy No. (if applicable):	PM 107
Issuing Department:	Pharmacy	Policy Review Frequency:	Annually
Lines of Business (check all that apply):	<input checked="" type="checkbox"/> Medi-Cal	<input checked="" type="checkbox"/> Healthy Kids	<input checked="" type="checkbox"/> CMC

I. Purpose

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

II. Policy

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

III. Responsibilities

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

IV. References

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

POLICY

4. CA Health and Safety Code section 1367.20
5. CA Health and Safety Code section 1368.016
6. Department of Managed Health Care Technical Assistance Guide, Grievances and Appeals, Requirement GA-002: Grievance Filing
7. Medicare Prescription Drug Benefit Manual, Chapter 6 Part D Drugs and Formulary Requirements, 10.9 DESI Drugs
8. Medicare Prescription Drug Benefit Manual, Chapter 6 Part D Drugs and Formulary Requirements, 30.2 Provision of Adequate Formulary
9. SCFHP DHCS Contract
10. NCQA, Quality Management and Improvement, 2016, Q17: Practice Guidelines and UM 4, Appropriate Professionals

V. Approval/Revision History

First Level Approval			Second Level Approval	
 <hr/> Signature Johanna Liu, PharmD <hr/> Name Director of Quality and Pharmacy <hr/> Title 03/17/2017 <hr/> Date			 <hr/> Signature Jeff Robertson, MD <hr/> Name Chief Medical Officer <hr/> Title 03/17/2017 <hr/> Date	
Version Number	Change (Original/ Reviewed/ Revised)	Reviewing Committee (if applicable)	Committee Action/Date (Recommend or Approve)	Board Action/Date (Approve or Ratify)
1	Original	Pharmacy & Therapeutics Committee	Approved 3/24/2016	
1	Reviewed	Pharmacy & Therapeutics Committee	Approved 3/16/2017	

POLICY



Santa Clara
Family Health Plan

Policy Title:	Prior Authorization	Policy No.:	PH03
Replaces Policy Title (if applicable):	Issuing Notices to providers and Members of a Pharmacy Medication PA Request Denial Prior Authorization Member Notification Regarding Drug PA Determinations	Replaces Policy No. (if applicable):	PM 102 PM 106 PM 125
Issuing Department:	Pharmacy	Policy Review Frequency:	Annually
Lines of Business (check all that apply):	<input checked="" type="checkbox"/> Medi-Cal	<input checked="" type="checkbox"/> Healthy Kids	<input checked="" type="checkbox"/> CMC

I. Purpose

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

II. Policy

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

III. Responsibilities

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

IV. References

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

POLICY

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

V. Approval/Revision History

First Level Approval			Second Level Approval	
				
Signature Johanna Liu, PharmD			Signature Jeff Robertson, MD	
Name Director of Quality and Pharmacy			Name Chief Medical Officer	
Title March 17, 2017			Title March 17, 2017	
Date			Date	
Version Number	Change (Original/ Reviewed/ Revised)	Reviewing Committee (if applicable)	Committee Action/Date (Recommend or Approve)	Board Action/Date (Approve or Ratify)
1	Original	Pharmacy & Therapeutics Committee	Approve 3/24/2016	
1	Reviewed	Pharmacy & Therapeutics Committee	Approved 3/16/2017	

POLICY



Santa Clara
Family Health Plan

Policy Title:	Pharmacy Clinical Programs and Quality Monitoring		Policy No.:	PH04
Replaces Policy Title (if applicable):	Pharmacy Over and Under Utilization Policy	Replaces Policy No. (if applicable):	PM 109	
	Inter-Rater Reliability Policy		PM 126	
	Medicare Coverage Determination Oversight Policy		PM 226	
Issuing Department:	Pharmacy		Policy Review Frequency:	Bi-annually
Lines of Business (check all that apply):	<input checked="" type="checkbox"/> Medi-Cal	<input checked="" type="checkbox"/> Healthy Kids	<input checked="" type="checkbox"/> CMC	

I. Purpose

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

II. Policy

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

III. Responsibilities

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



IV. References

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

POLICY

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

V. Approval/Revision History

First Level Approval		Second Level Approval		
				
Signature Johanna Liu, PharmD		Signature Jeff Robertson, MD		
Name Director of Quality and Pharmacy		Name Chief Medical Officer		
Title June 15, 2017		Title June 15, 2017		
Date		Date		
Version Number	Change (Original/ Reviewed/ Revised)	Reviewing Committee (if applicable)	Committee Action/Date (Recommend or Approve)	Board Action/Date (Approve or Ratify)
1	Original	Pharmacy & Therapeutics Committee	Approved 3/24/2016	
1	Reviewed	Pharmacy & Therapeutics Committee	Approved 3/16/2017	
2	Revised	Pharmacy & Therapeutics Committee	Approved 6/15/2017	

POLICY



Santa Clara
Family Health Plan

Policy Title:	Continuity of Care for Pharmacy Services		Policy No.:	PH05
Replaces Policy Title (if applicable):	Cal MediConnect Transition Policy	Replaces Policy No. (if applicable):	PM 100	
	Emergency Supply of Medications from a Retail Pharmacy		PM 108	
	Pharmacy Network Access		PM 112	
	Continuation of Drug Therapy for a New and Current Members		PM 122	
Issuing Department:	Pharmacy		Policy Review Frequency:	Annually
Lines of Business (check all that apply):	<input checked="" type="checkbox"/> Medi-Cal	<input checked="" type="checkbox"/> Healthy Kids	<input checked="" type="checkbox"/> CMC	

I. Purpose

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

II. Policy

- A. SCFHP shall define how and when medication management procedures allow for continuity of care for identified medical conditions, taking into consideration the safest and most effective method of treatment the member condition
- B. SCFHP defines the pharmacy network and the network’s availability to the member
 - 1. It is the policy of SCFHP that there are 24-hour pharmacies available to members for after-hour prescription dispensing
- C. The Plan will define the timing of medication dispensing including the amount of medication and coverage days to be included
 - 1. It is the policy of SCFHP that Cal MediConnect (CMC) members shall be provided with transition fills for non-formulary medications within the first 90 days of coverage under the new plan
 - 2. It is the policy of SCFHP that CMC members shall be provided with transition fills within the first 90 days of coverage in a new benefit under an existing plan if there are negative changes between benefit years
- D. SCFHP defines in its written procedures the handling of medications in the long-term care setting
- E. SCFHP defines how communication of transition medication management will be done with the member
- F. Specific to the Medi-Cal line of business, SCFHP defines how an emergency 72-hour supply of medications are available on all drugs regardless of formulary status to support transition of care
 - 1. The Plan shall define how members will be allowed to continue to use any (single source) drugs that are part of a prescribed therapy in effect for the member immediately prior to the date of enrollment, whether or not the drug is covered, until the prescribed therapy is no longer prescribed by the provider.

POLICY


III. Responsibilities

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

IV. References

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

V. Approval/Revision History

First Level Approval		Second Level Approval		
				
Signature Johanna Liu, PharmD		Signature Jeff Robertson, MD		
Name Director of Quality and Pharmacy		Name Chief Medical Officer		
Title March 17, 2017		Title March 17, 2017		
Date		Date		
Version Number	Change (Original/ Reviewed/ Revised)	Reviewing Committee (if applicable)	Committee Action/Date (Recommend or Approve)	Board Action/Date (Approve or Ratify)
1	Original	Pharmacy & Therapeutics Committee	Approved 3/24/2016	
1	Reviewed	Pharmacy & Therapeutics Committee	Approved 3/16/2017	

POLICY



Santa Clara
Family Health Plan

Policy Title:	Pharmacy Communications	Policy No.:	PH06
Replaces Policy Title (if applicable):	Furnishing of the SCFHP Drug Formulary to Members and Providers	Replaces Policy No. (if applicable):	PM 103
Issuing Department:	Pharmacy	Policy Review Frequency:	Annually
Lines of Business (check all that apply):	<input checked="" type="checkbox"/> Medi-Cal	<input checked="" type="checkbox"/> Healthy Kids	<input checked="" type="checkbox"/> CMC

I. Purpose

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

II. Policy

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

III. Responsibilities

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

IV. References

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

POLICY

V. Approval/Revision History

First Level Approval		Second Level Approval		
				
Signature Johanna Liu, PharmD		Signature Jeff Robertson, MD		
Name Director of Quality and Pharmacy		Name Chief Medical Officer		
Title March 17, 2017		Title March 17, 2017		
Date		Date		
Version Number	Change (Original/Reviewed/Revised)	Reviewing Committee (if applicable)	Committee Action/Date (Recommend or Approve)	Board Action/Date (Approve or Ratify)
1	Original	Pharmacy & Therapeutics Committee	Approved 3/24/2016	
1	Reviewed	Pharmacy & Therapeutics Committee	Approved 3/16/2017	

POLICY



Santa Clara
Family Health Plan

Policy Title:	Drug Recalls	Policy No.:	PH07
Replaces Policy Title (if applicable):		Replaces Policy No. (if applicable):	
Issuing Department:	Pharmacy	Policy Review Frequency:	Annually
Lines of Business (check all that apply):	<input type="checkbox"/> Medi-Cal	<input type="checkbox"/> Healthy Kids	<input checked="" type="checkbox"/> CMC

I. Purpose

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

II. Policy

- A. SCFHP adopts a written process to describe how the Plan will notify members and prescribing practitioners affected by a Class II recall or voluntary drug withdrawals from the market for safety reasons within 30 calendar days of the FDA notification.
- B. The plan defines how members and prescribing practitioners for Class I recalls are notified within 15 days or as soon as possible, not to exceed 30 days of the FDA notification.

III. Responsibilities

- A. Director of Pharmacy, or designee, will monitor drug recalls for Class I and II and ensure letters are sent to affected members and their prescribing physicians.
- B. Director of Marketing, or designee, will write and maintain a draft letter template that is CMS approved and available for use when there is a drug recall.

IV. References

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

POLICY

V. Approval/Revision History

First Level Approval			Second Level Approval	
 Signature Johanna Liu, PharmD			 Signature Jeff Robertson, MD	
Name Director of Quality and Pharmacy			Name Chief Medical Officer	
Title March 17, 2017			Title March 17, 2017	
Date			Date	
Version Number	Change (Original/ Reviewed/ Revised)	Reviewing Committee (if applicable)	Committee Action/Date (Recommend or Approve)	Board Action/Date (Approve or Ratify)
1	Original	Pharmacy & Therapeutics Committee	Approve 3/24/2016	
1	Reviewed	Pharmacy & Therapeutics Committee	Approved 3/16/2017	

POLICY



Santa Clara
Family Health Plan

Policy Title:	Pain Management Drugs for Terminally Ill	Policy No.:	PH08
Replaces Policy Title (if applicable):		Replaces Policy No. (if applicable):	
Issuing Department:	Pharmacy	Policy Review Frequency:	Annually
Lines of Business (check all that apply):	<input checked="" type="checkbox"/> Medi-Cal	<input checked="" type="checkbox"/> Healthy Kids	<input type="checkbox"/> CMC

I. Purpose

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

II. Policy

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

III. Responsibilities

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

IV. References

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

POLICY

V. Approval/Revision History

First Level Approval			Second Level Approval	
 <hr/> Signature Johanna Liu, PharmD <hr/> Name Director of Quality and Pharmacy <hr/> Title March 17, 2017 <hr/> Date			 <hr/> Signature Jeff Robertson, MD <hr/> Name Chief Medical Officer <hr/> Title March 17, 2017 <hr/> Date	
Version Number	Change (Original/Reviewed/Revised)	Reviewing Committee (if applicable)	Committee Action/Date (Recommend or Approve)	Board Action/Date (Approve or Ratify)
1	Original	Pharmacy & Therapeutics Committee	Approved 3/24/2016	
2	Revised	Pharmacy & Therapeutics Committee	Approved 3/16/2017	

POLICY



Santa Clara
Family Health Plan

Policy Title:	Medications for Members with Behavioral Health Conditions	Policy No.:	PH09
Replaces Policy Title (if applicable):		Replaces Policy No. (if applicable):	
Issuing Department:	Pharmacy	Policy Review Frequency:	Annually
Lines of Business (check all that apply):	<input checked="" type="checkbox"/> Medi-Cal	<input checked="" type="checkbox"/> Healthy Kids	<input checked="" type="checkbox"/> CMC

I. Purpose

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

II. Policy

- A. Santa Clara Family Health Plan (SCFHP) shall maintain written procedures on how the plan provides prescription coverage for the diagnosis and medically necessary treatment of behavioral health parity diagnoses under the same terms and conditions applied to other medical conditions.
- B. The plan shall not impose quantitative or non-quantitative treatment limitations more stringent on mental health and substance use disorder drug as compared to medical/surgical drugs prescriptions [42 CFR 438.900 et seq.]
- C. The Plan shall address the application of co-payments for psycho-pharmacologic drugs that are to be consistent with and not more stringent than limits for drugs for other medical conditions.

III. Responsibilities

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

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

IV. References

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

POLICY

V. Approval/Revision History

First Level Approval			Second Level Approval	
 <hr/> Signature Johanna Liu, PharmD, MBA <hr/> Name Director of Quality and Pharmacy <hr/> Title March 17, 2017 <hr/> Date			 <hr/> Signature Jeff Robertson, MD <hr/> Name Chief Medical Officer <hr/> Title March 17, 2017 <hr/> Date	
Version Number	Change (Original/ Reviewed/ Revised)	Reviewing Committee (if applicable)	Committee Action/Date (Recommend or Approve)	Board Action/Date (Approve or Ratify)
1	Original	Pharmacy & Therapeutics Committee	Approved 3/24/2016	
1	Reviewed	Pharmacy & Therapeutics Committee	Approved 3/16/2017	
2	Revised	Pharmacy & Therapeutics Committee	Pending 4Q2017 P&T	



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):	<input type="checkbox"/> Medi-Cal	<input type="checkbox"/> Healthy Kids	<input checked="" type="checkbox"/> 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 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., 90 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 day fill (unless the enrollee presents with a prescription written for less than 30 days in which case the Plan must allow multiple fills to provide up to a total of 30 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 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

V. Approval/Revision History

First Level Approval			Second Level Approval	
				
Signature Johanna Liu, PharmD			Signature Jeff Robertson, MD	
Name Director of Quality and Pharmacy			Name Chief Medical Officer	
Title June 02, 2017			Title June 02, 2017	
Date			Date	
Version Number	Change (Original/Reviewed/Revised)	Reviewing Committee (if applicable)	Committee Action/Date (Recommend or Approve)	Board Action/Date (Approve or Ratify)
1	Original	Pharmacy & Therapeutics Committee	Approved 6/15/2017	

POLICY



Santa Clara
Family Health Plan

Policy Title:	340B Program Compliance	Policy No.:	PH11
Replaces Policy Title (if applicable):		Replaces Policy No. (if applicable):	
Issuing Department:	Pharmacy	Policy Review Frequency:	Annually
Lines of Business (check all that apply):	<input checked="" type="checkbox"/> Medi-Cal	<input checked="" type="checkbox"/> Healthy Kids	<input type="checkbox"/> CMC

I. Purpose

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

II. Policy

- A. SCFHP Pharmacy Department will comply with all requirements and restrictions of the Public Health Service Act Section 340B pertaining to a managed care organization (MCO) and the prohibition against duplicate discount/rebates under Medicaid pertaining.
- B. The department will work with the Finance and Information Technology Departments to ensure the Department of Health Care Services 340B data reporting requirements are met [Patient Protection and Affordable Care Act of 2010, Public Law 111-148].

III. Responsibilities

- A. Director of Pharmacy, or designee, will maintain knowledge of regulation and policy changes that impact 340B program including, but not limited to, Health Resources & Service Administration/Office of Pharmacy Affairs rules.
- B. Director of Pharmacy, or designee, with the Pharmacy Benefit Manager (PBM) will ensure claims system availability of National Council for Prescription Drug Programs (NCPDP) Submission Clarification code 20 for 340B eligibility claim identification [California’s W&I Code Section 14105.46].
- C. Directory of Pharmacy, or designee, with the PBM will assist the Finance Department integrity audits.

IV. References

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

POLICY

V. Approval/Revision History

First Level Approval			Second Level Approval	
				
Signature Johanna Liu, PharmD			Signature Jeff Robertson, MD	
Name Director of Quality and Pharmacy			Name Chief Medical Officer	
Title 08/08/2017			Title 09/11/2017	
Date			Date	
Version Number	Change (Original/ Reviewed/ Revised)	Reviewing Committee (if applicable)	Committee Action/Date (Recommend or Approve)	Board Action/Date (Approve or Ratify)
1	Original	Pharmacy & Therapeutics Committee	Approved 09/21/2017	

POLICY



Santa Clara
Family Health Plan

Policy Title:	Medications for Cancer Clinical Trial	Policy No.:	PH14
Replaces Policy Title (if applicable):		Replaces Policy No. (if applicable):	
Issuing Department:	Pharmacy	Policy Review Frequency:	Annually
Lines of Business (check all that apply):	<input checked="" type="checkbox"/> Medi-Cal	<input type="checkbox"/> Healthy Kids	<input type="checkbox"/> CMC

I. Purpose

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

II. Policy

- A. SCFHP shall define the process for coverage of routine patient care costs related to the clinical trial, including drugs that would otherwise be covered under the plan if those drugs were not provided in connection with an approved clinical trial program.
- B. Routine patient care costs does not include the costs associated with the provision of:
 - a. Drugs or devices that have not been approved by the federal Food and Drug Administration (FDA) and that are associated with the clinical trial.
- C. The plan shall provide coverage of routine patient care costs, including other drug coverage given that the cancer clinical trial involves a drug that is exempt under federal regulations from a new drug application or approved by one of the following:
 - a. National Institutes of Health (NIH);
 - b. The federal FDA, in the form of an investigational new drug application;
 - c. Department of Defense; or
 - d. Veterans' Administration.
- D. The plan may restrict coverage for clinical trials to participating hospitals and physicians in California if the protocol for the clinical trial is not provided.

III. Responsibilities

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

IV. References

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

POLICY

V. Approval/Revision History

First Level Approval			Second Level Approval	
 <hr/> Signature Johanna Liu, PharmD <hr/> Name Director of Quality and Pharmacy <hr/> Title 09/05/2017 <hr/> Date			 <hr/> Signature Jeff Robertson, MD <hr/> Name Chief Medical Officer <hr/> Title 09/13/2017 <hr/> Date	
Version Number	Change (Original/Reviewed/Revised)	Reviewing Committee (if applicable)	Committee Action/Date (Recommend or Approve)	Board Action/Date (Approve or Ratify)
1	Original	Pharmacy & Therapeutics Committee	Approved 09/21/2017	

Recently Approved - High Interest and Impact



November 2017 – February 2018

Entity	Disease State	FDA Approval	Route	Therapeutic Role	Net PMPM
Hemlibra (emicizumab)	Hemophilia A	November 16 th , 2017	SQ	Competitor	\$-0.08 – \$0.01
Ozempic (semaglutide)	Diabetes	December 5 th , 2017	SQ	Competitor	\$0.00
Steglatro (ertugliflozin)	Diabetes	December 20 th , 2017	Oral	Competitor	\$0.00
Symdeko (tezacaftor/ivacaftor)	Cystic Fibrosis	February 12 th , 2018	Oral	Competitor	\$0.002-\$0.003

High Interest and Impact Pipeline Agents



1H2018

Entity	Disease State	Anticipated FDA Decision	Route	Therapeutic Role	Net PMPM
tildrakizumab	Plaque Psoriasis	March 24 th , 2018	SQ	Competitor	\$0.00
apalutamide	Prostate Cancer	April 2018	Oral	Breakthrough Therapy	\$0.03 – \$0.04
AndexXa (andexanet alfa)	Factor Xa Reversal Agent	May 4 th , 2018	IV	Breakthrough Therapy	\$0.03 – \$0.05
Aimovig (erenumab)	Migraine	May 17 th , 2018	SQ	Additive	\$0.06 – \$0.30
fremanezumab	Migraine	June 2018	SQ	Additive	

 = Medical Cost

Generic Pipeline 2018 1st Quarter

HIGH IMPACT

2018
ProAir HFA
Tracleer*
Byetta
Kaletra

March 2018
Sensipar*

April 2018
Nuvaring

May 2018
Adcirca

June 2018
Remodulin

July 2018
Letairis

August 2018
Ampyra

Sept 2018
Cialis

1Q18

2Q18

3Q18

Jan 2018
Forfivo XL
Viread

Feb 2018
Solodyn*
Treximet 85/500
Zortress*

1Q18
Sustiva 600mg

June 2018
Abstral
Onexton

July 2018
Acanya

2018
Androgel (1.62%)
Proventil HFA

Sept 2018
Moviprep

3Q18
Levitra

MEDIUM /LOW IMPACT

*NO exclusivity