Regular Meeting of the

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

Thursday, September 19, 2019, 6:00-8:00 PM
Santa Clara Family Health Plan, Redwood Conference Room
6201 San Ignacio Ave, San Jose, CA 95119

AGENDA

1.	**Roll Call / Establish Quorum**	Dr. Lin	6:00	5 min
2.	**Public Comment** Members of the public may speak to any item not on the agenda; two minutes per speaker. The Committee reserves the right to limit the duration of public comment period to 30 minutes	Dr. Lin	6:05	5 min
3.	**Open Meeting Minutes** Review SCFHP 2Q2019 P&T Open Minutes **Possible Action:** Approve SCFHP P&T Open Minutes	Dr. Lin	6:10	2 min
4.	**Standing Agenda Items**			
	a. CMO Health Plan Updates	Dr. Nakahira	6:12	5 min
	b. Plan/Global Medi-Cal Drug Use Review Concomitant Anticholinergic and Antipsychotic Use	Dr. Otomo	6:17	3 min
	c. Appeals & Grievance 2Q2019 Report	Mr. Breakbill	6:20	3 min
	d. P&T Committee Charter **Possible Action:** Approve P&T Committee Charter	Dr. Huynh	6:23	4 min

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

5.	**Closed Meeting Minutes** Review SCFHP 2Q2019 P&T Closed Minutes **Possible Action:** Approve SCFHP P&T Closed Minutes	Dr. Lin	6:27	2 min
6.	**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. Huynh	6:34	2 min
	d. Drug Utilization & Spend	Dr. McCarty	6:36	10 min

7. **Discussion and Recommendations for Changes to SCFHP's Cal MediConnect Formulary & Coverage Determination Criteria**
    a. MedImpact 2Q2019 P&T Minutes — Dr. McCarty — 6:46 — 2 min
    b. MedImpact 3Q2019 P&T Ad Hoc Minutes
    c. MedImpact 3Q2019 P&T Part D actions

    Possible Action: Approve MedImpact Minutes & Actions

8. **Discussion and Recommendations for Changes to SCFHP's Medi-Cal & Healthy Kids Formulary & Prior Authorization Criteria**
    a. Old Business/Follow-Up — Dr. Huynh — 6:48 — 2 min
        i. Ciprodex Indication
        ii. Mycobutin TB Treatment Duration
    b. Formulary Modifications — Dr. Otomo — 6:50 — 5 min

    Possible Action: Approve recommendations
    c. Fee-for-service Contract Drug List Comparability — Dr. McCarty — 6:55 — 5 min

    Possible Action: Approve recommendations
    d. Prior Authorization Criteria — Dr. Otomo — 7:00 — 10 min
        i. <u>New or Revised Criteria</u>
            1. Brand Name
            2. Enbrel (etanercept)
            3. Humira (adalimumab)
            4. Insulin Pens
            5. Januvia (sitagliptin)
            6. Off-label
            7. Oncology
            8. Opioid Safety Edits
            9. Quantity Limit
            10. Taltz (ixekizumab)
            11. Trintellix (vortioxetine)
            12. Xelpros (latanoprost)
            13. Zyvox (linezolid)

        ii. <u>Annual Review</u>
            1. Compound Medications
            2. Duragesic (fentanyl patch)
            3. Emend (aprepitant)
            4. Myrbetriq (mirabegron)
            5. Nicotrol (nicotine)
            6. Opioids – Reauthorization
            7. Penlac (ciclopirox solution)
            8. Retacrit (epoetin alfa-epbx)

        Possible Action: Approve criteria

9. **New Drugs and Class Reviews** — Dr. McCarty — 7:10 — 45 min
    a. Sleep Pharmacology
        i. Sunosi (solriamfetol)
        ii. Wakix (pitolisant)
    b. Rheumatoid Arthritis: Rinvoq (upadacitinib)
    c. Oncology Update

i. Xpovio (selinexor)
ii. Piqray (alpelisib)
iii. Polivy (polatuzumab vedotin-piiq)
iv. Turalio (pexidartinib)

d. Community-Acquired Bacterial Pneumonia: Xenleta (lefamulin)
e. Irritable Bowel Syndrome with Constipation **informational only*
    i. tenapanor
    ii. tegaserod
f. Vyleesi (bremelanotide) **informational only*
g. Lumateperone**informational only*
h. Semaglutide (oral) **informational only*
i. New Derivatives/Formulations/Combinations **informational only*
j. Biosimilar Update **informational only*
k. New and Expanded Indications **informational only*

Possible Action: Approve recommendations

Reconvene in Open Session

10. Discussion Items			
a. New and Generic Pipeline	Dr. McCarty	7:55	5 min
11. Adjournment	Dr. Lin	8:00	

Next meeting Thursday, December 12, 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.
- The Committee may take other actions relating to the issues as may be determined following consideration of the matter and discussion of the possible action.
- In compliance with the Americans with Disabilities Act, those requiring accommodations in this meeting should notify Nancy Aguirre 48 hours prior to the meeting at 408-874-1835.
- To obtain a copy of any supporting document that is available, contact Nancy Aguirre at 408-874-1835. Agenda materials distributed less than 72 hours before a meeting can be inspected at the Santa Clara Family Health Plan offices at 6201 San Ignacio Ave, San Jose, CA 95119.
- This agenda and meeting documents are available at www.scfhp.com

Open Meeting Minutes

MINUTES – *Open Session*

Regular Meeting of the

Santa Clara County Health Authority
Pharmacy & Therapeutics Committee

Thursday, June 20, 2019, 6:00 PM - 8:00 PM
Santa Clara Family Health Plan, Redwood
6201 San Ignacio Ave, San Jose, CA 95119

Voting Committee Members	Specialty	Present (Y or N)
Jimmy Lin, MD, Chairperson	Internal Medicine	Y
Hoa Bui, BS, RPh	Community Pharmacy (Walgreens)	N
Minh Thai, MD	Family Practice	N
Amara Balakrishnan, MD	Pediatrics	Y
Peter Nguyen, MD	Family Practice	N
Jesse Parashar-Rokicki, MD	Family Practice	Y
Narinder Singh, PharmD	Health System Pharmacy (SCVMC)	Y
Ali Alkoraishi, MD	Adult & Child Psychiatry	Y
Dolly Goel, MD	VHP Chief Medical Officer	N
Xuan Cung, PharmD	VHP Pharmacy Supervisor	Y
Laurie Nakahira, DO	SCFHP Chief Medical Officer	Y
Dang Huynh, PharmD	SCFHP Pharmacy Director	Y

Non-Voting Committee Members	Specialty	Present (Y or N)
Tami Otomo, PharmD	SCFHP Clinical Pharmacist	Y
Michelle Huynh	SCFHP Pharmacy Coordinator	Y
Duyen Nguyen, PharmD	SCFHP Clinical Pharmacist	Y
Amy McCarty, PharmD	MedImpact	Y
Darryl Breakbill	SCFHP Appeals & Grievance Director	Y
Nancy Aguirre	SCFHP Administrative Assistant	Y
Kelsey Kaku, PharmD	VMC Pharmacy Resident (PGY-2)	Y

1. **Introduction**
   Jimmy Lin, Chair, called the meeting to order at 6:08 pm. Roll call was taken. Missing one committee member to reach a quorum. Meeting commenced while pending the arrival of Dr. Alkoraishi.

2. **Public Comment**
   There were no public comments.

3. Meeting Minutes

The review of the March 21st, 2019 Pharmacy and Therapeutics Committee meeting minutes were tabled. Pending the arrival of Dr. Alkoraishi.

4. Standing Agenda Items

a. CMO Health Plan Updates

Dr. Nakahira announced Dang Huynh as the new Santa Clara Family Health Plan (SCFHP) Pharmacy Director.

Dr. Nakahira noted SCFHP was in the middle of the DHCS & DMHC audit during the last Pharmacy and Therapeutics Committee meeting in March, 2019. Since then, SCFHP has received a draft audit report from DHCS and the Plan is currently responding to their findings. DMHC has yet to submit a report. Anticipating a report to be submitted by early July, 2019.

b. SCFHP/DHCS Global DUR

Dr. Otomo presented the updates on the Plan's global drug utilization review (DUR) programs:

i. Anticholinergic Initiative:

This is a retrospective DUR program specifically looking at Medi-Cal members ages 65 and older with use of second-generation antipsychotic and anticholinergic medication.

Data revealed a total of two (2) members met the criteria. The data showed that each member had one provider for both the anticholinergic medication and the antipsychotic medication. Since there were only two impacted providers, it was the committee's opinion during the last P&T Committee meeting to conduct a direct telephonic outreach to each provider rather than a mailing.

The two impacted providers were cautioned of the potential risks of concomitant of these drug classes. Both providers were aware of these risks and attested that the members are stable on therapy.

In conclusion, in SCFHP's Medi-Cal population of members 65 years and older, benztropine or trihexyphenidyl and a second-generation antipsychotic, does not appear to be commonly co-prescribed, which is good.

Dr. Ali Alkoraishi arrived at 6:21pm. A quorum was establish at this time. Review of the Pharmacy & Therapeutics Committee meeting minutes of the March 21st, 2019 meeting commenced.

Dr. Lin motioned to accept the meeting minutes as presented. It was motioned by Dr. Nakahira and seconded by Dr. Alkoraishi. The motion carried.

c. Appeals & Grievance

Mr. Breakbill presented the following Appeals & Grievance reports:

i. 2018 4th Quarter Report:

Pharmacy appeals were 50% overturned and 37% were upheld, with 6% partially favorable. Partly favorable is when a prescriber will ask for beyond what is recommended.

ii. 2019 1st Quarter Report:

Format was changed to reflect total amount rather than percentage. Data reveals 19 of the pharmacy appeals for Medi-Cal were overturned, 50 of them were upheld, and 1 was partially favorable. For Cal Medi-Connect, 16 were overturned and 18 were upheld.

d. Emergency Supply Report

Dr. Nguyen presented the Emergency Supply Report. Dr. Nguyen explained the goal of the report is to evaluate access to medications prescribed after emergency room (ER) visits and to determine (if) any barriers to care exists.

i. 2018 2nd Quarter Report:
Evaluated patients diagnosed with urinary tract infections (UTI) and if they were prescribed medications within 72 hours of their ER visit.

There were no issues for approved or denied claims. Denied claims were a result of patient's primary insurance being outside of the Health Plan. For members who did not have a claim (18 members), data revealed most of these patients had a prescription filled several days before, or more than 4 days after their ER visit.

ii. 2018 3rd Quarter Report:
There were no issues identified for approved or denied claims. For members who did not have claim, data revealed the same results for 2018's 2nd quarter report.

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

5. Closed Meeting Minutes

Previous quarter's closed meeting minutes approved.

6. Metrics & Financial Updates

Dr. Nakahira presented the membership reports. Dr. Otomo presented the pharmacy dashboard.
Dr. McCarty presented the Drug Use Evaluation (DUE). Dr. McCarty presented the drug utilization & spend.

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

Dr. McCarty presented MedImpact minutes and Part D actions. Both were approved.

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

Dr. Otomo presented formulary modifications and were approved. Dr. McCarty presented CDL updates from February-May 2019 and were approved. Dr. Nguyen presented the PA criteria changes and were approved. Annual PA criteria were reviewed by committee and approved.

9. New Drugs and Class Reviews

Dr. McCarty presented new drugs and class reviews. Recommendations were approved.

Reconvene to Open Session
Committee reconvened to open session at 7:40pm

10. Discussion Items

New and Generic Pipeline

Dr. McCarty presented the new and generic pipeline.
In May, 2019, AVXS-101 came to market with Zolgensma, a gene therapy for Spinal Muscular Atrophy. Cost is high but results are promising. Study included 15 children. 13 out of 15 children responded significantly.

Oral semaglutide (diabetes)-C will come to market in September 2019. First oral treatment in its class. Other treatments are injectable. Anticipating a big impact in utilization when oral semaglutide comes to market.

11. Adjournment

Next meeting is Thursday, September 19th, 2019.

The meeting was adjourned at 7:48pm.

_____ _____

Jimmy Lin, MD
Chair of Pharmacy & Therapeutics Committee

Date

Standing Agenda Items

August 30, 2019

Clinical Review Update: Concomitant Anticholinergic and Antipsychotic Use

Learning Objectives:

- Understand the role of anticholinergic medications in the prevention and treatment of antipsychotic-induced extrapyramidal symptoms (EPS).
- Describe factors that should be considered when deciding to initiate and/or continue the concomitant use of anticholinergic with antipsychotic medication therapy.

Key Points:

- Anticholinergic medications, including benztropine and trihexyphenidyl, are often prescribed to prevent or treat antipsychotic-induced EPS; however, the need for continued therapy with anticholinergics is not often reassessed and many patients continue to use these medications.
- The consensus among the medical community is that prophylaxis of EPS with anticholinergics is generally not indicated in patients receiving antipsychotics, in particular among patients who are prescribed second-generation antipsychotics.
- Long-term use of anticholinergic medications is associated with cognitive impairment and worsening of tardive dyskinesia, especially among persons 65 years of age or older.
- Among the 268,245 Medi-Cal beneficiaries with a paid claim for any antipsychotic medication during the measurement year, a total of 29,807 (11%) beneficiaries had concomitant use of anticholinergic medication during this period. Among this population, a total of 15,487 (6%) beneficiaries also had at least six paid claims for an anticholinergic medication during this same time period, suggesting long-term use of concomitant anticholinergic and antipsychotic medications.
- Concomitant use of anticholinergic medications was higher among the 23,191 Medi-Cal beneficiaries with at least one paid claim for a first-generation antipsychotic medication (n = 9,767; 42%), in comparison to the 260,655 Medi-Cal beneficiaries with paid claims exclusively for second-generation antipsychotic medications (n = 27,137; 10%).
- Continued use of anticholinergic medications should be re-evaluated in patients with controlled symptoms every three months.

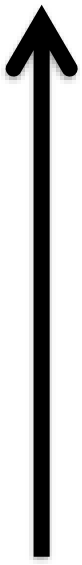
Background

Anticholinergic medications, including benztropine and trihexyphenidyl, are often prescribed to prevent or treat antipsychotic-induced EPS, including tremor, rigidity, bradykinesia, and acute dystonia.[1] However, the need for continued therapy with anticholinergics is not often reassessed and many patients continue to use these medications for several years or even decades.[1] Prescribers may be reluctant to discontinue anticholinergics even when patients are prescribed second-generation antipsychotics, which are less likely than first-generation antipsychotics to induce EPS.[1-5]

Despite the widespread use of anticholinergic medications for prophylaxis and treatment of antipsychotic-induced EPS, there is a lack of systematic reviews and meta-analyses supporting this practice, and the long-term benefit of anticholinergic use has not been established.[1,6] In fact, several adverse effects have been reported from long-term use, including cognitive impairment and worsening of tardive dyskinesia, especially among persons 65 years of age or older.[5,7,8] The 2009 Schizophrenia Patient Outcomes Research Team (PORT) treatment recommendations state that the prophylactic use of anticholinergics to reduce the incidence of EPS was not warranted in patients treated with second-generation antipsychotics but should be evaluated on a case-by-case basis for patients treated with first-generation antipsychotics.[9,10]

The consensus among the medical community is that prophylaxis of EPS with anticholinergics is generally not indicated in patients receiving antipsychotics and that anticholinergic use should be limited to when parkinsonism arises and when other measures, such as dose reduction, have failed.[11] As differences in the risk for EPS are correlated to the relative potency of antipsychotics, switching to antipsychotics with a lower propensity for EPS may also help limit or avoid the use of anticholinergics (Table 1).[9,10]

Table 1. General Ranking of Selected First- and Second-Generation Antipsychotics by Propensity for EPS[9,10,12-15]

High potency first-generation antipsychotics: Fluphenazine, haloperidol, pimozide, thiothixene, trifluoperazine	**Highest propensity for EPS** 
Mid potency first-generation antipsychotics: Loxapine, perphenazine	
Second-generation antipsychotics: Paliperidone, risperidone	
Second-generation antipsychotics: Asenapine, cariprazine, lurasidone	
Low potency first-generation antipsychotics: Chlorpromazine, thioridazine	
Second-generation antipsychotics: Aripiprazole, brexpiprazole, olanzapine, ziprasidone	
Second-generation antipsychotics: Quetiapine, iloperidone, pimavanserin	
Second-generation antipsychotics: Clozapine	**Lowest propensity for EPS**

Summary of Current Treatment Guidelines for Prophylactic Use of Anticholinergic Medications[9,10,16-18]

Current treatment guidelines describe the following factors that should be considered in decisions regarding the prophylactic use of anticholinergic medications in acute-phase treatment:

- Propensity of the antipsychotic medication to cause EPS
- Patient preferences
- Patient's prior history of EPS
- Other risk factors for EPS (especially dystonia)
- Risk factors for and potential consequences of anticholinergic side effects

Use of Anticholinergic Medications in the Medi-Cal Population
A retrospective cohort study was conducted to evaluate the use of anticholinergic medications in the Medi-Cal population. All paid pharmacy claims for benztropine and trihexyphenidyl for dates of service from January 1, 2018, through December 31, 2018, were reviewed. Beneficiaries were then evaluated for concomitant use of antipsychotic medications during the same measurement year. Data were then stratified by concomitant use of first- or second-generation antipsychotics, with additional analyses conducted by individual antipsychotic medication. Descriptive statistics were used to summarize data into tables. Data analyses were performed using IBM® SPSS®, version 26.0 (Chicago, IL).

Results
Across all age groups, there were 31,118 unique beneficiaries identified with a paid claim for benztropine and/or trihexyphenidyl that has a days' supply greater than or equal to 30 days during the one-year measurement period. The majority of these beneficiaries (n = 29,006; 93%) had a paid claim for benztropine and 375 beneficiaries (1%) had at least one paid claim for both benztropine and trihexiphenadyl at distinct time periods (non-concomitant). To determine if anticholinergic use was primarily short-term, the total number of paid claims with a days' supply greater than or equal to 30 days was calculated for each beneficiary during the same one-year period (Table 2). More than half of the study population (52%) had at least six paid claims for an anticholinergic medication during the measurement year, suggesting long-term use during at least six months of the year, and 17% had paid claims greater than or equal to a one-year supply.

Table 2. Anticholinergic Use Among Medi-Cal Beneficiaries from January 1, 2018, through December 31, 2018

Number of paid claims for an anticholinergic medication ≥30 days' supply during measurement year	Utilizing Beneficiaries n (%)
≥12	5,216 (17%)
6 – 11	10,776 (35%)
2 – 5	9,395 (30%)
1	5,731 (18%)
TOTAL	**31,118 (100%)**

Among those beneficiaries with at least one paid claim for an anticholinergic medication, a total of 529 beneficiaries (2%) were 65 years of age or older, with 217 of these beneficiaries having at least six paid claims for an anticholinergic medication during the measurement year. As stated previously, the risk of adverse events related to anticholinergic medication use is increased in this population, and both benztropine and trihexyphenidyl appear on the American Geriatrics Society 2019 Updated AGS Beers Criteria® for Potentially Inappropriate Medication Use in Older Adults reference tool.[8] Among beneficiaries younger than 65 years of age (n = 30,630), approximately half (51%) of beneficiaries had at least six paid claims for an anticholinergic medication during the measurement year, suggesting the rate of chronic use of anticholinergic medications was higher among older adults during this time period.

An additional evaluation was conducted to determine if anticholinergic use was linked to the propensity for antipsychotic-induced EPS. Pharmacy claims data for all Medi-Cal beneficiaries were reviewed for concomitant use of antipsychotics and anticholinergics. Among those beneficiaries with a paid claim for an anticholinergic medication with greater than or equal to a 30-day supply, a total of 29,807 (96%) beneficiaries also had at least one paid claim for an antipsychotic medication during the same time period. Because of the differences in clinical recommendations for anticholinergic use, the claims data were stratified by first- and second-generation antipsychotics.

Table 3. Concomitant Anticholinergic Medication Use in Medi-Cal Beneficiaries With a Paid Claim for an Antipsychotic Medication Between January 1, 2018, and December 31, 2018*

Category	Total Utilizing Beneficiaries	Percent of Utilizing Beneficiaries with Concomitant Anticholinergic Use		
		No Use (0 paid claims)	Low Use (<6 paid claims)	High Use (≥6 paid claims)
First-Generation Antipsychotic Medications	CHLORPROMAZINE (n = 3,946)	74%	11%	15%
	FLUPHENAZINE (n = 1,692)	48%	22%	30%
	HALOPERIDOL (n = 15,208)	52%	22%	26%
	LOXAPINE (n = 630)	65%	14%	21%
	PERPHENAZINE (n = 1,932)	69%	13%	17%
	PIMOZIDE (n = 78)	92%	5%	3%
	THIORIDAZINE (n = 303)	81%	8%	11%
	THIOTHIXENE (n = 405)	47%	16%	37%
	TRIFLUOPERAZINE (n = 436)	54%	15%	31%
	ANY (n = 23,191)	58%	19%	23%
Second-Generation Antipsychotic Medications	ARIPIPRAZOLE (n = 75,087)	91%	5%	4%
	ASENAPINE (n = 2,692)	81%	9%	10%
	BREXPIPRAZOLE (n = 2,497)	89%	5%	6%
	CARIPRAZINE (n = 1,820)	83%	8%	9%
	CLOZAPINE (n = 4,246)	71%	15%	14%
	ILOPERIDONE (n = 779)	72%	8%	19%
	LURASIDONE (n = 29,649)	88%	7%	5%
	OLANZAPINE (n = 51,384)	86%	7%	7%
	PALIPERIDONE (n = 12,725)	71%	14%	15%
	QUETIAPINE (n = 86,264)	92%	4%	4%
	RISPERIDONE (n = 54,045)	82%	9%	9%
	ZIPRASIDONE (n = 9,686)	85%	7%	8%
	ANY (n = 260,655)	90%	5%	5%
	TOTAL (n = 268,245)	**89%**	**5%**	**6%**

* Beneficiaries with paid claims for more than one antipsychotic medication were included in the cohort for each antipsychotic medication in order to calculate concomitant rates of anticholinergic use for each antipsychotic medication.

As shown in Table 3, the rate of concomitant use of anticholinergics is higher among utilizing beneficiaries with a paid claim for a first-generation antipsychotic medication (42%) than among utilizing beneficiaries with a paid claim for a second-generation antipsychotic medication (10%). Concomitant anticholinergic use with second-generation antipsychotics did not seem to be correlated with EPS propensity; however, as anticholinergic use among beneficiaries with a paid claim for a higher-propensity second-generation antipsychotic like paliperidone was the same (29%) as use for beneficiaries with a paid claim for clozapine, which is thought to have the lowest propensity for EPS.

Of note, there were 4,399 beneficiaries age 65 years or older with a paid claim for an antipsychotic medication, with 11% (n = 488) having concomitant use of anticholinergic medication. Concomitant use of anticholinergic medications among these older adults was observed in 38% of those with a paid claim for a first-generation antipsychotic medication and in 11% of those with a paid claim for a second-generation antipsychotic medication, which are similar rates to the overall population.

Clinical Recommendations:

- Decisions regarding the prophylactic use of anticholinergic medications to prevent EPS should be determined on a case-by-case basis, in consideration of both patient-specific and medication-specific factors.
- In general, for patients taking second-generation antipsychotics with lower propensity for EPS, prophylactic anticholinergic medications are not recommended.
- When using an anticholinergic medication to treat acute dystonia, it is important to use the lowest dose that is able to treat the dystonia and to continue the anticholinergic medication for the shortest time needed to prevent dystonia from recurring.
- For patients who have parkinsonism associated with antipsychotic therapy, it is preferable to either lower the dosage of the antipsychotic medication or switch to another antipsychotic medication before treating with a concomitant anticholinergic medication.
- Continued use of anticholinergic medications in patients with controlled symptoms should be re-evaluated every three months.
- Older patients and/or persons with high genetic risk of cognitive disorder who use anticholinergic medications are at increased risk of cognitive decline and dementia. Providers should refer to the American Geriatrics Society 2019 Updated AGS Beers Criteria® for Potentially Inappropriate Medication Use in Older Adults reference tool and consider discontinuation of anticholinergic medications in these populations.

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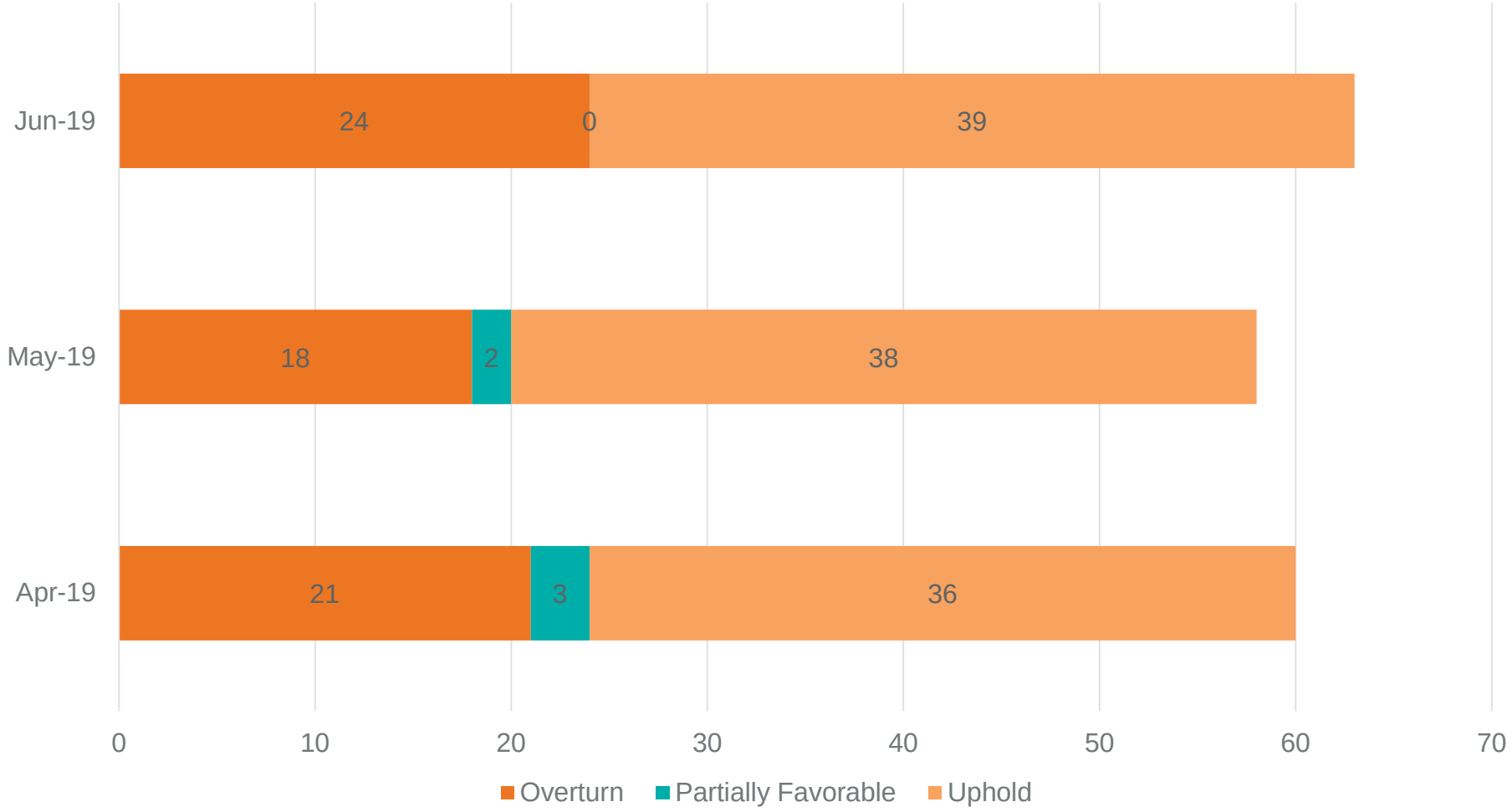
Santa Clara Family Health Plan™

Grievance & Appeals Department

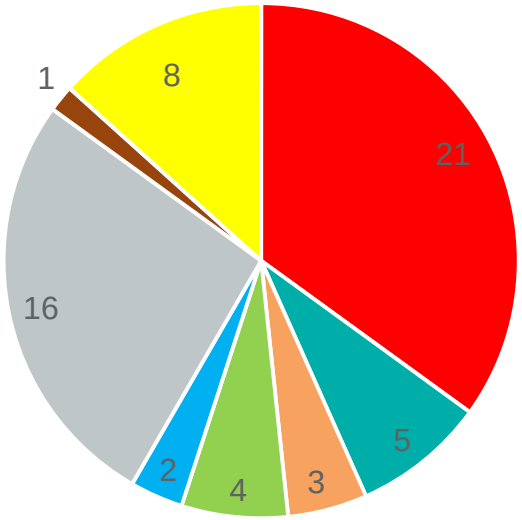
Q2 2019 Reporting

Q2 2019: Medi-Cal Appeals by Determination

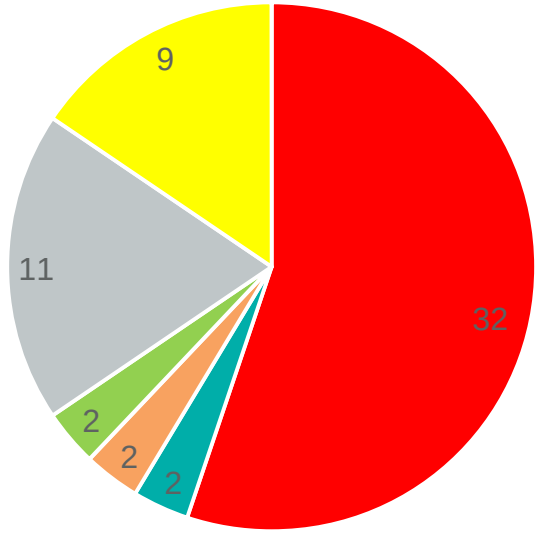


Q2 2019: Medi-Cal Appeals by Rationale

Apr-19



May-19



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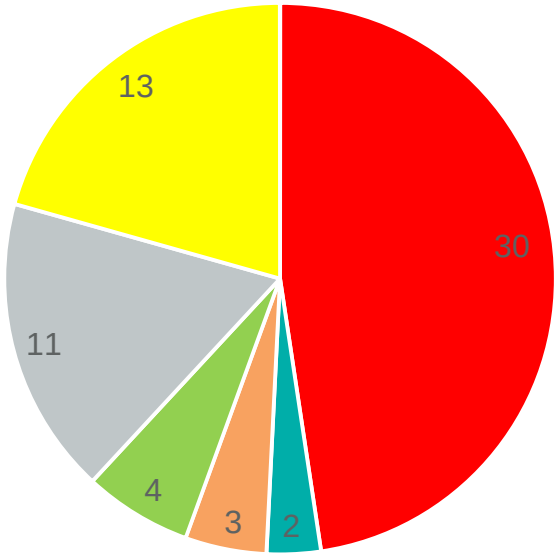
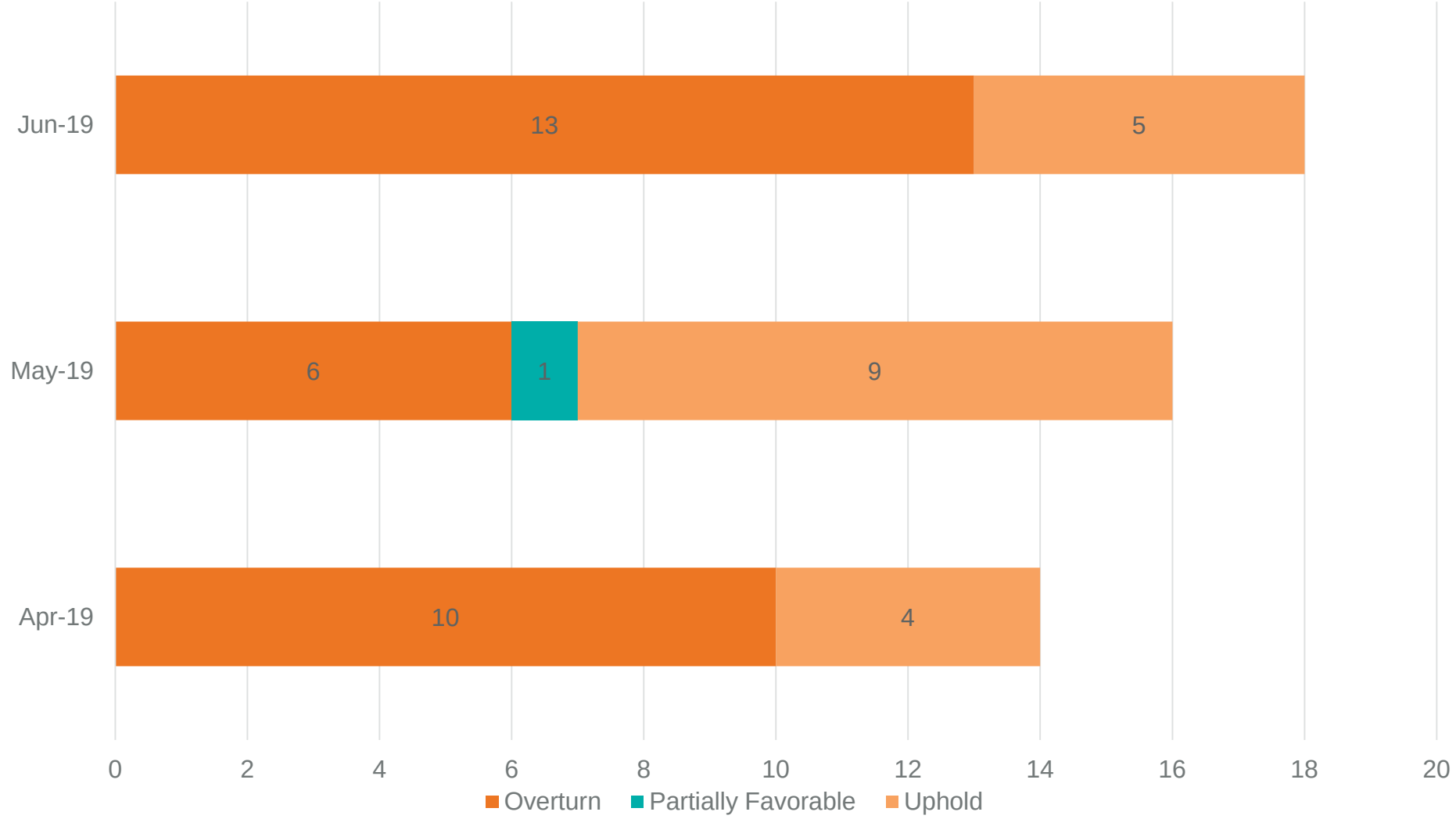


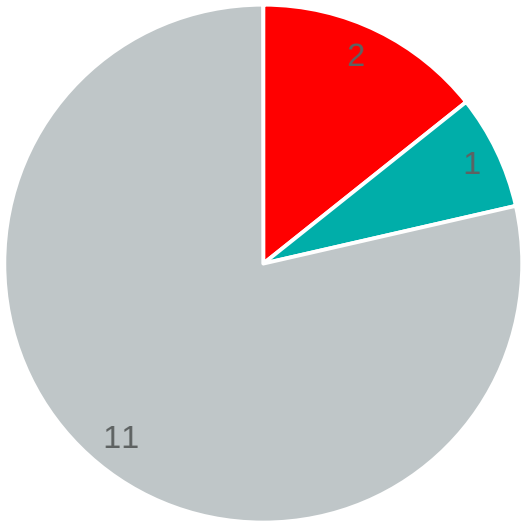
- Uphold, Lack of Medical Necessity
- Uphold, Non-Covered Benefit
- Uphold, Criteria Not Met
- Uphold, Other Health Coverage
- Uphold, Member Not Eligible
- Overturn, Medically Necessary
- Overturn, Covered Benefit Not Provided
- Overturn, Member's Best Interest

Q2 2019: Cal MediConnect Appeals by Determination



Q2 2019: CalMediConnect Appeals by Rationale

Apr-19



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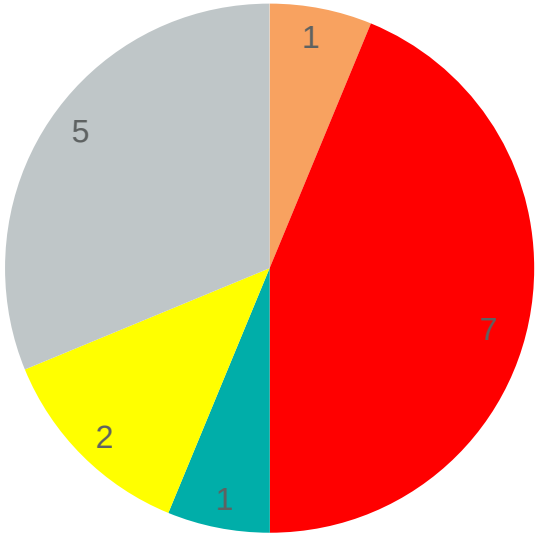

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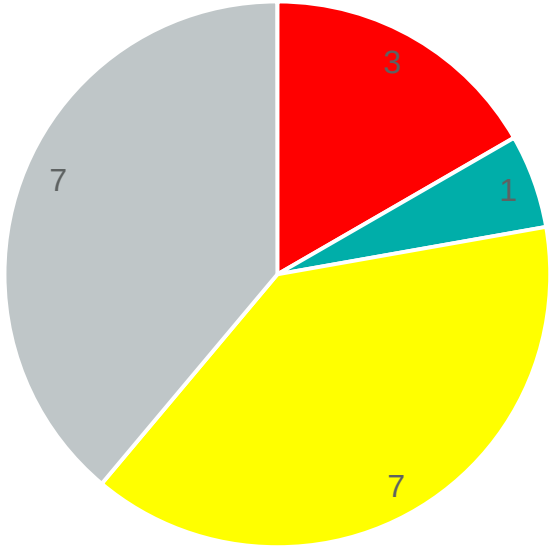

- Uphold, Criteria Not Met
- Uphold, Lack of Med. Necessity
- Uphold, Non-Covered Benefit
- Overturn, Member's Best Interest
- Overturn, Medically Necessary

- Uphold, Lack of Medical Necessity
- Uphold, Non-Covered Benefit
- Overturn, Member's Best Interest
- Overturn, Medically Necessary

Santa Clara County Health Authority

Pharmacy and Therapeutics Committee Charter

Purpose

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

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

Members

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

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

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

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

Meetings

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

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

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

Responsibilities

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

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

Duration of Charter

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

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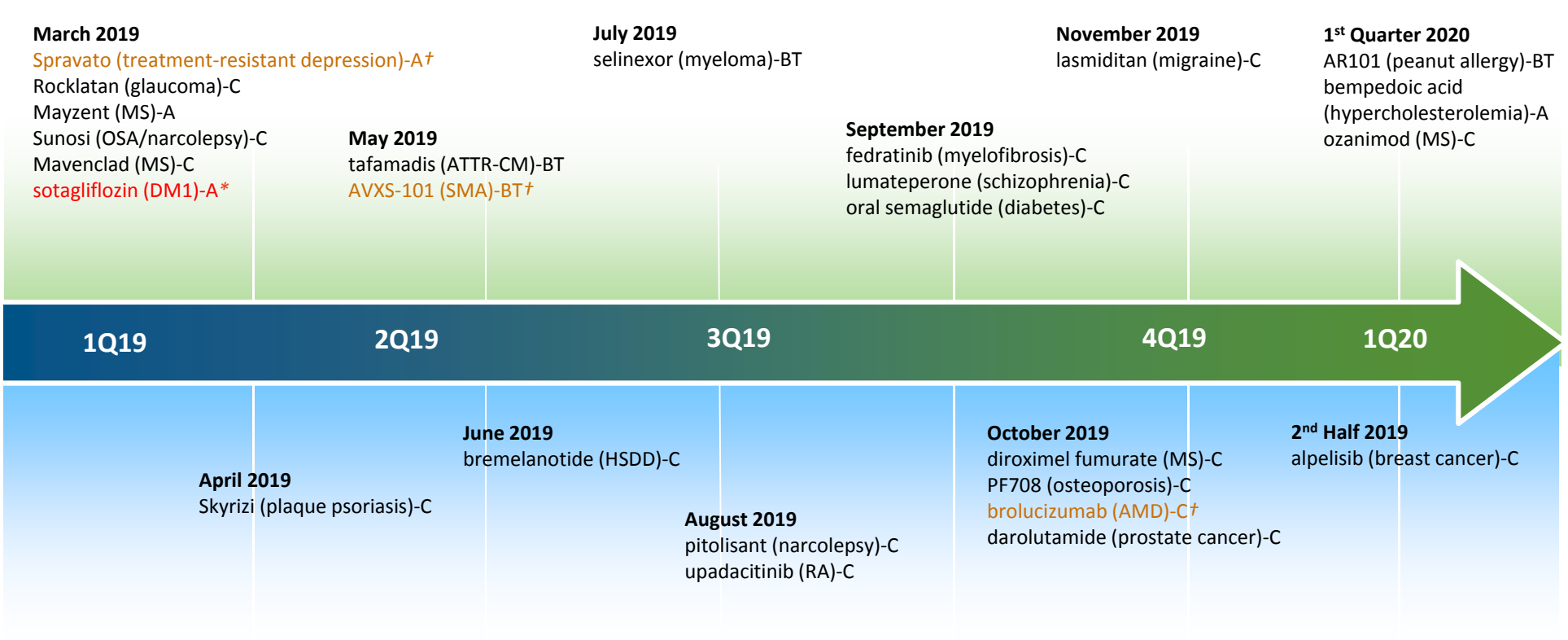
CY Version	Change (Original/ Reviewed / Revised)	Reviewing Director of Pharmacy	Director of Pharmacy Review Date	Reviewing Committee (if applicable)	Committee Action/Date (Recommend or Approve)
2017	Revised	Johanna Liu, PharmD, MBA	09/05/2017	Pharmacy & Therapeutics Committee	09/21/2017
2018	Revised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

Discussion Items

High Impact-Interest Agent Pipeline



March 2019
Spravato (treatment-resistant depression)-A†
Rocklatan (glaucoma)-C
Mayzent (MS)-A
Sunosi (OSA/narcolepsy)-C
Mavenclad (MS)-C
sotagliflozin (DM1)-A*

May 2019
tafamadis (ATTR-CM)-BT
AVXS-101 (SMA)-BT†

July 2019
selinexor (myeloma)-BT

September 2019
fedratinib (myelofibrosis)-C
lumateperone (schizophrenia)-C
oral semaglutide (diabetes)-C

November 2019
lasmiditan (migraine)-C

1st Quarter 2020
AR101 (peanut allergy)-BT
bempedoic acid (hypercholesterolemia)-A
ozanimod (MS)-C

April 2019
Skyrizi (plaque psoriasis)-C

June 2019
bremelanotide (HSDD)-C

August 2019
pitolisant (narcolepsy)-C
upadacitinib (RA)-C

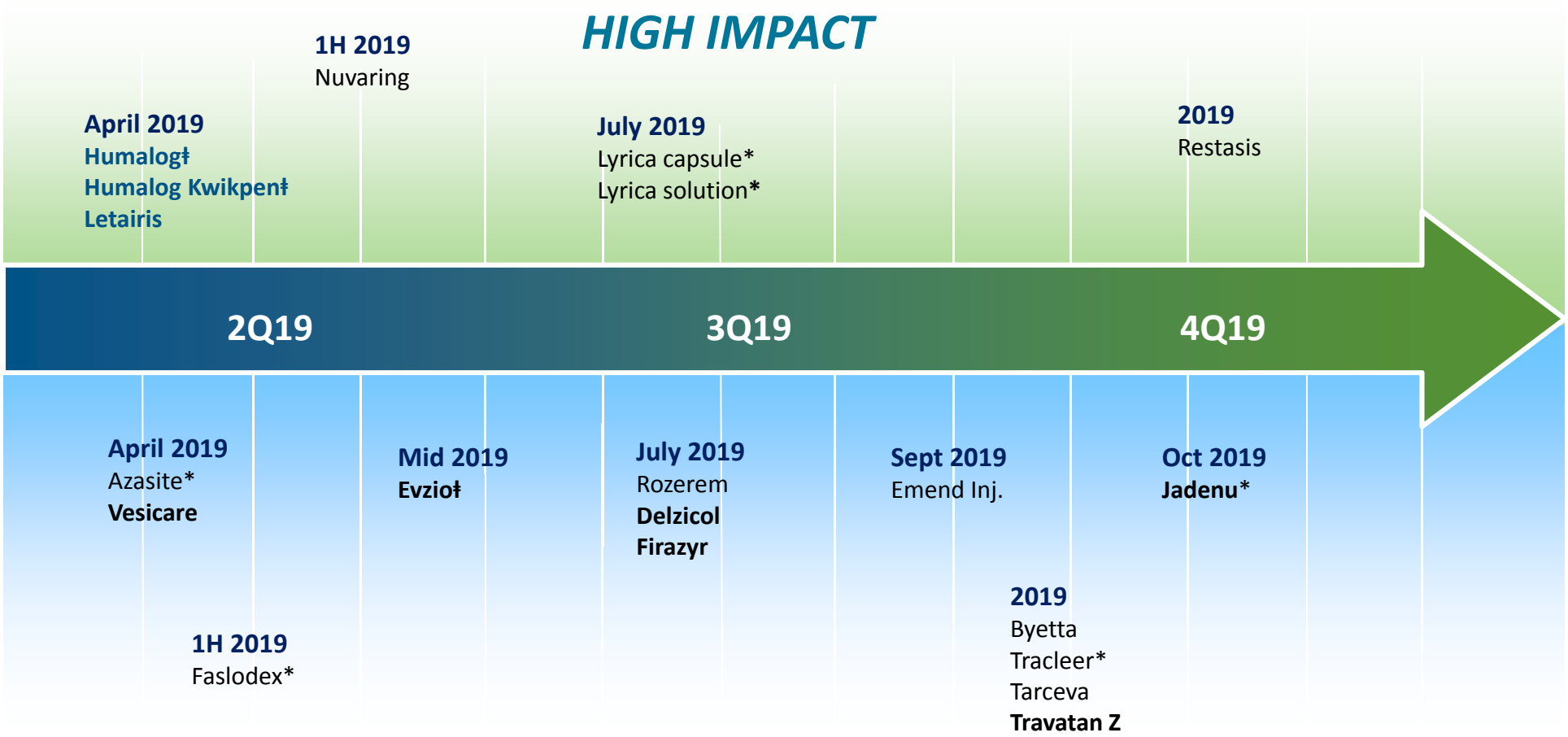
October 2019
diroximel fumurate (MS)-C
PF708 (osteoporosis)-C
brolucizumab (AMD)-C†
darolutamide (prostate cancer)-C

2nd Half 2019
alpelisib (breast cancer)-C

Not Yet Filed
crizanlizumab (sickle cell disease)-A†
leronlimab (HIV)-A
roxadustat (anemia of CKD)-C
voxelotor (sickle cell disease)-BT
eflapegrastim (neutropenia)-C

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*
* = *Complete Response Letter*

Generic Pipeline



MEDIUM /LOW IMPACT

*NO exclusivity
‡ Authorized Generic