AGENDA

For a Regular Meeting of the

Santa Clara County Health Authority
Pharmacy and Therapeutics Committee

Thursday, March 21, 2018, 6:00-8:00 PM
Santa Clara Family Health Plan, Redwood Conference Room
6201 San Ignacio Blvd., San Jose, CA 95119

1.	**Introductions**	Dr. Lin	6:00	5 min.
2.	**Public Comment** Members of the public may speak to any item not on the agenda; two minutes per speaker. The Committee reserves the right to limit the duration of public comment period to 30 minutes	Dr. Lin	6:05	5 min.
3.	**Meeting Minutes** Review SCFHP 4Q2018 P&T minutes **Possible Action:** Approve minutes	Dr. Lin	6:10	3 min.
4.	**Standing Agenda Items**			
	a. CMO Health Plan Updates	Dr. Nakahira	6:13	3 min.
	b. SCFHP/DHCS Global DUR	Dr. Otomo	6:16	5 min.
	i. Morphine Equivalency Initiative			
	ii. Anticholinergic Initiative			
	c. Opioid Utilization Monitoring	Dr. Otomo	6:21	3 min.
	d. Annual Pharmacy Policy Review	Dr. Liu	6:24	5 min.
	i. Annual Review			

1. PH01 Pharmacy and Therapeutics Committee
2. PH02 Formulary Development and Guideline Management
3. PH03 Prior Authorization
4. PH04 Pharmacy Clinical Programs and Quality Monitoring
5. PH05 continuity of Care for Pharmacy Services
6. PH06 Pharmacy Communications
7. PH07 Drug Recalls
8. PH08 Pain Management Drugs for Terminally Ill
9. PH09 Medications for Members with Behavioral Health Conditions
10. PH11 340B Program Compliance
11. PH14 Medications for Cancer Clinical Trial

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

5. **Metrics & Financial Updates**

a.	Membership Report	Dr. Nakahira	6:29	2 min.
b.	Pharmacy Dashboard	Dr. Otomo	6:31	3 min.
c.	Drug Use Evaluation	Dr. McCarty	6:34	2 min.
d.	Drug Utilization & Spend	Dr. McCarty	6:36	10 min.

6. **Discussion and Recommendations for Changes to SCFHP Cal MediConnect (CMC) Formulary & Coverage Determination Criteria**

a.	MedImpact 4Q2018 P&T Meetings Minutes	Dr. McCarty	6:46	2 min.
b.	MedImpact 1Q2019 P&T Part D Actions		6:48	2 min.

Possible Action: Approve MedImpact Minutes & Actions

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

a.	Formulary Modifications	Dr. Otomo	6:50	5 min.
	Possible Action: Approve recommendations			
b.	DHCS Medi-Cal CDL Updates & Comparibility	Dr. McCarty	6:55	10 min.
	Possible Action: Approve recommendations			
c.	Prior Authorization Criteria	Dr. Nguyen	7:05	10 min.

   i. New & Changes to Criteria
      1. Oncology
      2. Hepatitis C
      3. Oxycontin
      4. Mavyret
      5. Malarone
      6. Letairis
      7. Savella
      8. Evista
      9. Firvanq
      10. Protopic
      11. General UM (Utilization Management)

Possible Action: Approve criteria

8. **Discussion and Recommendations for Changes to SCFHP Medical Benefit Drug Prior Authorization Grid for SCFHP CMC, Medi-Cal, & Healthy Kids**

a.	Prior Authorization & Step Therapy Review	Dr. Huynh	7:15	5 min.
	Possible Action: Approve recommendations			

9. **New Drugs and Class Reviews** — Dr. McCarthy — 7:20 — 35 min.
   a. Diabetes (sotagliflozin)
   b. Cardiovascular Outcomes (Vascepa)
   c. Multiple Sclerosis (siponimod, cladribine) *informational only
   d. New Entities *informational only
   e. Psoriasis Update (Risankizumab) *informational only
   f. Oncology Update*informational only
   g. Biosimilar Update *informational only

Possible Action: Approve recommendations

Reconvene in Open Session

10. **Discussion Items**
    New Drugs and Generic Pipeline — Dr. McCarty — 7:55 — 5 min.

11. **Adjournment** — Dr. Lin — 8:00
    Next meeting Thursday, June 20, 2019

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 Nancy Aguirre 48 hours prior to the meeting at 408-874-1835.

- To obtain a copy of any supporting document that is available, contact Nancy Aguirre at 408-874-1835. Agenda materials distributed less than 72 hours before a meeting can be inspected at the Santa Clara Family Health Plan offices at 6201 San Ignacio Avenue, San Jose.

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

Meeting Minutes

Regular Meeting of the
Santa Clara County Health Authority d.b.a. Santa Clara Family Health Plan
OPEN SESSION - **Pharmacy & Therapeutics Committee**
Thursday, December 13, 2018
6:00 PM - 8:00 PM
6201 San Ignacio Avenue San Jose, CA 95119

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	Y
Amara Balakrishnan, MD	Pediatrics	Y
Peter Nguyen, MD	Family Practice	Y
Jesse Parashar-Rokicki, MD	Family Practice	N
Narinder Singh, PharmD	Health System Pharmacy (SCVMC)	N
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
Laurie Nakahira, MD	SCFHP Chief Medical Officer	Y
Jeff Robertson, MD	SCFHP Medical Director	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	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 6:06 PM.	
2	**Public Comment**	
	No public comment.	

3	**Past Meeting Minutes**	
	The SCFHP 3Q2018 P&T Minutes from September 20, 2018 were reviewed by the Committee as submitted.	Upon motion duly made and seconded, the SCFHP 3Q2018 P&T Minutes from September 20, 2018 were approved and will be forwarded to the QI Committee and Board of Directors.
4	**Plan Updates**	
	CMO Health Plan Updates Dr. Nakahira introduced herself as the new Chief Medical Officer at the plan and shared her professional background.	
	Appeals & Grievances Dr. Huynh presented the Appeals & Grievances report Q3 2017 through Q3 2018. Slight decrease in Medi-Cal appeals, downward trend. Slight decrease in Part C & D Appeals, downward trend. Committee asked about the most common grievance. Dr. Liu responded that she believes that the most common grievance is regarding transportation.	
	SCFHP/DHCS Global DUR Dr. Otomo presented updates on the plan's global drug utilization review (DUR) programs. SCFHP will be mirroring two DHCS DUR programs for Medi-Cal line of business: (1) to improve the quality of care among members 65 years of age and older taking a 2nd generation antipsychotic with an anticholinergic (benztropine and/or trihexyphenidyl), and (2) to improve the quality of pain treatment among non-cancer, non-hospice members at increased risk of opioid overdose. Currently working on the data reporting, then will determine the member/provider impact to conduct educational mailings.	
	DHCS Provider Enrollment (APL 17-019) Dr. Huynh presented the All Plan Letter (APL) stating that managed care health plan network providers must enroll in the Medi-Cal Program.	
	Consumer Assessment of Health Care Provider And Systems (CAHPS) Dr. Liu shared information about the CAHPS survey, which is a member satisfaction survey where SCFHP Cal MediConnect members are contacted by an external administrator (DSS Research) to ask about	

	their views on different benefit areas. This survey happens in Q2 of every year. Survey will be facilitated in English and Spanish with a pilot in Vietnamese and Chinese.	
	Emergency Supply Report 4Q2017 & 1Q2018 Dr. Nguyen presented the Emergency Prescription Access Report for 4Q17 and 1Q18.	
	Adjourn to Closed Session Committee adjourned to closed session at 6:48 PM 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, Recommendations for Changes to SCFHP Medical Benefit Drug Prior Authorization Grid for All Lines of Business, and New Drugs and Class Reviews.	
	Reconvene in Open Session Committee reconvened to open session at 7:56 PM.	
8	**Discussion Items**	
	New Drugs and Generic Pipeline Dr. McCarty presented the new drugs and generic pipeline. High impact-interest drugs include: Onpattro, Takhzyro, dasotraline, Ajovy, Emgality, Talzenna, Xofluza, lorlatinib, solriamfetol, caplacizumab, bremelanotide, netarsudil/latnoprost, siponimod, sotaglifozin, risankizumab, selinexor, cladribine, and esketamine. High impact generic pipeline drugs include: Onfi, Byetta, Nuvaring, Remodulin, Epclusa, Harvoni, Tracleer, Restasis, and Sensipar.	
9	**Adjournment at 7:59 PM**	

Standing Agenda Items

Santa Clara Family Health Plan™

RETROSPECTIVE DRUG UTILIZATION REVIEW (DUR)
MORPHINE EQUIVALENCY INITIATIVE

OBJECTIVE:
To improve the quality of pain treatment among non-cancer, non-hospice Santa Clara Family Health Plan (SCFHP) members at increased risk of opioid overdose

BACKGROUND:
- In 2016, the Centers for Disease Control and Prevention (CDC) released a guideline for prescribing opioids for chronic pain and reported that between 1999 and 2014, more than 165,000 people in the United States died from opioid overdose. Although there is no established safe dose of opioids, cumulative morphine equivalent daily dose (MEDD)* may be utilized as an indicator of potential dose-related risks, including overdose. Varying cumulative MEDD thresholds have been proposed by different organizations and experts as the point to trigger provider consultation to prevent serious adverse effects from opioid use. In 2017 and 2018, the Centers for Medicare & Medicaid Services (CMS) recommended that plans identify members with MEDD exceeding 120 mg as potential opioid overutilizers and provide case management when warranted.
- *Morphine equivalency may also be referred to as morphine equivalent dose (MED) or morphine milligram equivalents (MME), depending on the resource.

METHODS:
- Inclusion criteria:
  - Paid prescription opioid claims >14 days supply with fill dates during the measurement period (between October 1, 2017 and October 31, 2018).
    - Morphine equivalent daily dose (MEDD) was calculated for each claim.
    - Members with any month total of >120 MEDD were included.
  - Continuously eligible Medi-Cal member during the measurement period
- Exclusion criteria:
  - Not a continuously eligible member during the measurement period
  - Diagnosis of cancer
  - Residing in a long-term care facility or under hospice care
  - Approved prior authorization on file for the opioid medication on the fill date
  - Concomitant use of buprenorphine

SCFHP NEXT STEPS:
- Currently working with Finance department to identify members
- Mail an educational outreach letter and response form to the providers for the impacted members to improve the quality of pain treatment for these identified members
- Evaluate provider responses for case management opportunities

REFERENCES:
- Medi-Cal DUR Board:

    - Clinical Review: Morphine Equivalent Daily Dose to Prevent Opioid Overuse. September 30, 2015.
    - DUR Educational Outreach to Providers: Morphine Equivalent Daily Dose (MEDD) Letter. Last Update October 24, 2017.
- Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1):1–49. DOI: http://dx.doi.org/10.15585/mmwr.rr6501e1.
- Medical Board of California. Guidelines for prescribing controlled substances for pain. November 2014. Available at: http://www.mbc.ca.gov/Licensees/Prescribing/Pain_Guidelines.pdf. Accessed February 13, 2019.
- Washington State Agency Medical Directors' Group. Interagency Guideline on Prescribing Opioids for Pain. June 2015. Available at: http://www.agencymeddirectors.wa.gov/Files/2015AMDG Opioid Guideline.pdf. Accessed February 13, 2019.
- Announcement of Calendar Year (CY) 2017 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. April 4, 2016. Available at: https://www.cms.gov/Medicare/Health-plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2017.pdf. Accessed February 13, 2019.
- Announcement of Calendar Year (CY) 2018 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter and Request for Information. April 3, 2017. Available at: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2018.pdf. Accessed February 13, 2019.

Santa Clara Family Health Plan™

RETROSPECTIVE DRUG UTILIZATION REVIEW (DUR)
ANTICHOLINERGIC INITIATIVE

OBJECTIVE:

- To improve the quality of care among Santa Clara Family Health Plan's (SCFHP) Medi-Cal members age 65 years and older with concomitant use of second-generation antipsychotic and anticholinergic medications

BACKGROUND:

- Anticholinergics, including benztropine and trihexyphenidyl, are commonly used to prevent and treat antipsychotic-induced extrapyramidal symptoms (EPS) such as akathisia, dystonia, and parkinsonism. However, there is a lack of systematic reviews and meta-analyses that support this practice. When assessment of ongoing medical necessity of anticholinergics is not routinely conducted, long-term use of these agents may contribute to cognitive impairment, confusion, and exacerbation of tardive dyskinesia, especially in patients 65 years of age and older.

METHODS:

- Inclusion criteria:
  - Pharmacy claims with fill dates during the measurement period (between September 1, 2017 and September 30, 2018)
  - Continuously eligible Medi-Cal member during the measurement period
  - 65 years of age and older
  - Regular, concomitant use of second-generation antipsychotic medications and anticholinergics, defined as both:
    - Total days supply greater than 180 days of a second-generation antipsychotic medication; and
    - Total days supply greater than 180 days of benztropine and/or trihexyphenidyl
- A total of two members met the inclusion criteria listed above.

SCFHP NEXT STEPS:

- Mail an educational outreach letter and response form to the two impacted providers to improve the quality of care for identified members
- Evaluate provider responses for case management opportunities

REFERENCES:

- Medi-Cal DUR Board:
  - Clinical Review: Concomitant Use of Anticholinergics and Antipsychotics. November 30, 2015.
  - DUR Educational Outreach to Providers: Anticholinergic Letter. Last Update October 24, 2017.
- Lehman AF, Lieberman JA, Dixon LB, et al. Practice Guideline for the Treatment of Patients With Schizophrenia, 2nd ed. *Am J Psychiatry*. 2004;161(2 suppl)1-56. Available at:

http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/schizophrenia.pdf. Accessed: February 11, 2019.

- Kreyenbuhl J, Buchanan RW, Dickerson FB, et al. The Schizophrenia Patient Outcomes Research Team (PORT): Updated Treatment Recommendations 2009. *Schizophr Bull*. 2010;36(1):94-103. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2800150/. Accessed February 11, 2019.

Opioids – Cal MediConnect

CMS Opioid Overutilization Monitoring System Reports	SCFHP Opioid Clinical Program	Point-of-Sale Safety Edits
Quarterly Average daily morphine milligram equivalent (MME) ≥ 90 for any duration within the most recent 6 months AND *either*: • ≥ 3 opioid prescribers + ≥3 opioid dispensing pharmacies, *or* • ≥ 5 opioid prescribers	Quarterly ≥ 2 opioid prescriptions, *and* ≥ 3 opioid prescribers, *and* ≥ 3 opioid dispensing pharmacies	1. Opioid cumulative dosing – Care coordination edit 2. Opioid cumulative dosing – Hard edit 3. Opioid-benzodiazepine concurrent use edit 4. Opioid-naïve 7-day supply limitation 5. Duplicative long-acting opioid therapy edit

Exclusions apply for all

Opioids – Medi-Cal & Healthy Kids

- **Point-of-Sale Safety Edits**
  - H.R.6, Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act requirements:
    1. Opioid cumulative dosing edit(s)
    2. Opioid-benzodiazepine concurrent use edit
    3. Opioid-antipsychotic concurrent use edit
    4. Antipsychotic prescribing for children

  - Implementation by October 1, 2019

POLICY

Santa Clara
Family Health Plan

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

I. Purpose

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

II. Policy

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

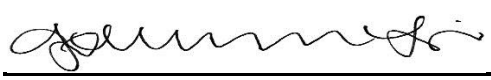
III. Responsibilities

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

IV. References

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

V. Approval/Revision History

First Level Approval	Second Level Approval
	
Signature Johanna Liu, PharmD	Signature Jeff Robertson, MD
Name Director of Quality and Pharmacy	Name Chief Medical Officer
Title March 15, 2018	Title March 15, 2018
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**	
1	**Reviewed**	**Pharmacy & Therapeutics Committee**	**Approved 3/15/2018**	

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):	☒ Medi-Cal ☒ Healthy Kids		☒ CMC

I. Purpose

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

II. Policy

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

III. Responsibilities

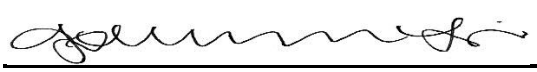
A. Chief Medical Officer, or designee, shall ensure the P&T Committee follows this policy.
B. Director of Pharmacy, or designee, shall coordinate and prepare clinical materials. He/she shall also oversee delegates that perform duties from this policy.

IV. References

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

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

V. Approval/Revision History

First Level Approval	Second Level Approval
 Signature Johanna Liu, PharmD Name Director of Quality and Pharmacy Title March 15, 2018 Date	 Signature Jeff Robertson, MD Name Chief Medical Officer Title March 15, 2018 Date

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1	**Original**	**Pharmacy & Therapeutics Committee**	**Approved 3/24/2016**	
1	**Reviewed**	**Pharmacy & Therapeutics Committee**	**Approved 3/16/2017**	
1	**Reviewed**	**Pharmacy & Therapeutics Committee**	**Approved 3/15/2018**	

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):	☒ Medi-Cal	☒ Healthy Kids	☒ CMC

I. Purpose

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

II. Policy

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

III. Responsibilities

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

IV. References

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

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

V. Approval/Revision History

First Level Approval	Second Level Approval
	
Signature Johanna Liu, PharmD	Signature Jeff Robertson, MD
Name Director of Quality and Pharmacy	Name Chief Medical Officer
Title March 15, 2018	Title March 15, 2018
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**	
1	**Reviewed**	**Pharmacy & Therapeutics Committee**	**Approved 3/15/2018**	

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 Inter-Rater Reliability Policy Medicare Coverage Determination Oversight Policy	**Replaces Policy No. (if applicable):**	PM 109 PM 126 PM 226
Issuing Department:	Pharmacy	**Policy Review Frequency:**	Bi-annually
Lines of Business (check all that apply):	☒ Medi-Cal	☒ Healthy Kids	☒ CMC

I. Purpose

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

II. Policy

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

III. Responsibilities

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

IV. References

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

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

V. Approval/Revision History

First Level Approval	Second Level Approval
	
Signature Johanna Liu, PharmD	Signature Jeff Robertson, MD
Name Director of Quality and Pharmacy	Name Chief Medical Officer
Title March 15, 2018	Title March 15, 2018
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	
2	Reviewed	Pharmacy & Therapeutics Committee	Approved 3/15/2018	

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 Emergency Supply of Medications from a Retail Pharmacy Pharmacy Network Access Continuation of Drug Therapy for a New and Current Members	**Replaces Policy No. (if applicable):**	PM 100 PM 108 PM 112 PM 122
Issuing Department:	Pharmacy	**Policy Review Frequency:**	Annually
Lines of Business (check all that apply):	☒ Medi-Cal	☒ Healthy Kids	☒ CMC

I. Purpose

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

II. Policy

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

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

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

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

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

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

POLICY

III. Responsibilities

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

IV. References

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

V. Approval/Revision History

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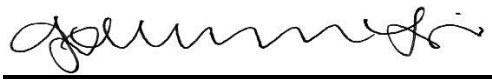	
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1	**Reviewed**	**Pharmacy & Therapeutics Committee**	**Approved 3/15/2018**	

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):	☒ Medi-Cal	☒ Healthy Kids	☒ CMC

I. Purpose

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

II. Policy

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

III. Responsibilities

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

IV. References

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

POLICY

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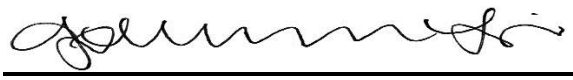	
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1	**Reviewed**	**Pharmacy & Therapeutics Committee**	**Approved 3/15/2018**	

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):	☐ Medi-Cal	☐ Healthy Kids	☒ CMC

I. Purpose

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

II. Policy

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

III. Responsibilities

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

IV. References

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

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1	**Reviewed**	**Pharmacy & Therapeutics Committee**	**Approved 3/15/2018**	

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):	☒ Medi-Cal	☒ Healthy Kids	☐ CMC

I. Purpose

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

II. Policy

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

III. Responsibilities

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

IV. References

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

V. Approval/Revision History

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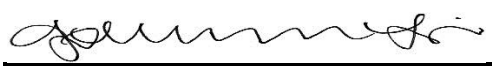	
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3	Reviewed	Pharmacy & Therapeutics Committee	Approved 3/15/2018	

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):	☒ Medi-Cal ☒ Healthy Kids		☒ CMC

I. Purpose

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

II. Policy

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

III. Responsibilities

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

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

IV. References

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

POLICY

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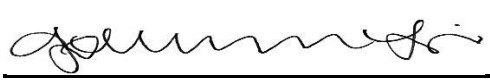	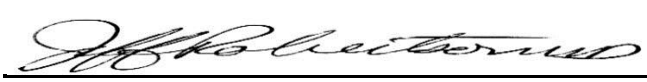
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1	**Reviewed**	**Pharmacy & Therapeutics Committee**	**Approved 3/15/2018**	

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):	☒ Medi-Cal ☒ Healthy Kids		☐ CMC

I. Purpose

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

II. Policy

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

III. Responsibilities

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

IV. References

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

POLICY

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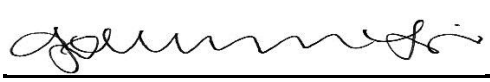	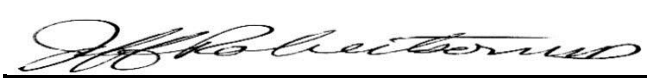
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1	**Reviewed**	**Pharmacy & Therapeutics Committee**	**Approved 03/15/2018**	

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):	☒ Medi-Cal ☐ Healthy Kids		☐ CMC

I. Purpose

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

II. Policy

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

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

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

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

III. Responsibilities

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

IV. References

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

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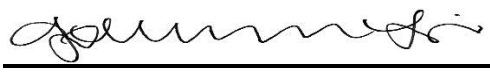	
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Discussion Items

High Impact-Interest Agent Pipeline

March 2019
esketamine† (treatment-resistant depression)-A
netarsudil/latanoprost (glaucoma)-C
siponimod (SPMS)-A
solriamfetol (OSA/narcolepsy)-C
sotagliflozin (DM1)-A

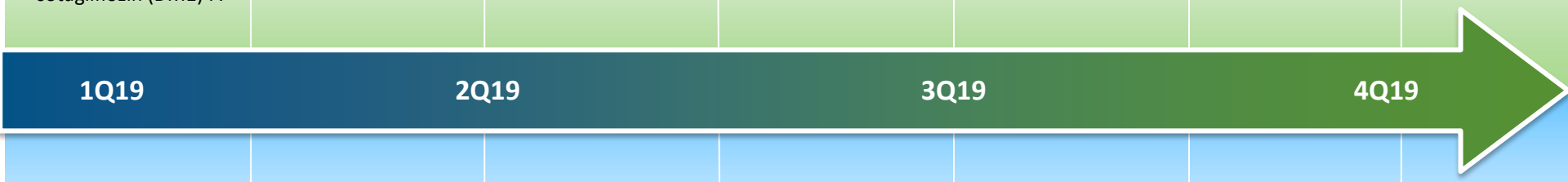
May 2019
AVXS-101† (SMA)-BT

1st Half 2019
alpelisib (breast cancer)-C

September 2019
lumateperone (schizophrenia)-C

November 2019
lasmiditan (migraine)-C

2nd Half 2019
AR101 (peanut allergy)-BT



February 2019
Cablivi (aTTP)-BT

April 2019
risankizumab (plaque psoriasis)-C
selinexor (myeloma)-BT
cladribine (MS)-C

June 2019
bremelanotide (HSDD)-C

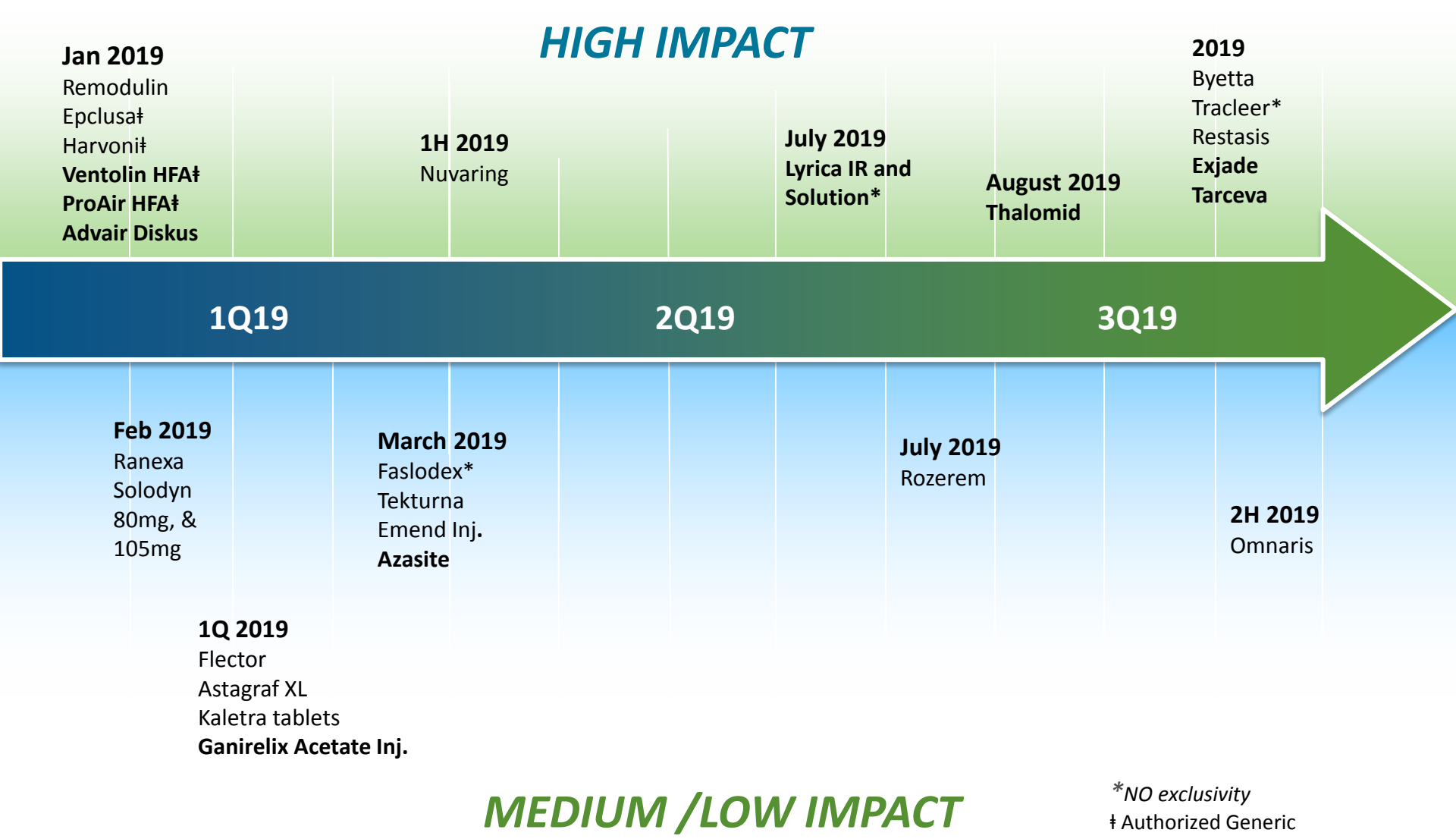
October 2019
diroximel fumurate (MS)-C
PF708 (osteoporosis)-C

December 2019
eflapegrastim (neutropenia)-C
fedratinib (myelofibrosis)-C
upadacitinib (RA)-C

Not Yet Filed
bempedoic acid-A (hypercholesterolemia)-C
brolucizumab (AMD)-C
crizanlizumab (sickle cell disease)-A
leronlimab (HIV)-A
pitolisant (narcolepsy)-C
roxadustat (anemia of CKD)-C
voxelotor (sickle cell disease)-BT

KEY
C = Pipeline agent will **compete** with current standard of care
A = Pipeline agent will be used in **addition** to current therapy or expands the patient population treated
BT = Pipeline agent is a **breakthrough**/novel treatment in an area where no comparable drug therapy previously existed
† = *Medical Cost*
* = *Delay in PDUFA*

Generic Pipeline



*NO exclusivity

‡ Authorized Generic