Regular Meeting of the

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

Thursday, December 17, 2020, 6:00 - 8:00 PM
Santa Clara Family Health Plan
6201 San Ignacio Ave, San Jose, CA 95119

Via Teleconference
(408) 638-0968
Meeting ID: 932 7690 1993
Passcode: **SCFHP2020**
https://zoom.us/j/93276901993

AGENDA

1.	**Roll Call / Establish Quorum**	Dr. Lin	6:00	5 min
2.	**Public Comment** Members of the public may speak to any item not on the agenda; two minutes per speaker. The Committee reserves the right to limit the duration of the public comment period to 30 minutes.	Dr. Lin	6:05	5 min
3.	**Open Meeting Minutes** Review Santa Clara Family Health Plan (SCFHP) 3Q2020 P&T Open Session Minutes. **Possible Action:** Approve SCFHP P&T Open Session Minutes	Dr. Lin	6:10	2 min
4.	**Standing Agenda Items**			
	a. Chief Medical Officer Health Plan Updates	Dr. Nakahira	6:12	10 min
	b. Medi-Cal Rx Update	Dr. Huynh	6:22	5 min
	c. Policy Review **i.** PH10 Cal MediConnect Part D Transition (2021) **Possible Action**: Approve Pharmacy Policy PH10 Cal MediConnect Part D Transition			
5.	**Plan/Global Medi-Cal Drug Use Review**	Dr. Otomo	6:27	3 min
	a. Drug Use Evaluation Update	Dr. Nguyen	6:30	5 min
	b. 2019 4th Quarter Report Emergency Supply Report			
	c. Grievance & Appeals Pharmacy Report: 2020 1st – 3rd Quarter Reports	Ms. Luong	6:35	5 min

Adjourn to Closed Session

Pursuant to Welfare and Institutions Code Section 14087.36 (w)

6.	**Closed Meeting Minutes** Review SCFHP 3Q2020 P&T Closed Session Minutes. **Possible Action:** Approve SCFHP P&T Closed Session Minutes	Dr. Lin	6:40	2 min

7. Metrics & Financial Updates			
a. Membership Report	Dr. Nakahira	6:42	3 min
b. Pharmacy Dashboard	Dr. Otomo	6:45	5 min
c. Pharmacy Member Portal Stats	Dr. Huynh	6:50	5 min
d. Drug Utilization & Spend	Dr. McCarty	6:55	5 min
8. Discussion and Recommendations for Changes to SCFHP's Cal MediConnect Formulary & Coverage Determination Criteria	Dr. McCarty	7:00	5 min
a. Pharmacy Benefit Manager 3Q2020 P&T Minutes			
b. Pharmacy Benefit Manager 4Q2020 P&T Part D Actions			
Possible Action: Approve MedImpact Minutes & Actions			
c. 2021 Medical Benefit Drug Prior Authorization Grid	Dr. Otomo	7:05	5 min
Possible Action: Approve 2021 Medical Benefit Drug Prior Authorization Grid for Cal MediConnect			
9. Discussion and Recommendations for Changes to SCFHP's Medi-Cal Formulary & Prior Authorization Criteria	Dr. Nguyen	7:10	1 min
a. Old Business/Follow-Up			
i. Cefdinir Point-of-sale Message Update			
b. Formulary Modifications	Dr. Otomo	7:11	5 min
Possible Action: Approve Formulary Addition and Modification Recommendations	Dr. McCarty	7:16	5 min
c. Fee-for-Service Contract Drug List Comparability			
Possible Action: Approve CDL Comparability Formulary Recommendations	Dr. Otomo	7:21	1 min
d. 2021 Medical Benefit Drug Prior Authorization Grid			
Possible Action: Approve 2021 Medical Benefit Drug Prior Authorization Grid for Medi-Cal	Dr. Nguyen	7:22	5 min
e. Prior Authorization Criteria			
i. **New or Revised Criteria**			
1. Protopic ointment			
2. Non-Formulary			
ii. **Annual Review**			
1. Norditropin Flexpro			
2. Zarxio			
Possible Action: Approve New/Revised and Annual Review Criteria			
10. New Drugs and Class Review			
a. Tardive Dyskinesia Review	Dr. Zhang	7:27	15 min
b. COVID-19 Vaccines			
c. Asthma Review	Dr. McCarty	7:42	15 min
d. Hereditary Angioedema (HAE) – Orladeyo			
e. New & Expanded Indications – Epidiolex, Spravato, Tremfya, and Simponi Aria			
Possible Action: Approve New Drug and Class Recommendations			
f. **Informational Only**			
i. Anemia Chronic Kidney Disease – Roxadustat			
ii. Systemic Lupus Erythematosus – Anifrolumab and Voclosporin			
iii. Acne – Winlevi			
iv. Duchenne Muscular Dystrophy – Viltepso			
v. Pain from Osteoarthritis – Tanezumab			
vi. Schizophrenia – Olanzapine/Samidorphan			

vii. Fatty Acid Metabolism – Dojolvi
viii. Attention Deficit Hyperactivity Disorder – Viloxazine
ix. Overactive Bladder – Vibegron
x. Heart Failure – Vericiguat
xi. Chemo-induced Neutropenia – Rolontis
xii. Hyperlipidemia – Inclisiran
xiii. Ophthalmic NSAIDs
xiv. New Derivatives, Formulations, and Combinations

Reconvene in Open Session

11. Discussion Items a. New and Generic Pipeline	Dr. McCarty	7:57	3 min
12. Adjournment Next meeting Thursday, March 18, 2021	Dr. Lin	8:00	

Notice to the Public—Meeting Procedures

- Persons wishing to address the Committee on any item on the agenda are requested to advise the Recorder so that the Chairperson can call on them when the item comes up for discussion.
- The Committee may take other actions relating to the issues as may be determined following consideration of the matter and discussion of the possible action.
- In compliance with the Americans with Disabilities Act, those requiring accommodations in this meeting should notify Nancy Aguirre 48 hours prior to the meeting at 408-874-1835.
- To obtain a copy of any supporting document that is available, contact Nancy Aguirre at 408-874-1835. Agenda materials distributed less than 72 hours before a meeting can be inspected at the Santa Clara Family Health Plan offices at 6201 San Ignacio Ave, San Jose, CA 95119.

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

Santa Clara Family Health Plan™

Pharmacy & Therapeutics Committee

OPEN MEETING MINUTES

Regular Meeting of the

Santa Clara County Health Authority

Pharmacy & Therapeutics Committee

Thursday, September 17, 2020, 6:00 PM – 8:00 PM

Santa Clara Family Health Plan

6201 San Ignacio Ave, San Jose, CA 95119

Minutes (Open)

DRAFT

Members Present
Ali Alkoraishi, MD
Amara Balakrishnan, MD
Hao Bui, BS, RPh
Xuan Cung, PharmD
Dang Huynh, PharmD, Director of Pharmacy and UM
Jimmy Lin, MD, Chair
Laurie Nakahira, DO, Chief Medical Officer
Peter Nguyen, DO
Jesse Parashar-Rokicki, MD
Narinder Singh, PharmD

Members Absent
Dolly Goel, MD

Staff Present
Duyen Nguyen, PharmD, Clinical Pharmacist
Tami Otomo, PharmD, Clinical Pharmacist
Jayne Giangreco, Manager, Administrative Services

Others Present
Amy McCarty, PharmD

1. **Roll Call**

   Jimmy Lin, MD, Chair, called the meeting to order at 6:09 pm. Roll call was taken and a quorum was established.

2. **Public Comment**

   There were no public comments.

3. **Meeting Minutes**

   The 2Q2020 P&T Committee Open meeting minutes were reviewed.

   It was moved, seconded and the open minutes of the June 18, 2020 P&T meeting were **unanimously approved.**

   Motion: Dr. Nguyen
   Second: Dr. Alkoraishi
   Ayes: Dr. Alkoraishi, Dr. Balakrishnan, Ms. Bui, Dr. Cung, Dr. Huynh, Dr. Lin, Dr. Nakahira, Dr. Nguyen, Dr. Parashar-Rokicki, Dr. Singh

Absent: Dr. Goel

4. Standing Agenda Items

a. Chief Medical Officer Health Plan Updates

Dr. Nakahira provided an update on the Plan's response to the two state of emergency orders for the wildfires and COVID-19. The Plan continues with outreach calls calls to our vulnerable population, which includes high-risk members and members over the age of 65 with comorbidities. The Plan also worked with Santa Clara County to ensure our vulnerable population is on the County's list for evacuation orders and power outages. The majority of SCFHP's staff continues to work from home, and it is anticipated this will continue until sometime in 2021, pending updates from the County and the state.

Dr. Nakahira continued with staff updates. She announced that Lucille Baxter is the new Manager of Quality and Health Education, Raman Singh is the new Case Management Director; and Dang Huynh accepted the position as Pharmacy and Utilization Management (UM) Director.

Dr. Nakahira provided an update on the Community Resource Center (CRC), which is projected to open in mid-October 2020. The CRC is located at North Capital and McKee. The CRC will offer health education classes. There will be some SCFHP staff working there. Members will be also be able to meet with Case Managers there if it is more convenient.

b. Medi-Cal Rx Update

Dr. Huynh presented an update on Medi-Cal Rx. Beginning January 1, 2021, the pharmacy benefit for Medi-Cal will be carved back into the state. Their claims processor will be Magellan. The Plan will continue to manage the clinical aspects of pharmacy adherence and providing disease and medication management. The call script was finalized and rolled out by the state, and Customer Service will receive training on how to answer member and provider questions. DHCS will be sending out 90 and 60 day notices before the transition. The Plan will be sending out the 30 day notice.

SCFHP will identify members who may require more assistance during this transition and will offer help with prescription transfers. This includes assisting members who receive mail order prescriptions from pharmacies outside of California to transition them to a pharmacy enrolled in Medi-Cal Rx . Members will need to take their new SCFHP ID card and their Medi-Cal Benefits Identification Card (BIC) to the pharmacy. Members can locate network pharmacies on the state's website. Dr. Huynh explained that if the state does not cover a medication that a member is currently taking, there will be a 180 day transition period for the member to continue getting that drug. The state will also honor active prior authorizations for up to one year; they are discussing the potential for extending those authorizations.

The Plan is updating all member and provider material with Medi-Cal Rx information. SCFHP will also be conducting additional provider and member communication. Training for providers is available on the Medi-Cal Rx website, and the Plan will be sending out a fax blast to providers to notify them of this training. Dr. Huynh explained that there are ongoing discussions to clarify coverage of certain items in the state's scope document. The Plan is evaluating care coordination strategies for items that may be partially carved out. SCFHP continues to work with plan partners and delegates to ensure that information from DHCS and Magellan is communicated in a timely manner.

c. Plan/Global Medi-Cal Drug Use Review (DUR)

Dr. Otomo stated that SCFHP participates in the state's Global Drug Use Review (DUR) Board quarterly meetings, then assesses DUR activities that need to be implemented at the plan. There were no actions for SCFHP from the last DUR meeting.

For the Plan's Drug Use Evaluation (DUE) program for 3rd quarter, the Plan targeted members who may have persistent asthma based on claims history and did not receive an asthma controller medication in a recent 12 month period. SCFHP will send out letters to impacted providers within our Cal MediConnect and Medi-Cal lines of business.

d. NCQA Member Portal Evaluation

Dr. Nguyen presented an overview of the NCQA Member Portal Evaluation, which is required by NCQA on an annual basis to ensure accuracy and quality of our website for our Cal MediConnect members. The 2020 analysis was just completed and the website met 100% of the NCQA criteria.

e. 2019 2nd and 3rd Quarter Report Emergency Supply Reports

i. 2019 2nd Quarter Report

Dr. Nguyen discussed the Emergency Prescription Access Report for 2Q2019, and there were no issues identified.

ii. 2019 3rd Quarter Report

Dr. Nguyen reviewed the results for 3Q2019. There was one issue identified regarding a member's prescription for cefpodoxime, which is a non-formulary drug. The member went to three different pharmacies to try to fill the prescription and did not receive the drug. The member was referred to Case Management for follow-up. To remedy this gap, SCFHP will implement a point-of-sale (POS) message on cefpodoxime informing pharmacies that cefdinir is our formulary alternative. Dr. Huynh stated the Plan will send out a fax blast to the pharmacy network reminding them that for our Medi-Cal patients, they can input an override to provide an emergency 3-day supply. Dr. Nguyen will provide an update on this case at the next meeting.

f. Appeals & Grievances Pharmacy Report

i. 2020 1st Quarter Report

ii. 2020 2nd Quarter Report

Dr. Huynh presented the Appeals & Grievances Pharmacy Reports on behalf of Ms. Luong. Data and descriptions in slide deck required additional clarification. Dr. Huynh stated that he would validate the information with the G&A team and send out the updated slides or provide an update at the next meeting.

Dr. Lin inquired if appeals are mainly submitted by members or providers, and Dr. Huynh replied that the majority of appeals are submitted by providers.

Adjourned to Closed Session at 6:38 p.m.
Pursuant to Welfare and Institutions Code Section 14087.36 (w)

5. Closed Meeting Minutes

The 2Q2020 P&T Committee Closed meeting minutes were reviewed.

It was moved, seconded and the closed minutes of the June 18, 2020 P&T meeting were **unanimously approved**.

6. Metrics and Financial Updates

a. Membership Report

Dr. Nakahira presented the Plan's membership.

b. Pharmacy Dashboard

Dr. Otomo reviewed the Pharmacy Dashboard for April 2020 through August 2020.

c. Drug Utilization and Spend

Dr. McCarty presented the Drug Utilization and Spend.

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

a. Pharmacy Benefit Manager 2Q2020 P&T Minutes
Dr. McCarty reviewed the Pharmacy Benefit Manager 2Q2020 P&T Minutes.

b. Pharmacy Benefit Manager 3Q2020 P&T Part D Actions
Dr. McCarty reviewed the Pharmacy Benefit Manager 3Q2020 P&T Part D Actions.

It was moved, seconded and the Pharmacy Benefit Manager 2Q2020 and 3Q2020 Part D Actions were **unanimously approved**.

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

a. Old Business/Follow-Up

i. Dapagliflozin combinations
Dr. Huynh provided a follow-up from the last meeting regarding adding Farxiga and its combinations.

b. Formulary Modifications
Dr. Otomo presented the formulary changes made since the June 2020 meeting to the Committee.

It was moved, seconded and the Medi-Cal Formulary Modifications were **unanimously approved**.

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

It was moved, seconded and the Fee-for-Service Contract Drug List Comparability recommendations were **unanimously approved**.

d. Prior Authorization Criteria

i. <u>New or Revised Criteria</u>
1. Enablex – *revised*
2. Myrbetriq - *revised*
3. Retacrit - *revised*
4. Penlac - *revised*

ii. <u>Annual Review</u>
1. Brand Name – *no changes*
2. Compounded Medications – *no changes*
3. Duragesic – *no changes*
4. Emend – *no changes*
5. Enbrel – *no changes*
6. Humira – *no changes*
7. Insulin Pens – *no changes*
8. Nicotrol – *no changes*
9. Off-label – *no changes*
10. Opioid Safety Edits – *no changes*
11. Quantity Limit – *no changes*

12. Taltz – *no changes*
13. Trintellix – *no changes*
14. Xelpros – *no changes*
15. Zyvox – *no changes*

Dr. Nguyen reviewed the revised PA criteria.

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

9. New Drugs and Class Reviews

a. New and Expanded Indications
Dr. McCarty presented an overview of the following drugs with new and expanded indications: Taltz, Cosentyx, Lynparza, Rubraca, Crysvita, Ilaris.

It was moved, seconded and the New and Expanded Indications recommendations were **unanimously approved.**

b. Oriahnn (elagolix, estradiol, norethindrone) – Uterine fibroids
Dr. McCarty gave an overview of uterine fibroids and a new drug, Oriahnn.

It was moved, seconded and recommendation for Oriahnn was **unanimously approved.**

Reconvene in Open Session at 7:18 p.m.

10. Discussion Items

a. New and Generic Pipeline
Dr. McCarty reviewed the New and Generic Pipeline. She noted that the major drug of interest in 3Q2020 is ofatumumab (Kesimpta), which is for multiple sclerosis and can be self-administered. In 4Q2020, a drug of interest is roxadustat, an oral agent for the treatment of anemia in chronic kidney disease. In 1Q2021, a drug of interest is aducanumab, a monoclonal antibody treatment for early stage Alzheimer's disease, which would make it the first biologic for this condition.

Dr. McCarty stated that drugs of interest in the generic pipeline are Nexium packets for oral suspension and Kuvan powder for oral suspension and tablet. Dr. Lin inquired as to whether or not Oxytrol or Humalog Mix 75/25 have been released as generics. Dr. McCarty replied that neither are available as generic products yet.

11. Adjournment
The meeting adjourned at 7:25 p.m. The next P&T Committee meeting will be on Thursday, December 17, 2020.

_____ _____
Jimmy Lin, MD, Chair Date

Santa Clara Family Health Plan™

Pharmacy & Therapeutics Committee

STANDING AGENDA ITEMS

Santa Clara Family Health Plan™

Policy Title:	**Cal MediConnect Part D Transition**	**Policy No.:**	PH10
Replaces Policy Title (if applicable):	Cal MediConnect Part D Transition Policy	**Replaces Policy No. (if applicable):**	PM100
Issuing Department:	Pharmacy	**Policy Review Frequency:**	Annual
Lines of Business (check all that apply):	☐ Medi-Cal	☒ 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 ensures that its transition policy will apply to non-formulary drugs, meaning both (1) drugs that are not on the plan's formulary, and (2) drugs that are on the 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 the plan's utilization management rules. The plan ensures that its policy addresses procedures 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.
   3. 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., 31 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 1 month's supply day fill (unless the enrollee presents with a prescription written for less than 31 days in which case the Plan must allow multiple fills to provide up to a total of 31 days of medication.) anytime during the first 90 days of a member's enrollment in a plan, beginning on the enrollee's effective date of coverage.
2. If a brand medication is being filled under transition, the previous claim must also be brand (based on Comprehensive NDC SPL Data Elements File [NSDE] marketing status). If a generic medication is being filled under transition, the previous claim can be either brand or generic (based on NSDE marketing status)

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

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

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

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

K. Cost-sharing for Transition supplies
1. The plan will ensure that cost-sharing for a temporary supply of drugs provided under its transition process will never exceed the statutory maximum co-payment amounts for low-income subsidy (LIS) eligible enrollees. For non-LIS enrollees, a sponsor must charge the same cost sharing for non-formulary Part D drugs provided during the transition that would apply for non- formulary drugs approved through a formulary exception in accordance with 42 CFR §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 includes a medical review that considers the clinical aspects of the drug, including any risks involved in switching.
      c. This medical review process includes the following steps:
         a. Outreach is made to the provider to offer therapeutically appropriate formulary alternatives.
         b. This provides the prescriber an opportunity to switch the member to a covered formulary medication.

c. If the prescriber feels the formulary alternatives are not clinically appropriate for the member, they can provide attestation that the alternatives would not be as effective or would cause adverse effects, which would lead to an approval of the requested medication.

d. The exception policy includes a process for switching new MMP plan members to therapeutically appropriate formulary alternatives failing an affirmative medical necessity determination. The Prescriber Transition Letter provides prescribers with instructions to access the plan's formulary, as well as instructions on additional information to provide in a supporting statement for an exception request.

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, §423.578(b)
2. Medicare Prescription Drug Benefit Manual, Chapter 6 Part D Drug and Formulary Requirements, 30.4 Transition
3. Medicare Marketing Guidelines

Drug Utilization Evaluation (DUE) Outcomes

Santa Clara Family Health Plan™

SANTA CLARA FAMILY HEALTH PLAN

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Asthma DUE

Asthma: Identifies members who received 4 or more prescriptions for an asthma medication over a 12-month period but did not receive an asthma controller medication in that same time frame.

Medi-Cal =

- 610 members identified (7/1/2018 to 6/30/2019)
- 327 unique prescribers were sent letters (9/30/2019)
- 525 members still active in follow up period (7/1/2019 to 6/30/2020)
- 320 members no longer identified in follow up period
- **Asthma DUE = 61% success rate**

Cal MediConnect =

- 69 members identified (7/1/2018 to 6/30/2019)
- 61 unique prescribers were sent letters (9/30/2019)
- 54 members still active in follow up period (7/1/2019 to 6/30/2020)
- 31 members no longer identified in follow up period
- **Asthma DUE = 57% success rate**

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Polypharmacy DUE

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

Cal MediConnect =

- 541 members identified (1/1/2020 to 3/31/2020)
- 251 unique prescribers were sent letters (7/6/2020)
- 538 members still active in follow up period (7/1/2020 to 9/30/2020)
- 241 members no longer identified in follow up period
- **Polypharmacy DUE = 45% success rate**

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Emergency Prescription Access Report
4th Quarter 2019
Santa Clara Family Health Plan

Analysis Goal: Evaluate access to medications prescribed pursuant to an emergency room (ER) visit and determine whether any barriers to care exist.

Methodology: Claims and encounter records for an emergency room visit during a calendar quarter will be evaluated and analyzed by network, primary diagnosis, and claims status. Prescription claims history will be evaluated to assess if any prescriptions were filled by the member within 72 hours of the ER visit date. Key diagnosis used will be urinary tract infection (UTI) due to clinical determination that such a diagnosis will require a prescription, particularly for antibiotic. Analysis includes: 1. Approved antibiotic claims: sampling of cases to evaluate for sufficient quantity based on diagnosis and medication per nationally recognized drug compendia and the Infectious Disease Society of America (IDSA) guidelines; 2. Denied antibiotic claims: sampling of cases to evaluate sufficient quantity based on diagnosis and medication as well as denial reasons; 3. No claims history: sampling of cases through claims history review as well as chart review of no related prescription claims history following an emergency room visit to identify non-pharmacy point-of-sale in-hospital dispensing or completion of in-house antibiotics regimen.

Per DHCS Audit in March 2020, the concern was why the SCFHP only chose the diagnosis of UTI to assess quarter after quarter. We assessed other potential diagnoses such as diabetes, pneumonia, etc, however, it was determined that chronic conditions such as diabetes are not ideal for this analysis due to the fact that a prescription may be not given at ER discharge. For pneumonia, members often get admitted to inpatient, hence, may be difficult to assess.

Summary of Findings:

Section 1 – ER Visits

In 2019Q4, SCFHP had total 21,737 ER visits from claims and encounter data.

Table 1: Members by Provider Network

Network	Unique Members	ER Visit Rx	ER Visit w/o Rx	Total ER Visits
No Network	996	295	1,029	1,324
Non-Delegated	1,680	1,304	1,200	2,504
Valley Health Plan	9,528	5,972	6,750	12,722
Palo Alto Medical Foundation	353	198	272	470
Physician Medical Group	3,111	1,975	1,973	3,948
Premier Care	622	420	349	769
Grand Total	16,290	10,164	11,573	21,737

Section 2 – Diagnosis

Table 2: Key Diagnosis

		4Q2019		
Code	Diagnosis	Rx	No Rx	% Rx
N390	UTI, SITE NOT SPEC	355	83	81%

Section 3 – Claims Analysis

Approved Claims

Treatment guidelines for urinary tract infection/uncomplicated cystitis treatment are typically for at least 3 days, with the exception of fluconazole, fosfomycin, and ofloxacin that are administered as a single dose. Of prescriptions processed, we evaluated quantity per day supply and total day supply. There were no prescriptions filled inappropriately for less than a quantity of 1 per day. In this section we will focus on approved prescriptions with 2 day supply or less to evaluate if sufficient quantity and day supplies were written.

Table 3: Approved Antibiotics Prescribed for UTI 2-Day Supply or Less

DRUG	Day Supply	Svc Prov Name	Approved
FLUCONAZOLE	**1**	SCVMC Acute Care Hospital	**1**
Grand Total			**1**

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

Denied Claims

We excluded those members who had primary insurance coverage outside of SCFHP. Two members total had denied prescription claims for antibiotics due to ineligibility. One member had a denied claim for Monurol 3 gram sachet. We requested chart notes for this member for further review, however, we were unable to obtain.

No Claims

83 unique members diagnosed with UTI ER claims did not result in a prescription processed within 72 hours. We initially excluded 37 members with primary insurance coverage outside of SCFHP from this analysis. We subsequently randomly chose a sample of approximately 20% of 46 members, which is 11 total members, using Excel. We requested 10 chart notes from different hospitals. We received and reviewed 3 appropriate charts. Findings are presented below.

Mbr	Hospital	DOS	Findings
1	Good Samaritan Hospital	10/31/2019	Per claims history: Ciprofloxacin 500mg tab filled #20/10 days on 10/28/2019
2	Good Samaritan Hospital	12/07/2019	Chart note reviewed: Rx for Cephalexin 500mg cap, #30/10 days
3	O'connor Hospital	12/08/2019	Chart note reviewed: Rx Nitrofurantoin 100mg cap, #20/10 days
4	Regional Medical Center of SJ	11/08/2019	Chart note reviewed: Rx for Ciprofloxacin 500mg tab, #14/7 days

Section 4 – Pharmacies

Pharmacy Locations

SCFHP has four 24-hour in-network pharmacies within Santa Clara County for members to access. In addition, the majority of retail chain pharmacies are opened until 9 P.M.

Table 4: 24-Hour In-Network Pharmacies in Santa Clara County

NABP	NPI	Pharmacy Name	Address	City	Zip
501507	1962417238	WALGREENS	121 E. EL CAMINO REAL	MT. VIEW	94040
514667	1730194002	WALGREENS	350 NORTH CAPITOL AVE.	SAN JOSE	95133
533011	1255346532	WALGREENS	440 BLOSSOM HILL ROAD	SAN JOSE	95123
552287	1710921549	CVS PHARMACY	2514 BERRYESSA RD	SAN JOSE	95132

Summary: Members with a diagnosis of UTI who do not have access to medications after an ER visit are at high risk for complications or readmissions. For approved claims were appropriate. For denied claims, one member had a denied claim for Monurol 3 gram sachet. We requested chart note for further review, however, were unable to obtain. For members with no antibiotic claims after an ER visit for UTI, we continue to find members who were given prescriptions did not fill them. No readmissions for the same diagnosis were found for sampled members from the previous quarter 2019Q3.

Next Steps: Continue quarterly assessment of emergency prescription access with medical and pharmacy data. Follow up on members who did not have prescription claims to identify any trends and readmissions. Cases with potential barriers of care will be forwarded to SCFHP Quality Department. There is an opportunity for improvement in the process of obtaining chart notes for future reports.

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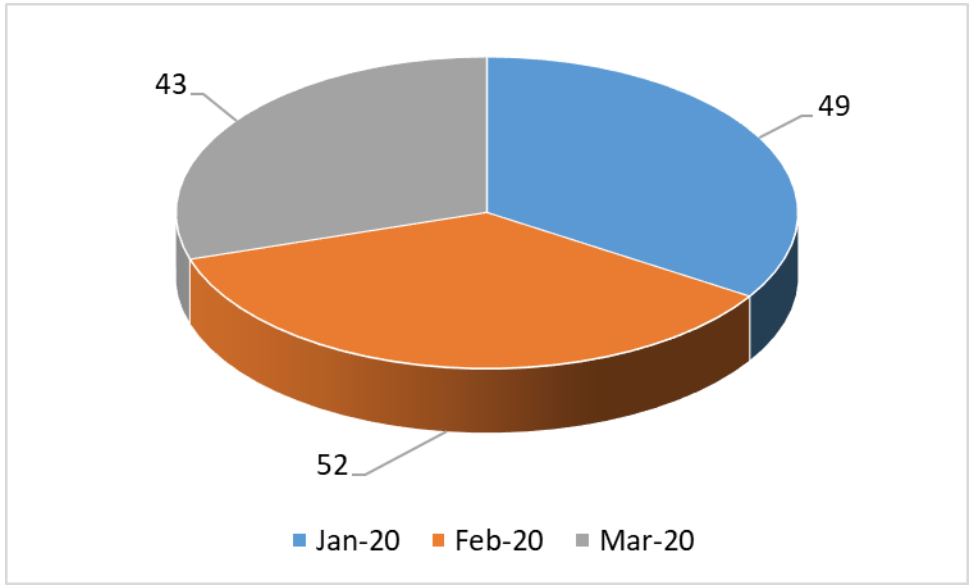
Q1 2020 Reporting

Q1 2020 Medi-Cal Appeals Volume



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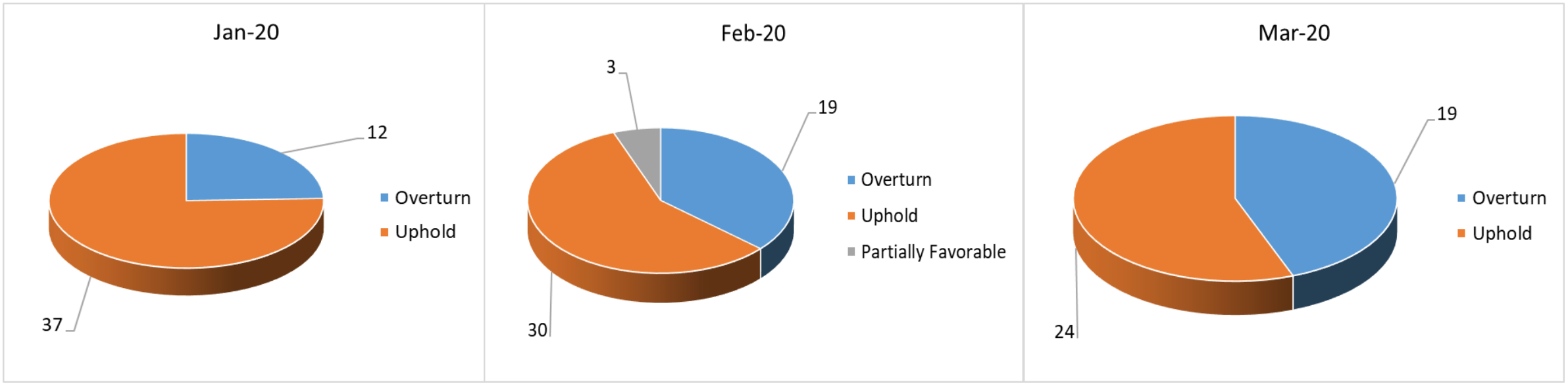

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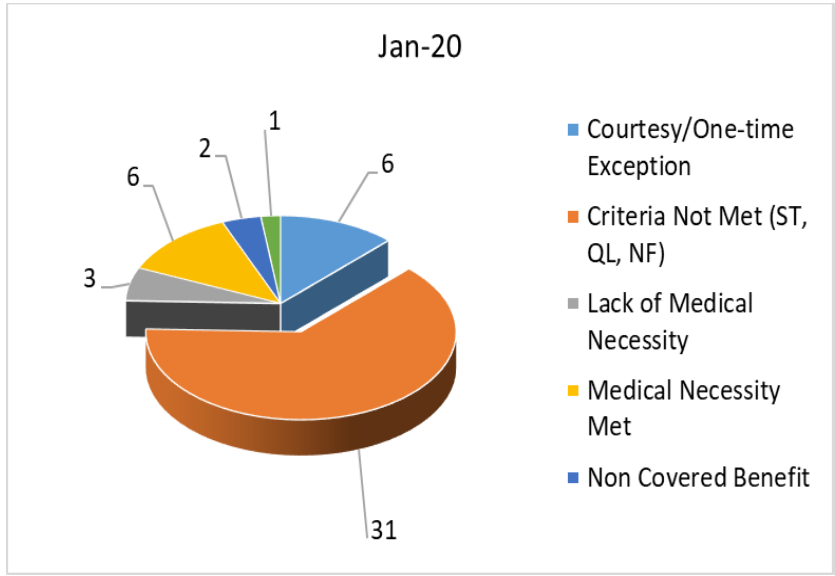

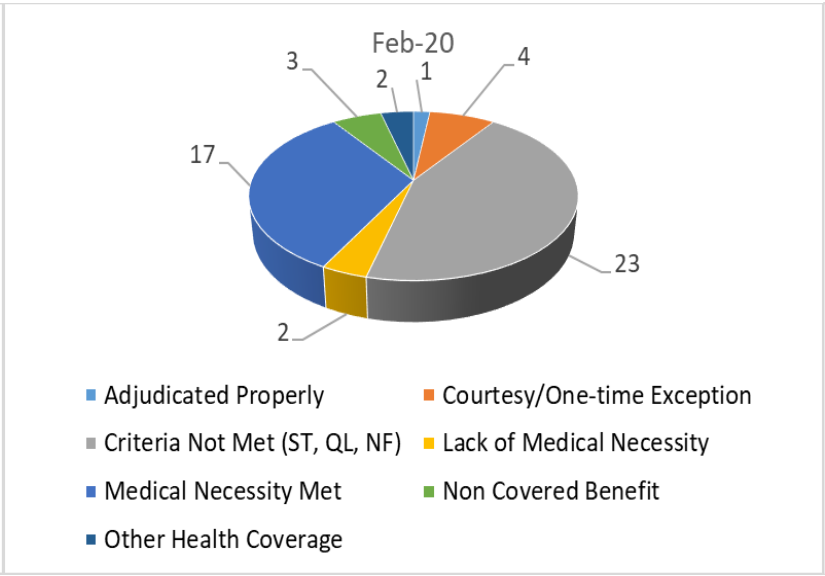

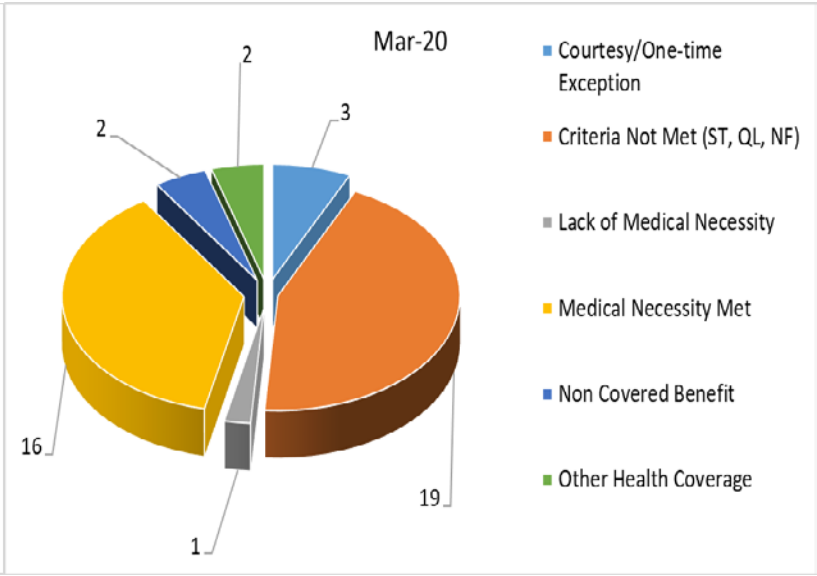

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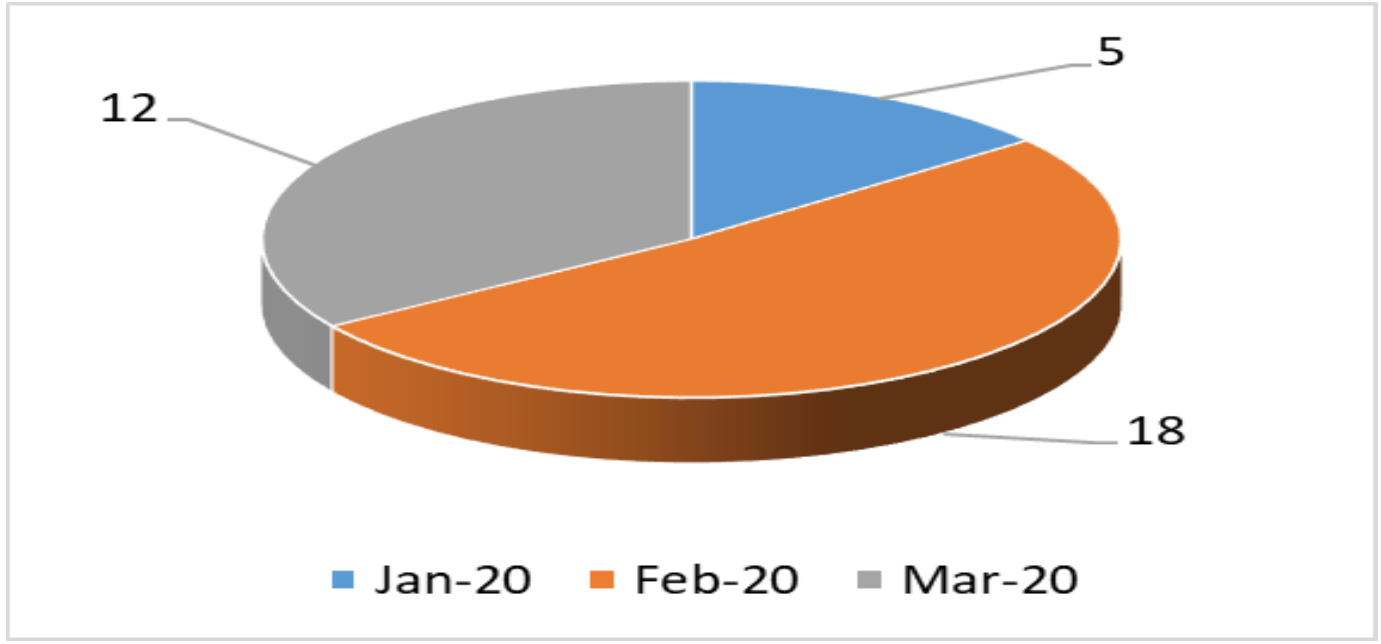

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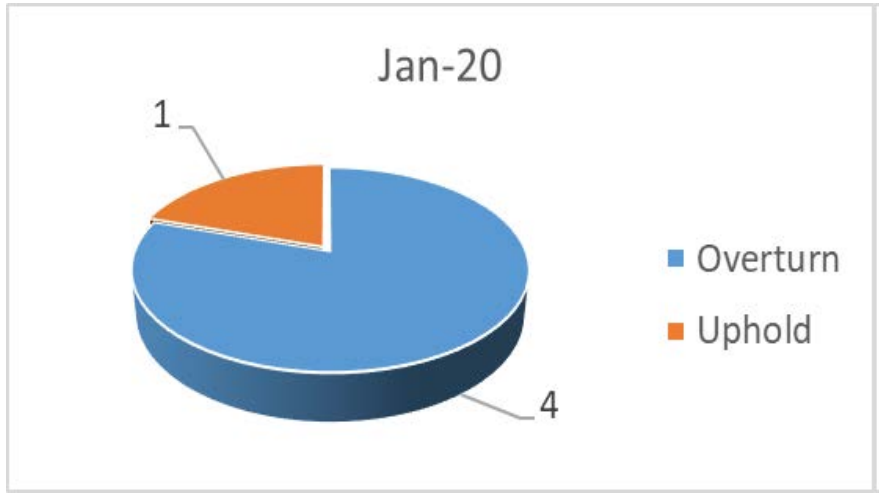

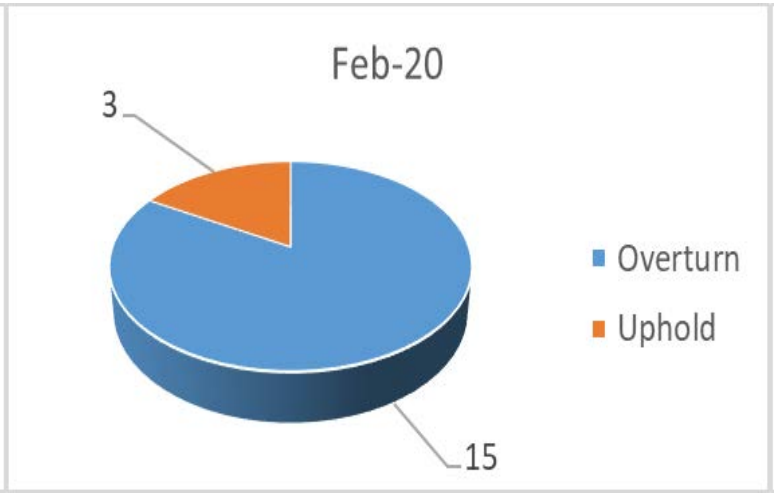

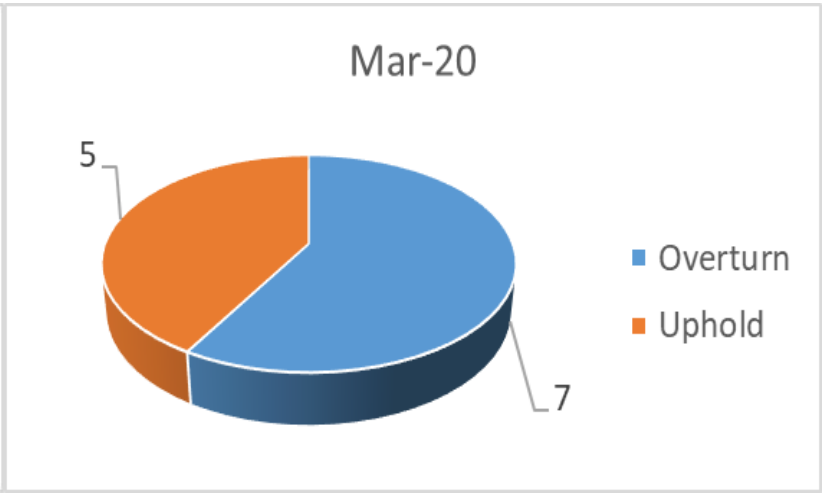

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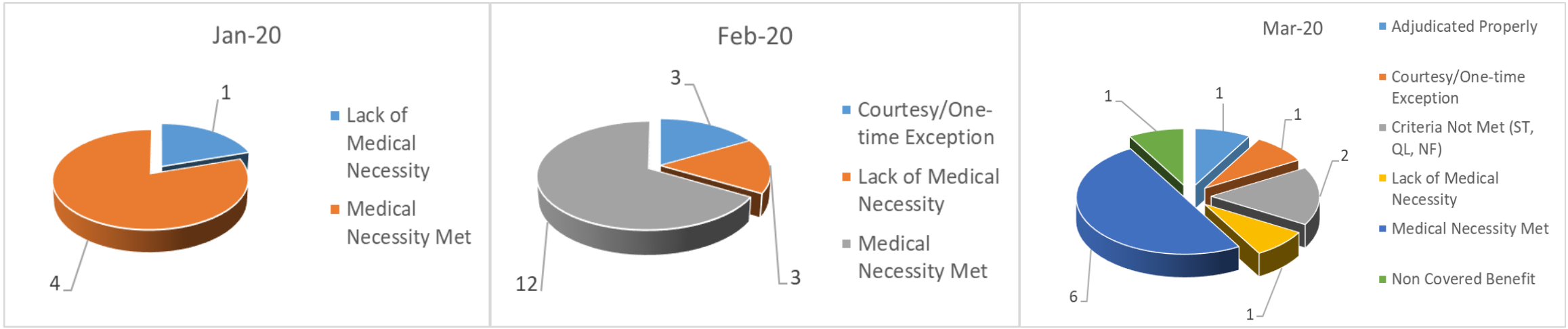

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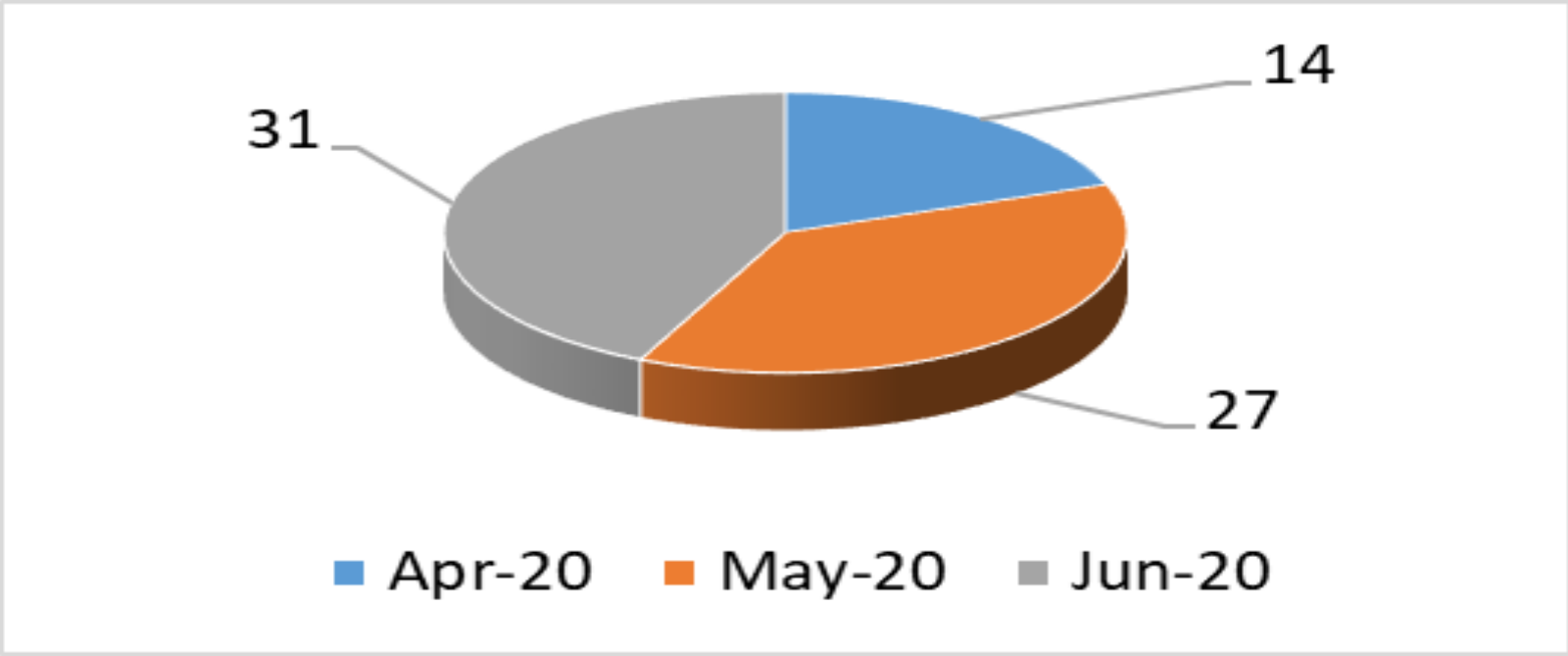

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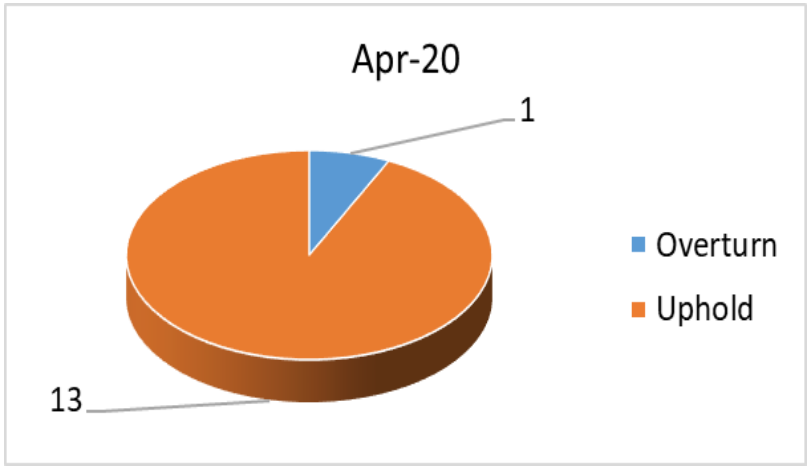

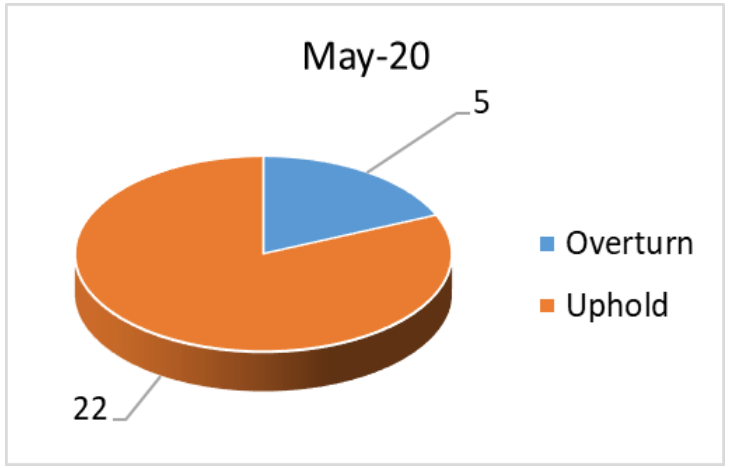

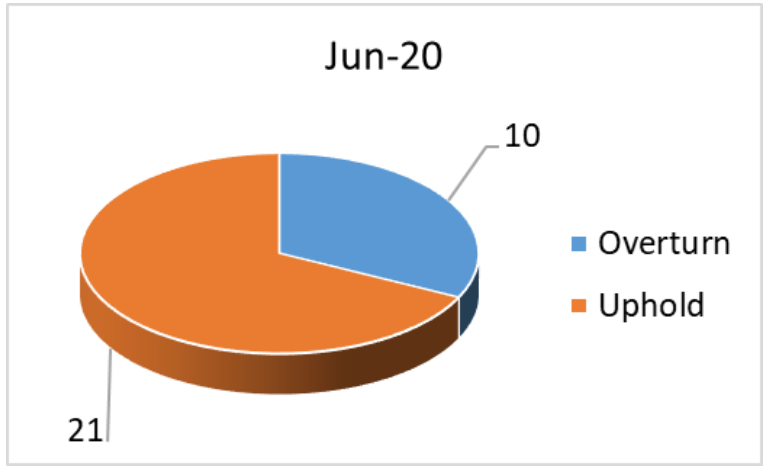

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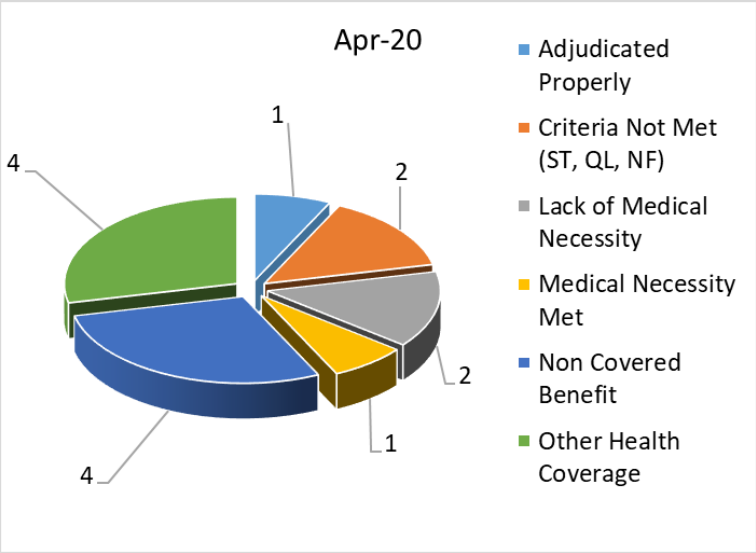

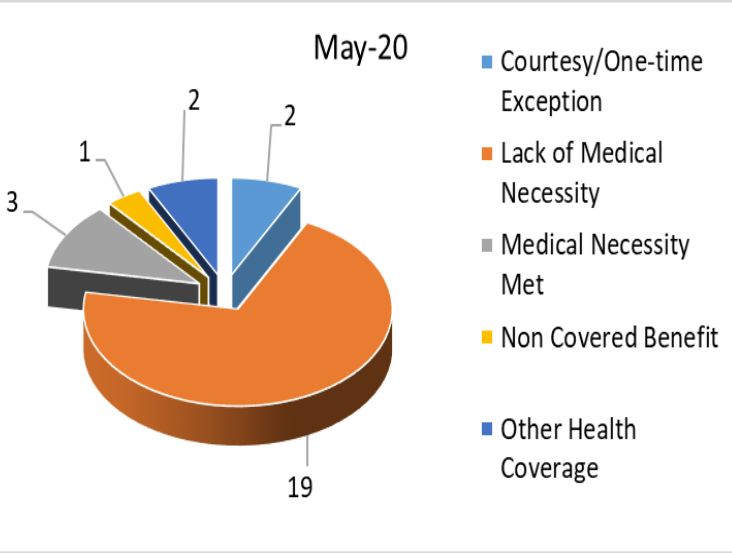

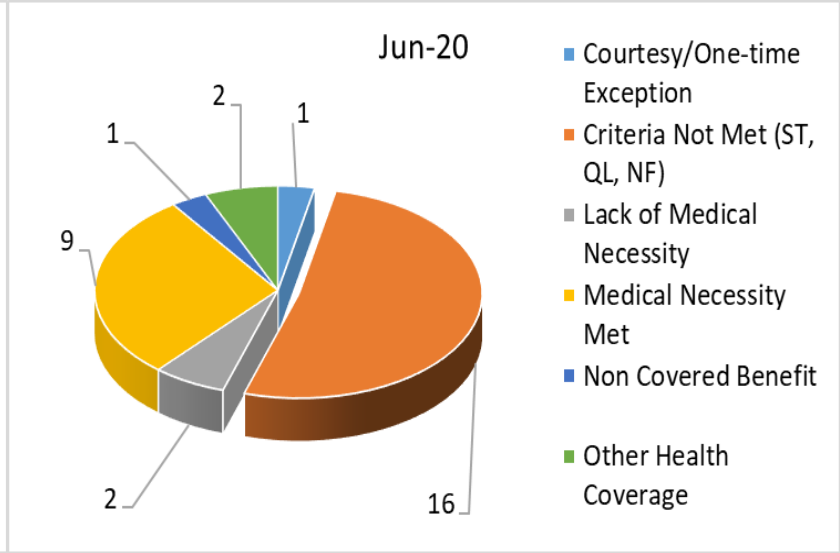

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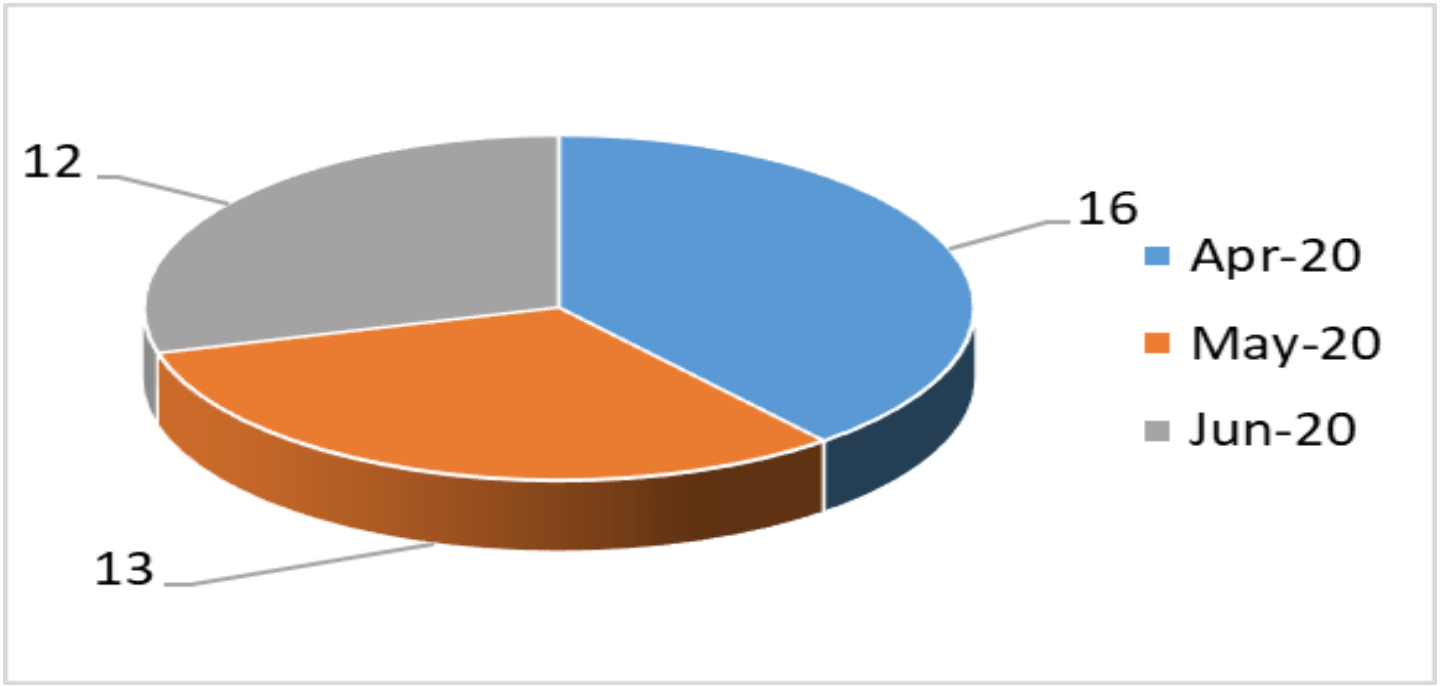

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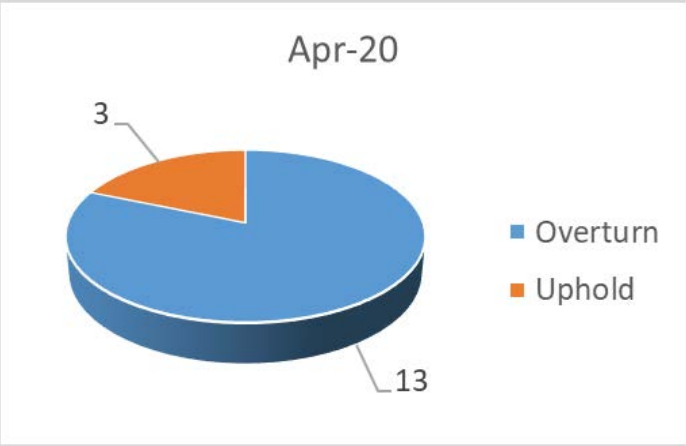

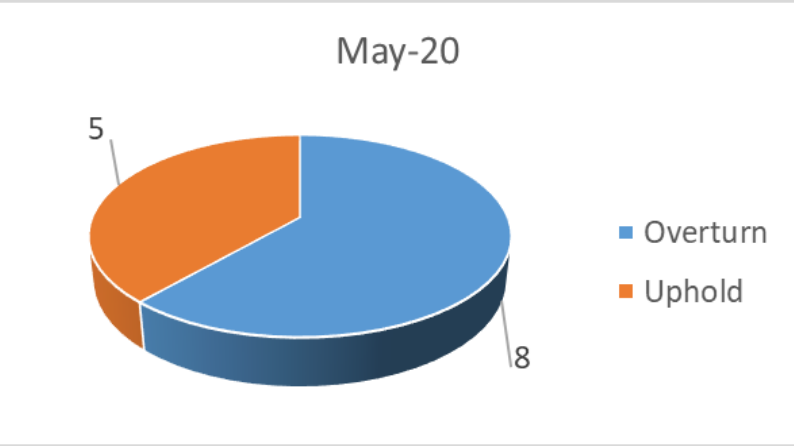

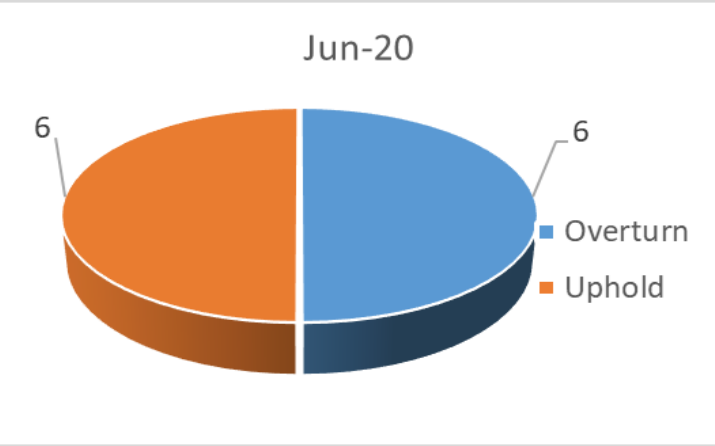

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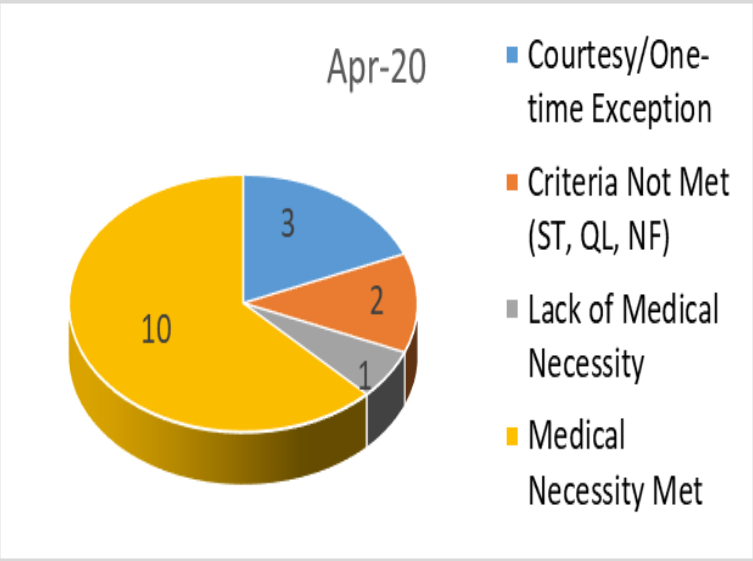

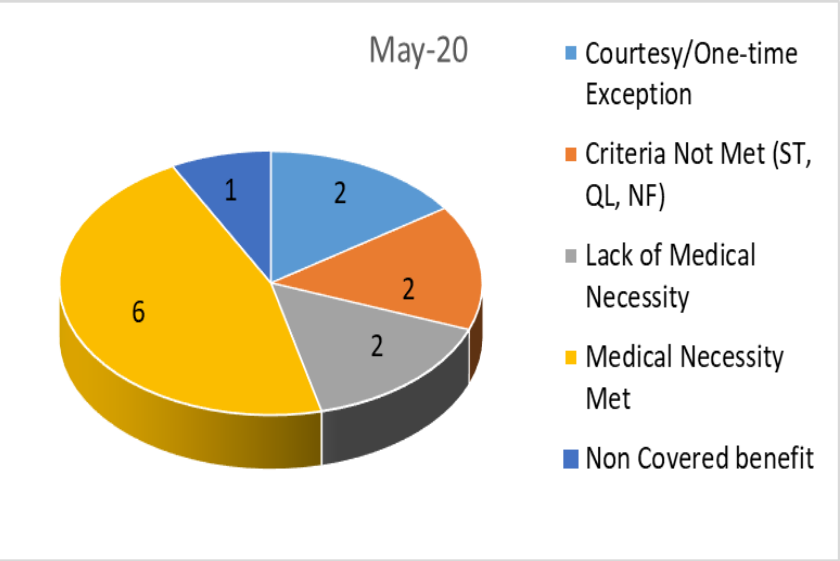

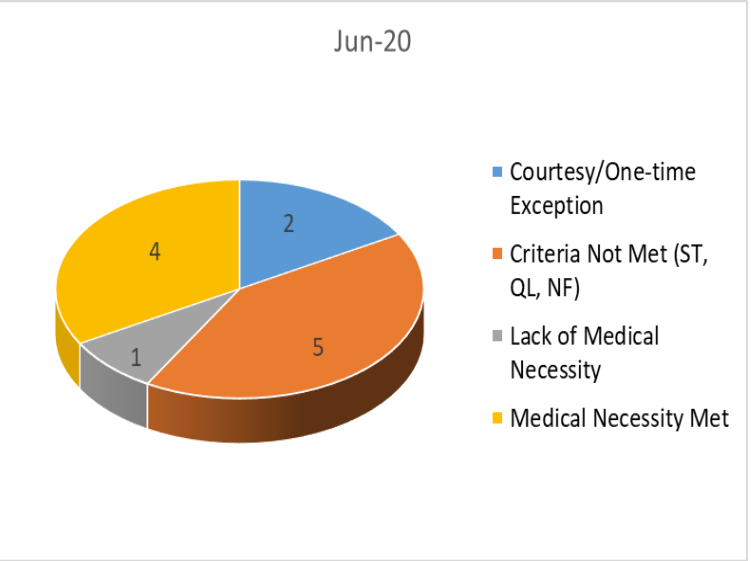

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Q3 2020 Reporting

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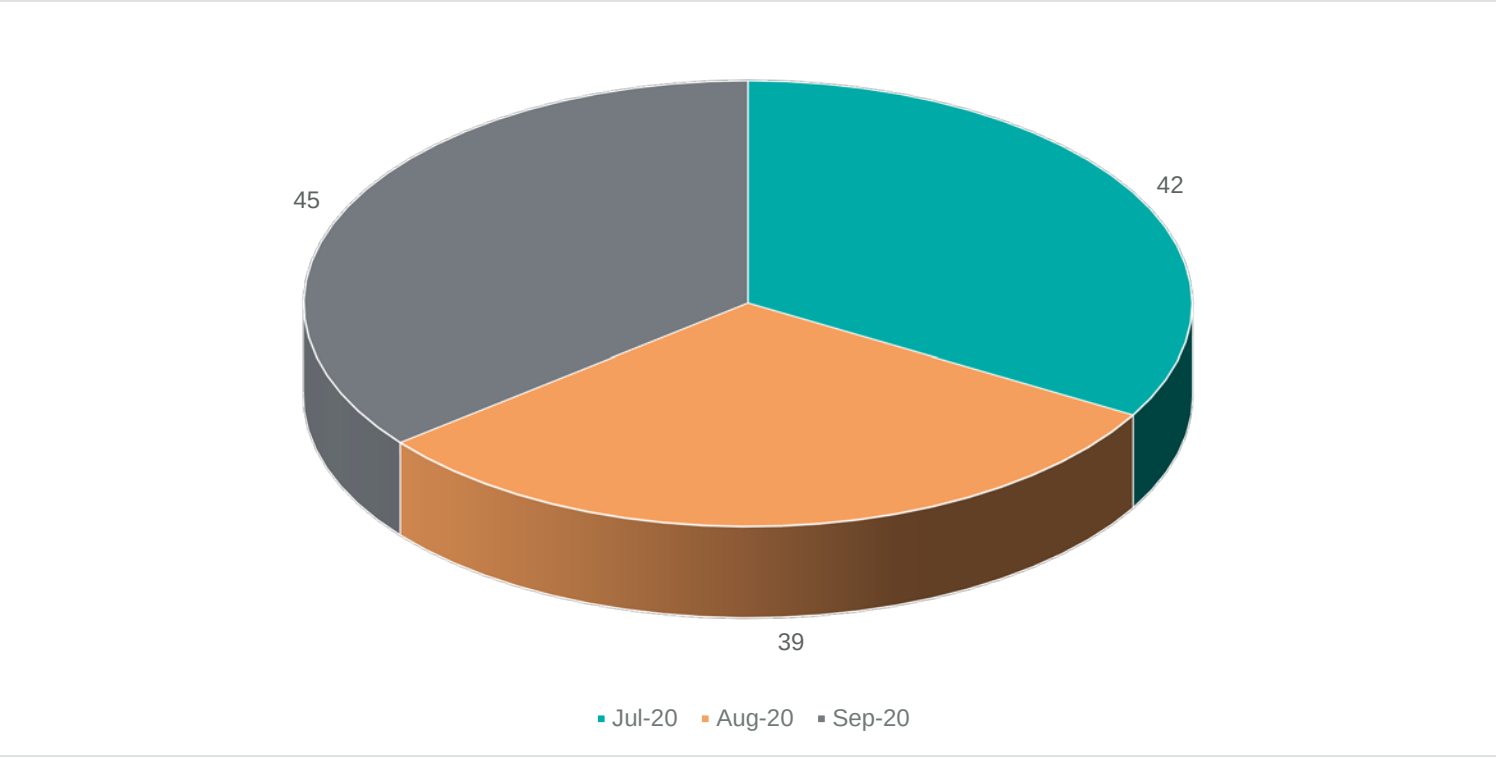
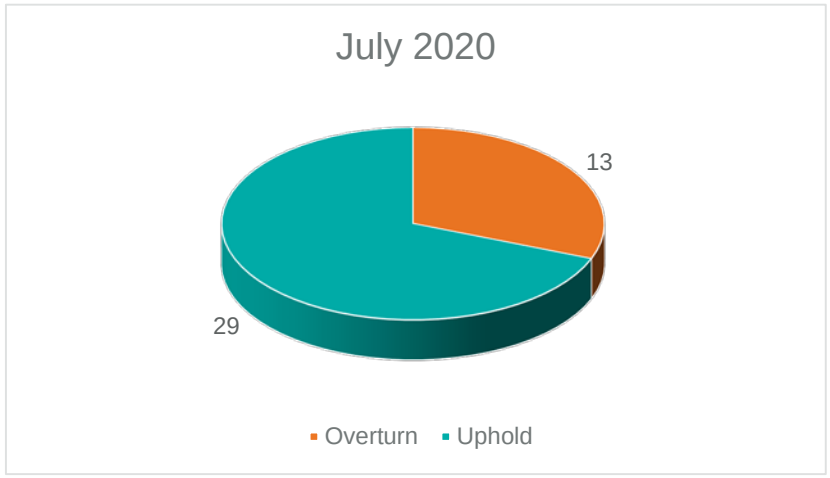
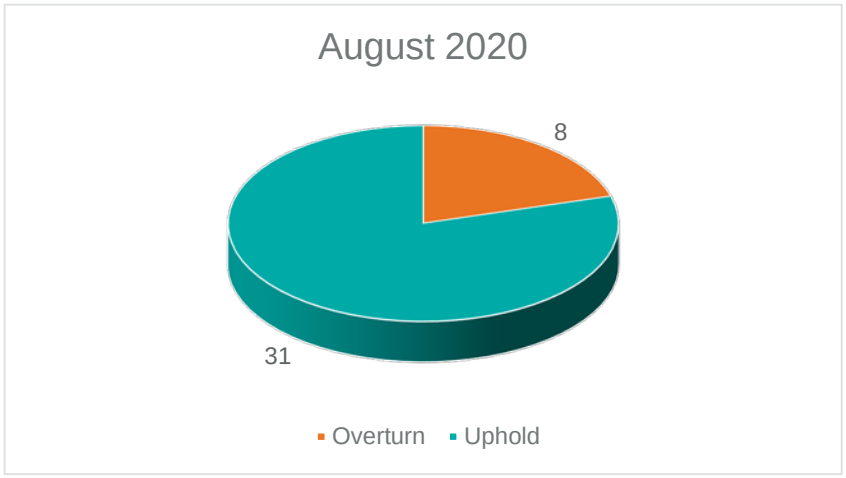
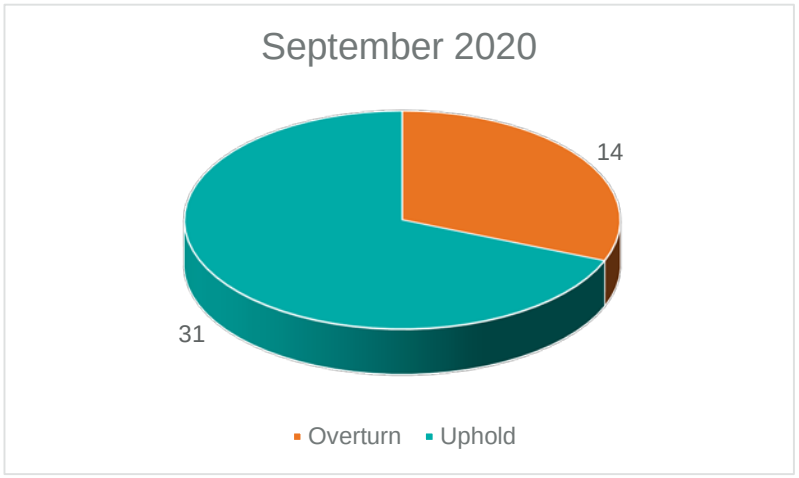


Q3 2020 MC Appeals by Decision

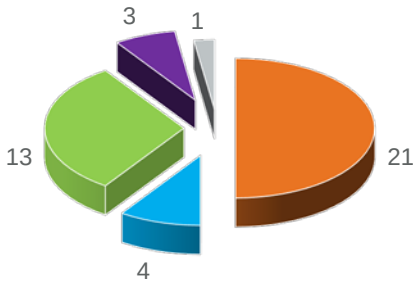






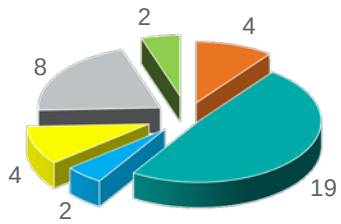
Q3 2020 MC Appeals by Rationale

July 2020



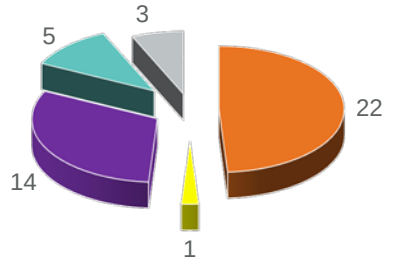
- Criteria Not Met (ST, QL, NF)
- Lack of Medical Necessity
- Medical Necessity Met
- Non Covered Benefit
- Other Health Coverage

August 2020



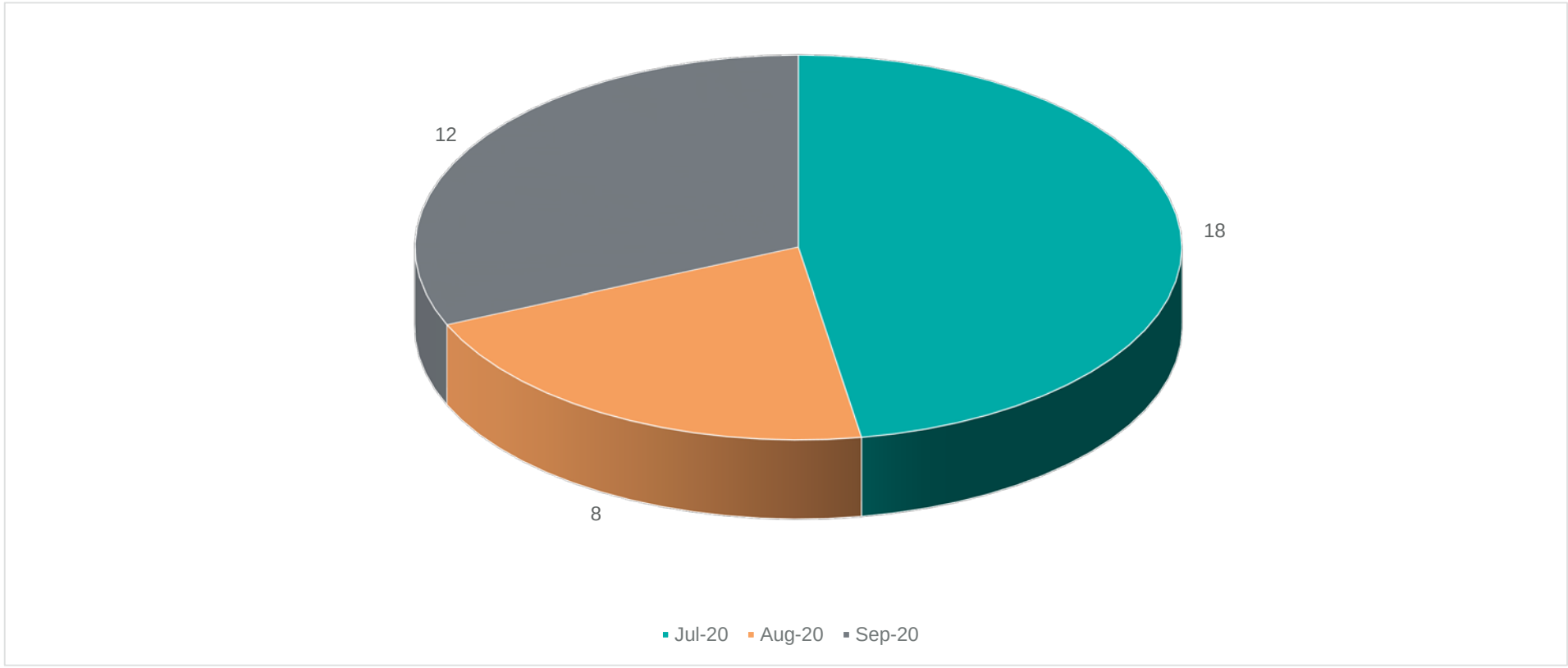
- Courtesy/One-time Exception
- Criteria Not Met (ST, QL, NF)
- Lack of Medical Necessity
- Medical Necessity Met
- Non Covered Benefit
- Other Health Coverage

September 2020

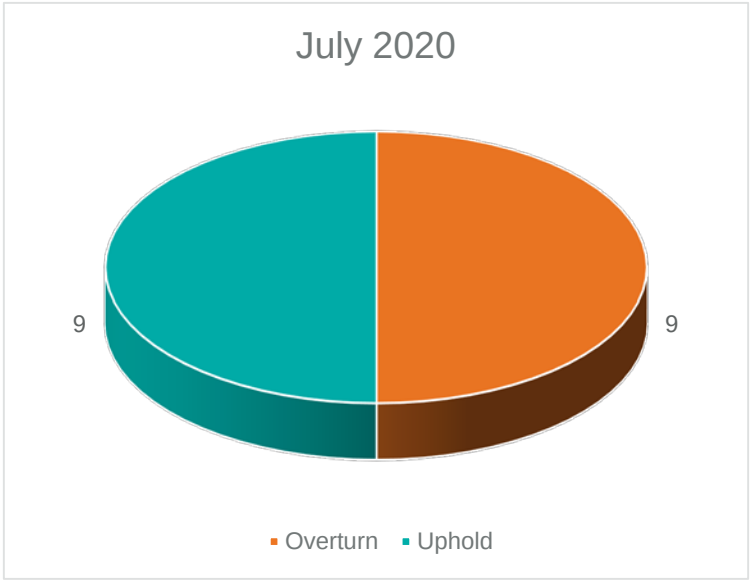


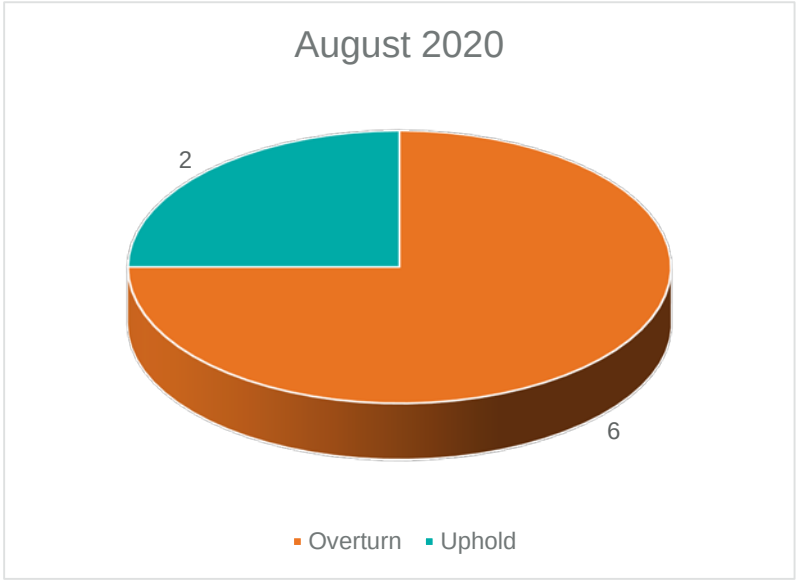
- Criteria Not Met (ST, QL, NF)
- Lack of Medical Necessity
- Medical Necessity Met
- Non Covered Benefit
- Other Health Coverage

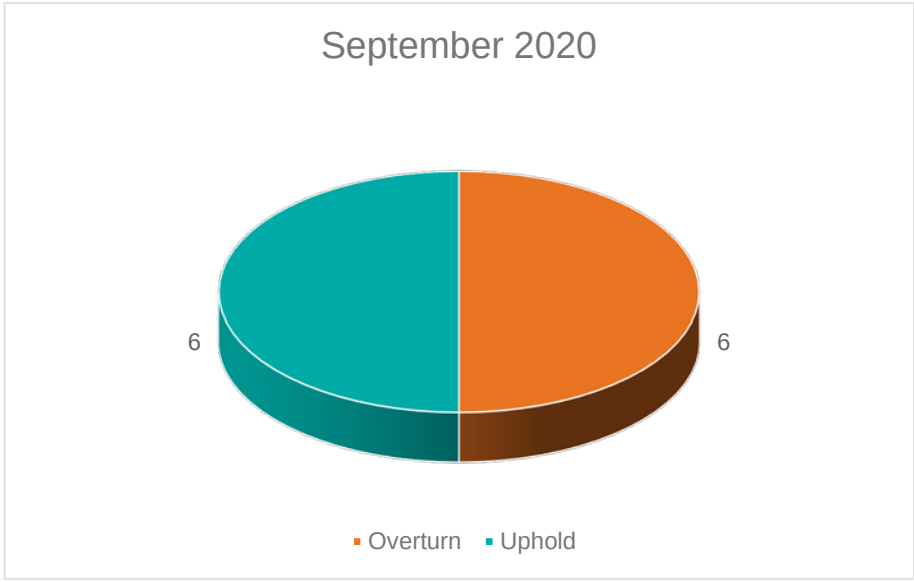
Q3 2020 Cal MediConnect Appeals Volume



Q3 2020 CMC Appeals by Decision

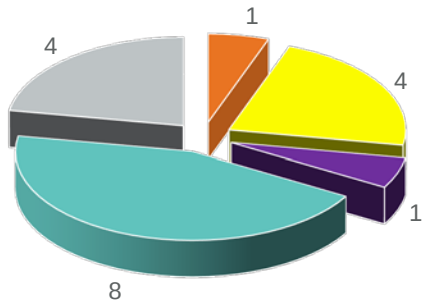






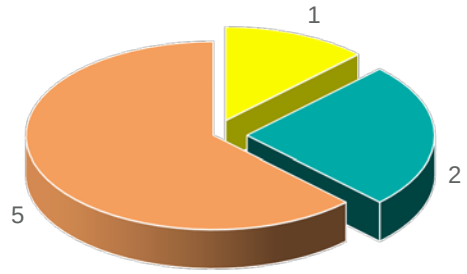
Q3 2020 CMC Appeals by Rationale

July 2020



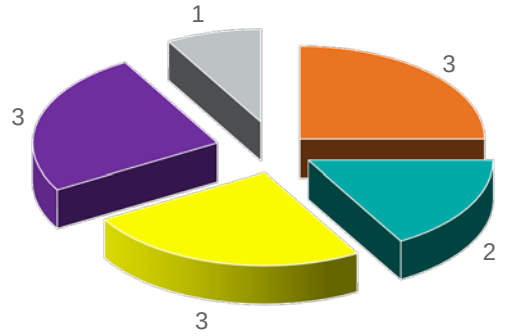
- Courtesy/One-time Exception
- Criteria Not Met (ST, QL, NF)
- Lack of Medical Necessity
- Medical Necessity Met
- Non Covered Benefit

August 2020



- Courtesy/One-time Exception
- Lack of Medical Necessity
- Medical Necessity Met

September 2020



- Courtesy/One-time Exception
- Criteria Not Met (ST, QL, NF)
- Lack of Medical Necessity
- Medical Necessity Met
- Non Covered Benefit

Santa Clara Family Health Plan™

Pharmacy & Therapeutics Committee

CLOSED MEETING MINUTES

Regular Meeting of the

Santa Clara County Health Authority

Pharmacy & Therapeutics Committee

Thursday, September 17, 2020, 6:00 PM – 8:00 PM

Santa Clara Family Health Plan

6201 San Ignacio Ave, San Jose, CA 95119

Minutes (Closed)

DRAFT

Members Present
Ali Alkoraishi, MD
Amara Balakrishnan, MD
Hao Bui, BS, RPh
Xuan Cung, PharmD
Dang Huynh, PharmD, Director of Pharmacy and UM
Jimmy Lin, MD, Chair
Laurie Nakahira, DO, Chief Medical Officer
Peter Nguyen, DO
Jesse Parashar-Rokicki, MD
Narinder Singh, PharmD

Members Absent
Dolly Goel, MD

Staff Present
Duyen Nguyen, PharmD, Clinical Pharmacist
Tami Otomo, PharmD, Clinical Pharmacist
Jayne Giangreco, Manager, Administrative Services

Others Present
Amy McCarty, PharmD

1. **Roll Call**

   Jimmy Lin, MD, Chair, called the meeting to order at 6:09 pm. Roll call was taken and a quorum was established.

2. **Public Comment**

   There were no public comments.

3. **Meeting Minutes**

   The 2Q2020 P&T Committee Open meeting minutes were reviewed.

   It was moved, seconded and the open minutes of the June 18, 2020 P&T meeting were **unanimously approved.**

   Motion: Dr. Nguyen
   Second: Dr. Alkoraishi
   Ayes: Dr. Alkoraishi, Dr. Balakrishnan, Ms. Bui, Dr. Cung, Dr. Huynh, Dr. Lin, Dr. Nakahira, Dr. Nguyen, Dr. Parashar-Rokicki, Dr. Singh

Absent: Dr. Goel

4. Standing Agenda Items

a. Chief Medical Officer Health Plan Updates

Dr. Nakahira provided an update on the Plan's response to the two state of emergency orders for the wildfires and COVID-19. The Plan continues with outreach calls calls to our vulnerable population, which includes high-risk members and members over the age of 65 with comorbidities. The Plan also worked with Santa Clara County to ensure our vulnerable population is on the County's list for evacuation orders and power outages. The majority of SCFHP's staff continues to work from home, and it is anticipated this will continue until sometime in 2021, pending updates from the County and the state.

Dr. Nakahira continued with staff updates. She announced that Lucille Baxter is the new Manager of Quality and Health Education, Raman Singh is the new Case Management Director; and Dang Huynh accepted the position as Pharmacy and Utilization Management (UM) Director.

Dr. Nakahira provided an update on the Community Resource Center (CRC), which is projected to open in mid-October 2020. The CRC is located at North Capital and McKee. The CRC will offer health education classes. There will be some SCFHP staff working there. Members will be also be able to meet with Case Managers there if it is more convenient.

b. Medi-Cal Rx Update

Dr. Huynh presented an update on Medi-Cal Rx. Beginning January 1, 2021, the pharmacy benefit for Medi-Cal will be carved back into the state. Their claims processor will be Magellan. The Plan will continue to manage the clinical aspects of pharmacy adherence and providing disease and medication management. The call script was finalized and rolled out by the state, and Customer Service will receive training on how to answer member and provider questions. DHCS will be sending out 90 and 60 day notices before the transition. The Plan will be sending out the 30 day notice.

SCFHP will identify members who may require more assistance during this transition and will offer help with prescription transfers. This includes assisting members who receive mail order prescriptions from pharmacies outside of California to transition them to a pharmacy enrolled in Medi-Cal Rx . Members will need to take their new SCFHP ID card and their Medi-Cal Benefits Identification Card (BIC) to the pharmacy. Members can locate network pharmacies on the state's website. Dr. Huynh explained that if the state does not cover a medication that a member is currently taking, there will be a 180 day transition period for the member to continue getting that drug. The state will also honor active prior authorizations for up to one year; they are discussing the potential for extending those authorizations.

The Plan is updating all member and provider material with Medi-Cal Rx information. SCFHP will also be conducting additional provider and member communication. Training for providers is available on the Medi-Cal Rx website, and the Plan will be sending out a fax blast to providers to notify them of this training. Dr. Huynh explained that there are ongoing discussions to clarify coverage of certain items in the state's scope document. The Plan is evaluating care coordination strategies for items that may be partially carved out. SCFHP continues to work with plan partners and delegates to ensure that information from DHCS and Magellan is communicated in a timely manner.

c. Plan/Global Medi-Cal Drug Use Review (DUR)

Dr. Otomo stated that SCFHP participates in the state's Global Drug Use Review (DUR) Board quarterly meetings, then assesses DUR activities that need to be implemented at the plan. There were no actions for SCFHP from the last DUR meeting.

For the Plan's Drug Use Evaluation (DUE) program for 3rd quarter, the Plan targeted members who may have persistent asthma based on claims history and did not receive an asthma controller medication in a recent 12 month period. SCFHP will send out letters to impacted providers within our Cal MediConnect and Medi-Cal lines of business.

d. NCQA Member Portal Evaluation

Dr. Nguyen presented an overview of the NCQA Member Portal Evaluation, which is required by NCQA on an annual basis to ensure accuracy and quality of our website for our Cal MediConnect members. The 2020 analysis was just completed and the website met 100% of the NCQA criteria.

e. 2019 2nd and 3rd Quarter Report Emergency Supply Reports

i. 2019 2nd Quarter Report

Dr. Nguyen discussed the Emergency Prescription Access Report for 2Q2019, and there were no issues identified.

ii. 2019 3rd Quarter Report

Dr. Nguyen reviewed the results for 3Q2019. There was one issue identified regarding a member's prescription for cefpodoxime, which is a non-formulary drug. The member went to three different pharmacies to try to fill the prescription and did not receive the drug. The member was referred to Case Management for follow-up. To remedy this gap, SCFHP will implement a point-of-sale (POS) message on cefpodoxime informing pharmacies that cefdinir is our formulary alternative. Dr. Huynh stated the Plan will send out a fax blast to the pharmacy network reminding them that for our Medi-Cal patients, they can input an override to provide an emergency 3-day supply. Dr. Nguyen will provide an update on this case at the next meeting.

f. Appeals & Grievances Pharmacy Report

i. 2020 1st Quarter Report

ii. 2020 2nd Quarter Report

Dr. Huynh presented the Appeals & Grievances Pharmacy Reports on behalf of Ms. Luong. Data and descriptions in slide deck required additional clarification. Dr. Huynh stated that he would validate the information with the G&A team and send out the updated slides or provide an update at the next meeting.

Dr. Lin inquired if appeals are mainly submitted by members or providers, and Dr. Huynh replied that the majority of appeals are submitted by providers.

Adjourned to Closed Session at 6:38 p.m.
Pursuant to Welfare and Institutions Code Section 14087.36 (w)

5. Closed Meeting Minutes

The 2Q2020 P&T Committee Closed meeting minutes were reviewed.

It was moved, seconded and the closed minutes of the June 18, 2020 P&T meeting were **unanimously approved**.

Motion: Dr. Nguyen
Second: Dr. Parashar-Rokicki
Ayes: Dr. Alkoraishi, Dr. Balakrishnan, Ms. Bui, Dr. Cung, Dr. Huynh, Dr. Lin, Dr. Nakahira, Dr. Nguyen, Dr. Parashar-Rokicki, Dr. Singh
Absent: Dr. Goel

6. Metrics and Financial Updates

a. Membership Report

Dr. Nakahira noted an increase in Medi-Cal membership, largely due to COVID-19. The increase in approximately 20,000 Medi-Cal members in the last 6 months is mostly due to members who were disenrolled from the state. The Plan anticipated an increase in enrollment due to job losses within the community, but this did not occur. DHCS is looking into the potential reasons why this has not been the case. The Plan also experienced an increase in CMC membership due to our Medicare Outreach team's continuous efforts. Over the last 12 months, CMC membership has increased by approximately 1,000 members.

b. Pharmacy Dashboard

Dr. Otomo reviewed the Pharmacy Dashboard for April 2020 through August 2020. For Medi-Cal, the PA volume in both July and August was approximately 1,200. The turnaround time was compliant for all months. For CMC, the PA volume dropped slightly in August. The turnaround time was compliant for all months. The medication therapy management (MTM) comprehensive medication review (CMR) completion rate was at 49% as of August 2020; the Plan is on track to achieve the MTM CMR completion rate of 55% by the end of 2020. The Pharmacy team's daily review of denied claims for CMC members was compliant for all months.

c. Drug Utilization and Spend

Dr. McCarty presented the Drug Utilization and Spend. For Medi-Cal, most of the top drug categories remained the same year-over-year (YOY) and quarter-over-quarter (QOQ). For CMC, neoplastic disease had the biggest change in trend YOY and QOQ; there was a lot of shifting of drug utilization among members and increased utilization of some of the higher cost neoplastic drugs.

Dr. Lin inquired if the Plan's spend is higher compared to last year. Dr. McCarty replied that spend is approximately 10% higher for both Cal MediConnect and Medi-Cal. However, SCFHP continues to outperform other similar plans in regards to trend, spend, and value-driven utilization. At the outset of COVID in March, there was a large spike in drug utilization, however, it appears to have leveled out and returned to baseline.

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

a. Pharmacy Benefit Manager 2Q2020 P&T Minutes

Dr. McCarty reviewed the Pharmacy Benefit Manager 2Q2020 P&T Minutes.

b. Pharmacy Benefit Manager 3Q2020 P&T Part D Actions

Dr. McCarty reviewed the Pharmacy Benefit Manager 3Q2020 P&T Part D Actions. All of the changes to the PBM's formulary for this quarter were positive changes. Dr. McCarty reminded the Committee that this is what SCFHP uses for the CMC formulary.

It was moved, seconded and the Pharmacy Benefit Manager 2Q2020 and 3Q2020 Part D Actions were **unanimously approved**.

Motion: Dr. Huynh
Second: Dr. Alkoraishi
Ayes: Dr. Alkoraishi, Dr. Balakrishnan, Ms. Bui, Dr. Cung, Dr. Huynh, Dr. Lin, Dr. Nakahira, Dr. Nguyen, Dr. Parashar-Rokicki, Dr. Singh
Absent: Dr. Goel

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

a. Old Business/Follow-Up

i. Dapagliflozin combinations

Dr. Huynh provided a follow-up to the ask from the last meeting regarding adding Farxiga and its combinations to formulary. Dr. Huynh stated that Farxiga and its combinations were added to the formulary in the interim with step therapy for metformin and quantity limit, however, the Plan needs approval from the Committee in the next agenda item for the drugs to remain on the formulary.

b. Formulary Modifications

Dr. Otomo presented the formulary changes made since the June 2020 meeting to the Committee.

It was moved, seconded and the Medi-Cal Formulary Modifications were **unanimously approved**.

Motion: Dr. Huynh
Second: Dr. Cung
Ayes: Dr. Alkoraishi, Dr. Balakrishnan, Ms. Bui, Dr. Cung, Dr. Huynh, Dr. Lin, Dr. Nakahira, Dr. Nguyen, Dr. Parashar-Rokicki, Dr. Singh
Absent: Dr. Goel

c. Fee-for-Service Contract Drug List Comparability

Dr. McCarty reviewed the Fee-for-Service Contract Drug List (CDL) Comparability for Medi-Cal. The majority of the changes were likely made in anticipation of the Medi-Cal Rx carve out effective January 1, 2021. There were no proposed actions for SCFHP.

Dr. Alkoraishi asked if Pristiq requires a prior authorization. Dr. McCarty responded that if a member is already receiving Pristiq through SCFHP, the member has an approved prior authorization on file. When the transition to Medi-Cal Rx occurs on January 1, 2021, the Plan defers to state requirements for coverage. The state will be honoring active prior authorizations for up to one year.

It was moved, seconded and the Fee-for-Service Contract Drug List Comparability recommendations were **unanimously approved**.

Motion: Dr. Huynh
Second: Dr. Nakahira
Ayes: Dr. Alkoraishi, Dr. Balakrishnan, Ms. Bui, Dr. Cung, Dr. Huynh, Dr. Lin, Dr. Nakahira, Dr. Nguyen, Dr. Parashar-Rokicki, Dr. Singh
Absent: Dr. Goel

d. Prior Authorization Criteria

i. <u>New or Revised Criteria</u>
   1. Enablex – *revised*
   2. Myrbetriq - *revised*
   3. Retacrit - *revised*
   4. Penlac - *revised*

ii. <u>Annual Review</u>
   1. Brand Name – *no changes*
   2. Compounded Medications – *no changes*
   3. Duragesic – *no changes*
   4. Emend – *no changes*
   5. Enbrel – *no changes*
   6. Humira – *no changes*
   7. Insulin Pens – *no changes*
   8. Nicotrol – *no changes*
   9. Off-label – *no changes*

10. Opioid Safety Edits – *no changes*
11. Quantity Limit – *no changes*
12. Taltz – *no changes*
13. Trintellix – *no changes*
14. Xelpros – *no changes*
15. Zyvox – *no changes*

Dr. Nguyen reviewed the revised PA criteria.

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

Motion: Dr. Nguyen
Second: Dr. Cung
Ayes: Dr. Alkoraishi, Dr. Balakrishnan, Ms. Bui, Dr. Cung, Dr. Huynh, Dr. Lin, Dr. Nakahira, Dr. Nguyen, Dr. Parashar-Rokicki, Dr. Singh
Absent: Dr. Goel

9. New Drugs and Class Reviews

a. New and Expanded Indications
Dr. McCarty presented an overview of the following drugs with new and expanded indications: Taltz, Cosentyx, Lynparza, Rubraca, Crysvita, Ilaris. There were no recommended actions

It was moved, seconded and the New and Expanded Indications recommendations were **unanimously approved.**

Motion: Dr. Huynh
Second: Dr. Cung
Ayes: Dr. Alkoraishi, Dr. Balakrishnan, Ms. Bui, Dr. Cung, Dr. Huynh, Dr. Lin, Dr. Nakahira, Dr. Nguyen, Dr. Parashar-Rokicki, Dr. Singh
Absent: Dr. Goel

b. Oriahnn (elagolix, estradiol, norethindrone) – Uterine fibroids
Dr. McCarty gave an overview of uterine fibroids and a new drug, Oriahnn, which is indicated for the management of heavy menstrual bleeding associated with uterine fibroids in premenopausal women. This is the first drug approved by the U.S. Food and Drug Administration (FDA) for this indication, but there are two other drugs in the pipeline and one of them may be more efficacious based on clinical studies. Dr. McCarty recommended to keep Oriahnn non-formulary and approve by exception.

It was moved, seconded and recommendation for Oriahnn was **unanimously approved.**

Motion: Dr. Huynh
Second: Dr. Nguyen
Ayes: Dr. Alkoraishi, Dr. Balakrishnan, Ms. Bui, Dr. Cung, Dr. Huynh, Dr. Lin, Dr. Nakahira, Dr. Nguyen, Dr. Parashar-Rokicki, Dr. Singh
Absent: Dr. Goel

c. **<u>Informational Only</u>**

i. Neuromyelitis Optica Spectrum Disorder (NMOSD)
ii. HIV Update
iii. Biosimilar Update
iv. New Derivatives, Formulations, Combinations
v. Isturia (osilodrostat) – Cushing's Disease

vi. Insulins: Semglee (insulin glargine), Lyumjev (insulin lispro-aabc)

Reconvene in Open Session at 7:18 p.m.

10. Discussion Items

a. New and Generic Pipeline

Dr. McCarty reviewed the New and Generic Pipeline. She noted that the major drug of interest in 3Q2020 is ofatumumab (Kesimpta), which is for multiple sclerosis and can be self-administered. In 4Q2020, a drug of interest is roxadustat, an oral agent for the treatment of anemia in chronic kidney disease. In 1Q2021, a drug of interest is aducanumab, a monoclonal antibody treatment for early stage Alzheimer's disease, which would make it the first biologic for this condition.

Dr. McCarty stated that drugs of interest in the generic pipeline are Nexium packets for oral suspension and Kuvan powder for oral suspension and tablet. Dr. Lin inquired as to whether or not Oxytrol or Humalog Mix 75/25 have been released as generics. Dr. McCarty replied that neither are available as generic products yet.

11. Adjournment

The meeting adjourned at 7:25 p.m. The next P&T Committee meeting will be on Thursday, December 17, 2020.

_____ _____

Jimmy Lin, MD, Chair Date

Santa Clara Family Health Plan™

Pharmacy & Therapeutics Committee

METRICS & FINANCIAL UPDATES

Membership

	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20
Medi-Cal	248,007	251,004	253,252	256,490	259,202	261,287
Cal MediConnect	9,029	9,266	9,428	9,570	9,679	9,820
Grand Total	**257,036**	**260,270**	**262,680**	**266,060**	**268,881**	**271,107**

Pharmacy Dashboard

	GOAL (if applicable)	Jul	Aug	Sep	Oct	Nov
Medi-Cal						
PA volume		1274	1196	1114	1177	1035
Standard PAs						
# Standard PA requests		1050	1023	924	959	861
# Approved PAs		665	679	606	631	561
# Denied PAs		199	169	155	167	135
PA approval rate		77%	80%	80%	79%	81%
# Standard PAs completed within 24 hours		1049	1023	923	957	859
% Standard PAs completed within 24 hours	95%	99.9%	100.0%	99.9%	99.8%	99.8%
Expedited PAs						
# Expedited PA requests		224	173	190	218	174
# Approved PAs		144	108	111	135	102
# Denied PAs		42	25	36	38	35
PA approval rate		77%	81%	76%	78%	74%
# Expedited PAs completed within 24 hours		224	173	190	218	173
% Expedited PAs completed within 24 hours	95%	100.0%	100.0%	100.0%	100.0%	99.4%
Biannual Inter-Rater Reliability	80%	TBD				

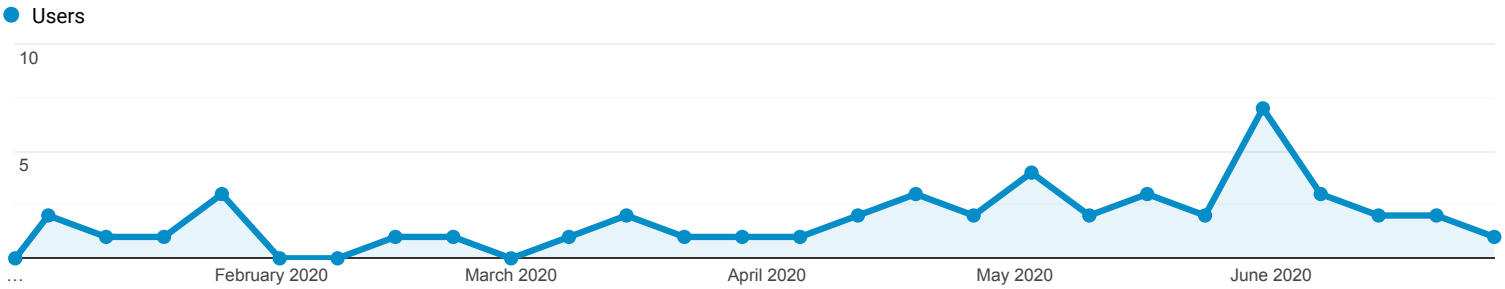
	GOAL (if applicable)	Jul	Aug	Sep	Oct	Nov
Cal MediConnect						
Total PA volume		179	135	122	131	124
Standard PAs						
# Standard PA requests		120	105	89	101	95
# Approved PAs		76	77	67	75	69
# Denied PAs		34	21	17	26	26
PA approval rate		69%	79%	80%	74%	73%
# Standard PAs completed within 72 hours		120	105	89	101	95
% Standard PAs completed within 72 hours	100%	100.0%	100.0%	100.0%	100.0%	100.0%
Expedited PAs						
# Expedited PA requests		59	30	33	30	29
# Approved PAs		30	22	22	19	19
# Denied PAs		18	5	6	11	10
PA approval rate		63%	81%	79%	63%	66%
# Expedited PAs completed within 24 hours		59	30	33	30	29
% Expedited PAs completed within 24 hours	100%	100.0%	100.0%	100.0%	100.0%	100.0%
PA audit sample size		20	20	20	20	20
PA audit pass		20	20	pending	20	pending
PA audit fail		0	0	pending	0	pending
PA pass rate	100%	100%	100%	pending	100%	pending
MTM Eligible Members (YTD)		9,618	9,824	10,068	10,299	pending
MTM Qualified Members (YTD)		1,253	1,310	1,377	1,427	pending
MTM CMR Completion (YTD)		537	636	697	805	pending
MTM CMR Completion Rate (YTD)	55% (at year end)	43%	49%	51%	56%	pending
MTM Monthly Oversight		Pass	Pass	pending	pending	pending
Total claims		54,881	54,646	56,329	59,718	53,996
Approved claims		30,535	30,258	31,863	33,078	30,062
Rejected/Reversed/Denied claims		24,346	24,388	24,466	26,640	23,934
Claim approval rate		56%	55%	57%	55%	56%
Transition fills		166	158	129	118	113
PDE rejection rate		0.02%	0.01%	0.03%	0.01%	0.01%
Denied claims - % reviewed	75%	100.00%	100.00%	100.00%	100.00%	100.00%
Formulary, PA, & ST posted on website by 1st of the month - Date		30-Jun	31-Jul	31-Aug	30-Sep	30-Oct
Formulary, PA, & ST posted on website by 1st of the month - Measure	100%	100%	100%	100%	100%	100%

Consumer Portal Overview - SAC06

All Users
0.02% Users

Jan 1, 2020 - Jun 30, 2020

Traffic Overview



Event Category	Users	Number of Sessions per User	Total Events	Avg. Session Duration
	22 % of Total: 0.02% (98,340)	**18.77** % of Total: 969.97% (1.94)	**686** % of Total: 0.04% (1,759,010)	**00:05:55** Avg for View: 00:05:14 (13.11%)
1. Login	**22** **(9.28%)**	3.73 (213.89%)	133 (19.39%)	00:03:10
2. Prescriptions Screen	**14** **(5.91%)**	1.71 (98.37%)	38 (5.54%)	00:06:25
3. Alerts & Notifications	**11** **(4.64%)**	2.00 (114.77%)	26 (3.79%)	00:05:28
4. Cart	**10** **(4.22%)**	1.50 (86.08%)	19 (2.77%)	00:06:29
5. dashboard-walkthrough-steps	**10** **(4.22%)**	1.00 (57.38%)	39 (5.69%)	00:07:25
6. Home	**10** **(4.22%)**	1.40 (80.34%)	24 (3.50%)	00:07:22
7. Add to Cart	**8** **(3.38%)**	1.62 (93.25%)	41 (5.98%)	00:07:19
8. Orders Screen	**7** **(2.95%)**	2.00 (114.77%)	16 (2.33%)	00:06:30
9. Prior Authorization Screen	**7** **(2.95%)**	1.71 (98.37%)	14 (2.04%)	00:07:00
10. Refill Prescription CTA	**6** **(2.53%)**	1.33 (76.51%)	9 (1.31%)	00:05:43

Rows 1 - 10 of 59

© 2020 Google

SAC06 Member Portal stats for 1-1-2020 to 6-30-2020

1 unique visitor (MP) – associated with IP Addresses

2	sac06-external	13	29	38.50%	02:50	0%

Containing | advanced | Metrics | display 25 of 1 | page 1 of 1 | Export

	Keyword	Visits	Pageviews	Bounce Rate	Engagement	Conversion %
1	drugpricing	13	29	38.50%	02:50	0%
	Total Results	**13**	**29**	-	-	-
	Total Results	**28**	**139**	-	-	-

Number of users – Visit: A visit consists of a series of page views that a single visitor makes during a period of activity. A visit ends after the visitor closes the browser, clears cookies, or is inactive for 30 minutes.
Number of visits – Page view: A page view is recorded when a page on your website is requested. Page views are dependent on the tracking method used: they can either be JavaScript tracking-based or hit-based.
Bounce Rate - The percentage of visits that contain only one page view.
Engagement - The average visit length (or average time on site) for all visits, excluding Bounces.
Visitor - A visitor is defined by a unique ID, which is usually stored in a cookie. Visitors can have multiple visits (i.e. returning visitors), but if the ID is deleted a new ID will be created during the next visit (i.e. a new visitor). Only the AGF and UGA tracking methods calculate visitors.

Spend and Trend Overview

Santa Clara Family Health Plan™

SANTA CLARA FAMILY HEALTH PLAN

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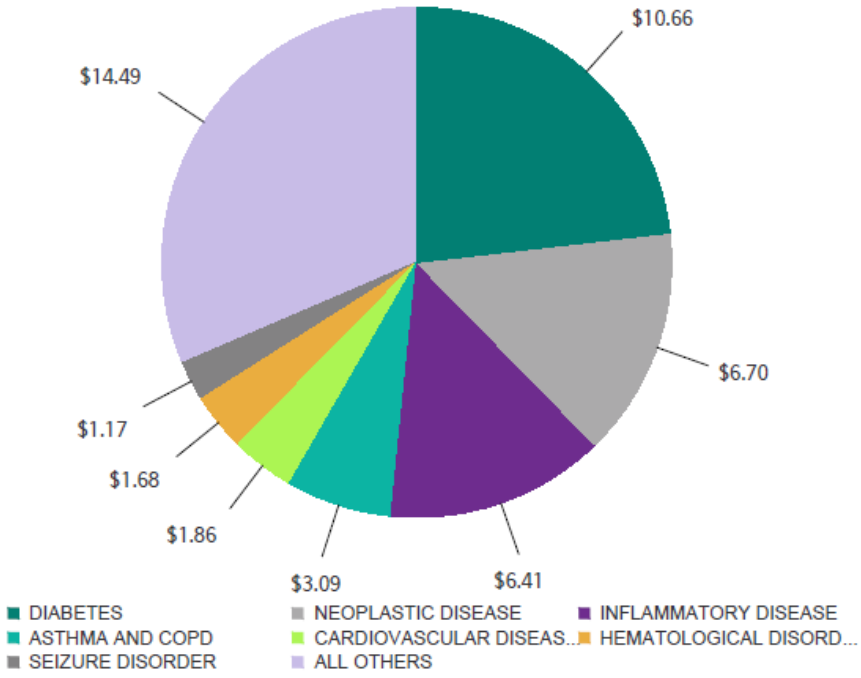
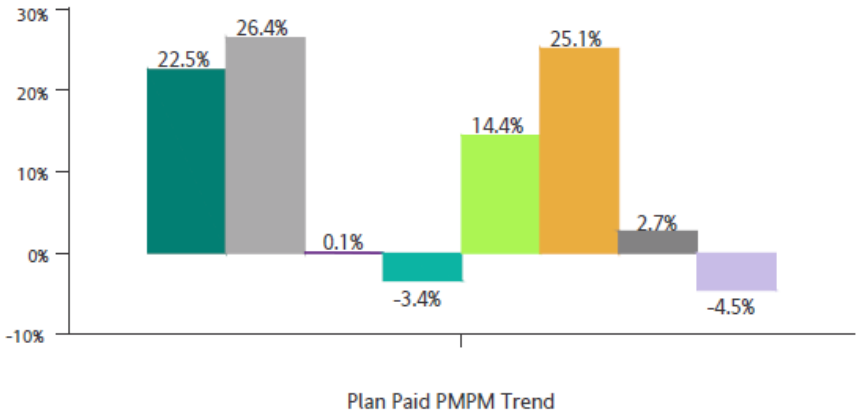
MEDI-CAL

Top Drug Categories

Top Categories by Plan Paid PMPM





Plan Paid PMPM Trend

Top Drug Categories (GTC) by Plan Paid PMPM

Rank	Prior Rank	Bench Rank	Drug Category	Utilizer Count	TC per DS	PMPM Change
1	1	1	DIABETES	9,315	$4.36	$1.96
2	3	3	NEOPLASTIC DISEASE	795	$72.65	$1.40
3	2	2	INFLAMMATORY DISEASE	11,550	$14.82	$0.01
4	4	4	ASTHMA AND COPD	6,713	$4.37	($0.11)
5	6	6	CARDIOVASCULAR DISEASE - HYPER	19,003	$0.49	$0.24
6	7	7	HEMATOLOGICAL DISORDERS	11,421	$1.19	$0.34
7	8	8	SEIZURE DISORDER	7,101	$1.35	$0.03
			ALL OTHERS		$1.12	($0.69)

Top Drug Categories (GTC) by Rx Count

Rank	Prior Rank	Bench Rank	Drug Category	Utilizer Count	TC per DS	Rx Trend
1	1	1	CARDIOVASCULAR DISEASE - HYPER	19,003	$0.49	-15.3%
2	3	4	VITAMIN AND/OR MINERAL DEFICIE	17,741	$0.12	9.7%
3	2	2	DIABETES	9,315	$4.36	-4.7%
4	4	5	ALLERGY	15,516	$0.22	-6.0%
5	6	3	BEHAVIORAL HEALTH - ANTIDEPRES	9,138	$0.40	-0.3%
6	5	9	CARDIOVASCULAR DISEASE - LIPID	14,482	$0.27	-12.8%
7	8	8	SEIZURE DISORDER	7,101	$1.35	-3.5%
			ALL OTHERS		$3.37	-7.9%

Report Period: 7/1/2020 to 9/30/2020 | Comparison Period: 7/1/2019 to 9/30/2019

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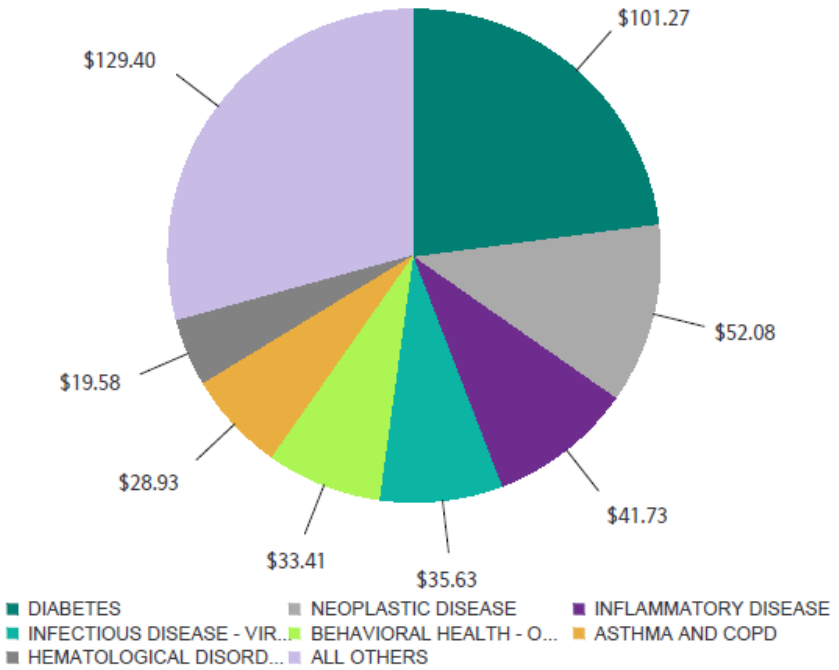
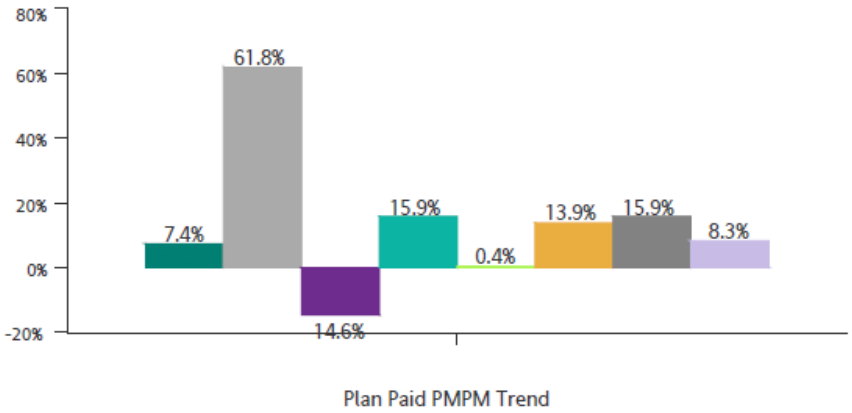
Top Drug Categories

Top Categories by Plan Paid PMPM





Plan Paid PMPM Trend

Top Drug Categories (GTC) by Plan Paid PMPM

Rank	Prior Rank	Bench Rank	Drug Category	Utilizer Count	TC per DS	PMPM Change
1	1	1	DIABETES	2,797	$5.08	$6.98
2	4	2	NEOPLASTIC DISEASE	220	$76.24	$19.90
3	2	5	INFLAMMATORY DISEASE	1,242	$19.51	($7.14)
4	5	6	INFECTIOUS DISEASE - VIRAL	239	$50.08	$4.88
5	3	3	BEHAVIORAL HEALTH - OTHER	1,234	$6.87	$0.15
6	6	4	ASTHMA AND COPD	1,137	$6.69	$3.52
7	7	7	HEMATOLOGICAL DISORDERS	2,705	$2.13	$2.68
			ALL OTHERS		$1.05	$9.97

Top Drug Categories (GTC) by Rx Count

Rank	Prior Rank	Bench Rank	Drug Category	Utilizer Count	TC per DS	Rx Trend
1	1	1	CARDIOVASCULAR DISEASE - HYPER	5,871	$0.32	13.7%
2	2	2	DIABETES	2,797	$5.08	13.2%
3	3	3	CARDIOVASCULAR DISEASE - LIPID	4,698	$0.47	18.4%
4	4	6	BEHAVIORAL HEALTH - OTHER	1,234	$6.87	9.5%
5	5	5	BEHAVIORAL HEALTH - ANTIDEPRES	1,731	$0.38	18.2%
6	8	4	VITAMIN AND/OR MINERAL DEFICIE	2,306	$0.05	29.3%
7	6	10	HEMATOLOGICAL DISORDERS	2,705	$2.13	16.6%
			ALL OTHERS		$4.30	13.7%

Report Period: 7/1/2020 to 9/30/2020 | Comparison Period: 7/1/2019 to 9/30/2019

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Santa Clara Family Health Plan™

Pharmacy & Therapeutics Committee

CAL MEDICONNECT FORMULARY & COVERAGE DETERMINATION

3Q20 Pharmacy & Therapeutics (P&T) Committee Minutes

Meeting Date/Time July 17, 2020, 8:30am – 2:00pm

Attendance Roster Note: meeting was held via videoconference due to COVID-19 pandemic

Voting Committee Members	Attending in Person	Attending via WebEx	Not Able to Attend
_____, MD (Chair, Psychiatry)	☐	☒	☐
_____, Pharm.D. (Co-Chair)	☐	☒	☐
_____, MD (Endocrinology	☐	☒	☐
_____, MD (Oncology)	☐	☒	☐
_____, MD (Obstetrics & Gynecology)	☐	☒	☐
_____, MD (Family Practice)	☐	☒	☐
_____, Pharm.D. (Geriatrics)	☐	☒	☐
_____, MD (Cardiology)	☐	☒	☐
_____, MD (Internal Medicine, Geriatrics)	☐	☐	☒
_____, MD (Internal Medicine, Geriatrics)	☐	☒	☐
_____, MD (Pediatrics, Allergy & Immunology)	☐	☒	☐
_____, MD (Internal Medicine, Palliative Care)	☐	☒	☐

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3Q20 Pharmacy & Therapeutics (P&T) Committee Minutes

Agenda Item	Summary
1. Agenda & Instructions	Roll call taken. Members present as reflected above. The meeting was called to order by Dr. _____, Committee Chair. The Chairman noted that, within the last 2 weeks, each committee member reviewed their annual conflict of interest statement and updated it as needed. He also asked if any members were recusing themselves from discussion/voting on any of the agenda items. No members recused themselves. The Chairman read the following statement: “All drugs or drug classes to be presented were reviewed using evidence-based criteria from credible sources including: 1. Peer-reviewed medical literature, 2. Accepted national treatment guidelines, 3. Drug compendia in common use, and 4. Other authoritative medical sources. Expert opinion has been obtained where necessary. The characteristics of each drug (or drug class) that were evaluated included: 1. Efficacy as well as relative efficacy compared to other similar medications. 2. Drug safety and relative risks of drug versus alternatives. 3. Cost considerations, including drug costs, comparative costs, and projected effect on other medical costs, where applicable. The Committee involves psychiatrists, pediatricians, and 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.”

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3Q20 Pharmacy & Therapeutics (P&T) Committee Minutes

CONSENT AGENDA

Agenda Item	Summary
	Discussion: The Committee considered all the information delivered prior to the P&T meeting (Tab 2 through Tab 11). There was no further discussion or debate. **Vote**: Approve the items in the 3Q20 P&T Consent Agenda as described below as presented. There was a proposal for a Motion which was properly seconded and approved. **Action**: The 3Q20 P&T Consent Agenda was approved. Follow up: None
2. Prior P&T Minutes	**Materials Prepared by**: _____, PharmD **Vote**: Approve following P&T Meeting Minutes as written: • 2Q20 P&T Committee Meeting Minutes • 2Q20 Ad Hoc P&T Committee Meeting Minutes 5-22-20 • CY2021 Part D Annual Pre-Plan Year P&T Meeting **Follow-up**: None

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3Q20 Pharmacy & Therapeutics (P&T) Committee Minutes

3.a. MedImpact Medicare Part D Proposed Actions – Executive Summary

Materials Prepared by: _____, PharmD

Pharmacy & Therapeutics (P&T) Committee General Consent		
General Considerations	Per Chapter 6 of the Medicare Prescription Drug Benefits Manual, a Part D sponsor's formulary must be developed and reviewed by a P&T committee that meets specific requirements with respect to: membership; conflict of interest; P&T member disclosure to CMS; meeting administration; formulary management; formulary exceptions; and P&T committee role. The P&T Committee must make a reasonable effort to review a new FDA approved drug product (or new FDA approved indication) within 90 days of its release onto the market and will make a decision on each new FDA approved drug product (or new FDA approved indication) within 180 days of its release onto the market, or a clinical justification will be provided if this timeframe is not met. For Medicare Part D, the P&T Committee will follow the CMS-mandated timelines. Formularies must include substantially all drugs in the six protected class categories: immunosuppressant (for prophylaxis of organ transplant rejection), antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic) that are FDA approved by the last CMS specified HPMS formulary upload date for the upcoming contract year. New drugs or newly approved uses for drugs within the six classes that come onto the market after the CMS specified formulary upload date will be subject to an expedited P&T committee review. The expedited review process requires P&T committees to make a decision within 90 days, rather than the normal 180-day requirement. At the end of the 90 day period, these drugs must be added to Part D plan formularies. References: Medicare Prescription Drug Benefit Manual -Chapter 6 - Part D Drugs and Formulary Requirements Section 30	
Tab 3b	Formulary Structure White Paper	2019 Standard Part D Formulary Structure White Paper serves to describe the MedImpact Standard Part D Formularies for 2019. Part D Formularies are available with a number of options to support the structural and operational reporting requirements of the Part D program. Plan Sponsors should use this document to determine which formulary options best meet their needs for the 2019 plan year. Tables below show bucket description and distribuiton of buckets between the three main formulary structures supported by standard.
Tab 3c	Legend	Table listing and explaining short forms and colors used in the material.

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	Tab 3d	Line-extensions	Line Extensions are new salts, enantiomers or prodrugs of existing drugs. Formulary Placement and Utilization Management decisions for line extensions are aligned with the existing drugs. Most of the line extensions are added to formulary with the utilization management that are approved and applied for existing drugs and placement is brought retrospectively to P&T. Although there are some instances when we bring proposals to P&T for line extensions. For example Xelpros which is a new branded product of the existing generic entity. Drug placements highlighted in green on this tab are line extensions pending the P&T committee's review and approval for prospective formulary placement and utilization management. -Drug placements highlighted in blue represent placement proposals for drugs made by manufacturers that are currently non-participating (i.e. manufacturers who do no have a agreement with CMS to provide discount on brand drugs while medicare benefeciaries are in coverage gap.) and hence non-D eligible. Once they become Part D eligible we will apply the proposed placements.
	Tab 3e	New Generics	Formulary Placement and Utilization Management decisions for new generics are mostly made the week the drug is available in the drug file. Utilization Managment is utilized from applied and approved reference brand names. Placement proposals are brought retrospectively to P&T for review and approval.

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	Tab 3f	New FDA approved drugs	Formulary placement and utilization management decisions on new drugs are based on cost, clinical and rebate related implications. If a new drug meets the specialty cost threshold (>$670/month) it's placed on formulary at the next effective date (usually the Saturday after the drug is available in the drug file). Placement for newly FDA approved drugs that do not meet specialty are brought to P&T for review and approval. Drug placements highlighted in green on this tab are line extensions pending the P&T committee's review and approval for prospective formulary placement and utilization management. Drug placements highlighted in blue represent placement proposals for drugs made by manufacturers that are currently non-participating labelers (i.e. manufacturers who do not have an agreement with CMS to provide discount on brand drugs while Medicare beneficiaries are in coverage gap.) and are therefore not eligible for Part D coverage. When the drugs become Part D eligible we will apply the proposed placements and utilization management.
	Tab 3g	Proposed/Updated Utilization Management Edits	This tab displays any quantity limits, prior authorization and step therapy restrictions applied to line extensions, new generics and any utilization management edits proposed for new drugs. Additionally, this tab provides updates to any existing utilization mangement edits or criteria.
	Tab 3h	Expedited Review	This tab is reserved for any high impact drugs or protected class drugs (PCD) released the week of P&T and expeditious review is warranted.
	Tab 3i	Other Formulary Changes	This tab includes some formulary enhancements and CMS approved negative changes (E.x. brand generic offsets).

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	Tab 3j	New FDA approved indications	CMS requires a review of all new indications for drugs on formulary to determine if any changes in placement or utilization management are necessary. New indications are reviewed by Drug Information and changes to formulary status or existing prior authorization criteria as a result are summarized here. For prior authorization (PA) criteria update details refer to the Drug Information documents.

3.b. White Paper	Please refer to the tables appended to the end of this document for items 3.b through 3.j.
3.c. Legend	
3.d. Line Extensions	
3.e. First Time Generics	
3.f. New FDA approved drugs	
3.g. Proposed/ Updated UM Edits	
3.h. Expedited Review	
3.i. Other Formulary Actions	
3.j. New FDA Approved Indications	

4. MAC List

Material Prepared by: _____, Pharm.D.

- Retroactive look at the drugs that have had an interim MAC or Maximum allowable cost applied
- These drugs have recently had A-rated **generics** approved
- The MAC price is applied when the drug becomes available
- P&T retroactively approves the products with a MAC applied over the past quarter
- MAC
  - Reimbursement limit per individual multiple-source pharmaceutical entity, strength, and dosage form (e.g., $0.50 per fluoxetine 20 mg capsule).
  - Established by health plans and PBMs for private-sector clients and by many states for multiple-source pharmaceuticals paid for by their Medicaid and other state funded programs.

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Brand Name	Generic Name	Strength	Dosage Form	Interim Approval Date
Depen	Penicillamine	250mg	Tablet	5/1/20
Dyrenium	Triamterene	100mg	Capsule	5/1/20
n/a	Chlorzoxazone	375mg	Tablet	5/1/20
Moxeza	Moxifloxacin	0.5%	Ophth Drops	5/1/20
Taclonex	Calcipotriene / Betamethasone Diproprionate	0.005% / 0.064%	Topical Suspension	5/1/20

Brand Name	Generic Name	Strength	Dosage Form	Interim Approval Date
Vimovo	Esomeprazole / Naproxen	20mg / 500mg		5/1/20
Vimovo	Esomeprazole / Naproxen	20mg / 375mg		5/1/20
Zortress	Everolimus	0.25mg	Tablet	5/1/20
Zortress	Everolimus	0.5mg	Tablet	5/1/20
Zortress	Everolimus	0.75mg	Tablet	5/1/20
Dymista	Azelastine	137mcg / 50mcg / spray	Nasal Spray	5/1/20

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5. Utilization Management

a. "Per Label" Utilization Management

i. New/expanded indications (_____)

Drug	New/Expanded Indication	Proposed Actions
Pomalyst (pomalidomide)	**Kaposi Sarcoma** • Treatment of Kaposi sarcoma (KS) in adults with 1) AIDS-related KS (after failure of highly active antiretroviral therapy) and 2) in adults with KS who are HIV-negative. **Multipole Myeloma** • In combination with dexamethasone, adult patients with multiple myeloma (MM) who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on or within 60 days of completion of the last therapy.	**REVISE PA** to include new indication, age (for both indications), and QL **MAINTAIN** other PA criteria
Brilinta (ticagrelor)	**Reduce Risk of MI** • To reduce the risk of a first myocardial infarction (MI) or stroke in patients with coronary artery disease at high risk for such events.	**REVISE PA** to include new indication and QL **MAINTAIN** other PA criteria
Dupixent (dupilumab)	**Atopic Dermatitis** • For the treatment of patients 6 years and older with moderate to severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.	**REVISE PA** to include expanded indication in pediatric patients 6 years of age and older (including QL) **MAINTAIN** other PA criteria
Sirturo (bedaquiline)	**MDR-TB** • Combination therapy in adult and pediatric patients (5 years and older and weighing at least 15 kg) with pulmonary multi-drug resistant tuberculosis (MDR-TB). Reserve for use when an effective treatment regimen cannot otherwise be provided.	**REVISE PA** to include expanded indication in patients 5 years of age and older (including QL) (age update for FDA approved indications only) **MAINTAIN** other PA criteria
Zejula (niraparib)	**Ovarian, Fallopian, Peritoneal Cancer** • Maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy.	**REVISE PA** for new indication, age, quantity limit **MAINTAIN** other PA criteria

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Drug	New/Expanded Indication	Proposed Actions
Lynparza (olaparib)	**Advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer** • in combination with bevacizumab for the maintenance treatment, for adult patients who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency positive status defined by either a deleterious or suspected deleterious BRCA-mutation, and/or genomic instability. **Metastatic castration-resistant prostate cancer (mCRPC)** • adult patients with deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated mCRPC who have progressed following prior treatment with enzalutamide or abiraterone.	**REVISE PA** for new indications, age, quantity limit **MAINTAIN** other PA criteria
Keytruda (pembrolizumab)	**Dosing Frequency** • Dosage of 400 mg every 6 weeks across all adult indications **Tumor mutational burden-high (TMB-H):** • adult and pediatric patients with unresectable or metastatic tumor mutational burden–high (at least 10 mutations/megabase) solid tumors (TMB-H), as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options. **Cutaneous Squamous Cell Carcinoma (cSCC)** • for the treatment of patients with recurrent or metastatic cutaneous squamous cell carcinoma that is not curable by surgery or radiation **Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Colorectal Cancer (CRC)** • for the first-line treatment of patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer (CRC).	**REVISE PA** for new QL; for TMB-H, cSCC, and MSH-H/dMMR CRC new indications and QL (including max 24 months, per label) **MAINTAIN** other PA criteria

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Drug	New/Expanded Indication	Proposed Actions
Opdivo (nivolumab)	**Non-small cell lung cancer (NSCLC)** • Adults with metastatic NSCLC expressing PD-L1(≥1%) as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations, as first-line treatment in combination with ipilimumab. • Adults with metastatic or recurrent NSCLC with no EGFR or ALK genomic tumor aberrations as first-line treatment, in combination with ipilimumab and 2 cycles of platinum-doublet chemotherapy **Hepatocellular carcinoma** • patients with hepatocellular carcinoma who have been previously treated with sorafenib, as a single agent or in combination with ipilimumab. **Esophageal squamous cell carcinoma** • patients with unresectable advanced, recurrent or metastatic esophageal squamous cell carcinoma after prior fluoropyrimidine- and platinum-based chemotherapy.	**REVISE PA** for new indications, for NSCLC indications also include duration QL to include up to 2 years without disease progression and age **MAINTAIN** other PA criteria
Yervoy (ipilimumab)	**Non-small cell lung cancer (NSCLC)** • Adults with metastatic NSCLC expressing PD-L1 (≥1%) as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations, as first-line treatment in combination with nivolumab. • Adults with metastatic or recurrent NSCLC with no EGFR or ALK genomic tumor aberrations as first-line treatment, in combination with ipilimumab and 2 cycles of platinum-doublet chemotherapy	**REVISE PA** for new indications, age, quantity limit (to include up to 2 years without disease progression) **MAINTAIN** other PA criteria
Alunbrig (brigatinib)	**Non-small cell lung cancer (NSCLC)** • For the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test.	**REVISE PA** for updated indication, age, quantity limit **MAINTAIN** other PA criteria
Rubraca (rucaparib)	**Prostate Cancer** • Adults with a deleterious *BRCA* mutation (germline and/or somatic)–associated metastatic castration-resistant prostate cancer who have been treated with androgen receptor–directed therapy and a taxane-based chemotherapy.	**REVISE PA** for new indication, age, quantity limit **MAINTAIN** other PA criteria

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3Q20 Pharmacy & Therapeutics (P&T) Committee Minutes

Drug	New/Expanded Indication	Proposed Actions
Tecentriq (atezolizumab)	**Non-small cell lung cancer (NSCLC)** • For the first-line treatment of metastatic non-small cell lung cancer in adult patients whose tumors have high programmed death-ligand 1 (PD-L1) expression (PD-L1 stained ≥50% of tumor cells or PD-L1 stained tumor-infiltrating immune cells covering ≥10% of the tumor area), as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations. **Hepatocellular carcinoma** • in combination with bevacizumab, for the treatment of patients with unresectable or metastatic hepatocellular carcinoma who have not received prior systemic therapy.	**REVISE PA** for new indications, age, quantity limit **MAINTAIN** other PA criteria
Avastin (bevacizumab)	**Hepatocellular carcinoma** • in combination with atezolizumab, for the treatment of patients with unresectable or metastatic hepatocellular carcinoma who have not received prior systemic therapy.	**REVISE PA** for new indication **MAINTAIN** other PA criteria
Cyramza (ramucirumab)	**Non-small cell lung cancer (NSCLC)** • in combination with erlotinib, for the first-line treatment of patients with metastatic non–small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor exon 19 deletions or exon 21 substitution mutations.	**REVREVISE PA** for expanded indication **MAINTAIN** other PA criteria
Inlyta (axitinib)	**Renal Cell Carcinoma (RCC)** • in combination with avelumab or pembrolizumab, for the first-line treatment of patients with advanced renal cell carcinoma (RCC)	**REVISE PA** for new indication, quantity limit **MAINTAIN** other PA criteria
Mylotarg (gemtuzumab ozogamicin)	**Acute Myeloid Leukemia (AML)** • newly-diagnosed CD33-positive acute myeloid leukemia (AML) to include pediatric patients 1 month and older.	**REVISE PA** for expanded indication, age **MAINTAIN** other PA criteria

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Drug	New/Expanded Indication	Proposed Actions
Tazverik (tazemetostat)	**Follicular Lymphoma** • Adults with relapsed or refractory follicular lymphoma whose tumors are positive for an EZH2 mutation as detected by an FDA-approved test and who have received at least 2 prior systemic therapies Adult patients with relapsed or refractory follicular lymphoma who have no satisfactory alternative treatment options	**REVISE PA** for new indications, age, QL **MAINTAIN** other PA criteria
Xpovio (selinexor)	**Diffuse Large B-Cell Lymphoma** • For the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from follicular lymphoma, after at least 2 lines of systemic therapy.	**REVISE PA** for new indication, age, QL **MAINTAIN** other PA criteria
Bavencio (avelumab)	**Urothelial Carcinoma (UC)** • for maintenance treatment of patients with locally advanced or metastatic urothelial carcinoma (UC) that has not progressed with first-line platinum-containing chemotherapy	**REVISE PA** for new indication, QL (800 mg every 2 weeks); Update QL per label for the other indications (same as UC) **MAINTAIN** other PA criteria

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ii. Quarterly Review (_____)

Drug	Current Indication(s)	Other/Previous Indication(s)	Proposed Actions
Enverm (mebendazole)	For treatment of patients two years of age and older with gastrointestinal infections caused by: *Ancylostoma duodenale* (hookworm), *Ascaris lumbricoides* (roundworm), *Enterobius vermicularis* (pinworm), *Necator americanus* (hookworm), and *Trichuris trichiura* (whipworm)	For treatment of patients with gastrointestinal infections caused by: *Ancylostoma duodenale* (hookworm), *Ascaris lumbricoides* (roundworm), *Enterobius vermicularis* (pinworm), *Necator americanus* (hookworm), and *Trichuris trichiura* (whipworm)	**REVISE** PA for clarification in indicated age range (≥2 years) • **Rationale:** FDA-approved indication **MAINTAIN** other PA criteria (i.e. ST, documentation of diagnostic confirmation)
Lynparza (olaparib)	For the treatment of adult patients with deleterious or suspected deleterious g*BRCA*m, HER2-negative metastatic breast cancer who have been treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting. (Patients with hormone receptor (HR)-positive breast cancer should have been treated with a prior endocrine therapy or be considered inappropriate for endocrine therapy.)	• Ovarian cancer • Pancreatic cancer • Prostate cancer	**REVISE** PA for clarification in indicated age range (adults) • **Rationale:** FDA-approved indication **MAINTAIN** other PA criteria
Sylatron (pegylated-interferon alfa-2B)	Adjuvant treatment of melanoma with microscopic or gross nodal involvement within 84 days of definitive surgical resection including complete lymphadenectomy	---	**REVISE** PA to **REMOVE QL** • **Rationale:** FDA-approved dosing based on weight with no maximum dosage **MAINTAIN** all other PA criteria

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iii. New entities

- Koselugo (selumetinib); neurofibromatosis type 1 (NF1) (_____)
  - **Therapeutic Designation:** Novel
  - **Prior Authorization**: **NEW**
    - Indication: Neurofibromatosis type 1 (NF1)
    - Age edit: 2-17 years old
    - Other criteria: Patient has symptomatic, inoperable plexiform neurofibromas (PN)
    - Quantity Limit:
      i. 10 mg: #300 per 30 days
      ii. 25 mg: #120 per 30 days
  - **Rationale**:
    - Per FDA labeled indication and dosing
    - PA for appropriate utilization

- Pemazyre (pemigatinib); cholangiocarcinoma (_____)
  - **Therapeutic Designation:** Novel
  - **Prior Authorization: NEW**
    - Indication: Unresectable locally advanced or metastatic cholangiocarcinoma
    - Age edit: 18 years of age or older
    - Other criteria:
      i. Previously treated
      ii. Fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test
    - Quantity Limit: #14 per 21 days
  - **Rationale**:
    - Per FDA labeled indication and dosing
    - PA for appropriate utilization

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- Qinlock (ripretinib); gastrointestinal stromal tumor (GIST) (_____)
  - **Therapeutic Designation:** Novel
  - **Prior Authorization:** **NEW**
    - Indication: Advanced gastrointestinal stromal tumor (GIST)
    - Age edit: 18 years of age or older
    - Other criteria: Received prior treatment with 3 or more kinase inhibitors, including imatinib
    - Quantity Limit: #90 per 30 days
  - **Rationale**:
    - Per FDA labeled indication and dosing
    - PA for appropriate utilization

- Zepzelca (lurbinectedin); metastatic small cell lung cancer (SCLC) (_____)
  - **Therapeutic Designation:** Novel
  - **Prior Authorization:** **NEW**
    - Indication: metastatic small cell lung cancer (SCLC)
    - Other Criteria:
      i. The patient is 18 years of age or older
      ii. The patient has experienced disease progression on or after platinum-based chemotherapy (e.g. carboplatin, cisplatin)
    - Quantity Limit: one fill per 21 days
  - **Rationale**:
    - Per FDA labeled indication
    - PA for appropriate utilization

- Tukysa (tucatinib); advanced or metastatic HER2-positive breast cancer (_____)
  - **Therapeutic Designation:** Novel
  - **Prior Authorization:** **NEW**
    - Indication: Advanced unresectable or metastatic HER2 positive breast cancer, including those with brain metastases, in combination with trastuzumab and capecitabine

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- Age edit: 18 years of age or older
- Other criteria: Received prior treatment with 1 or more anti-HER2 targeted therapy, specifically either trastuzumab or trastuzumab with pertuzumab
- Quantity Limit: 50 mg #10 per day and 150 mg: #4 per day

- **Rationale**:
  - Per FDA labeled indication and dosing
  - PA for appropriate utilization

- Tabrecta (capmatinib); mNSCLC (_____)
  - **Therapeutic Designation:** Novel
  - **Prior Authorization:** **NEW**
    - Indication: Treatment of adult patients with metastatic non-small cell lung cancer (mNSCLC) whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test.
    - Quantity Limit: 4 tablets per day (all strengths)
  - **Rationale**:
    - Per FDA labeled indication and dosing
    - PA for appropriate utilization
- Retevmo (selpercatinib); mNSCLC and thyroid cancer (_____)
  - **Therapeutic Designation:** Novel
  - **Prior Authorization:** **NEW**
    - Indication - Treatment of:
      i. Adult patients with metastatic RET fusion-positive non-small cell lung cancer (NSCLC)
      ii. Adult and pediatric patients 12 years of age and older with advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy
      iii. Adult and pediatric patients 12 years of age and older with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate)
    - Quantity Limit: 6 per day (40 mg capsules) or 4 per day (80 mg capsules)
  - **Rationale**:

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- Per FDA labeled indication and dosing
- PA for appropriate utilization

- Nyvepria (pegfilgrastim-apgf) – Neulasta biosimilar
  - **Therapeutic Designation:**

Pegfilgrastim Product	Therapeutic Designation	Rationale
Neulasta Biosimilars (**Nyvepria**, Ziextenzo, Udencya, Fulphila)	**Equivalent NEW**	Meets FDA definition for Biosimilar Product (highly similar and has no clinically meaningful differences from an existing FDA-approved reference product)
Neulasta	**Equivalent with Caveat* MAINTAIN** **Should be available without a step therapy requirement if the PA request is for the Neulasta Onpro Kit and the patient has a barrier to access (per physician attestation).*	

  - **Prior Authorization: NEW**
    - Align with Neulasta per FDA-approved indications
    - Step Therapy (in PA): trial of or contraindication to up to 2 preferred G-CSFs for aligned indications
      i. **Exception applicable to all FDA-approved indications**: no step therapy requirement if the PA request is for the Neulasta Onpro kit and the physician attests that the patient has a barrier to access (e.g., travel barriers, or the patient is unable to return to the clinic for their Neulasta injections)
  - **Rationale**:
    - Ensure patient access to the Neulasta Onpro Kit as it is the only available on-body device that delivers pegfilgrastim 27 hours after application, allowing the patient to go home after chemotherapy treatment
    - Align with existing PA criteria for reference product and biosimilars in same space
    - Allow for step therapy when indications are aligned among therapeutically equivalent products, to promote use of preferred agent(s)

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- Hulio (adalimumab-fkjp) – Humira biosimilar
  - **Therapeutic Designation:**

Adalimumab Product	Therapeutic Designation	Rationale
Humira and Humira Biosimilars (**Hulio**, Abrilada, Amjevita, Cyltezo, Hadlima, Hyrimoz)	**Equivalent NEW**	Meets FDA definition for Biosimilar Product (highly similar and has no clinically meaningful differences from an existing FDA-approved reference product)

  - **Prior Authorization: NEW**
    - Align with existing clinical criteria in PA for Humira and other Humira biosimilars where indications are shared
    - Step Therapy (in PA): trial of or contraindication to up to 2 preferred immunomodulating agents for aligned indications AND up to 1 preferred adalimumab product
  - **Rationale**:
    - Align with existing PA criteria for reference product and biosimilars in same space
    - Allow for step therapy when indications are aligned among therapeutically equivalent products, to promote use of preferred agent(s) [including within biosimilar basket]

b. Exclusions (_____)

i. MedPerform Only

Excluded Drug	Preferred Alternative	Cost
Insulin Lispro Protamine Mix (generic for **Humalog Mix 75-25 Kwikpen**) 100 units/mL; 3mL prefilled pen	Alternate insulin products	AWP = $21.22/mL
Insulin Lispro Junior Kwikpen (generic for **Humalog Junior Kwikpen**) 100 units/mL; 3mL prefilled pen	Alternate insulin products	AWP = $21.22/mL

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Methylphenidate ER (generic for **Aptensio XR**) 10, 15, 20, 30, 40, 50, and 60 mg ER capsules	Alternative ADHD products (e.g. Adderall XR, Concerta, Vyvanse)	AWP = $10.00/15 mg tabs AWP = $10.00/Other tabs
Dayvigo (lemborexant) 5 and 10 mg tablets	Alternative insomnia products (e.g. zolpidem, zaleplon, eszopiclone)	AWP = $11/tablet
Lyumjev (insulin lispro-aabc) 100 units/mL; 3mL prefilled pen 200 units/mL; 3mL prefilled pen 100 units/mL; 10 mL vial	Alternate insulin products	AWP = $127/U-100 pen AWP = $255/U-200 pen AWP = $330/vial

ii. FDA-Approved, Non-Essential Products (Agents also excluded on MedPerform; Optionally excluded on Portfolio)

Excluded Drug	Preferred Alternative	Cost
BPCO-Balsam Peru/Castor Oil (generic for **Venelex**) 5-gram tube; 20 per carton	OTC topical ointments for wound care, First aid/wound care dressings	AWP = $1.88/gram
Zilxi (minocycline 1.5% foam [30g can])	Topical metronidazole or azelaic acid	AWP = $19.40/gram
Helidac therapy (blister pack with bismuth subsalicylate, metronidazole, tetracycline; 2- 262.4 mg chewable tablets, 1- 250 mg tablet, 1- 500mg capsule; [56 blister packs])	OTC bismuth subsalicylate, metronidazole tablets or capsules, tetracycline capsules	AWP = $20.68/blister pack
Doxycycline hyclate (generic for **Doryx**; 50, 75, 100, 150, and 200 mg DR tablets)	Doxycycline monohydrate or immediate release doxycycline hyclate tablets and capsules	MAC = $3.99 to $17.99 per tablet
Dorxy MPC (doxycycline hyclate; 120 mg DR tablets)	Doxycycline monohydrate or immediate release doxycycline hyclate tablets and capsules	AWP = $15.00/tablet

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Doxycycline monohydrate (generic for **Oracea**; 40 mg IR/DR caps)	Doxycycline monohydrate 50 mg capsules, other strengths of doxycycline monohydrate	MAC = $17.53/capsule

Excluded Drug	Preferred Alternative	Cost
Osmolex ER kit (amantadine ER; dosing kit of 129 mg & 193 mg tablets [60 tablets in kit with one 30-count bottle of each strength])	Amantadine 100 mg capsules or tablets.	AWP = $540/kit

iii. High Cost, Non-Essential Products (Agents also excluded on MedPerform; Optionally excluded on Portfolio)

Excluded Drug	Preferred Alternative	Cost
Halucort (Hyaluronic acid gel [30g pump dispenser])	OTC hydrogel/gel products for wound care, first aid/wound care dressing	AWP = $32.17/gram
Prenara (capsule containing prenatal vitamins with ferrous fumarate and folic acid)	Prenatal, Mynatal and other lower cost prenatal/pregnancy vitamins	AWP = $56.50/capsule
Gabapentin-naproxen cmpd kit (5-10% external cream [1 box of 51g])	Diclofenac gel, topical lidocaine, topical capsaicin, other topical analgesics	AWP = $7.66/gram
Onycho-Med external kit (2% miconazole nitrate solution and 250 mg terbinafine hydrochloride powder for reconstitution [10 mL box kit])	OTC topical terbinafine, OTC topical miconazole	AWP = $6.03/mL
Oveeza (folic acid-vit B12-alpha lipoic acid-coenzyme Q10-omega 3 0.5 mg softgel capsule)	Folic acid, vitamin B12, alpha lipoic acid, coenzyme Q10, omega-3 agents	AWP = $39.60/capsule

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Lipritin (9 gabapentin 100 mg capsules, 30 g of lidocaine-prilocaine 2.5%-2.5% cream, 15 - 6 cm x 7 cm dressings, and 1-chronocap)	Gabapentin 100 mg capsules, lidocaine-prilocaine 2.5%-2.5% cream, first aid/wound dressings	AWP = $4,091/kit

Excluded Drug	Preferred Alternative	Cost
Econasil (85g tube of Econazole nitrate cream 1%; 20 4”x 4” gauze pads; 1 roll of Silicone tape)	Econazole nitrate 1% cream (or other topical antifungals), first aid/wound dressing	AWP = $4,091/kit
Fluopar (30g tube of fluocinonide cream 0.1%, 118 mL tube of Skin Repair Complex [dimethicone cream 5%])	Fluocinonide 0.1% cream (or other topical corticosteroids), OTC skin protectants	AWP = $3,862/kit
Nuvakaan II (2x30g tubes lidocaine/prilocaine 2.5-2.5%; 15 sheets of Nuvazil [silicone gel scar dressings])	lidocaine-prilocaine 2.5%-2.5% cream (or other topical anesthetics), OTC silicone scar prevention products	AWP = $1,823/kit
Nopioid-TC kit (Terocin [lidocaine 4%-menthol 4% patches], 10 patches; cyclobenzaprine hydrochloride 7.5 mg tablets, 1 bottle of 30)	OTC Terocin patches, other lidocaine-menthol patches, topical lidocaine, other topical analgesics, cyclobenzaprine hydrochloride tablets, other muscle relaxants.	AWP = $853.20/kit
Econasil kit (Econazole nitrate cream 1% [85g tube], gauze pads 4”x 4” [20]; Silicone tape [1 roll])	Econazole nitrate 1% cream (or 0ther topical steroids), OTC skin protectants	AWP = $4,091/kit
Lidotin kit (gabapentin 100 mg capsules [24]; lidocaine 3.88% cream [3 oz tube], silicone gel sheets, [40 mm x 60 mm – 15], Chronocap, sterile alcohol prep pads [20], 70% isopropyl alcohol)	Generic gabapentin, lidocaine 3% cream, OTC silicone scar prevention products	AWP = $4,091/kit

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	Gabapal kit (gabapentin 100 mg capsules [24], chronocap; Lidotrol (lidocaine) 3.88% cream [3 oz tube]; sterile gauze pads [20-4"x4"]; silicone tape roll)	Generic gabapentin 100 mg capsules, lidocaine 3% cream (or other topical lidocaine), first aid/wound dressings	AWP = $3,862/kit
	Pentican kit (gabapentin 100 mg capsules [9], chronocap; lidocaine 5% patch, alcohol prep pads [10])	Generic gabapentin 100 mg capsules, generic lidocaine 5% patch (or other topical lidocaine), first aid/wound dressings	AWP = $4,091/kit
	Excluded Drug	**Preferred Alternative**	**Cost**
	Diclovix M kit (1.5% diclofenac sodium topical solution [150 mL dropper bottle] and 8% menthol gel [85 g packet])	Diclofenac gel, OTC methyl salicylate/menthol, and other topical analgesics	AWP = $1,950/kit

6. Non-D Formulary Action Grids

Materials Prepared By: Formulary Administration & Strategy department
Reviewer: _____, Pharm.D.

The following spreadsheets (appended to the end of this document) are referred to as the 2Q20 Formulary Action Grids. They list all the non-Part-D formulary changes that were made effective on July 1, 2020. The majority of changes were a result of decisions made at the 2Q20 P&T Committee, and other changes were included that resulted from business formulary strategy decisions that did not require any changes to P&T-approved clinical strategies.
These grids are being brought to P&T as information, so the members can review the final formulary strategies and have the opportunity to express concerns or ask questions if they have any. Our goal is to ensure that P&T has oversight over the formulary process to ensure clinical appropriateness. As the Director of Drug Information, I am advising the committee members that it is my opinion that all the decisions outlined in the documents adhere to the clinical intent of the decisions made at previous P&T Committee meetings.

7. High Cost Generic Program Update.

Material Prepared By: _____, Pharm.D.

MedImpact's High-Cost Generics Program (HCG Programs) are clinical programs focused on ameliorating the rising generic drug spend by targeting high-cost generics (HCGs) and their brand equivalents. For a product to be designated as an HCG, there must be at least one clinically appropriate therapeutic alternative(s) available that provides significant cost savings.

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Lower-cost alternatives to HCGs may include one of the following:

- Same generic drug, slight differences in dosage
- Different formulation of the same drug (e.g., a tablet in place of a capsule)
- Different delivery system of the same drug (e.g., immediate release instead of extended release)
- Individual drug components taken separately in place of a high cost combination product
- Different generic drug(s) that have accepted use to treat the same condition(s)
- Over-the-counter product (OTC products not covered by the plan)

The High-Cost Generic Choice Program (HCG Choice) places HCGs on a tier with greater member cost-sharing relative to the lower-cost alternatives. Members have the choice to continue the drug at a higher copay/coinsurance or may elect to switch to lower-cost alternatives.

The High-Cost Generic Exclusion (HCG X) program excludes HCGs and their brand equivalents from the plan's formulary or benefit. Clients may select an exception process for HCG excluded drugs.

HCGs added to either program are considered negative formulary changes. Communications are sent proactively to members with recent claims before the benefit change. Clients may choose to further mitigate potential member disruption by the use of short-term grandfathering of existing utilizing members.

Proposed Action:
Approve the recommended additions/updates to the relevant HCG programs including designated HCGs and corresponding clinically appropriate lower-cost alternative(s) as described

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8. Updated Annual P&T Work Plan for 2020	**Material Prepared by:** _____, Pharm.D.
	
	4Q2020 – October 2020
	
	Medicare Part D Annual Review
	
	Annual Formulary Review
	
	Annual P&T Work Plan
	
	Therapeutic Class/Disease Reviews with Monograph
	• Anemia of CKD
	  ○ roxadustat
	• Lupus
	  ○ voclosporin
	  ○ anifrolumab
	
	UM Drug or Drug Class Reviews
	• berotralstat [hereditary angioedema (HAE)]
	• inclisiran (hyperlipidemia)
	• viloxazine (ADHD)
	• olanzapine/samidorphan (schizophrenia, bipolar disease)
	• Rolontis (neutropenia)
	• Winlevi (topical acne)
	• filgotinib (rheumatoid Arthritis)
	• Tlando (hypogonadism)
	• JZP 258 (low sodium Xyrem)
	• Adlarity (donepezil) transdermal patch
	
	“Per label” UM Drug Reviews
	• ASTX727 (MDS)
	• CC-486 (AML)
	• triheptanoin (fatty acid oxid disorder)
	• belantamab mafodotin (multiple myeloma)
	• KTE-X19 (mantle cell lymphoma)

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- tafasitamab (DLBCL)
- viltolarsen (Duchenne Muscular Dystrophy)
- Ryoncil (remestemcel-L) (acute GVHD)

Quarterly update

- Utilization Management for Review: New & Expanded Indications; New Derivatives, Formulations, Combinations; "Miscellaneous" Quarterly Review

*schedule of review pending based on timing of data readout and FDA filing

2021 P&T Meeting Schedule	
P&T Meeting	**Date**
1Q21	January 22
2Q21	April 23
Annual Part D	May 21
3Q21	July 16
4Q21	October 15

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9. ACA Essential Health Benefit (EHB) Zero Dollar Copay Update

Material Prepared by: _____, Pharm.D.

Addition of Twirla to Contraceptive Zero Cost Share Override PA

Situation
• Twirla (levonorgestrel/ethinyl estradiol) is a new, single source brand transdermal contraceptive. • Per the ACA/EHB Zero dollar, plans must make exceptions and waive cost sharing where a generic would be medically inappropriate.
Background
• As not mandated to include <u>all</u> contraceptives by the ACA/EHB/Zero Dollar for the standard offering, MI has had this PA in place as a method of exception to ensure patients <u>are able to receive all</u> contraceptive products, and that they be able to receive them for zero dollar, where applicable. • There is already a prior authorization (Contraceptive Zero Cost Share Override) in place that approves all SSB and MSB contraception products for medical necessity, contraindication, or step: **SSB** with no preferred generic agents/therapeutically equivalent products available where there is **a medical necessary reason** (per provider documentation). **SSB or MSB** where either 1) two preferred products **are medically inappropriate** (or one if only one agent available) 2) patient **has tried <u>or</u>** has a **documented medical contraindication** to two preferred products (or one if only one agent available) 3) requested drug is considered as **medically necessary**.
Assessment
• Currently the Zero Cost Share Override prior authorization includes a pathway to all SSB or MSB contraceptives to be provided for zero dollars, where the applicable medical necessity, contraindication and/or step is met.
Recommendation
• Add Twirla to the Contraceptive Zero Cost Share Override PA: Allows patient access to the brand Twirla for medical necessity, contraindications to, or historical step through preferred agents on the EHB/Zero dollar list

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Addition of Aromatase Inhibitor(s) to the EHB Zero Dollar List

Plan

Market Basket: Agents for Breast Cancer Prevention		
Drug	**Therapeutic Designation**	**Rationale**
Arimidex (anastrozole)	Equivalent – **NEW**	Same designation within UPSTF recommendation.
Aromasin (exemestane)	Equivalent – **NEW**	
Evista (raloxifene)	Equivalent – **NEW**	
Soltamox (tamoxifen)	Equivalent – **NEW**	

- Add anastrozole and exemestane to the ACA/EHB Zero dollar list for breast cancer risk reduction:
  - ✓ Age limitation: 35 and older (exemestane) or 40 to 70 years old (anastrozole)
  - ✓ Quantity Limit: anastrozole (1 per day) and exemestane (1 per day)
    - *Raloxifene already has a QL of 1 per day*
- Rationale: Based on USPSTF Grade B recommendation to include aromatase inhibitors. Choice of aromatase inhibitors is based on NCCN guidelines. Choice to include both agents is based on ages studied (35+ for exemestane; 40+ for anastrozole), as neither are FDA approved for this indication and costs are relatively low. Claims outside of age edit will process at plan-designated copay, if applicable.

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Affordable Care Act Essential Health Benefit $0 Copay List

ACA EHB $0 LIST UPDATES

Optional Table: Influenza

Each year around July, the influenza vaccines for the season become available. The vaccines are updated annually for the CDC-recommended circulating flu viruses for that season and become available as a variety of formulations, including trivalent and quadrivalent options; each year they are considered new entities.

Proposed action: P&T approval to allow QL of 1 dose/180 days (routine use) and age edits for products indicated in adults only for each of the new influenza vaccines each year.

Yearly Influenza Vaccines	Age per label	Age edit	Quantity limit
Afluria 20**-20** (3YR UP)	3 years and older		1 dose per 180 days
Afluria 20**-20** (6-35MO)	6 months to 35 months		1 dose per 180 days
Afluria 20**-20**	6 months and older		1 dose per 180 days
Fluad 20**-20**	**65 years and older**	Yes	1 dose per 180 days
Fluarix 20**-20**	6 months and older		1 dose per 180 days
Flublok 20**-20**	**18 years and older**	Yes	1 dose per 180 days
Flucelvax 20**-20**	4 year and older		1 dose per 180 days
Flulaval 20**-20**	6 months and older		1 dose per 180 days
Flumist 20**-20**	2-49 years old		1 dose per 180 days
Fluzone High-Dose 20**-20**	**65 years and older**	Yes	1 dose per 180 days
Fluzone 2019-2020	6 months and older		1 dose per 180 days
Other Influenza vaccine product	Per label	If adult only	1 dose per 180 days

10. P&P 460-PD-1003, Pharmacy & Therapeutics Committee

Material Prepared by: _____, Pharm.D.

The procedure "460-PD-1003 Pharmacy & Therapeutics Committee, v21" is being proposed for approval of a single change, which can be summarized as follows:

- Add paragraph IV.E.2.c.iii.1. (p15-16) to clarify the Committee's position on multisource brand drugs (MSBs). This clarification states that branded drugs may be disadvantaged (e.g. excluded) compared to their interchangeable generic products. A caveat is included to prevent Narrow Therapeutic Index drugs (NTI's) from being excluded.

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- Below is a screenshot of the most commonly utilized branded drugs that could be excluded in favor of their interchangeable generics. The formulary exception process could still be utilized to access these MSB products.

MSB EXCLUSIONS

Top #100 - Standard MSB Utilization

Drugs	1Q20 RX Count
NUVARING	917
CARAFATE	257
TRAVATAN Z	228
VIVELLE-DOT	222
DEPO-TESTOSTERONE	217
WELLBUTRIN XL	214
KLOR-CON 10	195
CRESTOR	190
SOOLANTRA	188
TOPROL XL	178
NEXIUM	164
TRANSDERM-SCOP	160
ABILIFY	157
PLEXION	155
YAZ	154
FOCALIN XR	153
VIAGRA	148
CIALIS	120
BENICAR	111
URIBEL	106
COLCRYS	106
RELPAX	97
MINIVELLE	95
SENSIPAR	*82*
BEYAZ	81
LIPITOR	81
LEXAPRO	80
PRISTIQ	80
ZOLOFT	78
ADDERALL	75
ONFI	74
PREVIDENT 5000 PLUS	70
FLECTOR	70

Drugs	1Q20 RX Count
VESICARE	68
ANDROGEL	68
MINASTRIN 24 FE	68
BENICAR HCT	67
GOLYTELY	65
LOTEMAX	64
EVEKEO	62
EFFEXOR XR	60
TAMIFLU	59
GLEEVEC	*57*
ESTRACE	56
VAGIFEM	55
CLIMARA	49
DERMA-SMOOTHE-FS	49
ORACEA	48
YASMIN 28	47
VALTREX	47
DYMISTA	44
PYRIDIUM	43
CELEBREX	42
CYMBALTA	40
ULORIC	39
CELLCEPT	39
ADCIRCA	*39*
COREG CR	38
AMPYRA	*38*
PROVENTIL HFA	37
COZAAR	36
ELIDEL	35
CLODERM	35
DICLEGIS	34
AMBIEN	34
RETIN-A	33
SILVADENE	31

Drugs	1Q20 RX Count
XANAX	31
SAFYRAL	30
PROMETRIUM	30
NUVIGIL	29
BUTRANS	28
NORVIR	*28*
KLOR-CON	28
COSOPT PF	28
NATROBA	28
LOESTRIN FE	28
TRIBENZOR	27
NORVASC	27
BARACLUDE	*26*
FOCALIN	26
DIOVAN HCT	26
LIDODERM	26
PREVACID	25
SINGULAIR	25
RITALIN	25
XUREA	24
HEMMOREX-HC	23
FINACEA	22
TRICOR	22
PROZAC	22
LUNESTA	21
DYAZIDE	21
PRED FORTE	21
RANEXA	20
PATADAY	20
ZETIA	20
BRISDELLE	20
LOVAZA	20
PATANOL	20

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Italics – Specialty Drug

Request: Approve the changes to the procedure.

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11. Annual PA Guideline Review (July 2019 - June 2020)	**Material Prepared by:** _____, Pharm.D. **Report Objectives:** 1. To provide an overview of MedImpact's prior authorization (PA) guidelines for: a. Portfolio/Marketplace b. MedPerform c. Medicaid d. Non-Self-Administered (NSA) e. Medicare Part D **2.** To highlight the general trends and changes that have occurred over the past year for non Part D lines of business **Operational Overview:** • Weekly Process ○ Drug file updates include new drugs, new generics, line extensions (new formulations or strengths) • Monthly Process ○ Existing guidelines may be updated for: ○ New or expanded FDA indications ○ Regulatory updates associated with changes in federal or state regulations ○ CMS mandated changes due to: ▪ PA criteria kick-outs (standard & custom Part D guidelines) ▪ CMS memos ○ Termed guidelines ○ Administrative changes (e.g., spelling/grammar, text format, line extensions) ○ Changes in formulary placement ○ Per client request • Quarterly Process ○ P&T Committee approval for: ▪ New guidelines with clinically appropriate criteria ▪ Existing guidelines with revisions in clinical criteria, step therapy, or quantity limit (UM changes) ○ Formulary Decision Review strategy • Annual Process ○ Changes planned for the subsequent year's Part D PA guideline set

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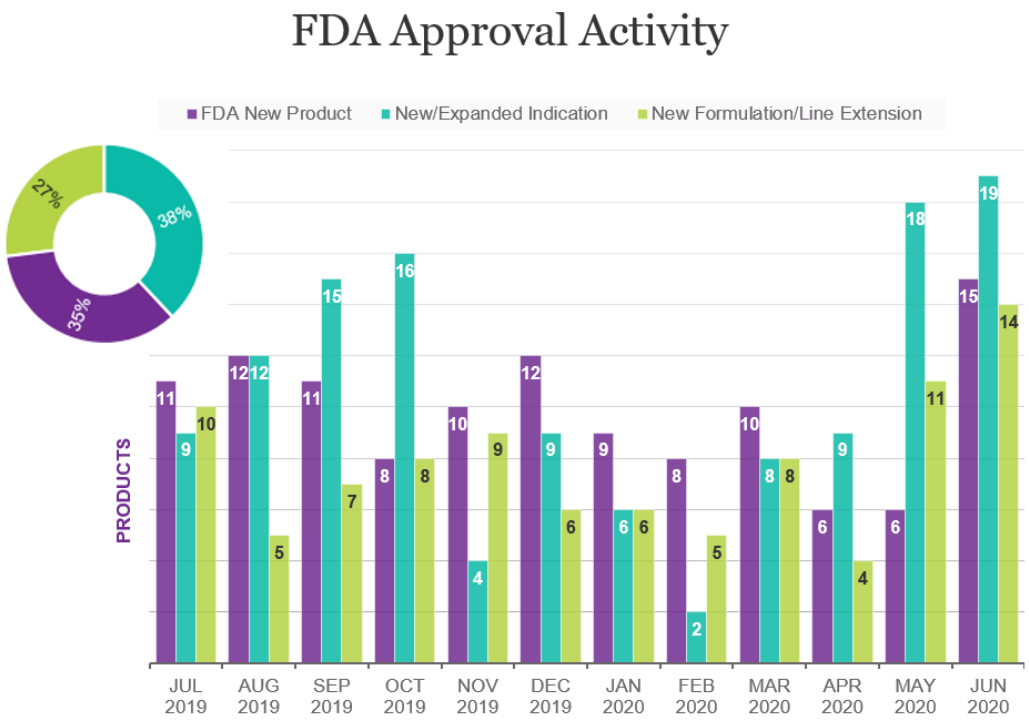
Trends:



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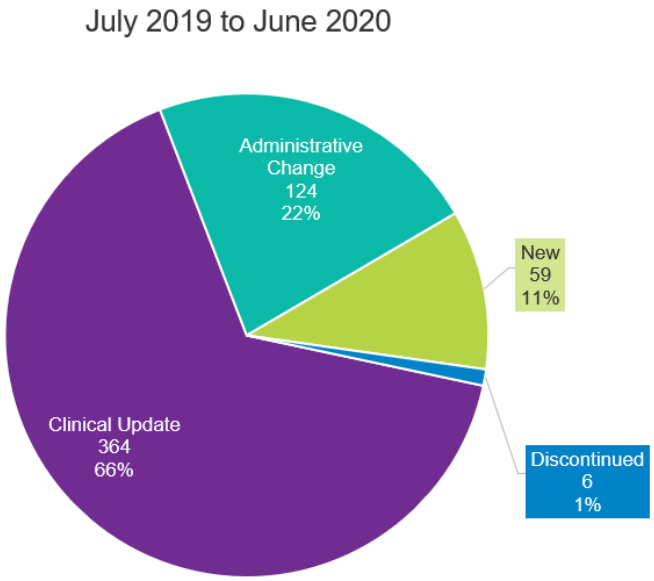
Non-Part D PA Guidelines Activity



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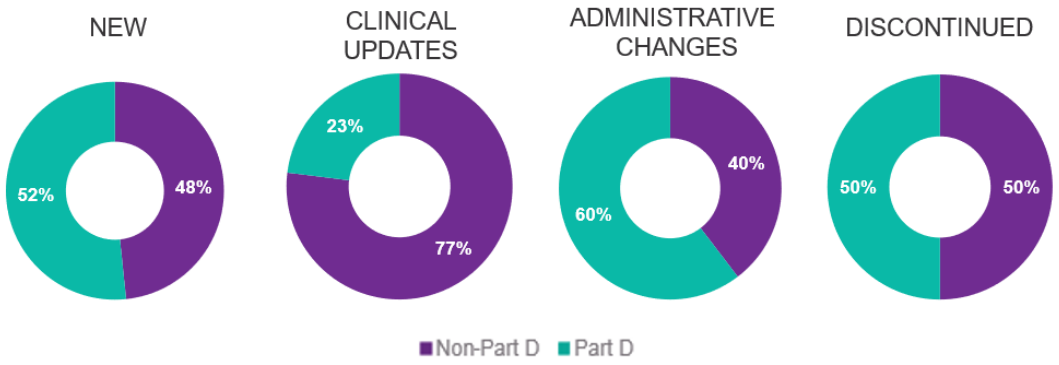
Prior Authorization Guidelines Summary



Standard Guideline Set	Type of Update			
	New	Clinical	Administrative	Discontinued
Part D	63	109	189	6
Non-Part D	59	364	124	6
Total	122	473	313	12

Numerous other tables were included to list the guidelines that were changed throughout the reporting period.

Recommendation: Accept report as information.

== End of Consent Agenda ==

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DRUG / THERAPEUTIC CLASS / DISEASE REVIEWS

Agenda Item	Summary
12. NMOSD Disease Review	**Presenter:** _____, Pharm.D. The Disease Review for Neuromyelitis Optica Spectrum Disorder (NMOSD) was presented, along with the Drug Reviews for Uplizna (inebilizumab) and satralizumab. **Therapeutic Designations:**

Market Basket: FDA-approved NMOSD agents

Drug	Therapeutic Designation	Rationale
Uplizna (inebilizumab)	Equivalent – **NEW**	Same place in therapy. Each agent has advantages and disadvantages, determined to be equitable overall.
satralizumab	Equivalent – **NEW**	
Soliris (eculizumab)	~~Novel~~ Equivalent – **UPDATE**	

Utilization Management:

Uplizna (inebilizumab)

Prior Authorization: NEW

Diagnosis: NMOSD (per FDA label)

Evidenced by both of the following:

Positive serologic test for anti-aquaporin-4 (APQ4) antibodies (per FDA label)

Physician attestation of the presence of ≥1 core clinical characteristics*

Concurrent use: No concurrent use of rituximab, satralizumab, or eculizumab

Age edit: 18 years and older (per FDA label)

Prescriber edit: Prescribed by or in consultation with neurologist

Quantity limit: Per FDA label

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Agenda Item	Summary
	Loading dose: 300 mg (3 x 10 mL vials) on weeks 0 and 2 Maintenance dose: 300 mg every 6 months (starting 6 months after induction) **Duration**: initial – 12 months; renewal – 12 months **Renewal Criteria**: Physician attestation of clinical benefit (reduction in relapse frequency from baseline or a decrease in NMOSD-related hospitalizations) **Rationale**: per FDA label indication and dosing, 2015 American Academy of Neurology diagnostic guideline, duplication of mechanism of action, consultant feedback, no data for combination regimens and high risk for infections, anti-AQP4 antibody serology tests commercially available at most major labs, clinical trial design **Satralizumab** **Prior Authorization: NEW** **Diagnosis**: NMOSD (per FDA label) Evidenced by both of the following: Positive serologic test for anti-aquaporin-4 (APQ4) antibodies (per FDA label) Physician attestation of the presence of ≥1 core clinical characteristic* **Concurrent use**: no concurrent use of rituximab, inebilizumab, or eculizumab **Age edit**: 18 years and older (per label) **Prescriber edit**: Prescribed by or in consultation with neurologist **Quantity limit**: Per FDA-approved dosing **Duration**: initial – 12 months; renewal – 12 months **Renewal Criteria**: Physician attestation of reduction in relapse frequency from baseline **Rationale**: per FDA label indication and dosing, 2015 American Academy of Neurology diagnostic guideline, duplication of mechanism of action, consultant feedback, no data for combination regimens and high risk for infections, anti-AQP4 antibody serology tests commercially available at most major labs, clinical trial design **Soliris (eculizumab)** **Prior Authorization: REVISE** **Diagnosis**: NMOSD (per FDA label) Evidenced by both of the following: Positive serologic test for anti-aquaporin-4 (AQP4) antibodies (per FDA label) Physician attestation of the presence of ≥1 core clinical characteristic* **Concurrent use**: No concurrent use of rituximab, inebilizumab or satralizumab ~~or within 90 days of Soliris initiation~~

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Agenda Item	Summary
	Age edit: 18 years and older (per FDA label) **Prescriber edit**: Prescribed by or in consultation with neurologist **Quantity limit**: 240 mL per 28 days (per FDA label) **Duration**: initial – 12 months; renewal – 12 months **Renewal Criteria**: Physician attestation of reduction in relapse frequency from baseline **Rationale**: per FDA label indication and dosing, 2015 American Academy of Neurology diagnostic guideline, duplication of mechanism of action, consultant feedback, no data for combination regimens and high risk for infections, anti-AQP4 antibody serology tests commercially available at most major labs, clinical trial design **External Review:** External review provided by a physician board certified neurologist. **Discussion:** Dr. _____ (Hem/Onc) asked if Uplizna is equivalent or superior to Rituxan, which is the established (off-label) standard of care. Dr. _____ (presenter) agreed that it would be ideal for the company to have a head to head trial against Rituxan. Dr. _____ (Hem/Onc) also asked if there are biomarkers available to track efficacy. Dr. _____ (presenter) replied that the anti-aquaporin-4 antibodies can assist with prognosis, but there are not yet biomarkers that can assist with measuring drug efficacy. **Vote:** Approve the monograph and proposed utilization management as presented. There was proposal for a Motion which was properly seconded and approved. **Action:** The monograph and proposed utilization management were approved. **Follow-up:** None

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3Q20 Pharmacy & Therapeutics (P&T) Committee Minutes

Agenda Item	Summary
13. Rukobia (fostemsavir); HIV	**Presenter:** _____, Pharm.D. The Drug Review for Rukobia (fostemsavir) was presented. **Therapeutic Designations:**

Market Basket: HIV Salvage Therapies

	Therapeutic Designation	Rationale
Rukobia (fostemsavir)	**Novel - NEW**	-Unique place in therapy for heavily treatment-experienced patients due to distinct mechanism of action
Trogarzo (ibalizumab-uiyk)	**Novel - MAINTAIN**	-Unique place in therapy for heavily treatment-experienced patients due to distinct mechanism of action
Fuzeon (enfuvirtide)	**Novel – MAINTAIN**	-Unique place in therapy due to distinct mechanism of action
Selzentry (maraviroc)	**Novel - MAINTAIN**	-Unique place in therapy due to distinct mechanism of action

Utilization Management:

Rukobia (fostemsavir)

Prior Authorization: NEW

Indication (per FDA label): In combination with other antiretrovirals, is indicated for the treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug-resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations

Quantity Limit (per FDA label): 2 tablets per 1 day

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Agenda Item	Summary
	Rationale Per FDA approved dosing, indication, and labeling Per external review feedback Promote lower cost alternatives **Trogarzo (ibalizumab-uiyk)** **Prior Authorization:** NEW **Indication** (per FDA label): In combination with other antiretrovirals, is indicated for the treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug-resistant HIV-1 infection failing their current antiretroviral regimen **Step Therapy**: Trial of or contraindication to up to two of the following: Selzentry, Trogarzo, Rukobia, and/or leronlimab **Quantity Limit** (per label): **MAINTAIN** **Rationale** Per FDA approved dosing, indication, and labeling Per national treatment guidelines Per external review feedback Promote lower cost alternatives **External Review:** External review provided by a physician board certified in Infectious Diseases. **Discussion:** None. **Vote:** Approve the monograph and proposed utilization management as presented. There was proposal for a Motion which was properly seconded and approved. **Action:** The monograph and proposed utilization management were approved. **Follow-up:** None

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UTILIZATION MANAGEMENT REVIEWS

Agenda Item	Summary
14. veverimer; metabolic acidosis of CKD	**Presenter:** _____, Pharm.D. The Drug Review for veverimer was presented: **Therapeutic Designations:** **Market Basket: Acid-Binding Resins** **Drug Name** / **Therapeutic Designation** / **Rationale** **Veverimer** / Novel – **NEW** / Novel mechanism of action without counterions **Utilization Management:** **Veverimer** **Prior Authorization: NEW** **Indication**: Per FDA label or metabolic acidosis in patients with chronic kidney disease **Age edit**: Per FDA label or 18 years and older **Step therapy**: Trial or contraindication to sodium bicarbonate or sodium citrate **Quantity limit**: Per FDA label **Other criteria**: Must not be receiving dialysis or have a diagnosis of end-stage renal disease **Approval duration**: Initial 3 months, renewal 12 months **Renewal criteria**: Documentation of serum bicarbonate within normal range or an increase of at least 4 mmol/L compared to baseline Must not be receiving dialysis or have a diagnosis of end-stage renal disease **Rationale** Per clinical trial design, national treatment guidelines, and FDA label Promote low net cost strategy

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3Q20 Pharmacy & Therapeutics (P&T) Committee Minutes

Agenda Item	Summary
	External Review: External review was not obtained for this review. **Discussion:** None **Vote:** Approve the proposed utilization management as presented. There was proposal for a Motion which was properly seconded and approved. **Action:** The proposed utilization management were approved. **Follow-up:** None

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3Q20 Pharmacy & Therapeutics (P&T) Committee Minutes

Agenda Item	Summary
15. Oriahnn (elagolix); uterine fibroids	**Presenter:** _____, Pharm.D. The Drug Review for Oriahnn (elagolix) was presented. **Therapeutic Designations:**

Market Basket: Heavy Menstrual Bleeding (HMB) Associated with Uterine Fibroids (UF)

		Therapeutic Designation	Rationale
Oriahnn (elagolix, norethindrone, estradiol)		Novel	• 1st item approved for UF HMB • Can be used up to 24 months • Overall well-tolerated
Tranexamic Acid (PO)		Equivalent off label	• Is a non-hormonal option, but has medical contraindications
Levonorgestrel intra-uterine device (IUD)	**Mirena** (5 years)	Equivalent off label	• May provide effective treatment but not all patients will qualify (hormonal product); also high expulsion rate and treatment failure rate
	Kyleena (5 years)	Equivalent off label	
	Skyla (3 years)	Equivalent off label	
	Liletta (6 years)	Equivalent off label	
Hormonal Contraceptives		Equivalent off label	• May provide effective treatment but not all patients will qualify (hormonal product); high treatment failure rate

Utilization Management:

Oriahnn (elagolix)

Prior Authorization: NEW

Diagnosis: for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women

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Agenda Item	Summary
	Age: 18 years of age and older **Prescriber**: by or in consultation with OB/GYN **Clinical step**: patient has tried and failed or has a contraindication to up to TWO of the following: Preferred contraceptive preparations [e.g., oral contraceptive, other form contraceptive, levonorgestrel intra-uterine device (IUD), etc.] OR Oral tranexamic acid **Trade step**: trial of preferred oral GnRH antagonists indicated for heavy menstrual bleeding associated with uterine fibroids (e.g., reulogolix, linzagolix when available) **Quantity limit**: 1 AM/1 PM per day; up to 24 months total in treatment duration per lifetime per FDA label **Duration**: 6 months (initial), 18 months (renewal) **Renewal criteria**: physician attestation of improvement of heavy menstrual bleeding **Rationale**: per FDA-approved indication and dosing, clinical trial design, and treatment guidelines, low net cost options tried first (clinical step) **External Review:** External review provided by a physician Board Certified in Obstetrics/Gynecology. **Discussion:** Dr. _____ (Internal Medicine) asked why the duration should be so long for the PA approval since this drug would most likely be used as a bridge to surgery. Dr. _____ (OB/GYN) agreed that while the drug is efficacious, surgery is the definitive treatment. Dr. _____ (co-chair) asked if the PA duration should be limited, or whether a small subset of patients might need the drug long term. Dr. _____ (OB/GYN) replied that the long-term treatement population is yet to be defined. Dr. _____ (presenter) stated that further studies in other oral GNRH agents are ongoing for longer treatment duration. Dr. _____ (co-chair) made a motion to approve the PA duration as proposed based on the drug label and clinical evidence. While the need for long term therapy is expected to be low, there may be patients who are not candidates for surgery who could need the drug. **Vote:** Approve the proposed utilization management as presented. There was proposal for a Motion which was properly seconded and approved. **Action:** The proposed utilization management were approved.

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3Q20 Pharmacy & Therapeutics (P&T) Committee Minutes

<table>
<tr><th>Agenda Item</th><th>Summary</th></tr>
<tr><td></td><td>Follow-up: None</td></tr>
<tr><td>16 Isturisa (osilodrostat); Cushing’s disease</td><td>
Presenter: _____, Pharm.D.

The Drug Review for Isturisa (osilodrostat) was presented.

Therapeutic Designations:
<table>
<tr><th colspan="3">Market Basket: Cushing’s Disease for whom pituitary surgery is not an option or has not been curative</th></tr>
<tr><th colspan="2">Drug</th><th>Designation</th><th>Rationale</th></tr>
<tr><td></td><td>Isturisa (osilodrostat)</td><td>EQUIVALENT -NEW</td><td>• Oral option demonstrating higher potential likelihood of a patient being a responder than other agents in this market basket</td></tr>
<tr><td></td><td>Signifor (pasireotide)</td><td>~~NOVEL~~ EQUIVALENT with caveat -NEW
(cannot be sole preferred)</td><td>• Overall low efficacy/high non-responder rate; twice daily subcutaneous injection</td></tr>
<tr><td></td><td>Signifor LAR (pasireotide pamoate)</td><td>EQUIVALENT with caveat -NEW
(cannot be sole preferred)</td><td>• NSA, Overall low efficacy/high non-responder rate</td></tr>
</table>
</td></tr>
</table>

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Agenda Item	Summary

Market Basket: Other agent for Cushing's Disease (off-label treatment or FDA approved symptom-based treatment)

Drug	Designation	Rationale
Korlym (mifepristone)	Novel – **MAINTAIN**	• FDA indicated for specific patients: to control hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery; may be useful in certain patients for symptoms of CS/CD
Cabergoline	**EQUIVALENT -NEW**	• Overall low efficacy/high non-responder rate, especially with ongoing use; often needs combined with other agents; may be useful in certain patients, but FDA label not specific to CS/CD
Ketoconazole	**EQUIVALENT -NEW**	• Low net cost option, readily available, 50% responder rate
Metopirone (metyrapone)	**EQUIVALENT -NEW**	• Used primarily for diagnostic agent, access difficulty for patients; may be useful in certain patients
Lysodren (mitotane)	**EQUIVALENT -NEW**	• May not be suitable for many patients due to long teratogenicity; may be useful in certain patients

Utilization Management:

Isturisa (osilodrostat)

Prior Authorization: NEW

Diagnosis: treatment of adult patients with Cushing's Disease (CD) for whom pituitary surgery is not an option or has not been curative
Age: 18 years of age and older
Prescriber: by or in consultation with endocrinologist
Clinical step: trial of or contraindication to ketoconazole
Trade step: trial of preferred agent for CD for whom pituitary surgery is not an option or has not been curative
Quantity limit: dose consolidation; comes as 1 mg, 5 mg, 10 mg
Dose is 1 – 30 mg BID
1 mg: 8 tabs/day, 5 mg: 2 tabs/day, 10 mg: 6 tabs/day

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Agenda Item	Summary
	Duration: 6 months (initial), 12 months (renewal) **Renewal criteria**: physician attestation that patient continues to have improvement of CD (e.g., clinically meaningful reduction in 24-hour urinary free cortisol and/or improvements in signs and symptoms of disease) and maintains tolerability to Isturisa **Rationale**: FDA-approved indication and dosing, treatment guidelines. Renewal criteria as many patients do not have clinical response, but a response would be noted by 6 months. **Signifor (pasireotide)** **Prior Authorization: REVISE** **Diagnosis**: treatment of adult patients with Cushing's Disease (CD) for whom pituitary surgery is not an option or has not been curative **Age**: 18 years of age and older **Prescriber**: by or in consultation with endocrinologist **Clinical step**: patient has tried or has contraindication to ketoconazole ~~metyrapone, or cabergoline~~ **Trade step**: trial of preferred agent for CD for whom pituitary surgery is not an option or has not been curative - **NEW** **Quantity limit**: 2 ampules/day **Duration**: 6 months (initial), 12 months (renewal) **Renewal criteria**: physician attestation that patient continues to have improvement of CD (e.g., clinically meaningful reduction in 24-hour urinary free cortisol and/or improvements in signs and symptoms of disease) and maintains tolerability to signifor- **NEW** **Rationale**: per FDA-approved indication and dosing, treatment guidelines; removal of clinical step because metyrapone is more of a diagnostic agent and has availability restrictions. Adding renewal criteria since some patients do not have clinical response, but response expected according to clinical trial within 6 months. **Korlym (mifepristone)** **Prior Authorization: REVISE** **Diagnosis**: Patient has endogenous Cushing's syndrome (CS) **AND**

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Agenda Item	Summary
	CS diagnosis confirmed by one of the following: 24-h Urine Free Cortisol (2+ tests to confirm), overnight 1 mg dexamethasone test, or late night salivary cortisol (2+ tests to confirm) AND hypercortisolism is not a result of chronic glucocorticoids **NEW** Diagnosis of type 2 diabetes or glucose intolerance **AND** Patient has failed or is not a candidate for surgical treatment of Cushing's syndrome Confirmed by: physician attestation **NEW** **Age**: 18 years of age and older -**NEW** **Prescriber**: by or in consultation with endocrinologist -**NEW** **Quantity limit**: 4 tablets/day **Duration**: 12 months (initial); 12 months (renewal) **Renewal criteria**: **NEW** physician attestation that patient continues to have improvement of glucose tolerance and/or stable glucose tolerance (e.g., reduced A1C, improved fasting glucose, etc.) physician attestation that patient continues to have tolerability to Korlym patient continues to not be candidate for surgical treatment or has failed surgery **Rationale**: per FDA-approved indication and dosing; Korlym is not indicated for the treatment of type 2 diabetes in absence of endogenous Cushing's syndrome Upon review of PAs for the past year (2019, overall 49 patients with 84% approval of PA), prescribing by non-endocrinologists; also noted some plans had renewal criteria to ensure continued use, which is reasonable for the standard offering as well Diagnosis criteria is from The Endocrine Society guidelines for the diagnosis of CS (2008) and the FDA label **Cabergoline** **Prior Authorization: MAINTAIN** **Diagnosis**: acromegaly, puerperal lactation inhibition, or hyperprolactinemia (prolactin level should be > 20ng/mL for men and > 24ng/mL for women) **Quantity limit**: 0.5 mg tablets – qty 16 per month/copay **Duration**: 12 months **Rationale**: per FDA-approved indication and dosing **External Review:**

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3Q20 Pharmacy & Therapeutics (P&T) Committee Minutes

Agenda Item	Summary
	External review was not obtained for this review. **Discussion:** None **Vote:** Approve the proposed utilization management as presented. There was proposal for a Motion which was properly seconded and approved. **Action:** The proposed utilization management were approved. **Follow-up:** None

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3Q20 Pharmacy & Therapeutics (P&T) Committee Minutes

<table>
<tr><th>Agenda Item</th><th>Summary</th></tr>
<tr><td>17 Phexxi (l-lactic acid, citric acid and potassium bitartrate); contraceptive</td><td>
Presenter: _____, Pharm.D.

The Drug Review for Phexxi (l-lactic acid, citric acid and potassium bitartrate) was presented.

Therapeutic Designations:
<table>
<tr><th colspan="3">Market Basket: Non-hormonal on-demand intravaginal contraceptive options</th></tr>
<tr><th></th><th>Therapeutic Designation</th><th>Rationale</th></tr>
<tr><td>Phexxi (lactic acid/citric acid/potassium bitartrate)</td><td>Equivalent - NEW</td><td>• PI: 27.5
• May be useful for patients who cannot use spermicide products, hormonal products, diaphragms, or male/female condoms</td></tr>
<tr><td>Sponge (nonoxynol 9)</td><td>Equivalent – NEW (OTC)</td><td>• PI: 12-24
• May be useful for patients who cannot use hormonal products, diaphragms, or male/female condoms</td></tr>
<tr><td>Gel (nonoxynol 9) gel</td><td rowspan="3">Equivalent – NEW (OTC)</td><td rowspan="3">• PI: 28
• May be useful for patients who cannot use hormonal products, diaphragms, or male/female condoms
• Similar rates and types of adverse reactions expected as compared to other agents in this market basket</td></tr>
<tr><td>Film (nonoxynol 9)</td></tr>
<tr><td>Foam (nonoxynol 9)</td></tr>
<tr><td>Diaphragm/cap</td><td>Equivalent – NEW (RX)</td><td>• PI: 12
• Should (diaphragm) or must (cap) be used with spermicide
• Is a prescription product that can last up to 2 years</td></tr>
</table>
</td></tr>
</table>

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3Q20 Pharmacy & Therapeutics (P&T) Committee Minutes

Agenda Item	Summary
	Utilization Management: **Phexxi (l-lactic acid, citric acid and potassium bitartrate)** **Prior Authorization – NEW** **Indications**: use for prevention of pregnancy in females of reproductive potential **Concurrent use**: Patient is NOT concurrently using vaginal ring products (e.g., Annovera, Nuvaring) Rationale: Per label Phexxi should not be used with vaginal ring products **Step**: previous trial of or contraindication to up to two preferred contraceptive agents (e.g., intrauterine device, hormonal implant/injection/patch/oral products) **Quantity limit**: 1 box (12 applicators)/month **Approval duration**: 12 months **Rationale**: Per FDA-approved indication and dosing, clinical trial design, optimizing low-net cost and preferred options **External Review:** External review provided by a physician Board Certified in Obstetrics/Gynecology. **Discussion:** None **Vote:** Approve the proposed utilization management as presented. There was proposal for a Motion which was properly seconded and approved. **Action:** The proposed utilization management were approved. **Follow-up:** None

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3Q20 Pharmacy & Therapeutics (P&T) Committee Minutes

Agenda Item	Summary
18. Somapacitan; growth hormone deficiency	**Presenter:** _____, Pharm.D. The Drug Review for somapacitan was presented. **Therapeutic Designations:**

Growth Hormone Market Basket		
Drug Name	**Therapeutic Designation**	**Rationale**
Somapacitan	Equivalent – **NEW**	Similar place in therapy
Genotropin	Equivalent – **MAINTAIN**	
Humatrope		
Norditropin Flexpro		
Nutropin AQ		
Omnitrope		
Saizen		
Zomacton		

Utilization Management:

Somapacitan

Prior Authorization: NEW

Indication: Treatment of adult growth hormone deficiency (per FDA label)
Age edit: 18 years and older
Prescriber: Prescribed by or in consultation with an endocrinologist
Step therapy: Trial/failure of, or contraindication to, up to 2 somatropin agents where appropriate
Other:
Physician attestation not being used for athletic enhancement or anti-aging properties

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Agenda Item	Summary
	Adults with growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases, hypothalamic disease, surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency **Quantity limit**: per FDA label **Approval duration**: 12 months (initial and renewal) **Renewal criteria**: Prescribed by or in consultation with an endocrinologist Physician attestation the patient has achieved and/or maintained a response to therapy as evidenced by clinical treatment goals (e.g. improved body composition, lipid panel, bone health, etc) **Rationale**: per FDA-approved indication and low net cost strategy **External Review:** External review was not obtained for this review. **Discussion:** None **Vote:** Approve the proposed utilization management as presented. There was proposal for a Motion which was properly seconded and approved. **Action:** The proposed utilization management were approved. **Follow-up:** None

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3Q20 Pharmacy & Therapeutics (P&T) Committee Minutes

Agenda Item	Summary
19. Viaskin Peanut; peanut allergy	**Presenter:** _____, Pharm.D. The Drug Review for Viaskin Peanut was presented. **Therapeutic Designations:**

Market Basket: Peanut-Specific Immunotherapy		
Drug Name	**Therapeutic Designation**	**Rationale**
Viaskin Peanut	Novel – **NEW**	Unique route of administration and clinical profile
Palforzia	Novel	Unique route of administration and clinical profile

Utilization Management:

Viaskin Peanut

Prior Authorization: NEW

Diagnosis: peanut allergy

Other criteria:

Diagnostic confirmation of peanut allergy by documentation of **ONE** of the following:

Positive skin prick test (wheal diameter ≥6 mm) or peanut-specific immunoglobulin E (≥0.7 kUA/L) within the past 24 months if the patient has undergone food challenge, **OR**

Positive skin prick test (wheal diameter ≥8 mm) or peanut-specific immunoglobulin E (≥14 kUA/L) within the past 24 months if the patient has **NOT** undergone food challenge

To be used in conjunction with a peanut-avoidant diet

Clinical history of allergic reaction to peanut

Patient is not on concurrent peanut-specific immunotherapy (e.g. Palforzia)

Age restriction: 4 to 11 years of age

Prescriber edit: by or in consultation with allergist/immunologist

Concurrent use edit: active prescription for epinephrine auto-injector/injection

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Agenda Item	Summary
	Quantity limit: 1 patch per day (per FDA-approved dosing) **Duration**: initial: 12 months; renewal: 24 months **Renewal**: To be used in conjunction with a peanut-avoidant diet Patient is not on concurrent peanut-specific immunotherapy (e.g. Palforzia) Prescriber edit as above Concurrent use edit as above ONE of the following: A) Physician attestation of persistent peanut allergy, **OR** B) Documentation of persistent peanut allergy by **ONE** of the following: Positive skin prick test (wheal diameter ≥6 mm) or peanut-specific immunoglobulin E (≥0.7 kUA/L) within the past 24 months if the patient has undergone food challenge, **OR** Positive skin prick test (wheal diameter ≥8 mm) or peanut-specific immunoglobulin E (≥14 kUA/L) within the past 24 months if the patient has **NOT** undergone food challenge **Rationale**: Per FDA-approved labeling and dosing, NIAID guidelines and AAAAI & ACAAI guidance, clinical trial design, external reviewer input, and ICER analysis To align with Palforzia criteria **Palforzia** **Prior Authorization: REVISE** **Diagnosis**: peanut allergy **Other criteria**: Diagnostic confirmation of peanut allergy by documentation of **ONE** of the following: Positive skin prick test (wheal diameter ≥3 mm) or peanut-specific immunoglobulin E (≥0.35 kUA/L) within the past 24 months if the patient has undergone food challenge, **OR** Positive skin prick test (wheal diameter ≥8 mm) or peanut-specific immunoglobulin E (≥14 kUA/L) within the past 24 months if the patient has NOT undergone food challenge To be used in conjunction with a peanut-avoidant diet Clinical history of allergic reaction to peanut Patient is not on concurrent peanut-specific immunotherapy (e.g. Viaskin Peanut)

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Agenda Item	Summary
	Age restriction: 4 to 17 years of age **Prescriber edit**: by or in consultation with allergist/immunologist **Concurrent use edit**: active prescription for epinephrine auto-injector/injection **Quantity limit**: 300 mg per day **Duration**: initial: 12 months; renewal: 24 months **Renewal**: To be used in conjunction with a peanut-avoidant diet Patient is not on concurrent peanut-specific immunotherapy (e.g. Viaskin Peanut) Prescriber edit as above Concurrent use edit as above **ONE** of the following: A) Physician attestation of persistent peanut allergy, **OR** B) Documentation of persistent peanut allergy by **ONE** of the following: Positive skin prick test (wheal diameter ≥3 mm) or peanut-specific immunoglobulin E (≥0.35 kUA/L) within the past 24 months if the patient has undergone food challenge, **OR** Positive skin prick test (wheal diameter ≥8 mm) or peanut-specific immunoglobulin E (≥14 kUA/L) within the past 24 months if the patient has NOT undergone food challenge **Rationale**: To reflect positivity thresholds used in the PALISADE and RAMSES clinical trials (the thresholds differ depending on whether or not patients were required to undergo food challenge as part of the inclusion criteria) To prevent inappropriate use Aligns with Viaskin Peanut criteria **External Review:** External review was obtained from a physician who is Board Certified in Allergy/Immunology **Discussion:** Dr. _____ (Allergy/Immunology) asked if the different criteria for a food challenge would be for a purposeful or accidental food challenge. Dr. _____ (Presenter) and Dr. _____ (Allergy/Immunology) agreed that it should be for purposeful food challenge, and the proposed UM will be modified accordingly. Dr. _____ (Allergy/Immunology) also asked if FDA denial is likely. Dr. _____ (presenter) did mention that the FDA advisory committee was cancelled, which is usually a bad sign for drug approval.

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3Q20 Pharmacy & Therapeutics (P&T) Committee Minutes

<table>
<tr><th>Agenda Item</th><th>Summary</th></tr>
<tr><td></td><td>Vote: Approve the proposed utilization management as presented. There was proposal for a Motion which was properly seconded and approved.

Action: The proposed utilization management were approved.

Follow-up: None</td></tr>
<tr><td>20. Roctavian (valoctocogene roxaparvovec; val-rox); Hemophilia A</td><td>Presenter: _____, Pharm.D.

The Drug Review for Roctavian (valoctocogene roxaparvovec; val-rox) was presented.

Therapeutic Designations:

<table>
<tr><th colspan="3">Market Basket: Factor VIII Gene Therapy</th></tr>
<tr><th>Drug Name</th><th>Therapeutic Designation</th><th>Rationale</th></tr>
<tr><td>Roctavian (valoctocogene roxaparvovec)</td><td>Novel – NEW</td><td>Unique place in therapy</td></tr>
</table>

Utilization Management:

Roctavian (valoctocogene roxaparvovec; val-rox)
Prior Authorization: NEW
Diagnosis: hemophilia A (congenital factor VIII deficiency; per FDA-approved label)
Age restriction: 18 years and older (or per FDA label)
Prescriber edit: by or in consultation with hematologist associated with a Hemophilia Treatment Center
Other criteria:
Documentation of genetic testing confirming hemophilia A
Documentation that patient has severe hemophilia A as defined by FVIII levels ≤1 IU/dL
Patient has been requiring prophylactic therapy with replacement FVIII concentrate for a minimum of 150 exposure days OR with non-replacement therapy (e.g. Hemlibra)
Documentation that patient meets EITHER of the following:
No history of FVIII inhibitors</td></tr>
</table>

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<table>
<tr><th>Agenda Item</th><th>Summary</th></tr>
<tr><td></td><td>Bethesda results of <0.6 Bethesda units (BU) based on two consecutive tests at least one week apart within the past 12 months
Documentation that patient does not have pre-existing immunity to the AAV5 capsid as determined by companion diagnostic test
QL: one fill (per FDA label) per lifetime
Rationale:
Per FDA-approved dosing and labeling, clinical trial design, consultant input
No renewal is intentional

External Review: External review was obtained from two physicians who are Board Certified in Hematology.

Discussion: Dr._____ (Allergy/Immunology) asked why patients didn't develop inhibitors. Dr. _____ (presenter) verified that the trials did measure for inhibitors and found none. She reported that the gene shared homology with the natural human gene. Dr. _____ asked why the proposal requires 150 days of previous treatment of factor VIII replacement therapy. Dr. _____ (presenter) replied that was based on clinical trial design and the findings in the literature that the risk of inhibitors generally wanes beyond 150 exposure days (to ensure that the risk of inhibitor development will be mitigated)..

Vote: Approve the proposed utilization management as presented. There was proposal for a Motion which was properly seconded and approved.

Action: The proposed utilization management were approved.

Follow-up: None</td></tr>
<tr><td>21. Utilization Management for Review

a. New & Expanded Indications

Sinuva (mometasone</td><td>Presenter: _____, Pharm.D.

The UM Review for Sinuva (mometasone sinus implant) was presented.

Therapeutic Designations:

<table>
<tr><td colspan="3">Market Basket: nasal polyps in patients ≥ 18 years of age who have had ethmoid sinus surgery</td></tr>
<tr><th>Drug</th><th>Therapeutic Designation</th><th>Rationale:</th></tr>
<tr><td>Sinuva (mometasone)</td><td>Equivalent to nasal corticosteroids - MAINTAIN</td><td>• Per label, clinical trial</td></tr>
</table>
</td></tr>
</table>

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Agenda Item	Summary
sinus implant); nasal polyps	**Utilization Management:** **Sinuva (mometasone sinus implant)** **Prior Authorization: REVISE** **Indication/Diagnosis**: Nasal polyps **Prescriber Edit**: otolaryngologist **Other criteria:** Patient has previously received ethmoid sinus surgery (ESS) Patient is a candidate for repeat ESS due to refractory moderate to severe symptoms of nasal obstruction/congestion or refractory nasal polyps in both ethmoid sinuses **Step therapy**: trial of ~~at least 2 of the following:~~ 90 days of a generic and/or preferred topical nasal corticosteroid (e.g., mometasone, fluticasone, beclomethasone, flunisolide, ciclesonide) **Age**: ≥ 18 years **QL**: initial: 2 intranasal implants (1 per nostril); renewal: 2 intranasal implants (1 per nostril) 4 implants per lifetime (2 per nostril) **Renewal criteria**: For repeat implant, patient must have ethmoid sinus polyps grade ≥ 1 on any side for re-implant (Repeat placement not indicated if polyp grade < 1) **AND** Patient does not have extensive ethmoid sinus polyp grade (grade 4 on at least one side) or extensive adhesions/synechiae (grade 3 or 4) **Rationale**: Per FDA labeled indication (t indicated for the treatment of nasal polyps in patients ≥ 18 years of age who have had ethmoid sinus surgery) and dosing, criteria for repeat use is from clinical trial design to minimize safety risks **External Review:** External review was not obtained for this UM review. **Discussion:** Dr. _____ (Allergy/Immunology) made a motion to reduce the step through a nasal steroid to a single step given that all nasal steroids are considered equally efficacious. The motion was carried and approved. **Vote:** Approve the proposed utilization management as presented. There was proposal for a Motion which was properly seconded and approved. **Action:** The proposed utilization management were approved.

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3Q20 Pharmacy & Therapeutics (P&T) Committee Minutes

<table>
<tr><th>Agenda Item</th><th>Summary</th></tr>
<tr><td></td><td>Follow-up: None</td></tr>
<tr><td>21. Utilization Management for Review

a. New & Expanded Indications

Non-Radiographic Axial Spondyloarthritis</td><td>
Presenter: _____, Pharm.D.

The UM Disease Review for Non-Radiographic Axial Spondyloarthritis (NR-SpA) was presented.

Therapeutic Designations:
<table>
<tr><th colspan="3">Market Basket: NR-SpA</th></tr>
<tr><th>Drug</th><th>Therapeutic Designation</th><th>Rationale:</th></tr>
<tr><td>NSAIDs</td><td>Equivalent first line</td><td>• First option in guidelines for active and stable NR-SpA
• Low-net-cost first line option first</td></tr>
<tr><td>Taltz (ixekizumab)</td><td>Equivalent second line</td><td>• Self-administer, every 4 weeks</td></tr>
<tr><td>Cosentyx (secukinumab)</td><td>Equivalent second line</td><td>• Self-administer, every 4 weeks after loading period, if utilized</td></tr>
<tr><td>Cimzia (certolizumab)</td><td>Equivalent second line</td><td>• Self-administer, every 2 weeks</td></tr>
</table>
Utilization Management:

Taltz (ixekizumab)
Prior Authorization – NEW for this indication
Indications: active non-radiographic axial spondyloarthritis (NR-SpA)
Age edit: > 18 years of age
Prescriber edit: Prescribed by or in consultation with a rheumatologist
Other criteria: Must meet ONE of the following objective signs of inflammation:
C-reactive protein (CRP) levels above the upper limit of normal
Sacroiliitis on magnetic resonance imaging (MRI)
Clinical Step: trial of or contraindication to NSAID
Trade Step: previous trial of or contraindication to UP TO TWO preferred immunomodulatory agents
</td></tr>
</table>

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Agenda Item	Summary
	Quantity limit: 80 mg for 28 days (per FDA label) **Duration**: initial: 6 months, renewal: 12 months **Renewal criteria**: Diagnosis of NR-SpA and patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy **Rationale**: Per FDA-approved indication and dosing, clinical trial design, guidelines, clinical criteria to support diagnosis of NR-SpA, and renewal criteria to align with Taltz's criteria for ankylosing spondylitis (AS). **Cosentyx (secukinumab)** **Prior Authorization – NEW for this indication** **Indications**: active non-radiographic axial spondyloarthritis (NR-SpA) **Age edit**: > 18 years of age **Prescriber edit**: Prescribed by or in consultation with a rheumatologist **Other criteria**: Must meet **ONE** of the following objective signs of inflammation: C-reactive protein (CRP) levels above the upper limit of normal Sacroiliitis on magnetic resonance imaging (MRI) **Clinical Step**: trial of or contraindication to NSAID **Trade Step**: previous trial of or contraindication to UP TO TWO preferred immunomodulatory agents **Quantity limit**: (specific NDCs for the 150 mg dose utilized, consistent with other indications) (per FDA label) **Initial**: 150 mg Q week x1 month if loading utilized then/or 150 mg Q4 weeks **Renewal**: 150 mg Q4 weeks **Approval, renewal duration**: initial: 6 months, renewal: 12 months **Renewal criteria**: Diagnosis of NR-SpA and patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy **Rationale**: Per FDA-approved indication and dosing, clinical trial design, guidelines, clinical criteria to support diagnosis of NR-SpA, and renewal criteria to align with Cosentyx criteria for ankylosing spondylitis (AS). **Cimzia (certolizumab)** **Prior Authorization – UPDATE** **Indications**: active non-radiographic axial spondyloarthritis (NR-SpA) **Age edit**: > 18 years of age **Prescriber edit**: Prescribed by or in consultation with a rheumatologist

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Agenda Item	Summary
	Other criteria: Must meet **ONE** of the following objective signs of inflammation: C-reactive protein (CRP) levels above the upper limit of normal Sacroiliitis on magnetic resonance imaging (MRI) **Clinical Step**: trial of or contraindication to NSAID -**NEW** **Trade Step**: Patient is pregnant, breastfeeding, or trying to become pregnant OR previous trial of or contraindication to UP TO TWO preferred immunomodulatory agents -**NEW** **Quantity limit**: **First month**: 1,200 mg for 28 days, **Subsequent doses**: 400 mg for 28 days **Duration**: initial: 6 months, renewal: 12 months **Renewal criteria**: Diagnosis of NR-SpA and patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy **Rationale**: Per FDA-approved indication and dosing, clinical trial design, guidelines, clinical criteria to support diagnosis of NR-SpA, and renewal criteria to align with Cimzia's criteria for ankylosing spondylitis (AS). **External Review:** External review was obtained from two physicians, each being Board Certified in Internal Medicine and Rheumatology. **Discussion:** None **Vote:** Approve the proposed utilization management as presented. There was proposal for a Motion which was properly seconded and approved. **Action:** The proposed utilization management were approved. **Follow-up:** None

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3Q20 Pharmacy & Therapeutics (P&T) Committee Minutes

Agenda Item	Summary
21. Utilization Management for Review a. New & Expanded Indications **Metastatic Castration-Resistant Prostate Cancer (mCRPC)**	**Presenter:** _____, Pharm.D. The UM Disease Review for Metastatic Castration-Resistant Prostate Cancer (mCRPC) was presented. **Therapeutic Designations:**

Market Basket: mCRPC abiraterone products		
Drug	**Therapeutic Designation**	**Rationale:**
Zytiga (abiraterone acetate)	**Equivalent – NEW**	• Abiraterone products
Yonsa (abiraterone acetate)	**Equivalent – MAINTAIN**	• Abiraterone products

Utilization Management:

Lynparza (olaparib)

Prior Authorization – REVISE

Indication: NEW PER LABEL

Metastatic castration-resistant prostate cancer (mCRPC) who have progressed following prior treatment with enzalutamide or abiraterone

Deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated

Age: adult 18+ years old **NEW PER LABEL**

Quantity Limit: per FDA dosing, 2 x 150 mg/day **NEW PER LABEL**

300 mg PO BID (comes as 150 mg and 100 mg tablets)

Other criteria for mCRPC: **NEW**

Concurrently using a gonadotropin-releasing hormone (GnRH) analog if the patient has not received a bilateral orchiectomy OR serum testosterone levels are <50 ng/dL (e.g., indicates castrate level)

Maintain other PA criteria

Rationale: Per FDA approved indication, dosing and clinical trial design

Rubraca (rucaparib)

Prior Authorization – REVISE

Indication: NEW PER LABEL

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Agenda Item	Summary
	Metastatic castration-resistant prostate cancer (mCRPC) who have progressed following prior treatment with androgen receptor-director therapy and a taxane-based chemotherapy Deleterious BRCA mutation (germline and/or somatic) **Age**: adult 18+ years old **NEW PER LABEL** **Quantity Limit**: FDA dosing, 2 x 300 mg/day **NEW PER LABEL** 600 mg PO BID (comes as 200 mg, 250 mg, and 300 mg tablets) **Other criteria for mCRPC: NEW** Concurrently using a gonadotropin-releasing hormone (GnRH) analog if the patient has not received a bilateral orchiectomy OR serum testosterone levels are <50 ng/dL (e.g., indicates castrate level) **Maintain other PA criteria** **Rationale:** Per FDA approved indication, dosing and clinical trial design **Zytiga (abiraterone acetate)** **Prior Authorization – REVISE** **Indication**: Indicated for the treatment of patients with: Metastatic castration-resistant prostate cancer (mCRPC) Metastatic high-risk castration-sensitive prostate cancer (CSPC) **Other criteria for all indications: NEW** Concurrently using a gonadotropin-releasing hormone (GnRH) analog if the patient has not received a bilateral orchiectomy OR serum testosterone levels are <50 ng/dL (e.g., indicates castrate level) **Other PA criteria, including**: Step trial of preferred abiraterone product - **NEW** Use in combination with prednisone (per label) - **MAINTAIN** Rationale: Per FDA approved indication, dosing and clinical trial design **Yonsa (abiraterone acetate)** **Prior Authorization – REVISE** **Indication**: Indicated for the treatment of patients with: Metastatic castration-resistant prostate cancer (mCRPC) **Other criteria for all indications: NEW**

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<table>
<tr><th>Agenda Item</th><th>Summary</th></tr>
<tr><td></td><td>Concurrently using a gonadotropin-releasing hormone (GnRH) analog if the patient has not received a bilateral orchiectomy OR serum testosterone levels are <50 ng/dL (e.g., indicates castrate level)
Maintain other PA criteria, including:
Step trial of preferred abiraterone product - MAINTAIN
Use in combination with methylprednisolone (per label) - MAINTAIN
Rationale: Per FDA approved indication, dosing and clinical trial design

External Review: External review was not obtained for this UM review.

Discussion: None

Vote: Approve the proposed utilization management as presented. There was proposal for a Motion which was properly seconded and approved.

Action: The proposed utilization management were approved.

Follow-up: None</td></tr>
<tr><td>21. Utilization Management for Review

a. New & Expanded Indications

Cysvita (burosumab-twza); tumor induced osteomalacia (TIO)</td><td>Presenter: _____, Pharm.D.

The UM Review for Cysvita (burosumab-twza) was presented.

Therapeutic Designations:

<table>
<tr><th colspan="3">Market Basket: Tumor Induced Osteomalacia</th></tr>
<tr><th>Drug</th><th>Therapeutic Designation</th><th>Rationale:</th></tr>
<tr><td>Crysvita (burosumab-twza)</td><td>Novel</td><td>• First/only approved agent for TIO</td></tr>
</table>

<table>
<tr><th colspan="3">Market Basket: X-linked hypophosphatemia (XLH)</th></tr>
<tr><th>Drug</th><th>Therapeutic Designation</th><th>Rationale:</th></tr>
<tr><td>Crysvita (burosumab-twza)</td><td>Novel</td><td>• Limited options for XLH treatment</td></tr>
</table>
</td></tr>
</table>

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3Q20 Pharmacy & Therapeutics (P&T) Committee Minutes

Agenda Item	Summary
	Utilization Management: **Cysvita (burosumab-twza) for Tumor Induced Osteomalacia** **Prior Authorization – NEW** **Indication**: Diagnosis of tumor induced osteomalacia (TIO) as confirmed by: Physician attestation of TIO symptoms (e.g., osteomalacia, excessive fractures, muscle weakness, fatigue, bone pain, etc.) **AND** Diagnosis of FGF23-related hypophosphatemia produced by underlying phosphaturic mesenchymal tumor (per FDA label) **AND** Tumor is not amenable to surgical excision or could not be located **Age**: 2 years of age and older **Clinical step**: evaluation of phosphate-based options, as demonstrated by one of the following: Trial/failure of phosphate/vitamin D analog therapy **OR** Physician attestation that patient disease condition, severity, and/or other variables indicate phosphate/vitamin D analog therapy is not preferable/advisable for this patient compared to anticipated outcomes with burosumab **Concurrent use**: patient has discontinued oral phosphate and/or active vitamin D analogs (e.g. calcitriol, paricalcitol, etc.) at least 1 week prior to Crysvita initiation **Prescriber**: prescribed by or in consultation with endocrinologist, nephrologist, orthopedic surgeon, or medical geneticist **Quantity limit**: 180 mg every 2 weeks (6 vials) (per FDA label) **Duration**: 6 months (initial); 12 months (renewal) **Renewal**: physician attestation of phos normalization (at or around lower end of normal is acceptable) of fasting serum phosphate levels (e.g., around or above the lower limit of the reference range for age and below 5 mg/dL) (language from FDA label) **Rationale**: per FDA labeling, medical literature for diagnosis/treatment, expected outcomes of Crysvita for TIO **Cysvita (burosumab-twza) for X-linked hypophosphatemia (XLH)** **Prior Authorization – REVISE** **Indication**: Diagnosis of XLH as confirmed by one of the following:

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Agenda Item	Summary
	Physician attestation of XLH symptoms (osteomalacia, excessive fractures, bowed legs, impaired growth, etc.) in combination with one of the following: Low phosphate (<3.2 mg/dL in pediatric patients; <2.5 in adults) + normal Vit. D levels Hyperexpression of FGF23 on assay Family history of XLH Genotyping confirmation of PHEX mutation causative of XLH **Age**: 6 months of age and older (per FDA label) **Clinical step**: evaluation of phosphate-based options, as demonstrated by one of the following: Trial/failure of phosphate/vitamin D analog therapy OR Physician attestation that patient disease condition, severity, and/or other variables indicate phosphate/vitamin D analog therapy is not preferable/advisable for this patient compared to anticipated outcomes with burosumab **Concurrent use**: patient will not be on concurrent phosphate or vitamin D analog supplementation **Prescriber**: prescribed by or in consultation with endocrinologist, nephrologist, orthopedic surgeon, or medical geneticist **Quantity limit**: 90 mg every 2 weeks (3 vials) (per FDA label) **Duration**: 6 months (initial); 12 months (renewal) **Renewal Criteria**: normalized blood phosphate levels as defined by reference range for age (language from FDA label) **Rationale**: per FDA labeling/clinical guidelines **External Review:** External review was not obtained for this UM review. **Discussion:** None **Vote:** Approve the proposed utilization management as presented. There was proposal for a Motion which was properly seconded and approved. **Action:** The proposed utilization management were approved. **Follow-up:** None

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3Q20 Pharmacy & Therapeutics (P&T) Committee Minutes

Agenda Item	Summary
21. Utilization Management for Review a. New & Expanded Indications **Ilaris (canakinumab); Active Still's Disease (including Adult-Onset Still's Disease, AOSD)**	**Presenter:** _____, Pharm.D. The UM Review for Ilaris (canakinumab) for the indication of Active Still's Disease (including Adult-Onset Still's Disease, AOSD) was presented. **Therapeutic Designations:**

Market Basket: Still's disease: SJIA

Drug	Therapeutic Designation	Rationale:
NSAIDs	Equivalent mild disease -NEW	• First option in guidelines but not typically used monotherapy • Low-net-cost option
Methotrexate/ DMARDs	Equivalent mild disease -NEW	• May be preferred in certain patients with primarily arthritis symptoms
Glucocorticoids	Equivalent mild disease -NEW	• May be option for escalation of therapy in certain patients
Ilaris (canakinumab)	Equivalent- MAINTAIN moderate-severe disease -NEW	• Some patients may require biologic first line
Actemra (tocilizumab)	Equivalent -MAINTAIN moderate-severe disease -NEW	• Some patients may require biologic first line

Market Basket: Still's disease: AOSD

Drug	Therapeutic Designation	Rationale:
NSAIDs	Equivalent mild disease -NEW	• First option in guidelines • Low-net-cost first line option first
Methotrexate/ DMARDs	Equivalent mild disease- NEW	• May be preferred in certain patients with primarily arthritis symptoms
Glucocorticoids	Equivalent mild disease -NEW	• May be option for escalation of therapy in certain patients
Ilaris (canakinumab)	Novel, moderate-severe disease -NEW	• Only FDA approved item for AOSD; Some may require biologic first line

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Agenda Item	Summary
	Utilization Management: **Ilaris (canakinumab): Adult Onset Still;s Disease (AOSD)** **Prior Authorization – NEW** **Diagnosis**: Active Still's disease to include Adult-Onset Still's Disease (ASOD) **Prescriber**: prescribed by or in consultation with rheumatologist, dermatologist, or immunologist **Clinical step**: previous trial of or contraindication to at least ONE of the following DMARDs (disease-modifying antirheumatic drugs) e.g., methotrexate, lefunomide, hydroxychloroquine, or sulfasalazine **Trade step**: previous trial of or contraindication to ONE preferred immunomodulator for AOSD **Quantity limit**: per FDA approved label (e.g., max of 2 vials/300 mg per 28 days) **Duration**: 6 months (initial); 12 months (renewal) **Renewal**: experienced or maintained a 20% or greater improvement in tender joint count or swollen count while on therapy OR physician attestation that patient has maintained or improved systemic inflammatory disease (e.g., fevers, pain, rash, arthritis, etc.) **Rationale**: Consistent with FDA labeling, clinical guidelines, items approved for ASOD, alignment with other agents used for arthritis conditions **Ilaris (canakinumab): Systemic Juvenile Idiopathic Arthritis (SJIA)** **Prior Authorization – REVISE** **Diagnosis**: Active Still's disease to include Systemic Juvenile Idiopathic Arthritis (SJIA) **Age**: 2 years of age or older **Prescriber**: prescribed by or in consultation with rheumatologist, dermatologist, or immunologist **Clinical step**: previous trial of or contraindication to at least **ONE** of the following DMARDs (disease-modifying antirheumatic drugs) e.g., methotrexate, lefunomide, hydroxychloroquine, or sulfasalazine **Trade step**: previous trial of or contraindication to ONE preferred immunomodulator for SJIA **Quantity limit**: per FDA approved label (e.g., max of 2 vials/300 mg per 28 days) **Duration**: 6 months (initial); 12 months (renewal) **Renewal Criteria**: experienced or maintained a 20% or greater improvement in tender joint count or swollen count while on therapy OR physician attestation that patient has maintained or improved systemic inflammatory disease (e.g., fevers, pain, rash, arthritis, etc.) **Rationale**: Consistent with FDA labeling, clinical guidelines, items approved for SJIA, alignment with other agents used for pediatric arthritis conditions

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Agenda Item	Summary
	Actemra (tocilizumab) subcutaneous: Systemic Juvenile Idiopathic Arthritis (SJIA) **Prior Authorization – UPDATE for SJIA** **Indication**: Systemic Juvenile Idiopathic Arthritis (SJIA) **Age**: 2 years of age or older **Prescriber**: prescribed by or in consultation with rheumatologist, dermatologist, or immunologist **Clinical step**: previous trial of or contraindication to at least ONE of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, lefunomide, hydroxychloroquine, or sulfasalazine **Trade step**: previous trial of or contraindication to ONE preferred immunomodulator for SJIA **Quantity limit**: per FDA approved label (e.g., max of 4 vials/injectors (162 mg each) per 28 days) **Duration**: 6 months (initial); 12 months (renewal) **Renewal Criteria**: experienced or maintained a 20% or greater improvement in tender joint count or swollen count while on therapy **OR** physician attestation that patient has maintained or improved systemic inflammatory disease (e.g., fevers, pain, rash, arthritis, etc.) **Rationale**: Consistent with FDA labeling, clinical guidelines, items approved for ASOD **External Review:** External review was not obtained for this UM review. **Discussion:** None **Vote:** Approve the proposed utilization management as presented. There was proposal for a Motion which was properly seconded and approved. **Action:** The proposed utilization management were approved. **Follow-up:** None

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<table>
<tr><th>Agenda Item</th><th>Summary</th></tr>
<tr><td></td><td></td></tr>
<tr><td>21. Utilization Management for Review

b. New Derivatives, Formulations,

Combinations</td><td>Presenter: _____, PharmD

<table>
<tr><th>Drug</th><th>Indication</th><th>Therapeutic designation</th><th>Proposed actions</th></tr>
<tr><td>Darzalex Faspro (daratumumab and hyaluronidase-fihj)

SQ injection</td><td>Multiple myeloma</td><td>Equivalent</td><td>ADD PA
• Indication: treatment of adult patients with multiple myeloma:
  • in combination with bortezomib, melphalan and prednisone in newly diagnosed patients who are ineligible for autologous stem cell transplant
  • in combination with lenalidomide and dexamethasone in newly diagnosed patients who are ineligible for autologous stem cell transplant and in patients with relapsed or refractory multiple myeloma who have received at least one prior therapy
  • in combination with bortezomib and dexamethasone in patients who have received at least one prior therapy
  • as monotherapy, in patients who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent.
• Age Edit: 18 years or older (per label)
• Auth Duration: 12 months</td></tr>
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Agenda Item	Summary			
	Nymalize (nimodipine) oral solution	Subarachnoid hemorrhage	**Equivalent**	**REVISE QL:** 360 mg/day for 21 days **MAINTAIN** all other criteria
	Licart (diclofenac epolamine) patch	Acute pain	**Equivalent**	**ADD PA (Part D Only)** • Indication: The topical treatment of acute pain due to minor strains, sprains, and contusions (per label) • Quantity limit: 1 patch per day (per label) • Step: Trial of authorized generic of Flector

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<table>
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<tr><td></td><td>
<table>
<tr><th>Drug</th><th>Indication</th><th>Therapeutic designation</th><th>Proposed actions</th></tr>
<tr><td>Kynmobi (apomorphine HCl) film</td><td>Parkinson’s disease</td><td>Equivalent</td><td>ADD PA:
Indication: the acute, intermittent treatment of “off” episodes in patients with Parkinson’s disease (per label)
Age: 18 years of age or older
QL: 5 films per day (per label); no QL on titration pack
Other: Optimization of pharmacotherapy as evidenced by BOTH of the following:
Change in levodopa/carbidopa dosing strategy or formulation AND
Trial of or contraindication to at least 2 Parkinson’s agents from two different classes: one dopamine agonist (i.e., ropinirole, pramipexole, rotigotine), one monoamine oxidase-inhibitor (MAO-I) (i.e., selegiline, rasagiline), one catechol-O-methyl transferase (COMT) inhibitors (i.e., entacapone, tolcapone)
Prescriber edit: Prescribed by or in consultation with a neurologist
Approval duration: initial: 6 months; renewal: 12 months
Renewal criteria:
Physician attestation of patient improvement with motor fluctuations during OFF episodes with the use of Kynmobi (e.g., improvement in speech, facial expression, tremor at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair)</td></tr>
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3Q20 Pharmacy & Therapeutics (P&T) Committee Minutes

Agenda Item	Summary

Drug	Indication	Therapeutic designation	Proposed actions
Jelmyto (mitomycin) hydrogel	Low-grade upper tract urothelial cancer	**Novel**	**ADD PA** • **Indication**: the treatment of adult patients with low-grade upper tract urothelial cancer (LG-UTUC) (per label) • **Age Edit:** 18 years or older (per label) • **Prescriber edit:** Prescribed by or in consultation with oncologist or urologist • **QL**: 1 box per 7 days (initial), 1 box per 30 days (renewal) (per label) • **Auth Duration:** 6 weeks (initial), 11 months (renewal) • **Renewal**: Physician attestation response was assessed no sooner than 3 months after initiation of Jelmyto and complete response was maintained at this time point
Valtoco (diazepam) nasal spray	Seizure clusters	**Equivalent with caveat**	**ADD ST:** Trial and failure of or contraindication to up to one product for the treatment of acute repetitive seizures **ADD QL:** 10 cartons per 30 days **Caveat**: Diastat may not be the sole required step for this product due to rectal administration concerns
Zilxi (minocycline) topical foam	Rosacea	**Equivalent**	**ADD ST:** Trial and failure of or contraindication to up to 2 topical agents and/or up to 1 oral tetracycline agent **ADD QL:** 30 g/30 days
Tivicay PD (dolutegravir) tablets for oral suspension	Human immunodeficiency virus type I	**Equivalent**	**ADD QL:** 6 tablets/day

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<table>
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<tr><td></td><td>
<table>
<tr><th>Drug</th><th>Indication</th><th>Therapeutic designation</th><th>Proposed actions</th></tr>
<tr><td>Bynfezia Pen (octreotide acetate) prefilled pen</td><td>Acromegaly, Severe diarrhea/flushing episodes associated with metastatic carcinoid tumors, Profuse watery diarrhea associated with vasoactive intestinal peptide tumors</td><td>Equivalent</td><td>ADD PA:
Indication: (per label)
Reduction of growth hormone (GH) and insulin-like growth factor 1 (IGF-1) in adult patients with acromegaly who have had inadequate response to or cannot be treated with surgical resection, pituitary irradiation, and bromocriptine mesylate at maximally tolerated doses
Treatment of severe diarrhea/flushing episodes associated with metastatic carcinoid tumors in adults
Treatment of profuse watery diarrhea associated with vasoactive intestinal peptide tumors (VIPomas) in adults
Age: 18 years of age and older (per label)
QL: 6 pens per 28 days (per label)
Approval duration: 6 months (initial) and 12 months (renewal)
Renewal criteria: Physician attestation of improvement or sustained remission of clinical symptoms</td></tr>
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3Q20 Pharmacy & Therapeutics (P&T) Committee Minutes

Agenda Item	Summary
21. Utilization Management for Review c. Quarterly Review	**Presenters:** _____, Pharm.D., _____, Pharm.D.

Continuous Glucose Monitor (CGM)	Indication	Therapeutic Designation	Proposed Actions
Dexcom G4, G5, G6	Diabetes	**Equivalent**	**Revise PA:** **Diagnosis**: add gestational diabetes **Extra criteria:** add that patient has a clinical need that can't be managed with SMBG AND has either tried or does not have access to a professional CGM from provider's office **Age**: Freestyle Libre 2.0, 4 years of age or above
Abbott FreeStyle Libre, Abbott Freestyle Libre 2.0	Diabetes	**Equivalent with caveat** Do not require step through if: patient is ≥2-18 **OR** insulin pump not compatible with Libre **OR** prescriber indicates has risk for or has severe hypoglycemia or unawareness (no alarms on Libre; will not apply to Libre 2.0)	
Medtronic Guardian Connect	Diabetes	**Equivalent with caveat** Can not be sole preferred CGM (requires SMBG for diabetes/insulin decisions)	
Eversense CGM System	Diabetes	**Equivalent** Cannot be sole preferred CGM (indicated for adults only)	

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Agenda Item	Summary	
	Insulin Pump	**T: Slim X2, T: Slim X2 with Basal-IQ, T:Slim X2 with Control-IQ, and MiniMed 670G**
	Indication	Diabetes
	Therapeutic Designation	**Equivalent with caveat**
	Proposed Actions	**Caveat**: : do not require a step through MiniMed 670G if type 2 diabetic **Prior Authorization – NEW** **Medical benefit**: If patient has coverage for insulin pump via the medical benefit, manufacturer program, or patient assistance program, this PA does not apply **Indication***:* Meets FDA approved indication for device **Diagnosis**: Diabetes Mellitus **Prescriber edit:** by or in consultation with an endocrinologist **Age edit:** Meets FDA age limit for device **Other criteria:** • Patient has completed a comprehensive diabetes education program within the preceding 24 months • Patient follows a maintenance program of at least 3 injections of insulin per day and frequent self-adjustments of insulin dose for the past 6 months • Patient requires glucose self-testing of at least 4 times per day on average in the preceding 2 months • Patient meets at least one of the following while on a multiple daily insulin injection regimen: -Glycosylated hemoglobin level (HbA1c) >7%; OR -History of recurring hypoglycemia; OR -Wide fluctuations in blood glucose before mealtime; OR -Dawn phenomenon with fasting blood glucose levels frequently exceeding 200 mg/dl; OR -History of severe glycemic excursions (i.e. sudden spikes in blood sugar levels) • Patient has not received pump within the last 4 years *-Exception:* (Pump is malfunctioning, not repairable, and not under warranty) **Step**: Trial of up to 1 preferred pump, where aligned per FDA approved indication and age range **Duration**: 1 month **Quantity Limit**: -Products with PA: 1 fill -Products without a PA: 1 pump per year

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3Q20 Pharmacy & Therapeutics (P&T) Committee Minutes

Agenda Item	Summary

Insulin Device	**Omnipod and Omnipod DASH**
Indication	Diabetes
Therapeutic Designation	**Equivalent with caveat**
Proposed Actions	**Caveat**: do not require a step through V-Go **Prior Authorization – NEW** **Medical benefit:** If patient has coverage for insulin device via the medical benefit, manufacturer program, or patient assistance program, this PA does not apply **Diagnosis**: Diabetes Mellitus **Prescriber edit**: by or in consultation with an endocrinologist **Other criteria:** • Patient has completed a comprehensive diabetes education program within the preceding 24 months • Patient follows a maintenance program of at least 3 injections of insulin per day and frequent self-adjustments of insulin dose for the past 6 months • Patient requires glucose self-testing of at least 4 times per day on average in the preceding 2 months • Patient meets at least one of the following while on a multiple daily insulin injection regimen: -Glycosylated hemoglobin level (HbA1c) >7%; OR -History of recurring hypoglycemia; OR -Wide fluctuations in blood glucose before mealtime; OR -Dawn phenomenon with fasting blood glucose levels frequently exceeding 200 mg/dl; OR -History of severe glycemic excursions (i.e. sudden spikes in blood sugar levels) • Patient has not received device (personal diabetes manager (PDM) within the last 4 years) *-Exception:* (Device is malfunctioning, not repairable, and not under warranty) **Step**: Trial of up to 1 preferred device, where aligned per FDA approved indication and age range **Duration**: 1 month **Quantity Limit:** -Products with PA: 1 fill -Products without a PA: 1 device per year -Pods: no QL

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3Q20 Pharmacy & Therapeutics (P&T) Committee Minutes

Agenda Item	Summary	
	Insulin Device	**V-Go 20, 30, 40**
	Indication	Diabetes
	Therapeutic Designation	**Novel**
	Proposed Actions	**Prior Authorization – NEW** **Diagnosis**: Diabetes Mellitus **Prescriber edit:** by or in consultation with an endocrinologist **Age edit:** 18 years old and older **Other criteria:** • Patient follows a maintenance program of at least 3 injections of insulin per day • Patient has worked with physician to adjust dose of insulin for the past 6 months and has not met glucose goals • Patient does not require regular adjustments/modifications to basal rate during a 24 hour period • Patient requires bolus insulin dosing in increments of 2 units per bolus • Patient does not require a total daily insulin exceeding 76 units • Patient meets at least one of the following while on a multiple daily insulin injection regimen: -Glycosylated hemoglobin level (HbA1c) >7%; OR -History of recurring hypoglycemia; OR -Wide fluctuations in blood glucose before mealtime; OR -Dawn phenomenon with fasting blood glucose levels frequently exceeding 200 mg/dl; OR -History of severe glycemic excursions (i.e. sudden spikes in blood sugar levels) **Step**: Trial of up to 1 preferred device, where aligned per FDA approved indication and age range **Duration**: initial: 12 months; renewal: 12 months **Renewal Criteria:** • Positive patient response to therapy and is adherent to physician follow-up visits

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3Q20 Pharmacy & Therapeutics (P&T) Committee Minutes

Agenda Item	Summary

Drug	Indication	Therapeutic Designation	Proposed Actions
Brand Atypical Antipsychotics (Caplyta, Fanapt, Latuda, Rexulti, Saphris, and Vraylar)	Schizophrenia	**Equivalent with caveat**	**REVISE ST:** Trial of up to two generic and/or one brand preferred atypical antipsychotic **MAINTAIN QL** **Caveat**: only where indications align
Secuado (asenapine)	Schizophrenia	**Equivalent with caveat**	**REVISE ST:** Trial of another asenapine formulation and/or up to two generic and/or one brand preferred atypical antipsychotic **MAINTAIN** all other criteria **Caveat**: only where indications align
Evamist (estradiol)	Vasomotor Symptoms	**Equivalent with caveat**	**REVISE ST**: Trial of a generic or a brand preferred transdermal agent **MAINTAIN QL** **Caveat**: only where indications align
Arcapta Neohaler (indacaterol)	COPD	**N/A**	**REVISE ST:** Trial of up to two preferred LABAs
Tudorza Pressair (aclidinium)	COPD	**N/A**	**REVISE ST**: Trial of up to two preferred LAMAs
Seebri Neohaler (glycopyrrolate)	COPD	**N/A**	**REVISE ST**: Trial of up to two preferred LAMAs

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3Q20 Pharmacy & Therapeutics (P&T) Committee Minutes

<table>
<tr><th>Agenda Item</th><th>Summary</th></tr>
<tr><td></td><td>
<table>
<tr><th>Drug</th><th>Indication</th><th>Therapeutic Designation</th><th>Proposed Actions</th></tr>
<tr><td>Semglee (insulin glargine)</td><td>Type 1 and Type 2 diabetes</td><td>Equivalent</td><td>ADD QL: Prefilled pen: 10 pens (30 mL) per 28 days; vials: 4 vials (40 mL) per 28 days
ADD ST: Trial of up to 2 preferred long acting insulins</td></tr>
<tr><td>Lyumjev (insulin lispro-aabc)</td><td>Type 1 and Type 2 diabetes</td><td>Equivalent</td><td>ADD QL: U-100 prefilled pens: 10 pens (30 mL) per 28 days; U-200 prefilled pens: 4 pens (12 mL) per 28 days; vials: 4 vials (40 mL) per 28 days
ADD ST: Trial of up to 2 preferred rapid acting insulins</td></tr>
<tr><td>Doryx (doxycycline hyclate)</td><td>Treat or prevent infections susceptive to the agent</td><td>N/A</td><td>EXCLUDE</td></tr>
<tr><td>Doryx MPC (doxycycline hyclate)</td><td>Treat or prevent infections susceptive to the agent</td><td>N/A</td><td>EXCLUDE</td></tr>
<tr><td>Oracea (doxycycline monohydrate)</td><td>Inflammatory lesions of rosacea in adults</td><td>N/A</td><td>EXCLUDE</td></tr>
<tr><td>Kaletra (100-25 mg lopinavir-ritonavir tablets)</td><td>HIV-1 infection in adults and pediatric patients (≥14 days)</td><td>N/A</td><td>REVISE QL: 10 tablets per day</td></tr>
</table>
</td></tr>
<tr><td>Adjournment

Next Meeting:</td><td>Vote: Adjourn the meeting. There was a proposal for a motion which was properly seconded and approved.

The next scheduled P&T Committee Meeting will be held on Oct 16, 2020

Follow-up: None</td></tr>
</table>

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3Q20 Pharmacy & Therapeutics (P&T) Committee Minutes

Agenda Item	Summary
	Minutes Accepted by: _____, M.D. **Minutes Submitted by**: _____, Pharm.D.

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2020 Standard Part D Formulary Structure White Paper

Updated February 14th, 2019

INTRODUCTION

This document serves to describe the MedImpact Standard Part D Formularies for 2020. Part D Formularies are available with a number of options to support the structural and operational reporting requirements of the Part D program. Plan Sponsors should use this document to determine which formulary options best meet their needs for the 2020 plan year.

Please note that tremendous strategic, clinical, and operational effort goes into making our Standard Part D Formularies valuable, effective, operationally sound, and CMS-compliant. Significant annual changes in CMS processes and requirements, levied under extremely aggressive time frames, result in formulary process evolution each and every year to meet and exceed CMS mandates. As a result of the significant work involved in creating the available options for the MedImpact Standard Part D Formularies for each plan year, deviations from the options outlined in this document are not possible for the 2020 Medicare plan year. MedImpact is proud to offer our Part D Standard Formulary offerings to you as an integral component of a successful 2020 CMS contract year.

MEDIMPACT PART D STANDARD FORMULARY MAIN OPTIONS

At the highest level, MedImpact has 2 Standard Part D Formularies to consider:

MedImpact Advantage Formulary – The Advantage formulary is a net cost-focused formulary with significantly greater restrictions. It is intended for a closed formulary design. The Advantage formulary is often used when greater cost control is desired.

MedImpact Plus Formulary – The Plus formulary is designed for broader access and is intended for a closed formulary design under a variety of different tier structures. The Plus formulary is often used in situations where offering more generous beneficiary access to drug coverage is desired.

In order to reduce "two of class" issues and to better streamline our formularies, we will continue to apply a MedImpact custom therapeutic classification to our 2020 Part D formularies. The MedImpact custom therapeutic classification is based on a modification of the AHFS classification scheme and is intended to meet CMS formulary guidance requirements for the 2020 plan year.

Please note that the drugs with PA Type 2 (PA Required with New Starts Only), ST Type 1 (Step Therapy), or ST Type 2 (Step Therapy withNew Starts Only) will have a look back of 120 days in most cases, to identifymembers considered "currently taking" a drug. This look back will allow sequential 30 and 90 days fills.

For Advantage plans continuing with the Advantage option in 2020, please note that the Standard Advantage Part D offering will contain less formulary agents. This is being done to contain costs and remain competitive in the market place.

YOUR 2020 PART D STANDARD FORMULARY

MedImpact Standard Part D Formularies will offer a variety of options for the 2020 CMS contract year. Starting with Section 3 of the 2020 Part D Implementation Questionnaire (IQ), please select your preferred Standard Formulary Type and tier structure from our formulary options.

Similar to 2019, we will be utilizing a modular approach to our formularies that categorizes the drugs within "buckets". MedImpact will collectively place the drugs in each bucket into the appropriate tier levels based on the plan sponsor's chosen benefit design. Our bucket naming convention is also similar to 2019.

Distinctions will be seen between Generic, Brand, and Specialty drug bucketing represented by the letters G, B, and S with subcategories for each, which offers the potential for different tier positioning (if applicable). Please refer to the table below that outlines the descriptions of the 2020 formulary structure and formulary options with examples of drug bucket placement.

Based on CMS CY2019 Plan Benefit Package (PBP) Software and Formulary Submission titled: Appendix C Formulary proposed 2019 Tier Model. *"The optional 5th or 6th tier can be used as an excluded-drug-only or for other meaningful offerings such as $0 vaccine-only tier, Select Care or Select Diabetes Drugs."*

MedImpact will provide an optional tier to place select drugs in any desired combinations. For example:

(1) STAR drugs
AND/OR
(2) Select Insulins
AND/OR
(3) Vaccines

SUPPLEMENTAL FORMULARY OPTIONS

As in previous years, we will continue to offer several formulary/benefit options within your MedImpact Standard Part D Formularies for 2020. Please refer to previous CMS communications and 2020 Formulary Instructions for more details regarding these various options. The options include:

- **OTC**
  MedImpact will define a standard subset of cost-effective **Over-The-Counter** drugs for each formulary that can be optionally covered by your plan based upon specific CMS-defined coverage rules.

- **HI**
  MedImpact will define a standard subset of drugs that may be used as an optional **Home Infusion Carve-out** for MAPD plans as defined by CMS guidelines.

- **FFF**
  MedImpact will define a standard set of **Free First Fill** drugs that may be used in conjunction with this optional benefit as defined by CMS guidelines.

- **GC**
  MedImpact Standard Part D Formularies will support **Gap Coverage** by ***tier*** for 2020. This choice is made through your plan bid; no formulary supplemental files are required.
- **ENH (also known as CMS Exclude Supplemental File)**
  MedImpact will define a standard set of drugs which are not Part D eligible that may be covered under a supplemental benefit. For 2020, this list will include ***generic*** Viagra 25mg, 50 mg, and 100mg tablets with a quantity limit of 6 tablets per 30 days.

NEW for 2020

- **Partial Non-Extended Days' Supply (Partial NDS)**

MedImpact Standard Part D Formularies will expand the Partial Non-Extended Days' Supply offering for 2020 to include specialty drugs, select opioids, and/or select benzodiazepines. Plan sponsors are required to submit to CMS on their bid which tiers will contain drugs that are limited to a one-month supply. Since opioids and benzodiazepines are disseminated throughout various tiers, plan sponsors selecting to apply partial Non-Extended Days' Supply to benzodiazepines and/or opioids will need to indicate this for all formulary tiers on the bid.

STANDARD FORMULARY REFERENCE TABLES

2020 MedImpact Standard Part D Formulary Bucket Structure

Drug Bucket	Content	Description
G-L	Low Cost Generics	A subset of generic drugs which carry a preferred designation, generally costing less than $10 per 30 days.
G-L-STAR	Low Cost STAR Generics	Low cost generic drugs which include select hypertension, oral diabetes, and hyperlipidemia drugs.
G-M	Medium Cost Generics	Available Generic drugs, generally costing between $10 and $50 per 30 days.
G-M-STAR	Medium Cost STAR Generics	Medium cost generic drugs which include select hypertension, oral diabetes, and hyperlipidemia drugs.
G-H	High Cost Generics	Generic drugs generally costing more than $50 per 30 days.
G-VH	Other Generics	Generic drugs with a high price in comparison to other generics within the class designated to be up tiered for plans utilizing non-preferred drug tier.
G-X	Non Formulary Generics for PEM clients	Exclusion of specified generic drugs involved with the Patent Exclusivity Management (PEM) program. Claims will deny with the following POS message: "IF CLAIM FOR GENERIC PRODUCT DENIES FOR NON-FORMULARY, PLEASE DISPENSE BRAND %%%%%%. USE DAW 9" Generic will process on generic tier with PA override. This bucket to be used in conjunction with bucket BMSREB-GH or BMSREB-GL. For clients that select not to participate in PEM, these drugs will be placed in the high cost generic tier.

G-INS	Generic Insulins	Tier 5 or 6 option for select generic insulin products.
G-VACC	Generic Vaccines	Tier 5 or 6 option for select generic vaccine products.
G-PPM	Generic Plus Medium	Available Generic drugs on the Plus formulary only, generally costing between $10 and $50 per 30 days
G-PPH	Generic Plus High Cost	Generic drugs on the Plus formulary only, with a high price in comparison to its corresponding multisource brand counterpart or other generics within the class, generally costing more than $50 per 30 days.
B-L	Preferred Brand Drugs	Brand drugs which carry a preferred designation based on net cost and preferential rebate contract discounts.
B-M	Other Brands	Other formulary brand drugs.
B-H	Non Preferred Brand Drugs	Non Preferred brand drugs only available on Plus Plans.
B-PP	Plus Formulary Preferred Brands	Brand drugs which carry a preferred designation based on net cost which make placement on a Plus formulary only at preferred brand copay (including rebate considerations) financially advantageous to the Plan versus placement at non-preferred brand copay.
BMSREB-GL	Multisource Brands in Generic tier	Preferred multisource brand (MSB) drugs placed on a generic tier corresponding to bucket G-L. These specified MSB drugs allow for continued rebate reimbursement and allow for the MSB drug to remain on all formularies. Used in conjunction with bucket G-X. For clients that select not to participate in PEM, these drugs will be placed in the preferred brand tier.

BMSREB-GH	Multisource Brands in Generic tier	Preferred multisource brand (MSB) drugs placed on a generic tier corresponding to bucket G-H. These specified MSB drugs allow for continued rebate reimbursement and allow for the MSB drug to remain on all formularies. Used in conjunction with bucket G-X. For clients that select not to participate in PEM, these drugs will be placed in the preferred brand tier.
B-INS	Brand Insulins	Tier 5 or 6 option for select brand insulin products.
B-VACC	Brand Vaccines	Tier 5 or 6 option for select brand vaccine products.
S-L	Specialty Generics	Generic drugs that meet the CMS designation for Specialty tier.
S-PPL	Specialty Generic Plus	Generic drugs on the Plus formulary only, which meet the CMS designation for Specialty tier.
S-M	Specialty Brands	Brand drugs that meet the CMS designation for Specialty tier.
S-PPM	Specialty Brand Plus Only	Brand drugs on the Plus formulary only, which meet the CMS designation for Specialty tier.
S-X	Excluded Specialty Generics	Exclusion of specified generic drugs involved with the Patent Exclusivity Management (PEM) program. Claims will deny with the following POS message: "IF CLAIM FOR GENERIC PRODUCT DENIES FOR NON-FORMULARY, PLEASE DISPENSE BRAND %%%%%%. USE DAW 9" For clients that select not to participate in PEM, these drugs will be placed in the same tier as generic specialty drugs.
OTC-B	Special OTC agents - Both	Special OTC agents covered on all formularies if OTC is selected as a supplemental formulary option

2020 FORMULARY STRUCTURE ADVANTAGE FORMULARY

2020 Tier Structure	2020 Option	2020 Tier Label					
		Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Tier 6
ADVANTAGE							
Blue Shading* = CMS Tier label to be used for PBP Bid Submission							
ALL GENERICS AT SAME TIER							
1 Tier	A	•Generic •Preferred Brand •Other Brand •Specialty Drugs					
2 Tier	A	Generic*	Brand*				
		•Generic •Specialty Generic	•Preferred Brand •Other Brand •Specialty Brand				
3 Tier	A	Generic*	Brand*	Specialty*			
		•Generic	•Preferred Brand •Other Brand	•Specialty Tier			
4 Tier	A	Generic*	Preferred Brand*	Non-Preferred Brand*	Specialty*		
		•Generic	•Preferred Brand	•Other Brand	•Specialty Tier		
LOW COST GENERICS PREFERRED (<$10)							
5 Tier	A	Preferred Generic*	Generic*	Preferred Brand*	Non-Preferred Brand*	Specialty*	
		•Low-Cost Generic	•Medium-Cost Generic •High-Cost Generic	•Preferred Brand	•Other Brand	•Specialty Tier	
6 Tier	A	Preferred Generic*	Generic*	Preferred Brand*	Non-Preferred Brand*	Specialty*	Optional*
		•Low-Cost Generic	•Medium-Cost Generic •High-Cost Generic	•Preferred Brand	•Other Brand	•Specialty Tier	•Optional STAR drugs Vaccines Select insulins
LOW & MEDIUM COST GENERICS PREFERRED (<$50)							
5 Tier	B	Preferred Generic*	Generic*	Preferred Brand*	Non-Preferred Brand*	Specialty*	
		•Low-Cost Generic •Medium-Cost Generic	•High-Cost Generic	•Preferred Brand	•Other Brand	•Specialty Tier	
6 Tier	B	Preferred Generic*	Generic*	Preferred Brand*	Non-Preferred Brand*	Specialty*	Optional*
		•Low-Cost Generic •Medium-Cost Generic	•High-Cost Generic	•Preferred Brand	•Other Brand	•Specialty Tier	•Optional STAR drugs Vaccines Select insulins
OTHER GENERICS NON-PREFERRED							
5 Tier	C	Preferred Generic*	Generic*	Preferred Brand*	Non-Preferred Drug*	Specialty*	
		•Low-Cost Generic	•Medium-Cost Generic •High-Cost Generic	•Preferred Brand	• Other Generic • Other Brand	•Specialty Tier	
6 Tier	C	Preferred Generic*	Generic*	Preferred Brand*	Non-Preferred Drug*	Specialty*	Optional*
		•Low-Cost Generic	•Medium-Cost Generic •High-Cost Generic	•Preferred Brand	• Other Generic • Other Brand	•Specialty Tier	•Optional STAR drugs Vaccines Select insulins
LOW & MEDIUM COST GENERICS PREFERRED & OTHER GENERICS NON-PREFERRED							
4 Tier	B	Preferred Generic*	Preferred Brand*	Non-Preferred Drug*	Specialty*		
		•Low-Cost Generic •Medium-Cost Generic •High-Cost Generic	•Preferred Brand	• Other Generic • Other Brand	•Specialty Tier		

Formulary Structure Example 1: Advantage: 5 Tier B, OTC - No

Tier	Description	Drug Buckets
1	Preferred Generic	G-L, G-M, G-INS, G-VACC
2	Generic	G-H
3	Preferred Brand	B-L, B-INS, B-VACC
4	Non-Preferred Brand	B-M
5	Specialty Tier	S-L, S-M

PLUS CLOSED FORMULARY

2020 Tier Structure	2020 Option	2020 Tier Label					
		Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Tier 6
PLUS CLOSED							
Blue Shading* = CMS Tier label to be used for PBP Bid Submission							
ALL GENERICS AT SAME TIER							
1 Tier	A	•Generic •Preferred Brand •Other Brand •Specialty Drugs					
4 Tier	A	Generic*	Preferred Brand*	Non-Preferred Brand*	Specialty*		
		•Generic	•Preferred Brand	•Non-Preferred Brand •Other Brand	•Specialty Tier		
LOW COST GENERICS PREFERRED (<$10)							
5 Tier	A	Preferred Generic*	Generic*	Preferred Brand*	Non-Preferred Brand*	Specialty*	
		•Low-Cost Generic	•Medium-Cost Generic •High-Cost Generic	•Preferred Brand	•Non-Preferred Brand •Other Brand	•Specialty Tier	
6 Tier	A	Preferred Generic*	Generic*	Preferred Brand*	Non-Preferred Brand*	Specialty*	Optional*
		•Low-Cost Generic	•Medium-Cost Generic •High-Cost Generic	•Preferred Brand	•Non-Preferred Brand •Other Brand	•Specialty Tier	•Optional STAR drugs Vaccines Select insulins
LOW & MEDIUM COST GENERICS PREFERRED (<$50)							
5 Tier	B	Preferred Generic*	Generic*	Preferred Brand*	Non-Preferred Brand*	Specialty*	
		•Low-Cost Generic •Medium-Cost Generic	•High-Cost Generic	•Preferred Brand	•Non-Preferred Brand •Other Brand	•Specialty Tier	
6 Tier	B	Preferred Generic*	Generic*	Preferred Brand*	Non-Preferred Brand*	Specialty*	Optional*
		•Low-Cost Generic •Medium-Cost Generic	•High-Cost Generic	•Preferred Brand	•Non-Preferred Brand •Other Brand	•Specialty Tier	•Optional STAR drugs Vaccines Select insulins
OTHER GENERICS NON-PREFERRED							
4 Tier	B	Preferred Generic*	Preferred Brand*	Non-Preferred Drug*	Specialty*		
		•Low-Cost Generic •Medium-Cost Generic •High-Cost Generic	•Preferred Brand	•Other Generic •Non-Preferred Brand •Other Brand	•Specialty Tier		
5 Tier	C	Preferred Generic*	Generic*	Preferred Brand*	Non-Preferred Drug*	Specialty*	
		•Low-Cost Generic	•Medium-Cost Generic •High-Cost Generic	•Preferred Brand	•Other Generic •Non-Preferred Brand •Other Brand	•Specialty Tier	
	D	Preferred Generic*	Preferred Brand*	Non-Preferred Drug*	Specialty*	Optional*	
		•Low-Cost Generic •Medium-Cost Generic •High-Cost Generic	•Preferred Brand	•Other Generic •Non-Preferred Brand •Other Brand	•Specialty Tier	•Optional STAR buckets Vaccines Insulins	
6 Tier	C	Preferred Generic*	Generic*	Preferred Brand*	Non-Preferred Drug*	Specialty*	Optional*
		•Low-Cost Generic	•Medium-Cost Generic •High-Cost Generic	•Preferred Brand	•Other Generic •Non-Preferred Brand •Other Brand	•Specialty Tier	•Optional STAR drugs Vaccines Select insulins

Formulary Structure Example 2: Plus Closed: 6 Tier B, Star Buckets in Optional tier, OTC – No

Tier	Description	Drug Buckets
1	Preferred Generic	G-L, G-M, G-PPM, G-INS, G-VACC
2	Generic	G-H, G-PPH
3	Preferred Brand	B-L, B-PP, B-INS, B-VACC
4	Non-Preferred Brand	B-M, B-H
5	Specialty Tier	S-L, S-M, S-PPL, S-PPM
6	Optional Tier	G-L STAR, G-M STAR

Formulary Structure Example 3: Plus Closed: 5 Tier C, OTC - No

Tier	Description	Drug Buckets
1	Preferred Generic	G-L
2	Generic	G-M, G-H, G-PPH, , G-PPM, G-INS, G-VACC
3	Preferred Brand	B-L, B-PP, B-INS, B-VACC
4	Non-Preferred Drug	B-M, B-H, G-VH, G-PPVH
5	Specialty Tier	S-L, S-M, S-PPL, S-PPM

PART D LEGEND

Formulary Actions
NC = No Change
Grey = Not Applicable
Green = Add with P&T Committee Approval
Blue = Add with P&T approval pending CMS eligibility due to labeler status
Formulary Placement
G-L = Low Cost Formulary Generics
G-M = Formulary Generics
G-H = High Cost Generics
G-INS = Generic insulin products for Advantage and Plus
G-INSP= Generic insulin products on Plus formulary only
G-NP = Non-Preferred Generic
G-L STAR = Low Cost Generics (Select Generic Statins, Select Generic ACE-I/ARBs, Select Oral Generic Anti-Diabetic drug)
G-M STAR = Medium Cost Generics (Select Generic Statins, Select Generic ACE-I/ARBs, Select Oral Generic Anti-Diabetic drug)
G-VH = Very High Cost Generics
B-L = Formulary Preferred Brand
B-M = Plus and Advantage Formulary Brand
B-H = Plus Formulary Brand
G-PPM, G-PPH, G-PPVH, B-PP, S-PPL, S-PPM = Plus Formulary
B-NP = Non-Preferred Brand
B-INSP = Brand insulin products for the Plus formulary only
S-L = Specialty Generic Drug
S-M = Specialty Brand Drug
S-NP = Specialty Non-Preferred Drug
G-VACC, B-VACC = Vaccines
B-INS = Brand insulin products for the Advantage and Plus
B-MS*, S-MS* = Multi-source Brand
OTC-L-A, OTC-L-P, OTC-L-B = OTC Adv, Plus or Both (zero copay), if plan participates in OTC supplemental coverage
BMSREB-GL, BMSREB-GH = Brand PEM Drug
SMSREB = Specialty Brand PEM Drug
INS-REBGH = Insulin Brand PEM Drug
S-X = Specialty Generic PEM Drug
G-X = Generic PEM Drug
INS-X = Generic Insulin PEM Drug
ENH-EDL = Enhanced Drugs
PEND = Pending

Prescribing Guidelines
AGE = Age Restriction
QL = Quantity Limit
HRM PA = High Risk Medication
PA, BvD = Payment Determination
PA, TIRF = Payment Determination
ST = Step Therapy
PA = Prior Authorization
PAGL = PA guideline

* The corresponding multi-source brand for a new generic will be moved to bucket B-MS or S-MS once a CMS proxy for the generic is provided. The generic proxy must have an ANDA (abbreviated new drug application) in compliance with the CMS regulation and 60 day member notification has been given.

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I. Interim Approved Line-Extensions

Drug					Formulary Status	Prescribing Limitations						Notes	Effective Date
						Plus			Advantage				
Brand Name	Generic Name	Strength	Dosage Form	Route	Drug Bucket	PA	ST	QL	PA	ST	QL		
HIZENTRA	IMMUN GLOB G(IGG)/PRO/IGA 0-50	1 G/5 ML, 2 G/10 ML, 4 G/20 ML	SYRINGE	SUBCUTANE.	S-NP	IMMUNE GLOBULIN BVD DETERMINATION	NONE	NONE				Line extension will follow placement of existing formulary agents	4/18/2020
EPINEPHRINE PROFESSIONAL KIT	EPINEPHRINE	1 MG/ML(1)	KIT	INJECTION	B-MS	NONE	NONE	NONE				Non-Labeler	TBD
EPINEPHRINE PROFESSIONAL EMS	EPINEPHRINE	1 MG/ML(1)	KIT	INJECTION	B-MS	NONE	NONE	NONE				Non-Labeler	TBD
ROMIDEPSIN	ROMIDEPSIN	27.5 MG/5.5 ML	VIAL	INTRAVEN.	S-NP	ROMIDEPSIN	NONE	NONE				Line extension will follow placement of existing formulary agents	4/25/2020
EMERPHED	EPHEDRINE SULFATE	50 MG/10 ML	VIAL	INTRAVEN.	NA							Non-Labeler	TBD
JELMYTO	MITOMYCIN	40 MG	KIT	URETHRAL	S-M	MITOMYCIN	NONE	4/28	MITOMYCIN	NONE	4/28	Non-Labeler	TBD
FENSOLVI	LEUPROLIDE ACETATE	45 MG	SYRINGE	SUBCUTANE.	S-NP	NONE	NONE	NONE				Lower cost/similar drug entity available will move the drug to a non-preferred tier/placement	5/16/2020
HALOG	HALCINONIDE	0.1 %	SOLUTION	TOPICAL	B-NP	NONE	NONE	NONE				Line extension will follow placement of existing formulary agents	10/1/2020
NYMALIZE	NIMODIPINE	30 MG/5 ML, 60 MG/10 ML	SYRINGE	ORAL	S-NP	NIMODIPINE SOLUTION	NONE	1260/21				Clinical and cost information justifies the need for formulary placement with UM	5/16/2020
JYNARQUE	TOLVAPTAN	15 MG-15 MG, 30 MG-15 MG	TABLET SEQ	ORAL	S-M	TOLVAPTAN	NONE	56/28	TOLVAPTAN	NONE	56/28	Line extension will follow placement of existing formulary agents	5/30/2020
OSMOLEX ER	AMANTADINE HCL	322 MG/DAY	TAB BP 24H	ORAL	B-M	NONE	AMANTADINE ER	60/30	NONE	AMANTADINE ER	60/30	Line extension will follow placement of existing formulary agents	5/30/2020
LICART	DICLOFENAC EPOLAMINE	1.3 %	PATCH TD24	TRANSDERM.	B-NP	DICLOFENAC EPOLAMINE - LICART	NONE	30/30				Lower cost/similar drug entity available will move the drug to a non-preferred tier/placement	10/1/2020
DILAUDID	HYDROMORPHONE HCL/PF	0.2 MG/ML	SYRINGE	INJECTION	B-NP	NONE	NONE	NONE				Line extension will follow placement of existing formulary agents	5/30/2020
SOVALDI	SOFOSBUVIR	150 MG	PELLET PACK	ORAL	S-M	SOFOSBUVIR	NONE	28/28	SOFOSBUVIR	NONE	28/28	Line extension will follow placement of existing formulary agents	6/6/2020
SOVALDI	SOFOSBUVIR	200 MG	PELLET PACK	ORAL	S-M	SOFOSBUVIR	NONE	56/28	SOFOSBUVIR	NONE	56/28	Line extension will follow placement of existing formulary agents	6/6/2020
HARVONI	LEDIPASVIR/SOFOSBUVIR	45 MG-200 MG	PELLET PACK	ORAL	S-M	LEDIPASVIR-SOFOSBUVIR	NONE	56/28	LEDIPASVIR-SOFOSBUVIR	NONE	56/28	Line extension will follow placement of existing formulary agents	6/6/2020
HARVONI	LEDIPASVIR/SOFOSBUVIR	33.75 MG-150 MG	PELLET PACK	ORAL	S-M	LEDIPASVIR-SOFOSBUVIR	NONE	28/28	LEDIPASVIR-SOFOSBUVIR	NONE	28/28	Line extension will follow placement of existing formulary agents	6/6/2020
KYNMOBI	APOMORPHINE HCL	10 MG, 15 MG, 20 MG, 25 MG, 30 MG	FILM	SUBLINGUAL	S-M	APOMORPHINE - SL	NONE	150/30	APOMORPHINE - SL	NONE	150/30	Clinical and cost information justifies the need for formulary placement with UM	6/20/2020
KYNMOBI	APOMORPHINE HCL	10 MG-15 MG-20 MG	FILM	SUBLINGUAL	S-M	APOMORPHINE - SL	NONE	NONE	APOMORPHINE - SL	NONE	NONE	Clinical and cost information justifies the need for formulary placement with UM	6/20/2020
ZILXI	MINOCYCLINE HCL	1.5 %	FOAM	TOPICAL	B-NP	NONE	NONE	NONE				Lower cost/similar drug entity available will move the drug to a non-preferred tier/placement	10/1/2020
TIVICAY PD	DOLUTEGRAVIR SODIUM	5 MG	TAB SUSP	ORAL	B-M	NONE	NONE	NONE	NONE	NONE	NONE	Line extension will follow placement of existing formulary agents	6/27/2020
BYNFEZIA	OCTREOTIDE ACETATE	2500 MCG/ML	PEN INJCTR	SUBCUT	S-M	NONE	NONE	NONE	NONE	NONE	NONE	Line extension will follow placement of existing formulary agents	7/4/2020
XPOVIO	SELINEXOR	120 MG/WEEK	TABLET	ORAL	S-M	SELINEXOR	NONE	24/28	SELINEXOR	NONE	24/28	Line extension will follow placement of existing formulary agents	7/4/2020
XPOVIO	SELINEXOR	40 MG/WEEK	TABLET	ORAL	S-M	SELINEXOR	NONE	8/28	SELINEXOR	NONE	8/28	Line extension will follow placement of existing formulary agents	7/4/2020
TWIRLA	LEVONORGESTREL/ETHIN.ESTRADIOL	120-30/24H	PATCH TDWK	TRANSDERM.	B-NP	NONE	NONE	QL by ratio 3/28				Lower cost/similar drug entity available will move the drug to a non-preferred tier/placement	7/11/2020

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II. Interim Approved First-time Generic

Drug					Formulary Status	Prescribing Limitations						Notes	Effective Date
						Plus			Advantage				
Generic Name	Reference Brand Name	Strength	Dosage Form	Route	Drug Bucket	PA	ST	QL	PA	ST	QL		
INSULIN LISPRO JUNIOR KWIKPEN	HUMALOG JUNIOR KWIKPEN	100/ML	INS PEN HF	SUBCUTANE.	B-NP	NONE	INSULIN-RAPID ACTING	30/28				IR directed placement	4/18/2020
INSULIN LISPRO PROTAMINE MIX	HUMALOG MIX 75-25 KWIKPEN	75-25/ML	INSULIN PEN	SUBCUTANE.	B-NP	NONE	INSULIN-RAPID ACTING MIX	30/28				IR directed placement	4/18/2020
NICARDIPINE HCL-0.9% NACL	NICARDIPINE IN NACL, ISO-OSM	40 MG/200 ML, 20 MG/200 ML	PIGGYBACK	INTRAVEN.	NA							Marketing status mismatch	5/2/2020
METHYLPHENIDATE ER	APTENSIO XR	10 MG, 15 MG, 20 MG, 30 MG, 40 MG, 50 MG, 60 MG	CSBP 40-60	ORAL	NA							Marketing status mismatch	5/9/2020
MICAFUNGIN	MYCAMINE	50 MG, 100 MG	VIAL	INTRAVEN.	SL-NP	NONE	NONE	NONE				Generic will mirror the placement of brand	5/9/2020
TOLVAPTAN	SAMSCA	30 MG	TABLET	ORAL	SL-NP	NONE	NONE	60/30				Generic will mirror the placement of brand	5/30/2020
SODIUM FLUORIDE SENSITIVE	PREVIDENT 5000	1.1 %-5 %	PASTE (ML)	DENTAL	NA							Generic will mirror the placement of brand	6/20/2020
SODIUM FLUORIDE	PREVIDENT 5000	1.1 %	PASTE (ML)	DENTAL	NA							Generic will mirror the placement of brand	6/20/2020
DESONIDE	DESONATE	0.05 %	GEL (GRAM)	TOPICAL	G-NP	NONE	NONE	NONE				Generic will mirror the placement of brand	6/27/2020

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I. Interim Approved Line-Extension:

Drug					Formulary Status	Prescribing Limitations						Notes	Effective Date
						Plus			Advantage				
Brand Name	Generic Name	Strength	Dosage Form	Route	Drug Bucket	PA	ST	QL	PA	ST	QL		
ONTRUZANT	TRASTUZUMAB-DTTB	150 MG, 420 MG	VIAL	INTRAVEN.	S-M	TRASTUZUMAB-DTTB	NONE	NONE	TRASTUZUMAB-DTTB	NONE	NONE	Line extension will follow placement of existing formulary agents	4/25/2020
KOSELUGO	SELUMETINIB/VITAMIN E TPGS	10 MG	CAPSULE	ORAL	S-M	SELUMETINIB	NONE	300/30	SELUMETINIB	NONE	300/30	PCD with a unique formulation/indication	4/25/2020
KOSELUGO	SELUMETINIB/VITAMIN E TPGS	25 MG	CAPSULE	ORAL	S-M	SELUMETINIB	NONE	120/30	SELUMETINIB	NONE	120/30	PCD with a unique formulation/indication	4/25/2020
ISTURISA	OSILODROSTAT PHOSPHATE	1 MG	TABLET	ORAL	S-NP	OSILODROSTAT	NONE	1800/30				Clinical and cost information justifies the need for formulary placement with UM	4/25/2020
ISTURISA	OSILODROSTAT PHOSPHATE	5 MG	TABLET	ORAL	S-NP	OSILODROSTAT	NONE	360/30				Clinical and cost information justifies the need for formulary placement with UM	4/25/2020
ISTURISA	OSILODROSTAT PHOSPHATE	10 MG	TABLET	ORAL	S-NP	OSILODROSTAT	NONE	180/30				Clinical and cost information justifies the need for formulary placement with UM	4/25/2020
PEMAZYRE	PEMIGATINIB	4.5 MG, 9 MG, 13.5 MG	TABLET	ORAL	S-M	PEMIGATINIB	NONE	14/21	PEMIGATINIB	NONE	14/21	PCD with a unique formulation/indication	5/2/2020
TUKYSA	TUCATINIB	50 MG	TABLET	ORAL	S-M	TUCATINIB	NONE	360/30	TUCATINIB	NONE	360/30	PCD with a unique formulation/indication	5/2/2020
TUKYSA	TUCATINIB	150 MG	TABLET	ORAL	S-M	TUCATINIB	NONE	120/30	TUCATINIB	NONE	120/30	PCD with a unique formulation/indication	5/2/2020
TRODELVY	SACITUZUMAB GOVITECAN-HZIY	180 MG	VIAL	INTRAVEN.	S-M	SACITUZUMAB	NONE	NONE	SACITUZUMAB	NONE	NONE	PCD with a unique formulation/indication	6/6/2020
DARZALEX FASPRO	DARATUMUMAB-HYALURONIDASE-FIHJ	1800 MG-30000 UNITS	VIAL	SUBCUTANE.	S-M	DARATUMUMAB-HYALURONIDASE-FIHJ	NONE	NONE	DARATUMUMAB-HYALURONIDASE-FIHJ	NONE	NONE	PCD with a unique formulation/indication	5/16/2020
DAYVIGO	LEMBOREXANT	5 MG, 10 MG	TABLET	ORAL	B-NP	NONE	LEMBOREXANT	30/30				IR directed placement	10/1/2020
RETEVMO	SELPERCATINIB	80 MG	CAPSULE	ORAL	S-M	SELPERCATINIB	NONE	120/30	SELPERCATINIB	NONE	120/30	PCD with a unique formulation/indication	5/23/2020
RETEVMO	SELPERCATINIB	40 MG	CAPSULE	ORAL	S-M	SELPERCATINIB	NONE	180/30	SELPERCATINIB	NONE	180/30	PCD with a unique formulation/indication	5/23/2020
TABRECTA	CAPMATINIB HYDROCHLORIDE	150 MG, 200 MG	TABLET	ORAL	S-M	CAPMATINIB	NONE	120/30	CAPMATINIB	NONE	120/30	PCD with a unique formulation/indication	5/23/2020
QINLOCK	RIPRETINIB	50 MG	TABLET	ORAL	S-M	RIPRETINIB	NONE	90/30	RIPRETINIB	NONE	90/30	PCD with a unique formulation/indication	5/30/2020
AVSOLA	INFLIXIMAB-AXXQ	100 MG	VIAL	INTRAVEN.	S-M	NFLIXIMAB-AXXQ	NONE	NONE	NFLIXIMAB-AXXQ	NONE	NONE	IR directed placement	6/6/2020
ZEPOSIA	OZANIMOD HYDROCHLORIDE	0.23 MG-0.46 MG	CAP DS PK	ORAL	S-M	OZANIMOD	NONE	NONE	OZANIMOD	NONE	NONE	IR directed placement	6/6/2020
ZEPOSIA	OZANIMOD HYDROCHLORIDE	0.92 MG	CAPSULE	ORAL	S-M	OZANIMOD	NONE	30/30	OZANIMOD	NONE	30/30	IR directed placement	6/6/2020
ZEPOSIA	OZANIMOD HYDROCHLORIDE	0.23 MG-0.92 MG	CAP DS PK	ORAL	S-M	OZANIMOD	NONE	NONE	OZANIMOD	NONE	NONE	IR directed placement	6/6/2020
NEXLIZET	BEMPEDOIC ACID/EZETIMIBE	180 MG-10 MG	TABLET	ORAL	B-L	NONE	NONE	30/30	NONE	NONE	30/30	Clinical and cost information justifies the need for formulary placement with UM	10/1/2020
ORIAHNN	ELAGOLIX/ESTRADIOL/NORETHINDRN	300 MG-1 MG-0.5 MG	CAP SEQ	ORAL	S-NP	ELAGOLIX/ESTRADIOL/ NORETHINDRONE	NONE	56/28				Clinical and cost information justifies the need for formulary placement with UM	6/13/2020
PHEXXI	LACTIC ACID/CITRIC/POTASSIUM	1.8-1-0.4%	GEL/PF APP	VAGINAL	B-NP	LACTIC ACID/CITRIC/POTASSIUM	NONE	60/30				Non-Labeler	TBD
LYUMJEV	INSULIN LISPRO-AABC	100/ML	VIAL	SUBCUTANE.	B-NP	NONE	INSULIN-RAPID ACTING	40/28				IR directed placement	10/1/2020
LYUMJEV KWIKPEN U-100	INSULIN LISPRO-AABC	100/ML	INSULIN PEN	SUBCUTANE.	B-NP	NONE	INSULIN-RAPID ACTING	30/28				IR directed placement	10/1/2020
LYUMJEV KWIKPEN U-200	INSULIN LISPRO-AABC	200/ML (3)	INSULIN PEN	SUBCUTANE.	B-NP	NONE	INSULIN-RAPID ACTING	30/28				IR directed placement	10/1/2020
ZEPZELCA	LURBINECTEDIN	4 MG	VIAL	INTRAVEN	S-M	LURBINECTEDIN	NONE	NONE	LURBINECTEDIN	NONE	NONE	PCD with a unique formulation/indication	7/4/2020
HELIDAC	BISMUTH SSAL/METRONID/TETRACYC	250 MG-500 MG	COMBO. PKG	ORAL	S-NP	NONE	NONE	NONE				Lower cost/similar drug entity available will move the drug to a non-preferred tier/placement	7/4/2020
UPLIZNA	INEBILIZUMAB-CDON	100 MG/10 ML	VIAL	INTRAVEN	S-NP	INEBILIZUMAB-CDON	NONE	90/365				Non-Labeler	TBD
PHESGO	PERTUZUMAB-TRASTUZUMAB-HY-ZZXF	1200-600MG	VIAL	SUBCUTANE.	S-M	PERTUZUMAB-TRASTUZUMAB-HY-ZZXF	NONE	15/21	PERTUZUMAB-TRASTUZUMAB-HY-ZZXF	NONE	15/21	PCD with a unique formulation/indication	7/11/2020
PHESGO	PERTUZUMAB-TRASTUZUMAB-HY-ZZXF	600-600 MG	VIAL	SUBCUTANE.	S-M	PERTUZUMAB-TRASTUZUMAB-HY-ZZXF	NONE	10/21	PERTUZUMAB-TRASTUZUMAB-HY-ZZXF	NONE	10/21	PCD with a unique formulation/indication	7/11/2020

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V. Proposed Utilization Management Edits

1. Updates to Step Therapy Edits

STGD	Action	Proposed Criteria	Notes	Effective Date
LEMBOREXANT	NEW	PRIOR CLAIM FOR BELSOMRA AND ONE OF THE FOLLOWING GENERIC INSOMNIA AGENTS: ESZOPICLONE, ZALEPLON, OR ZOLPIDEM IR TABLETS WITHIN THE PAST 365 DAYS.		10/1/2020
OPHTHALMIC PROSTAGLANDINS	Update	PRIOR CLAIM FOR FORMULARY VERSION OF LATANOPROST (GENERIC XALATAN OR XALATAN) AND ONE OF THE FOLLOWING: ALPHAGAN P 0.1%, AZOPT, COMBIGAN, LUMIGAN 0.01%, SIMBRINZA, ROCKLATAN OR FORMULARY VERSION OF TRAVOPROST WITHIN THE PAST 365 DAYS.	IR directed placment	7/1/2020

2. Updates to Prior Authorization Edits

PAGD	Action	Criteria Field	Notes	Effective Date
IPILIMUMAB	Update	Coverage Duration	UM change request	6/1/2020
IXEKIZUMAB	Update	Other Criteria	UM change request	6/1/2020
GOLODIRSEN	Update	Other Criteria	UM change request	5/25/2020
DIROXIMEL FUMARATE	Update	Other Criteria	UM change request	7/1/2020
INTERFERONS FOR MS-BETASERON, EXTAVIA	Update	Required Medical Information	UM change request	7/1/2020
SOFOSBUVIR/VELPATASVIR	Update	Age Restrictions	UM change request	7/1/2020
NINTEDANIB	Update	Age Restrictions, Prescriber Restrictions, Coverage Duration, Other Criteria	UM change request	7/1/2020
PENICILLAMINE	Update	Other Criteria	UM change request	7/1/2020
IPILIMUMAB	Update	Exclusion Criteria, Coverage Duration	UM change request	8/1/2020
NIVOLUMAB	Update	Exclusion Criteria	UM change request	8/1/2020
AXITINIB	Update	Other Criteria	UM change request	8/1/2020
NINTEDANIB	Update	Exclusion Criteria		6/23/2020

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VII. Expedited New FDA Approved Drugs - Proposed Actions

Drug					Formulary Status	Prescribing Limitations						Notes	Effective Date
						Plus			Advantage				
Brand Name	Generic Name	Strength	Dosage Form	Route	Drug Bucket	PA	ST	QL	PA	ST	QL		

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VI. Other Formulary Changes

Drug					Formulary Status	Prescribing Limitations						Notes	Effective Date
						Plus			Advantage				
Brand Name	Generic Name	Strength	Dosage Form	Route	Drug Bucket	PA	ST	QL	PA	ST	QL		
COPAXONE	GLATIRAMER ACETATE	20 MG/ML	SYRINGE	SUBCUTANE.	S-M	GLATIRAMER ACETATE	NONE	30/30	GLATIRAMER ACETATE	NONE	30/30	Drug bucket previously S-MS, IR directed placement	4/18/2020
COPAXONE	GLATIRAMER ACETATE	40 MG/ML	SYRINGE	SUBCUTANE.	S-M	GLATIRAMER ACETATE	NONE	12/28	GLATIRAMER ACETATE	NONE	12/28	Drug bucket previously S-MS, IR directed placement	4/18/2020
DEXTROSE IN WATER	DEXTROSE 50 % IN WATER	0.5	VIAL	INTRAVEN.	B-M	TOTAL PARENTERAL NUTRITION AGENT BVD DETERMINATION	NONE	NONE	TOTAL PARENTERAL NUTRITION AGENT BVD DETERMINATION	NONE	NONE	New drug entity	4/25/2020
BRAFTOVI	ENCORAFENIB	50 MG	CAPSULE	ORAL	S-M	NONE	NONE	120/30	NONE	NONE	120/30	Removed PA from drug entity	1/1/2020
EVEROLIMUS	EVEROLIMUS	0.25 MG	TABLET	ORAL	G-VH	IMMUNOSUPPRESSANT BVD DETERMINATION	NONE	NONE	IMMUNOSUPPRESSANT BVD DETERMINATION	NONE	NONE	Drug bucket previously S-L	5/2/2020
TALICIA	OMEPRAZOLE/AMOXICILL/RIFABUTIN	10MG-250MG	CAP IR DR	ORAL	B-NP	NONE	NONE	168/14				Drug bucket previously S-NP	5/2/2020
TERIPARATIDE	TERIPARATIDE	20MCG/DOSE	PEN INJCTR	SUBCUTANE.	B-L	TERIPARATIDE	NONE	2.48/28	TERIPARATIDE	NONE	2.48/28	Drug bucket previously S-NP, IR directed placement	5/16/2020
ROCKLATAN	NETARSUDIL MESYLAT/LATANOPROST	0.02-0.005	DROPS	OPHTHALMIC	B-L	NONE	NONE	2.5/25	NONE	NONE	2.5/25	Removed step therapy from drug entity, IR directed placement	7/1/2020
HYDROXYPROGESTERON E CAPROATE	HYDROXYPROGESTERONE CAPROAT/PF	250 MG/ML	VIAL	INTRAMUSC.	S-NP	NONE	NONE	NONE				Removed PA from drug entity	5/16/2020
MAKENA	HYDROXYPROGESTERONE CAPROAT/PF	250 MG/ML	VIAL	INTRAMUSC.	S-MS	NONE	NONE	NONE				Removed PA from drug entity	5/16/2020
MAKENA	HYDROXYPROGESTERONE CAPROAT/PF	275 MG/1.1	AUTO INJCT	SUBCUTANE.	S-NP	NONE	NONE	NONE				Removed PA from drug entity	5/16/2020
HYDROXYPROGESTERON E CAPROATE	HYDROXYPROGESTERONE CAPROATE	250 MG/ML	VIAL	INTRAMUSC.	S-L	NONE	NONE	NONE	NONE	NONE	NONE	Removed PA from drug entity	5/16/2020
MAKENA	HYDROXYPROGESTERONE CAPROATE	250 MG/ML	VIAL	INTRAMUSC.	S-MS	NONE	NONE	NONE				Removed PA from drug entity	5/16/2020
TESTOSTERONE	TESTOSTERONE	12.5/1.25G	GEL MD PMP	TRANSDERM.	G-H	TESTOSTERONE	NONE	300/30	TESTOSTERONE	NONE	300/30	Drug bucket previously G-NP	5/23/2020
TESTOSTERONE	TESTOSTERONE	20.25/1.25	GEL MD PMP	TRANSDERM.	G-H	TESTOSTERONE	NONE	150/30	TESTOSTERONE	NONE	150/30	Drug bucket previously G-NP	5/23/2020
TESTOSTERONE	TESTOSTERONE	30MG/1.5ML	GEL MD PMP	TRANSDERM.	G-H	TESTOSTERONE	NONE	180/30	TESTOSTERONE	NONE	180/30	Drug bucket previously G-NP	5/23/2020
HAILEY FE	NORETHINDRONE-E.ESTRADIOL-IRON	1MG-20(21)	TABLET	ORAL	G-M	NONE	NONE	NONE	NONE	NONE	NONE	New drug entity	6/13/2020
ACETYLCYSTEINE	ACETYLCYSTEINE	200 MG/ML	VIAL	INTRAVEN.	G-H	NONE	NONE	NONE	NONE	NONE	NONE	Removed PA from drug entity	6/13/2020
ACETADOTE	ACETYLCYSTEINE	200 MG/ML	VIAL	INTRAVEN.	B-MS	NONE	NONE	NONE				Removed PA from drug entity	6/13/2020
HAILEY FE	NORETHINDRONE-E.ESTRADIOL-IRON	1.5-30(21)	TABLET	ORAL	G-M	NONE	NONE	NONE	NONE	NONE	NONE	New drug entity	6/20/2020
INLYTA	AXITINIB	5 MG	TABLET	ORAL	S-M	AXITINIB	NONE	120/30	AXITINIB	NONE	120/30	Updated QL from 60/30 to 120/30	6/20/2020
VANADOM	CARISOPRODOL	350 MG	TABLET	ORAL	G-NP	HIGH RISK DRUGS IN THE ELDERLY - SKELETAL MUSCLE RELAXANTS	NONE	120/30				New drug entity	6/20/2020
BCG VACCINE (TICE STRAIN	BCG VACCINE, LIVE/PF	50 MG	VIAL	INJECTION	B-VACC	NONE	NONE	NONE	NONE	NONE	NONE	Removed PA from drug entity	6/20/2020
NEXLETOL	BEMPEDOIC ACID	180 MG	TABLET	ORAL	B-L	NONE	NONE	30/30	NONE	NONE	30/30	Drug bucket previously B-M, Remove PA from drug entity, IR directed placement	10/1/2020

Negative Change Requests (NCR) - Maintenance changes

Drug					Formulary Status	Prescribing Limitations						Notes	Effective Date
						Plus			Advantage				
Brand Name	Generic Name	Strength	Dosage Form	Route	Drug Bucket	PA	ST	QL	PA	ST	QL		
ZORTRESS	EVEROLIMUS	0.25 MG, 0.5 MG, 0.75 MG	TABLET	ORAL	S-MS	IMMUNOSUPPRESSANT BVD DETERMINATION	NONE	NONE				Drug bucket previously S-M, brand/generic offset	8/1/2020
DARAPRIM	PYRIMETHAMINE	25 MG	TABLET	ORAL	S-MS	PYRIMETHAMINE	NONE	NONE				Drug bucket previously S-M, brand/generic offset	9/1/2020
PROGLYCEM	DIAZOXIDE	50 MG/ML	ORAL SUSP	ORAL	B-MS	NONE	NONE	NONE				Drug bucket previously B-M, brand/generic offset	9/1/2020
PRILOVIXIL	LIDOCAINE/PRILOCAINE	2.5 %-2.5%	KIT	TOPICAL	NA	NONE	NONE	NONE				Drug bucket previously G-VH, not a Part D drug	10/1/2020
GEODON	ZIPRASIDONE MESYLATE	FNL 20MG/1	VIAL	INTRAMUSC.	B-MS	NONE	NONE	6/28				Drug bucket previously B-M, brand/generic offset	10/1/2020
JADENU	DEFERASIROX	180 MG	TABLET	ORAL	S-MS	DEFERASIROX	NONE	NONE				Drug bucket previously S-M, brand/generic offset	10/1/2020
ORFADIN	NITISINONE	10 MG	CAPSULE	ORAL	S-MS	NITISINONE	NONE	NONE				Drug bucket previously S-M, brand/generic offset	10/1/2020
ORFADIN	NITISINONE	2 MG	CAPSULE	ORAL	S-MS	NITISINONE	NONE	NONE				Drug bucket previously S-M, brand/generic offset	10/1/2020
ORFADIN	NITISINONE	5 MG	CAPSULE	ORAL	S-MS	NITISINONE	NONE	NONE				Drug bucket previously S-M, brand/generic offset	10/1/2020

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IV. New FDA Approved Indications

Drug		Formulary Status		Prescribing Limitations				New (Expanded) Indications	Previous Indications
		Plus/Advantage		Plus		Advantage			
Brand Name	Generic Name	Current	Action	Current	Action	Current	Action		

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Formulary Action Grids Executive Summary

July 17, 2020 P&T Committee

Prepared by: Jeremy Lee, PharmD, BCPS, Director Drug Information, MedImpact

The following spreadsheets are referred to as the 2Q20 Formulary Action Grids. They list all the (non-Part D) formulary changes that were made effective on July 1, 2020. The majority of changes were a result of decisions made at the 2Q20 P&T Committee meeting, and other changes were included that resulted from business formulary strategy decisions that did not require any changes to P&T-approved clinical strategies.

These grids are being brought to P&T as information, so the members can review the final formulary strategies and have the opportunity to express concerns or ask questions if they have any. Our goal is to ensure that P&T has oversight over the formulary process to ensure clinical appropriateness. As the Director of Drug Information, I am advising the committee members that it is my opinion that all the decisions outlined in the documents adhere to the clinical intent of the decisions made at previous P&T Committee meetings.

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2Q20 MedImpact Managed Formulary Actions

Additions and/or Revisions effective: 7/1/2020
Deletions effective: 7/1/2020 for NEW member prescriptions
Grandfather until 10/1/2020 for EXISTING member prescriptions

RATIONALE OF CHANGES

Trade Relations Strategy
Approach based on a financial review to deliver low net cost opportunities through pharmaceutical manufacture agreement strategies while taking into consideration the expected market share shift, future pipeline products, member impact and plan impact.

Low Net Cost Strategy
Delivering cost-efficient and clinically appropriate formulary content to meet the pharmacy benefit management needs of MedImpact clients; including appropriate development of preferred drug lists with consideration of low net cost strategies that includes MAC lists, non-pharmaceutical manufacture agreement strategies, and other cost management tools.

Clinical/Safety Strategy
Delivering cost-efficient and clinically appropriate formulary content to promote member safety and savings through the evaluation of scientific evidence, standards of practice, peer-reviewed medical literature, clinical practice guidelines, and guidance from the U.S. Food and Drug Administration (FDA)/Center for Disease Control (CDC).

Regulatory Update
Formulary/utilization management changes to comply with federal and/or state statutes, regulations, rules and policy requirements that pertain to the administration of the pharmacy benefit.

LEGEND

Note: The drug names listed are for reference purposes and denote action on the chemical entity unless otherwise specified. Where generic and brand products for a chemical entity co-exist, coverage and copayment for each will be a function of plan benefit design.

FORMULARY		UTILIZATION MANAGEMENT (UM)		OPTIONAL BENEFIT EXCLUSION
Formulary Status	**Formulary Actions**	**UM Definition**	**UM Actions**	**Coverage for each category will be a function of plan benefit design. These products may be excluded on client benefits. Formulary and UM decisions only apply for clients who choose to provide coverage for these drug categories.**
F = Formulary	C = Change	AGE = Age restriction	A = Add UM	Antiobesity
NF = Non-Formulary	S = Sustain	QL = Quantity Limit	D = Delete UM	Cosmetic Indications
E = Excluded		ST = Step Therapy	C = Change UM	Dietary Supplements and Non-Drug Products
NC = Not covered		CU = Concurrent Use edit	E = Excluded drug from formulary	Erectile Dysfunction
		PA = Prior Authorization	S = Sustain UM	Infertility
				Medical Foods: Dietary supplements, Enteral Feeding,
				Non-Self Administered Drug (NSA)
				Ostomy Supplies
				Class O = Over the Counter Products
				Class Q = Products that are neither drugs nor devices, such as dietary supplements (including prenatal and other vitamins), medical foods, herbal preparations, and bulk flavorings or colorants

2Q20 Formulary Actions

Drug							Formulary Status				Utilization Management													
							Portfolio/9803		MedPerform		Portfolio Low		Portfolio Medium		Portfolio High		MedPerform Low		MedPerform Medium		MedPerform High			
Category	Brand Name	Generic Name	Strength	Dosage Form	Route	Brand Status	Current Status	Action	Current Status	Action	Current Status	Action	Current Status	Action	Current Status	Action	Current Status	Action	Current Status	Action	Current Status	Action	Rationale of Changes	Optional Benefit Exclusion	Client Communication - Commercial/HIEX
ALLERGY	AZELASTINE HCL	AZELASTINE HCL	205.5 MCG	SPRAY/PUMP	NASAL	GENERIC	F	S=F	F	S=F	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	Low Net Cost Strategy		N/A
ALLERGY	OLOPATADINE HCL	OLOPATADINE HCL	0.6 %	SPRAY/PUMP	NASAL	GENERIC	F	S=F	F	S=F	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	Low Net Cost Strategy		N/A
ASTHMA AND COPD	FASENRA	BENRALIZUMAB	30 MG/ML	SYRINGE	SUBCUTANE.	SSB	NF	S=NF	NF	S=NF	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Clinical/Safety Strategy	Non-Self Administered Drug (NSA)	N/A
ASTHMA AND COPD	FASENRA PEN	BENRALIZUMAB	30 MG/ML	AUTO INJCT	SUBCUTANE.	SSB	F	S=F	F	S=F	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Clinical/Safety Strategy		N/A
ASTHMA AND COPD	DUPIXENT	DUPILUMAB	200MG/1.14	SYRINGE	SUBCUTANE.	SSB	F	S=F	F	S=F	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Clinical/Safety Strategy		N/A
ASTHMA AND COPD	NUCALA	MEPOLIZUMAB	100 MG	VIAL	SUBCUTANE.	SSB	NF	S=NF	NF	S=NF	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Clinical/Safety Strategy	Non-Self Administered Drug (NSA)	N/A
ASTHMA AND COPD	NUCALA	MEPOLIZUMAB	100 MG/ML	SYRINGE	SUBCUTANE.	SSB	F	S=F	F	S=F	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Clinical/Safety Strategy		N/A
ASTHMA AND COPD	NUCALA	MEPOLIZUMAB	100 MG/ML	AUTO INJCT	SUBCUTANE.	SSB	F	S=F	F	S=F	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Clinical/Safety Strategy		N/A
ASTHMA AND COPD	CINQAIR	RESLIZUMAB	10 MG/ML	VIAL	INTRAVEN.	SSB	NF	S=NF	NF	S=NF	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Clinical/Safety Strategy	Non-Self Administered Drug (NSA)	N/A
ASTHMA AND COPD	DUPIXENT	DUPILUMAB	300 MG/2ML	SYRINGE	SUBCUTANE.	SSB	F	S=F	F	S=F	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Clinical/Safety Strategy		N/A
BEHAVIORAL HEALTH - OTHER	MYDAYIS	DEXTROAMPHETAMINE/AMPHETAMINE	12.5 MG	CPTP 24HR	ORAL	SSB	NF	C=F	E	C=F	QL	S=QL	QL ST	D=ST S=QL	QL ST	D=ST S=QL	E	D=E A=QL	E	D=E A=QL	E	D=E A=QL	Trade Relations Strategy		QL: LIMITED TO 1 CAPSULE PER DAY
BEHAVIORAL HEALTH - OTHER	MYDAYIS	DEXTROAMPHETAMINE/AMPHETAMINE	25 MG	CPTP 24HR	ORAL	SSB	NF	C=F	E	C=F	QL	S=QL	QL ST	D=ST S=QL	QL ST	D=ST S=QL	E	D=E A=QL	E	D=E A=QL	E	D=E A=QL	Trade Relations Strategy		QL: LIMITED TO 1 CAPSULE PER DAY
BEHAVIORAL HEALTH - OTHER	MYDAYIS	DEXTROAMPHETAMINE/AMPHETAMINE	37.5 MG	CPTP 24HR	ORAL	SSB	NF	C=F	E	C=F	QL	S=QL	QL ST	D=ST S=QL	QL ST	D=ST S=QL	E	D=E A=QL	E	D=E A=QL	E	D=E A=QL	Trade Relations Strategy		QL: LIMITED TO 1 CAPSULE PER DAY
BEHAVIORAL HEALTH - OTHER	MYDAYIS	DEXTROAMPHETAMINE/AMPHETAMINE	50 MG	CPTP 24HR	ORAL	SSB	NF	C=F	E	C=F	QL	S=QL	QL ST	D=ST S=QL	QL ST	D=ST S=QL	E	D=E A=QL	E	D=E A=QL	E	D=E A=QL	Trade Relations Strategy		QL: LIMITED TO 1 CAPSULE PER DAY
BEHAVIORAL HEALTH - OTHER	EMSAM	SELEGILINE	12MG/24HR	PATCH TD24	TRANSDERM.	SSB	NF	S=NF	NF	S=NF	QL	S=QL	QL	S=QL	QL	A=ST S=QL	QL	S=QL	QL	S=QL	QL	A=ST S=QL	Low Net Cost Strategy		ST: TRIAL OF PHENELZINE, TRANYLCYPROMINE, OR MARPLAN IN THE PREVIOUS 120 DAYS
BEHAVIORAL HEALTH - OTHER	EMSAM	SELEGILINE	6 MG/24 HR	PATCH TD24	TRANSDERM.	SSB	NF	S=NF	NF	S=NF	QL	S=QL	QL	S=QL	QL	A=ST S=QL	QL	S=QL	QL	S=QL	QL	A=ST S=QL	Low Net Cost Strategy		ST: TRIAL OF PHENELZINE, TRANYLCYPROMINE, OR MARPLAN IN THE PREVIOUS 120 DAYS
BEHAVIORAL HEALTH - OTHER	EMSAM	SELEGILINE	9 MG/24 HR	PATCH TD24	TRANSDERM.	SSB	NF	S=NF	NF	S=NF	QL	S=QL	QL	S=QL	QL	A=ST S=QL	QL	S=QL	QL	S=QL	QL	A=ST S=QL	Low Net Cost Strategy		ST: TRIAL OF PHENELZINE, TRANYLCYPROMINE, OR MARPLAN IN THE PREVIOUS 120 DAYS
CARDIOVASCULAR DISEASE - LIPID IRREGULARITY	NEXLETOL	BEMPEDOIC ACID	180 MG	TABLET	ORAL	SSB	NF	S=NF	NF	S=NF	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Clinical/Safety Strategy		N/A
CARDIOVASCULAR DISEASE - LIPID IRREGULARITY	JUXTAPID	LOMITAPIDE MESYLATE	10 MG	CAPSULE	ORAL	SSB	F	S=F	F	S=F	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Clinical/Safety Strategy		N/A
CARDIOVASCULAR DISEASE - LIPID IRREGULARITY	JUXTAPID	LOMITAPIDE MESYLATE	20 MG	CAPSULE	ORAL	SSB	F	S=F	F	S=F	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Clinical/Safety Strategy		N/A
CARDIOVASCULAR DISEASE - LIPID IRREGULARITY	JUXTAPID	LOMITAPIDE MESYLATE	30 MG	CAPSULE	ORAL	SSB	F	S=F	F	S=F	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Clinical/Safety Strategy		N/A
CARDIOVASCULAR DISEASE - LIPID IRREGULARITY	JUXTAPID	LOMITAPIDE MESYLATE	40 MG	CAPSULE	ORAL	SSB	F	S=F	F	S=F	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Clinical/Safety Strategy		N/A
CARDIOVASCULAR DISEASE - LIPID IRREGULARITY	JUXTAPID	LOMITAPIDE MESYLATE	5 MG	CAPSULE	ORAL	SSB	F	S=F	F	S=F	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Clinical/Safety Strategy		N/A
CARDIOVASCULAR DISEASE - LIPID IRREGULARITY	JUXTAPID	LOMITAPIDE MESYLATE	60 MG	CAPSULE	ORAL	SSB	F	S=F	F	S=F	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Clinical/Safety Strategy		N/A
CARDIOVASCULAR DISEASE - LIPID IRREGULARITY	NIACIN ER	NIACIN	1000 MG	TAB ER 24H	ORAL	GENERIC	F	S=F	F	S=F	ST	D=ST	ST	D=ST	ST	D=ST	ST	D=ST	ST	D=ST	ST	D=ST	Low Net Cost Strategy		N/A

2Q20 Formulary Actions

Drug							Formulary Status				Utilization Management													
							Portfolio/9803		MedPerform		Portfolio Low		Portfolio Medium		Portfolio High		MedPerform Low		MedPerform Medium		MedPerform High			
Category	Brand Name	Generic Name	Strength	Dosage Form	Route	Brand Status	Current Status	Action	Current Status	Action	Current Status	Action	Current Status	Action	Current Status	Action	Current Status	Action	Current Status	Action	Current Status	Action	Rationale of Changes	Optional Benefit Exclusion	Client Communication - Commercial/HIEX
CARDIOVASCULAR DISEASE - LIPID IRREGULARITY	NIACIN ER	NIACIN	500 MG	TAB ER 24H	ORAL	GENERIC	F	S=F	F	S=F	ST	D=ST	ST	D=ST	ST	D=ST	ST	D=ST	ST	D=ST	ST	D=ST	Low Net Cost Strategy		N/A
CARDIOVASCULAR DISEASE - LIPID IRREGULARITY	NIACIN ER	NIACIN	750 MG	TAB ER 24H	ORAL	GENERIC	F	S=F	F	S=F	ST	D=ST	ST	D=ST	ST	D=ST	ST	D=ST	ST	D=ST	ST	D=ST	Low Net Cost Strategy		N/A
CARDIOVASCULAR DISEASE - LIPID IRREGULARITY	PRALUENT PEN	ALIROCUMAB	150 MG/ML	PEN INJCTR	SUBCUTANE.	SSB	F	S=F	F	S=F	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Clinical/Safety Strategy		N/A
CARDIOVASCULAR DISEASE - LIPID IRREGULARITY	PRALUENT PEN	ALIROCUMAB	75 MG/ML	PEN INJCTR	SUBCUTANE.	SSB	F	S=F	F	S=F	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Clinical/Safety Strategy		N/A
CARDIOVASCULAR DISEASE - LIPID IRREGULARITY	REPATHA SURECLICK	EVOLOCUMAB	140 MG/ML	PEN INJCTR	SUBCUTANE.	SSB	F	S=F	F	S=F	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Clinical/Safety Strategy		N/A
CARDIOVASCULAR DISEASE - LIPID IRREGULARITY	REPATHA SYRINGE	EVOLOCUMAB	140 MG/ML	SYRINGE	SUBCUTANE.	SSB	F	S=F	F	S=F	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Clinical/Safety Strategy		N/A
CARDIOVASCULAR DISEASE - LIPID IRREGULARITY	REPATHA PUSHTRONEX	EVOLOCUMAB	420 MG/3.5	WEAR INJCT	SUBCUTANE.	SSB	F	S=F	F	S=F	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Clinical/Safety Strategy		N/A
DERMATOLOGY - ACNE	ARAZLO	TAZAROTENE	0.045 %	LOTION	TOPICAL	SSB	NF	S=NF	E	S=E	AGE	S=AGE	AGE	S=AGE	AGE	A=ST S=AGE	E	S=E	E	S=E	E	S=E	Low Net Cost Strategy		ST: TRIAL OF 1 OF THE FOLLOWING GENERIC TOPICALS: TAZAROTENE, TRETINOIN, OR ADAPALENE (GEL, CREAM, LOTION, OR SOLUTION) REQUIRED IN THE PAST 120 DAYS
DERMATOLOGY - ANTIINFECTIVE	KETOCONAZOLE	KETOCONAZOLE	2 %	FOAM	TOPICAL	GENERIC	NF	S=NF	E	S=E	NONE	NONE	NONE	NONE	NONE	A=ST	E	S=E	E	S=E	E	S=E	Low Net Cost Strategy		ST: TRIAL OF KETOCONAZOLE 2% CREAM OR SHAMPOO IN THE PREVIOUS 120 DAYS
DERMATOLOGY - ANTIINFECTIVE	XOLEGEL	KETOCONAZOLE	2 %	GEL (GRAM)	TOPICAL	SSB	NF	S=NF	E	S=E	NONE	NONE	NONE	NONE	NONE	A=ST	E	S=E	E	S=E	E	S=E	Low Net Cost Strategy		ST: TRIAL OF KETOCONAZOLE 2% CREAM OR SHAMPOO IN THE PREVIOUS 120 DAYS
DERMATOLOGY - ANTIINFLAMMATORY	PENNSAID	DICLOFENAC SODIUM	2.00%	SOLN PK(G)	TOPICAL	SSB	NF	S=NF	E	S=E	ST	C=ST	ST	C=ST	ST	C=ST	E	S=E	E	S=E	E	S=E			ST: TRIAL OF GENERIC DICLOFENAC GEL OR DROPS IN THE PREVIOUS 120 DAYS
DERMATOLOGY - ANTIINFLAMMATORY	PENNSAID	DICLOFENAC SODIUM	20MG/G(2%)	SOL MD PMP	TOPICAL	SSB	NF	S=NF	E	S=E	ST	C=ST	ST	C=ST	ST	C=ST	E	S=E	E	S=E	E	S=E	Low Net Cost Strategy		ST: TRIAL OF GENERIC DICLOFENAC GEL OR DROPS IN THE PREVIOUS 120 DAYS
DERMATOLOGY - MISCELLANEOUS	TARGRETIN	BEXAROTENE	1 %	GEL (GRAM)	TOPICAL	SSB	F	S=F	F	S=F	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Clinical/Safety Strategy		N/A
DERMATOLOGY - MISCELLANEOUS	LIDOCAINE	LIDOCAINE	5 %	OINT. (G)	TOPICAL	GENERIC	F	S=F	F	S=F	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	Low Net Cost Strategy		N/A
DERMATOLOGY - PSORIASIS/ECZEMA	TALTZ AUTOINJECTOR	IXEKIZUMAB	80 MG/ML	AUTO INJCT	SUBCUTANE.	SSB	NF	S=NF	E	S=E	PA	C=PA	PA	C=PA	PA	C=PA	E	S=E	E	S=E	E	S=E	Clinical/Safety Strategy		N/A
DERMATOLOGY - PSORIASIS/ECZEMA	TALTZ SYRINGE	IXEKIZUMAB	80 MG/ML	SYRINGE	SUBCUTANE.	SSB	NF	S=NF	E	S=E	PA	C=PA	PA	C=PA	PA	C=PA	E	S=E	E	S=E	E	S=E	Clinical/Safety Strategy		N/A
DERMATOLOGY - PSORIASIS/ECZEMA	COSENTYX PEN (2 PENS)	SECUKINUMAB	150 MG/ML	PEN INJCTR	SUBCUTANE.	SSB	F	S=F	F	S=F	PA,QL	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Clinical/Safety Strategy		N/A
DERMATOLOGY - PSORIASIS/ECZEMA	COSENTYX SYRINGE	SECUKINUMAB	150 MG/ML	SYRINGE	SUBCUTANE.	SSB	F	S=F	F	S=F	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Clinical/Safety Strategy		N/A
DIABETES	RIOMET ER	METFORMIN HCL	500 MG/5ML	SUS ER REC	ORAL	SSB	NF	S=NF	NF	S=NF	PA	D=PA	PA	D=PA A=ST	PA	D=PA A=ST	PA	D=PA	PA	D=PA A=ST	PA	D=PA A=ST	Low Net Cost Strategy		ST: TRIAL OF METFORMIN IR TABLETS/SOLUTION OR ER TABLETS IN THE PREVIOUS 120 DAYS
DIABETES	EVERSENSE SMART TRANSMITTER	BLOOD-GLUCOSE TRANSMITTER	N/A	EACH	MISCELL.	NON DRUG	NF	S=NF	NF	S=NF	NONE	A=PA	NONE	A=PA	NONE	A=PA	NONE	A=PA	NONE	A=PA	NONE	A=PA	Trade Relations Strategy		NOTE: CURRENT MEMBERS WILL BE PERPETUALLY GRANDFATHERED.

2Q20 Formulary Actions

Drug							Formulary Status				Utilization Management													
							Portfolio/9803		MedPerform		Portfolio Low		Portfolio Medium		Portfolio High		MedPerform Low		MedPerform Medium		MedPerform High			
Category	Brand Name	Generic Name	Strength	Dosage Form	Route	Brand Status	Current Status	Action	Current Status	Action	Current Status	Action	Current Status	Action	Current Status	Action	Current Status	Action	Current Status	Action	Current Status	Action	Rationale of Changes	Optional Benefit Exclusion	Client Communication - Commercial/HIEX
DIABETES	TANZEUM	ALBIGLUTIDE	30MG/0.5ML	PEN INJCTR	SUBCUTANE.	SSB	NF	S=NF	E	S=E	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	E	S=E	E	S=E	E	S=E	Trade Relations Strategy		ST: TRIAL OF VICTOZA, OZEMPIC, RYBELSUS, BYETTA, BYDUREON, BYDUREON BCISE OR TRULICITY IN THE PREVIOUS 120 DAYS
DIABETES	TANZEUM	ALBIGLUTIDE	50MG/0.5ML	PEN INJCTR	SUBCUTANE.	SSB	NF	S=NF	E	S=E	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	E	S=E	E	S=E	E	S=E	Trade Relations Strategy		ST: TRIAL OF VICTOZA, OZEMPIC, RYBELSUS, BYETTA, BYDUREON, BYDUREON BCISE OR TRULICITY IN THE PREVIOUS 120 DAYS
DIABETES	TRULICITY	DULAGLUTIDE	0.75MG/0.5	PEN INJCTR	SUBCUTANE.	SSB	F	S=F	F	S=F	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	TRULICITY	DULAGLUTIDE	1.5 MG/0.5	PEN INJCTR	SUBCUTANE.	SSB	F	S=F	F	S=F	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	BYETTA	EXENATIDE	10MCG/0.04	PEN INJCTR	SUBCUTANE.	SSB	F	S=F	F	S=F	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	BYETTA	EXENATIDE	5MCG/0.02	PEN INJCTR	SUBCUTANE.	SSB	F	S=F	F	S=F	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	BYDUREON	EXENATIDE MICROSPHERES	2 MG	VIAL	SUBCUTANE.	SSB	F	S=F	F	S=F	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	BYDUREON PEN	EXENATIDE MICROSPHERES	2MG/0.65ML	PEN INJCTR	SUBCUTANE.	SSB	F	S=F	F	S=F	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	BYDUREON BCISE	EXENATIDE MICROSPHERES	2MG/0.85ML	AUTO INJCT	SUBCUTANE.	SSB	F	S=F	F	S=F	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	VICTOZA 3-PAK	LIRAGLUTIDE	0.6 MG/0.1	PEN INJCTR	SUBCUTANE.	SSB	F	S=F	F	S=F	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	ADLYXIN	LIXISENATIDE	10-20 (1)	PEN INJCTR	SUBCUTANE.	SSB	NF	S=NF	E	S=E	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	E	S=E	E	S=E	E	S=E	Trade Relations Strategy		ST: TRIAL OF VICTOZA, OZEMPIC, RYBELSUS, BYETTA, BYDUREON, BYDUREON BCISE OR TRULICITY IN THE PREVIOUS 120 DAYS
DIABETES	ADLYXIN	LIXISENATIDE	20 MCG/0.2	PEN INJCTR	SUBCUTANE.	SSB	NF	S=NF	E	S=E	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	E	S=E	E	S=E	E	S=E	Trade Relations Strategy		ST: TRIAL OF VICTOZA, OZEMPIC, RYBELSUS, BYETTA, BYDUREON, BYDUREON BCISE OR TRULICITY IN THE PREVIOUS 120 DAYS
DIABETES	OZEMPIC	SEMAGLUTIDE	0.25 OR .5	PEN INJCTR	SUBCUTANE.	SSB	F	S=F	F	S=F	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	RYBELSUS	SEMAGLUTIDE	14 MG	TABLET	ORAL	SSB	F	S=F	F	S=F	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	OZEMPIC	SEMAGLUTIDE	1MG/0.75ML	PEN INJCTR	SUBCUTANE.	SSB	F	S=F	F	S=F	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	RYBELSUS	SEMAGLUTIDE	3 MG	TABLET	ORAL	SSB	F	S=F	F	S=F	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	RYBELSUS	SEMAGLUTIDE	7 MG	TABLET	ORAL	SSB	F	S=F	F	S=F	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	XULTOPHY 100-3.6	INSULIN DEGLUDEC/LIRAGLUTIDE	100-3.6/ML	INSULN PEN	SUBCUTANE.	SSB	F	S=F	F	S=F	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF ONE OF THE FOLLOWING: LANTUS, TOUJEO, LEVEMIR, TRESIBA, VICTOZA, OZEMPIC, RYBELSUS, BYETTA, BYDUREON, BYDUREON BCISE OR TRULICITY IN THE PREVIOUS 120 DAYS
DIABETES	SOLIQUA 100-33	INSULIN GLARGINE/LIXISENATIDE	100-33/ML	INSULN PEN	SUBCUTANE.	SSB	F	S=F	F	S=F	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF ONE OF THE FOLLOWING: LANTUS, TOUJEO, LEVEMIR, TRESIBA, VICTOZA, OZEMPIC, RYBELSUS, BYETTA, BYDUREON, BYDUREON BCISE OR TRULICITY IN THE PREVIOUS 120 DAYS
DIABETES	INVOKANA	CANAGLIFLOZIN	100 MG	TABLET	ORAL	SSB	NF	S=NF	E	S=E	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	E	S=E	E	S=E	E	S=E	Trade Relations Strategy		ST: TRIAL OF JARDIANCE, SYNJARDY, SYNJARDY XR, FARXIGA, OR XIGDUO XR IN THE PREVIOUS 120 DAYS.
DIABETES	INVOKANA	CANAGLIFLOZIN	300 MG	TABLET	ORAL	SSB	NF	S=NF	E	S=E	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	E	S=E	E	S=E	E	S=E	Trade Relations Strategy		ST: TRIAL OF JARDIANCE, SYNJARDY, SYNJARDY XR, FARXIGA, OR XIGDUO XR IN THE PREVIOUS 120 DAYS.
DIABETES	INVOKAMET	CANAGLIFLOZIN/METFORMIN HCL	150-1000MG	TABLET	ORAL	SSB	NF	S=NF	E	S=E	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	E	S=E	E	S=E	E	S=E	Trade Relations Strategy		ST: TRIAL OF JARDIANCE, SYNJARDY, SYNJARDY XR, FARXIGA, OR XIGDUO XR IN THE PREVIOUS 120 DAYS.
DIABETES	INVOKAMET XR	CANAGLIFLOZIN/METFORMIN HCL	150-1000MG	TAB BP 24H	ORAL	SSB	NF	S=NF	E	S=E	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	E	S=E	E	S=E	E	S=E	Trade Relations Strategy		ST: TRIAL OF JARDIANCE, SYNJARDY, SYNJARDY XR, FARXIGA, OR XIGDUO XR IN THE PREVIOUS 120 DAYS.
DIABETES	INVOKAMET	CANAGLIFLOZIN/METFORMIN HCL	150-500 MG	TABLET	ORAL	SSB	NF	S=NF	E	S=E	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	E	S=E	E	S=E	E	S=E	Trade Relations Strategy		ST: TRIAL OF JARDIANCE, SYNJARDY, SYNJARDY XR, FARXIGA, OR XIGDUO XR IN THE PREVIOUS 120 DAYS.
DIABETES	INVOKAMET XR	CANAGLIFLOZIN/METFORMIN HCL	150-500 MG	TAB BP 24H	ORAL	SSB	NF	S=NF	E	S=E	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	E	S=E	E	S=E	E	S=E	Trade Relations Strategy		ST: TRIAL OF JARDIANCE, SYNJARDY, SYNJARDY XR, FARXIGA, OR XIGDUO XR IN THE PREVIOUS 120 DAYS.
DIABETES	INVOKAMET	CANAGLIFLOZIN/METFORMIN HCL	50-1000 MG	TABLET	ORAL	SSB	NF	S=NF	E	S=E	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	E	S=E	E	S=E	E	S=E	Trade Relations Strategy		ST: TRIAL OF JARDIANCE, SYNJARDY, SYNJARDY XR, FARXIGA, OR XIGDUO XR IN THE PREVIOUS 120 DAYS.
DIABETES	INVOKAMET XR	CANAGLIFLOZIN/METFORMIN HCL	50-1000 MG	TAB BP 24H	ORAL	SSB	NF	S=NF	E	S=E	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	E	S=E	E	S=E	E	S=E	Trade Relations Strategy		ST: TRIAL OF JARDIANCE, SYNJARDY, SYNJARDY XR, FARXIGA, OR XIGDUO XR IN THE PREVIOUS 120 DAYS.
DIABETES	INVOKAMET	CANAGLIFLOZIN/METFORMIN HCL	50MG-500MG	TABLET	ORAL	SSB	NF	S=NF	E	S=E	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	E	S=E	E	S=E	E	S=E	Trade Relations Strategy		ST: TRIAL OF JARDIANCE, SYNJARDY, SYNJARDY XR, FARXIGA, OR XIGDUO XR IN THE PREVIOUS 120 DAYS.
DIABETES	INVOKAMET XR	CANAGLIFLOZIN/METFORMIN HCL	50MG-500MG	TAB BP 24H	ORAL	SSB	NF	S=NF	E	S=E	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	E	S=E	E	S=E	E	S=E	Trade Relations Strategy		ST: TRIAL OF JARDIANCE, SYNJARDY, SYNJARDY XR, FARXIGA, OR XIGDUO XR IN THE PREVIOUS 120 DAYS.
DIABETES	FARXIGA	DAPAGLIFLOZIN PROPANEDIOL	10 MG	TABLET	ORAL	SSB	F	S=F	F	S=F	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	FARXIGA	DAPAGLIFLOZIN PROPANEDIOL	5 MG	TABLET	ORAL	SSB	F	S=F	F	S=F	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	XIGDUO XR	DAPAGLIFLOZIN/METFORMIN HCL	10-1000 MG	TAB BP 24H	ORAL	SSB	F	S=F	F	S=F	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	XIGDUO XR	DAPAGLIFLOZIN/METFORMIN HCL	10MG-500MG	TAB BP 24H	ORAL	SSB	F	S=F	F	S=F	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	XIGDUO XR	DAPAGLIFLOZIN/METFORMIN HCL	2.5-1000MG	TAB BP 24H	ORAL	SSB	F	S=F	F	S=F	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	XIGDUO XR	DAPAGLIFLOZIN/METFORMIN HCL	5 MG-500MG	TAB BP 24H	ORAL	SSB	F	S=F	F	S=F	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A

2Q20 Formulary Actions

Drug							Formulary Status				Utilization Management													
							Portfolio/9803		MedPerform		Portfolio Low		Portfolio Medium		Portfolio High		MedPerform Low		MedPerform Medium		MedPerform High			
Category	Brand Name	Generic Name	Strength	Dosage Form	Route	Brand Status	Current Status	Action	Current Status	Action	Current Status	Action	Current Status	Action	Current Status	Action	Current Status	Action	Current Status	Action	Current Status	Action	Rationale of Changes	Optional Benefit Exclusion	Client Communication - Commercial/HIEX
DIABETES	XIGDUO XR	DAPAGLIFLOZIN/METFORMIN HCL	5MG-1000MG	TAB BP 24H	ORAL	SSB	F	S=F	F	S=F	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	QTERN	DAPAGLIFLOZIN/SAXAGLIPTIN HCL	10 MG-5 MG	TABLET	ORAL	SSB	NF	S=NF	E	S=E	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF JANUVIA, JANUMET, JANUMET XR, FARXIGA, XIGDUO XR, JARDIANCE, SYNJARDY, OR SYNJARDY XR IN THE PAST 120 DAYS
DIABETES	QTERN	DAPAGLIFLOZIN/SAXAGLIPTIN HCL	5 MG-5 MG	TABLET	ORAL	SSB	NF	S=NF	E	S=E	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF JANUVIA, JANUMET, JANUMET XR, FARXIGA, XIGDUO XR, JARDIANCE, SYNJARDY, OR SYNJARDY XR IN THE PAST 120 DAYS
DIABETES	TRIJARDY XR	EMPAGLIFLOZ/LINAGLIP/METFORMIN	10-5-1000	TAB BP 24H	ORAL	SSB	NF	S=NF	E	S=E	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	E	S=E	E	S=E	E	S=E	Trade Relations Strategy		ST: TRIAL OF JANUVIA, JANUMET, JANUMET XR, FARXIGA, XIGDUO XR, JARDIANCE, SYNJARDY, OR SYNJARDY XR IN THE PAST 120 DAYS
DIABETES	TRIJARDY XR	EMPAGLIFLOZ/LINAGLIP/METFORMIN	12.5-2.5MG	TAB BP 24H	ORAL	SSB	NF	S=NF	E	S=E	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	E	S=E	E	S=E	E	S=E	Trade Relations Strategy		ST: TRIAL OF JANUVIA, JANUMET, JANUMET XR, FARXIGA, XIGDUO XR, JARDIANCE, SYNJARDY, OR SYNJARDY XR IN THE PAST 120 DAYS
DIABETES	TRIJARDY XR	EMPAGLIFLOZ/LINAGLIP/METFORMIN	25-5-1000	TAB BP 24H	ORAL	SSB	NF	S=NF	E	S=E	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	E	S=E	E	S=E	E	S=E	Trade Relations Strategy		ST: TRIAL OF JANUVIA, JANUMET, JANUMET XR, FARXIGA, XIGDUO XR, JARDIANCE, SYNJARDY, OR SYNJARDY XR IN THE PAST 120 DAYS
DIABETES	TRIJARDY XR	EMPAGLIFLOZ/LINAGLIP/METFORMIN	5-2.5-1000	TAB BP 24H	ORAL	SSB	NF	S=NF	E	S=E	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	E	S=E	E	S=E	E	S=E	Trade Relations Strategy		ST: TRIAL OF JANUVIA, JANUMET, JANUMET XR, FARXIGA, XIGDUO XR, JARDIANCE, SYNJARDY, OR SYNJARDY XR IN THE PAST 120 DAYS
DIABETES	JARDIANCE	EMPAGLIFLOZIN	10 MG	TABLET	ORAL	SSB	F	S=F	F	S=F	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	JARDIANCE	EMPAGLIFLOZIN	25 MG	TABLET	ORAL	SSB	F	S=F	F	S=F	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	GLYXAMBI	EMPAGLIFLOZIN/LINAGLIPTIN	10 MG-5 MG	TABLET	ORAL	SSB	F	C=NF	F	C=NF	QL	S=QL	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	QL	S=QL	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF JANUVIA, JANUMET, JANUMET XR, FARXIGA, XIGDUO XR, JARDIANCE, SYNJARDY, OR SYNJARDY XR IN THE PAST 120 DAYS NOTE: CURRENT MEMBERS WILL BE GRANDFATHERED UNTIL 1/1/2021.
DIABETES	GLYXAMBI	EMPAGLIFLOZIN/LINAGLIPTIN	25 MG-5 MG	TABLET	ORAL	SSB	F	C=NF	F	C=NF	QL	S=QL	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	QL	S=QL	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF JANUVIA, JANUMET, JANUMET XR, FARXIGA, XIGDUO XR, JARDIANCE, SYNJARDY, OR SYNJARDY XR IN THE PAST 120 DAYS NOTE: CURRENT MEMBERS WILL BE GRANDFATHERED UNTIL 1/1/2021.
DIABETES	SYNJARDY XR	EMPAGLIFLOZIN/METFORMIN HCL	10-1000 MG	TAB BP 24H	ORAL	SSB	F	S=F	F	S=F	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	SYNJARDY	EMPAGLIFLOZIN/METFORMIN HCL	12.5-1000	TABLET	ORAL	SSB	F	S=F	F	S=F	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	SYNJARDY XR	EMPAGLIFLOZIN/METFORMIN HCL	12.5-1000	TAB BP 24H	ORAL	SSB	F	S=F	F	S=F	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	SYNJARDY	EMPAGLIFLOZIN/METFORMIN HCL	12.5-500MG	TABLET	ORAL	SSB	F	S=F	F	S=F	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	SYNJARDY XR	EMPAGLIFLOZIN/METFORMIN HCL	25-1000 MG	TAB BP 24H	ORAL	SSB	F	S=F	F	S=F	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	SYNJARDY	EMPAGLIFLOZIN/METFORMIN HCL	5 MG-500MG	TABLET	ORAL	SSB	F	S=F	F	S=F	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	SYNJARDY	EMPAGLIFLOZIN/METFORMIN HCL	5MG-1000MG	TABLET	ORAL	SSB	F	S=F	F	S=F	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	SYNJARDY XR	EMPAGLIFLOZIN/METFORMIN HCL	5MG-1000MG	TAB BP 24H	ORAL	SSB	F	S=F	F	S=F	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	QL	S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	STEGLATRO	ERTUGLIFLOZIN PIDOLATE	15 MG	TABLET	ORAL	SSB	NF	S=NF	E	S=E	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	E	S=E	E	S=E	E	S=E	Trade Relations Strategy		ST: TRIAL OF JARDIANCE, SYNJARDY, SYNJARDY XR, FARXIGA, OR XIGDUO XR IN THE PREVIOUS 120 DAYS
DIABETES	STEGLATRO	ERTUGLIFLOZIN PIDOLATE	5 MG	TABLET	ORAL	SSB	NF	S=NF	E	S=E	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	E	S=E	E	S=E	E	S=E	Trade Relations Strategy		ST: TRIAL OF JARDIANCE, SYNJARDY, SYNJARDY XR, FARXIGA, OR XIGDUO XR IN THE PREVIOUS 120 DAYS
DIABETES	SEGLUROMET	ERTUGLIFLOZIN/METFORMIN	2.5-1000MG	TABLET	ORAL	SSB	NF	S=NF	E	S=E	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	E	S=E	E	S=E	E	S=E	Trade Relations Strategy		ST: TRIAL OF JARDIANCE, SYNJARDY, SYNJARDY XR, FARXIGA, OR XIGDUO XR IN THE PREVIOUS 120 DAYS.
DIABETES	SEGLUROMET	ERTUGLIFLOZIN/METFORMIN	2.5-500 MG	TABLET	ORAL	SSB	NF	S=NF	E	S=E	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	E	S=E	E	S=E	E	S=E	Trade Relations Strategy		ST: TRIAL OF JARDIANCE, SYNJARDY, SYNJARDY XR, FARXIGA, OR XIGDUO XR IN THE PREVIOUS 120 DAYS.
DIABETES	SEGLUROMET	ERTUGLIFLOZIN/METFORMIN	7.5-1000MG	TABLET	ORAL	SSB	NF	S=NF	E	S=E	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	E	S=E	E	S=E	E	S=E	Trade Relations Strategy		ST: TRIAL OF JARDIANCE, SYNJARDY, SYNJARDY XR, FARXIGA, OR XIGDUO XR IN THE PREVIOUS 120 DAYS.
DIABETES	SEGLUROMET	ERTUGLIFLOZIN/METFORMIN	7.5-500 MG	TABLET	ORAL	SSB	NF	S=NF	E	S=E	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	E	S=E	E	S=E	E	S=E	Trade Relations Strategy		ST: TRIAL OF JARDIANCE, SYNJARDY, SYNJARDY XR, FARXIGA, OR XIGDUO XR IN THE PREVIOUS 120 DAYS.
DIABETES	STEGLUJAN	ERTUGLIFLOZIN/SITAGLIPTIN	15MG-100MG	TABLET	ORAL	SSB	NF	S=NF	E	S=E	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF JANUVIA, JANUMET, JANUMET XR, FARXIGA, XIGDUO XR, JARDIANCE, SYNJARDY, OR SYNJARDY XR IN THE PAST 120 DAYS
DIABETES	STEGLUJAN	ERTUGLIFLOZIN/SITAGLIPTIN	5 MG-100MG	TABLET	ORAL	SSB	NF	S=NF	E	S=E	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF JANUVIA, JANUMET, JANUMET XR, FARXIGA, XIGDUO XR, JARDIANCE, SYNJARDY, OR SYNJARDY XR IN THE PAST 120 DAYS
ENDOCRINE DISORDER - FERTILITY	TADALAFIL	TADALAFIL	10 MG	TABLET	ORAL	GENERIC	F	S=F	F	S=F	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	Low Net Cost Strategy		N/A
ENDOCRINE DISORDER - FERTILITY	TADALAFIL	TADALAFIL	20 MG	TABLET	ORAL	GENERIC	F	S=F	F	S=F	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	QL,ST	D=ST S=QL	Low Net Cost Strategy		N/A
ENDOCRINE DISORDER - OTHER	ACTHAR	CORTICOTROPIN	80 UNIT/ML	VIAL	INJECTION	SSB	NF	S=NF	NF	S=NF	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Clinical/Safety Strategy	Non-Self Administered Drug (NSA)	N/A

2Q20 Formulary Actions

Drug							Formulary Status				Utilization Management													
							Portfolio/9803		MedPerform		Portfolio Low		Portfolio Medium		Portfolio High		MedPerform Low		MedPerform Medium		MedPerform High			
Category	Brand Name	Generic Name	Strength	Dosage Form	Route	Brand Status	Current Status	Action	Current Status	Action	Current Status	Action	Current Status	Action	Current Status	Action	Current Status	Action	Current Status	Action	Current Status	Action	Rationale of Changes	Optional Benefit Exclusion	Client Communication - Commercial/HIEX
ENDOCRINE DISORDER - OTHER	INCRELEX	MECASERMIN	10 MG/ML	VIAL	SUBCUTANE.	SSB	NF	S=NF	NF	S=NF	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Clinical/Safety Strategy		N/A
HEMATOLOGICAL DISORDERS	REBLOZYL	LUSPATERCEPT-AAMT	25 MG	VIAL	SUBCUTANE.	SSB	NF	S=NF	NF	S=NF	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Clinical/Safety Strategy	Non-Self Administered Drug (NSA)	N/A
HEMATOLOGICAL DISORDERS	REBLOZYL	LUSPATERCEPT-AAMT	75 MG	VIAL	SUBCUTANE.	SSB	NF	S=NF	NF	S=NF	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Clinical/Safety Strategy	Non-Self Administered Drug (NSA)	N/A
INFECTIOUS DISEASE - VIRAL	HARVONI	LEDIPASVIR/SOFOSBUVIR	45MG-200MG	TABLET	ORAL	SSB	F	S=F	F	S=F	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Clinical/Safety Strategy		N/A
INFECTIOUS DISEASE - VIRAL	HARVONI	LEDIPASVIR/SOFOSBUVIR	90MG-400MG	TABLET	ORAL	GENERIC/MSB	F	S=F	F	S=F	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Clinical/Safety Strategy		N/A
INFECTIOUS DISEASE - VIRAL	EPCLUSA	SOFOSBUVIR/VELPATASVIR	400-100 MG	TABLET	ORAL	GENERIC/MSB	F	S=F	F	S=F	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Clinical/Safety Strategy		N/A
INFLAMMATORY DISEASE	HYALGAN	HYALURONATE SODIUM	10 MG/ML	VIAL	INTRAARTIC	SSB	NF	S=NF	NF	S=NF	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Clinical/Safety Strategy		N/A
INFLAMMATORY DISEASE	MULTIPLE BRAND NAMES	HYALURONATE SODIUM	10 MG/ML	SYRINGE	INTRAARTIC	SSB	NF	S=NF	NF	S=NF	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Clinical/Safety Strategy		N/A
INFLAMMATORY DISEASE	GELSYN-3	HYALURONATE SODIUM	16.8MG/2ML	SYRINGE	INTRAARTIC	SSB	NF	S=NF	NF	S=NF	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Clinical/Safety Strategy		N/A
INFLAMMATORY DISEASE	ORTHOVISC	HYALURONATE SODIUM	30 MG/2 ML	SYRINGE	INTRAARTIC	SSB	NF	S=NF	NF	S=NF	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Clinical/Safety Strategy		N/A
INFLAMMATORY DISEASE	DUROLANE	HYALURONATE SODIUM, STABILIZED	60 MG/3 ML	SYRINGE	INTRAARTIC	SSB	NF	S=NF	NF	S=NF	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Clinical/Safety Strategy		N/A
INFLAMMATORY DISEASE	MONOVISC	HYALURONATE SODIUM, STABILIZED	88 MG/4 ML	SYRINGE	INTRAARTIC	SSB	NF	S=NF	NF	S=NF	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Clinical/Safety Strategy		N/A
INFLAMMATORY DISEASE	HYMOVIS	HYALURONATE,MOD.,NON-CROSSLINK	24 MG/3 ML	SYRINGE	INTRAARTIC	SSB	NF	S=NF	NF	S=NF	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Clinical/Safety Strategy		N/A
INFLAMMATORY DISEASE	SYNVISC	HYLAN G-F 20	16MG/2ML	SYRINGE	INTRAARTIC	SSB	NF	S=NF	NF	S=NF	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Clinical/Safety Strategy		N/A
INFLAMMATORY DISEASE	SYNVISC-ONE	HYLAN G-F 20	48 MG/6 ML	SYRINGE	INTRAARTIC	SSB	NF	S=NF	NF	S=NF	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Clinical/Safety Strategy		N/A
LOWER GASTROINTESTINAL DISORDERS - OTHER	GATTEX	TEDUGLUTIDE	5 MG	KIT	SUBCUTANE.	SSB	F	S=F	F	S=F	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Clinical/Safety Strategy		N/A
MISCELLANEOUS AGENTS	SPINRAZA	NUSINERSEN SODIUM/PF	12MG/5ML	VIAL	INTRATHEC.	SSB	NF	S=NF	NF	S=NF	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Clinical/Safety Strategy	Non-Self Administered Drug (NSA)	N/A
NEOPLASTIC DISEASE	BELEODAQ	BELINOSTAT	500 MG	VIAL	INTRAVEN.	SSB	NF	S=NF	NF	S=NF	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Clinical/Safety Strategy	Non-Self Administered Drug (NSA)	N/A
NEOPLASTIC DISEASE	AVASTIN	BEVACIZUMAB	25 MG/ML	VIAL	INTRAVEN.	SSB	NF	S=NF	NF	S=NF	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Trade Relations Strategy	Non-Self Administered Drug (NSA)	N/A
NEOPLASTIC DISEASE	MVASI	BEVACIZUMAB-AWWB	25 MG/ML	VIAL	INTRAVEN.	SSB	NF	C=F	NF	C=F	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Trade Relations Strategy	Non-Self Administered Drug (NSA)	N/A
NEOPLASTIC DISEASE	ZIRABEV	BEVACIZUMAB-BVZR	25 MG/ML	VIAL	INTRAVEN.	SSB	NF	C=F	NF	C=F	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Trade Relations Strategy	Non-Self Administered Drug (NSA)	N/A
NEOPLASTIC DISEASE	BEXAROTENE	BEXAROTENE	75 MG	CAPSULE	ORAL	GENERIC	F	S=F	F	S=F	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Clinical/Safety Strategy		N/A
NEOPLASTIC DISEASE	CAPECITABINE	CAPECITABINE	150 MG	TABLET	ORAL	GENERIC	F	S=F	F	S=F	PA,QL	D=QL C=PA	PA,QL	D=QL C=PA	PA,QL	D=QL C=PA	PA,QL	D=QL C=PA	PA,QL	D=QL C=PA	PA,QL	D=QL C=PA	Clinical/Safety Strategy		N/A
NEOPLASTIC DISEASE	CAPECITABINE	CAPECITABINE	500 MG	TABLET	ORAL	GENERIC	F	S=F	F	S=F	PA,QL	D=QL C=PA	PA,QL	D=QL C=PA	PA,QL	D=QL C=PA	PA,QL	D=QL C=PA	PA,QL	D=QL C=PA	PA,QL	D=QL C=PA	Clinical/Safety Strategy		N/A
NEOPLASTIC DISEASE	IMFINZI	DURVALUMAB	120 MG/2.4	VIAL	INTRAVEN.	SSB	NF	S=NF	NF	S=NF	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Clinical/Safety Strategy	Non-Self Administered Drug (NSA)	N/A
NEOPLASTIC DISEASE	IMFINZI	DURVALUMAB	500MG/10ML	VIAL	INTRAVEN.	SSB	NF	S=NF	NF	S=NF	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Clinical/Safety Strategy	Non-Self Administered Drug (NSA)	N/A
NEOPLASTIC DISEASE	BRAFTOVI	ENCORAFENIB	50 MG	CAPSULE	ORAL	SSB	F	S=F	F	S=F	PA,QL	D=QL C=PA	PA,QL	D=QL C=PA	PA,QL	D=QL C=PA	PA,QL	D=QL C=PA	PA,QL	D=QL C=PA	PA,QL	D=QL C=PA	Clinical/Safety Strategy		N/A
NEOPLASTIC DISEASE	BRAFTOVI	ENCORAFENIB	75 MG	CAPSULE	ORAL	SSB	F	S=F	F	S=F	PA,QL	D=QL C=PA	PA,QL	D=QL C=PA	PA,QL	D=QL C=PA	PA,QL	D=QL C=PA	PA,QL	D=QL C=PA	PA,QL	D=QL C=PA	Clinical/Safety Strategy		N/A
NEOPLASTIC DISEASE	YERVOY	IPILIMUMAB	50 MG/10ML	VIAL	INTRAVEN.	SSB	NF	S=NF	NF	S=NF	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Clinical/Safety Strategy	Non-Self Administered Drug (NSA)	N/A

2Q20 Formulary Actions

Drug							Formulary Status				Utilization Management													
							Portfolio/9803		MedPerform		Portfolio Low		Portfolio Medium		Portfolio High		MedPerform Low		MedPerform Medium		MedPerform High			
Category	Brand Name	Generic Name	Strength	Dosage Form	Route	Brand Status	Current Status	Action	Current Status	Action	Current Status	Action	Current Status	Action	Current Status	Action	Current Status	Action	Current Status	Action	Current Status	Action	Rationale of Changes	Optional Benefit Exclusion	Client Communication - Commercial/HIEX
NEOPLASTIC DISEASE	NERLYNX	NERATINIB MALEATE	40 MG	TABLET	ORAL	SSB	NF	S=NF	NF	S=NF	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Clinical/Safety Strategy		N/A
NEOPLASTIC DISEASE	HERCEPTIN	TRASTUZUMAB	150 MG	VIAL	INTRAVEN.	SSB	NF	S=NF	NF	S=NF	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Trade Relations Strategy	Non-Self Administered Drug (NSA)	N/A
NEOPLASTIC DISEASE	HERCEPTIN	TRASTUZUMAB	440 MG	VIAL	INTRAVEN.	SSB	NF	S=NF	NF	S=NF	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Trade Relations Strategy	Non-Self Administered Drug (NSA)	N/A
NEOPLASTIC DISEASE	KANJINTI	TRASTUZUMAB-ANNS	150 MG	VIAL	INTRAVEN.	SSB	NF	C=F	NF	C=F	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Trade Relations Strategy	Non-Self Administered Drug (NSA)	N/A
NEOPLASTIC DISEASE	KANJINTI	TRASTUZUMAB-ANNS	420 MG	VIAL	INTRAVEN.	SSB	NF	C=F	NF	C=F	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Trade Relations Strategy	Non-Self Administered Drug (NSA)	N/A
NEOPLASTIC DISEASE	OGIVRI	TRASTUZUMAB-DKST	150 MG	VIAL	INTRAVEN.	SSB	NF	C=F	NF	C=F	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Trade Relations Strategy	Non-Self Administered Drug (NSA)	N/A
NEOPLASTIC DISEASE	OGIVRI	TRASTUZUMAB-DKST	420 MG	VIAL	INTRAVEN.	SSB	NF	C=F	NF	C=F	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Trade Relations Strategy	Non-Self Administered Drug (NSA)	N/A
NEOPLASTIC DISEASE	HERCEPTIN HYLECTA	TRASTUZUMAB-HYALURONIDASE-OYSK	600-10000	VIAL	SUBCUTANE.	SSB	NF	S=NF	NF	S=NF	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Trade Relations Strategy	Non-Self Administered Drug (NSA)	N/A
NEOPLASTIC DISEASE	TRAZIMERA	TRASTUZUMAB-QYYP	420 MG	VIAL	INTRAVEN.	SSB	NF	C=F	NF	C=F	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Trade Relations Strategy	Non-Self Administered Drug (NSA)	N/A
NEOPLASTIC DISEASE	MARQIBO	VINCRISTINE SULFATE LIPOSOMAL	FNL 5MG/31	KIT	INTRAVEN.	SSB	NF	S=NF	NF	S=NF	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Clinical/Safety Strategy	Non-Self Administered Drug (NSA)	N/A
OTHER DRUGS	MEPSEVII	VESTRONIDASE ALFA-VJBK	10 MG/5 ML	VIAL	INTRAVEN.	SSB	NF	S=NF	NF	S=NF	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Clinical/Safety Strategy	Non-Self Administered Drug (NSA)	N/A
OTHER DRUGS	MOZOBIL	PLERIXAFOR	24MG/1.2ML	VIAL	SUBCUTANE.	SSB	NF	S=NF	NF	S=NF	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Clinical/Safety Strategy	Non-Self Administered Drug (NSA)	N/A
OTHER DRUGS	ZAVESCA	MIGLUSTAT	100 MG	CAPSULE	ORAL	MSB/ GENERIC	F	S=F	F	S=F	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Clinical/Safety Strategy		N/A
OTHER RESPIRATORY DISORDERS	OFEV	NINTEDANIB ESYLATE	100 MG	CAPSULE	ORAL	SSB	F	S=F	F	S=F	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Clinical/Safety Strategy		N/A
OTHER RESPIRATORY DISORDERS	OFEV	NINTEDANIB ESYLATE	150 MG	CAPSULE	ORAL	SSB	F	S=F	F	S=F	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Clinical/Safety Strategy		N/A
PAIN MANAGEMENT - ANALGESICS	NURTEC ODT	RIMEGEPANT SULFATE	75 MG	TAB RAPDIS	ORAL	SSB	NF	S=NF	NF	S=NF	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	PA	C=PA	Clinical/Safety Strategy		N/A
PARKINSONS DISEASE	ZELAPAR	SELEGILINE HCL	1.25 MG	TAB RAPDIS	ORAL	SSB	NF	S=NF	NF	S=NF	QL	S=QL	QL	A=ST S=QL	QL	A=ST S=QL	QL	S=QL	QL	A=ST S=QL	QL	A=ST S=QL	Low Net Cost Strategy		ST: TRIAL OF GENERIC SELEGILINE CAPSULES OR TABLETS IN THE PREVIOUS 120 DAYS

2Q20 Formulary Actions

Drug							Formulary Status Marketplace (HIEX)		Utilization Management Marketplace (HIEX)				
Category	Brand Name	Generic Name	Strength	Dosage Form	Route	Brand Status	Current Status	Action	Current Status	Action	Rationale of Changes	Optional Benefit Exclusion	Client Communication - Commercial/HIEX
ALLERGY	AZELASTINE HCL	AZELASTINE HCL	205.5 MCG	SPRAY/PUMP	NASAL	GENERIC	1	S=1	QL,ST	D=ST S=QL	Low Net Cost Strategy		N/A
ALLERGY	OLOPATADINE HCL	OLOPATADINE HCL	0.6 %	SPRAY/PUMP	NASAL	GENERIC	1	S=1	QL,ST	D=ST S=QL	Low Net Cost Strategy		N/A
ASTHMA AND COPD	FASENRA	BENRALIZUMAB	30 MG/ML	SYRINGE	SUBCUTANE.	SSB	4	S=4	PA	C=PA	Clinical/Safety Strategy	Non-Self Administered Drug (NSA)	N/A
ASTHMA AND COPD	FASENRA PEN	BENRALIZUMAB	30 MG/ML	AUTO INJCT	SUBCUTANE.	SSB	4	S=4	PA	C=PA	Clinical/Safety Strategy		N/A
ASTHMA AND COPD	DUPIXENT	DUPILUMAB	200MG/1.14	SYRINGE	SUBCUTANE.	SSB	4	S=4	PA	C=PA	Clinical/Safety Strategy		N/A
ASTHMA AND COPD	NUCALA	MEPOLIZUMAB	100 MG	VIAL	SUBCUTANE.	SSB	4	S=4	PA	C=PA	Clinical/Safety Strategy	Non-Self Administered Drug (NSA)	N/A
ASTHMA AND COPD	NUCALA	MEPOLIZUMAB	100 MG/ML	SYRINGE	SUBCUTANE.	SSB	4	S=4	PA	C=PA	Clinical/Safety Strategy		N/A
ASTHMA AND COPD	NUCALA	MEPOLIZUMAB	100 MG/ML	AUTO INJCT	SUBCUTANE.	SSB	4	S=4	PA	C=PA	Clinical/Safety Strategy		N/A
ASTHMA AND COPD	CINQAIR	RESLIZUMAB	10 MG/ML	VIAL	INTRAVEN.	SSB	4	S=4	PA	C=PA	Clinical/Safety Strategy	Non-Self Administered Drug (NSA)	N/A
ASTHMA AND COPD	DUPIXENT	DUPILUMAB	300 MG/2ML	SYRINGE	SUBCUTANE.	SSB	4	S=4	PA	C=PA	Clinical/Safety Strategy		N/A
BEHAVIORAL HEALTH - OTHER	MYDAYIS	DEXTROAMPHETAMINE/AMPHETAMINE	12.5 MG	CPTP 24HR	ORAL	SSB	3	C=2	QL ST	D=ST S=QL	Trade Relations Strategy		N/A
BEHAVIORAL HEALTH - OTHER	MYDAYIS	DEXTROAMPHETAMINE/AMPHETAMINE	25 MG	CPTP 24HR	ORAL	SSB	3	C=2	QL ST	D=ST S=QL	Trade Relations Strategy		N/A
BEHAVIORAL HEALTH - OTHER	MYDAYIS	DEXTROAMPHETAMINE/AMPHETAMINE	37.5 MG	CPTP 24HR	ORAL	SSB	3	C=2	QL ST	D=ST S=QL	Trade Relations Strategy		N/A
BEHAVIORAL HEALTH - OTHER	MYDAYIS	DEXTROAMPHETAMINE/AMPHETAMINE	50 MG	CPTP 24HR	ORAL	SSB	3	C=2	QL ST	D=ST S=QL	Trade Relations Strategy		N/A
BEHAVIORAL HEALTH - OTHER	EMSAM	SELEGILINE	12MG/24HR	PATCH TD24	TRANSDERM.	SSB	3	S=3	QL	A=ST S=QL	Low Net Cost Strategy		ST: TRIAL OF PHENELZINE, TRANYLCYPROMINE, OR MARPLAN IN THE PREVIOUS 120 DAYS
BEHAVIORAL HEALTH - OTHER	EMSAM	SELEGILINE	6 MG/24 HR	PATCH TD24	TRANSDERM.	SSB	3	S=3	QL	A=ST S=QL	Low Net Cost Strategy		ST: TRIAL OF PHENELZINE, TRANYLCYPROMINE, OR MARPLAN IN THE PREVIOUS 120 DAYS
BEHAVIORAL HEALTH - OTHER	EMSAM	SELEGILINE	9 MG/24 HR	PATCH TD24	TRANSDERM.	SSB	3	S=3	QL	A=ST S=QL	Low Net Cost Strategy		ST: TRIAL OF PHENELZINE, TRANYLCYPROMINE, OR MARPLAN IN THE PREVIOUS 120 DAYS

2Q20 Formulary Actions

Drug							Formulary Status Marketplace (HIEX)		Utilization Management Marketplace (HIEX)				
Category	Brand Name	Generic Name	Strength	Dosage Form	Route	Brand Status	Current Status	Action	Current Status	Action	Rationale of Changes	Optional Benefit Exclusion	Client Communication - Commercial/HIEX
CARDIOVASCULAR DISEASE - LIPID IRREGULARITY	NEXLETOL	BEMPEDOIC ACID	180 MG	TABLET	ORAL	SSB	3	S=3	PA	C=PA	Clinical/Safety Strategy		N/A
CARDIOVASCULAR DISEASE - LIPID IRREGULARITY	JUXTAPID	LOMITAPIDE MESYLATE	10 MG	CAPSULE	ORAL	SSB	4	S=4	PA	C=PA	Clinical/Safety Strategy		N/A
CARDIOVASCULAR DISEASE - LIPID IRREGULARITY	JUXTAPID	LOMITAPIDE MESYLATE	20 MG	CAPSULE	ORAL	SSB	4	S=4	PA	C=PA	Clinical/Safety Strategy		N/A
CARDIOVASCULAR DISEASE - LIPID IRREGULARITY	JUXTAPID	LOMITAPIDE MESYLATE	30 MG	CAPSULE	ORAL	SSB	4	S=4	PA	C=PA	Clinical/Safety Strategy		N/A
CARDIOVASCULAR DISEASE - LIPID IRREGULARITY	JUXTAPID	LOMITAPIDE MESYLATE	40 MG	CAPSULE	ORAL	SSB	4	S=4	PA	C=PA	Clinical/Safety Strategy		N/A
CARDIOVASCULAR DISEASE - LIPID IRREGULARITY	JUXTAPID	LOMITAPIDE MESYLATE	5 MG	CAPSULE	ORAL	SSB	4	S=4	PA	C=PA	Clinical/Safety Strategy		N/A
CARDIOVASCULAR DISEASE - LIPID IRREGULARITY	JUXTAPID	LOMITAPIDE MESYLATE	60 MG	CAPSULE	ORAL	SSB	4	S=4	PA	C=PA	Clinical/Safety Strategy		N/A
CARDIOVASCULAR DISEASE - LIPID IRREGULARITY	NIACIN ER	NIACIN	1000 MG	TAB ER 24H	ORAL	GENERIC	1	S=1	ST	D=ST	Low Net Cost Strategy		N/A
CARDIOVASCULAR DISEASE - LIPID IRREGULARITY	NIACIN ER	NIACIN	500 MG	TAB ER 24H	ORAL	GENERIC	1	S=1	ST	D=ST	Low Net Cost Strategy		N/A
CARDIOVASCULAR DISEASE - LIPID IRREGULARITY	NIACIN ER	NIACIN	750 MG	TAB ER 24H	ORAL	GENERIC	1	S=1	ST	D=ST	Low Net Cost Strategy		N/A
CARDIOVASCULAR DISEASE - LIPID IRREGULARITY	PRALUENT PEN	ALIROCUMAB	150 MG/ML	PEN INJCTR	SUBCUTANE.	SSB	2	S=2	PA	C=PA	Clinical/Safety Strategy		N/A

2Q20 Formulary Actions

Drug							Formulary Status Marketplace (HIEX)		Utilization Management Marketplace (HIEX)				
Category	Brand Name	Generic Name	Strength	Dosage Form	Route	Brand Status	Current Status	Action	Current Status	Action	Rationale of Changes	Optional Benefit Exclusion	Client Communication - Commercial/HIEX
CARDIOVASCULAR DISEASE - LIPID IRREGULARITY	PRALUENT PEN	ALIROCUMAB	75 MG/ML	PEN INJCTR	SUBCUTANE.	SSB	2	S=2	PA	C=PA	Clinical/Safety Strategy		N/A
CARDIOVASCULAR DISEASE - LIPID IRREGULARITY	REPATHA SURECLICK	EVOLOCUMAB	140 MG/ML	PEN INJCTR	SUBCUTANE.	SSB	2	S=2	PA	C=PA	Clinical/Safety Strategy		N/A
CARDIOVASCULAR DISEASE - LIPID IRREGULARITY	REPATHA SYRINGE	EVOLOCUMAB	140 MG/ML	SYRINGE	SUBCUTANE.	SSB	2	S=2	PA	C=PA	Clinical/Safety Strategy		N/A
CARDIOVASCULAR DISEASE - LIPID IRREGULARITY	REPATHA PUSHTRONEX	EVOLOCUMAB	420 MG/3.5	WEAR INJCT	SUBCUTANE.	SSB	2	S=2	PA	C=PA	Clinical/Safety Strategy		N/A
DERMATOLOGY - ACNE	ARAZLO	TAZAROTENE	0.045 %	LOTION	TOPICAL	SSB	3	S=3	AGE	A=ST S=AGE	Low Net Cost Strategy		ST: TRIAL OF 1 OF THE FOLLOWING GENERIC TOPICALS: TAZAROTENE, TRETINOIN, OR ADAPALENE (GEL, CREAM, LOTION, OR SOLUTION) REQUIRED IN THE PAST 120 DAYS
DERMATOLOGY - ANTIINFECTIVE	KETOCONAZOLE	KETOCONAZOLE	2 %	FOAM	TOPICAL	GENERIC	1	S=1	NONE	A=ST	Low Net Cost Strategy		ST: TRIAL OF KETOCONAZOLE 2% CREAM OR SHAMPOO IN THE PREVIOUS 120 DAYS
DERMATOLOGY - ANTIINFECTIVE	XOLEGEL	KETOCONAZOLE	2 %	GEL (GRAM)	TOPICAL	SSB	3	S=3	NONE	A=ST	Low Net Cost Strategy		ST: TRIAL OF KETOCONAZOLE 2% CREAM OR SHAMPOO IN THE PREVIOUS 120 DAYS
DERMATOLOGY - ANTIINFLAMMATORY	PENNSAID	DICLOFENAC SODIUM	2.00%	SOLN PK(G)	TOPICAL	SSB	3	S=3	ST	C=ST			ST: TRIAL OF GENERIC DICLOFENAC GEL OR DROPS IN THE PREVIOUS 120 DAYS
DERMATOLOGY - ANTIINFLAMMATORY	PENNSAID	DICLOFENAC SODIUM	20MG/G(2%)	SOL MD PMP	TOPICAL	SSB	3	S=3	ST	C=ST	Low Net Cost Strategy		ST: TRIAL OF GENERIC DICLOFENAC GEL OR DROPS IN THE PREVIOUS 120 DAYS
DERMATOLOGY - MISCELLANEOUS	TARGRETIN	BEXAROTENE	1 %	GEL (GRAM)	TOPICAL	SSB	4	S=4	PA	C=PA	Clinical/Safety Strategy		N/A
DERMATOLOGY - MISCELLANEOUS	LIDOCAINE	LIDOCAINE	5 %	OINT. (G)	TOPICAL	GENERIC	1	S=1	QL,ST	D=ST S=QL	Low Net Cost Strategy		N/A
DERMATOLOGY - PSORIASIS/ECZEMA	TALTZ AUTOINJECTOR	IXEKIZUMAB	80 MG/ML	AUTO INJCT	SUBCUTANE.	SSB	4	S=4	PA	C=PA	Clinical/Safety Strategy		N/A

2Q20 Formulary Actions

Drug							Formulary Status Marketplace (HIEX)		Utilization Management Marketplace (HIEX)				
Category	Brand Name	Generic Name	Strength	Dosage Form	Route	Brand Status	Current Status	Action	Current Status	Action	Rationale of Changes	Optional Benefit Exclusion	Client Communication - Commercial/HIEX
DERMATOLOGY - PSORIASIS/ECZEMA	TALTZ SYRINGE	IXEKIZUMAB	80 MG/ML	SYRINGE	SUBCUTANE.	SSB	4	S=4	PA	C=PA	Clinical/Safety Strategy		N/A
DERMATOLOGY - PSORIASIS/ECZEMA	COSENTYX PEN (2 PENS)	SECUKINUMAB	150 MG/ML	PEN INJCTR	SUBCUTANE.	SSB	4	S=4	PA	C=PA	Clinical/Safety Strategy		N/A
DERMATOLOGY - PSORIASIS/ECZEMA	COSENTYX SYRINGE	SECUKINUMAB	150 MG/ML	SYRINGE	SUBCUTANE.	SSB	4	S=4	PA	C=PA	Clinical/Safety Strategy		N/A
DIABETES	RIOMET ER	METFORMIN HCL	500 MG/5ML	SUS ER REC	ORAL	SSB	3	S=3	PA	D=PA A=ST	Low Net Cost Strategy		ST: TRIAL OF METFORMIN IR TABLETS/SOLUTION OR ER TABLETS IN THE PREVIOUS 120 DAYS
DIABETES	EVERSENSE SMART TRANSMITTER	BLOOD-GLUCOSE TRANSMITTER	N/A	EACH	MISCELL.	NON DRUG	3	S=3	NONE	A=PA	Trade Relations Strategy		NOTE: CURRENT MEMBERS WILL BE PERPETUALLY GRANDFATHERED.
DIABETES	TANZEUM	ALBIGLUTIDE	30MG/0.5ML	PEN INJCTR	SUBCUTANE.	SSB	3	S=3	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF VICTOZA, OZEMPIC, RYBELSUS, BYETTA, BYDUREON, BYDUREON BCISE OR TRULICITY IN THE PREVIOUS 120 DAYS
DIABETES	TANZEUM	ALBIGLUTIDE	50MG/0.5ML	PEN INJCTR	SUBCUTANE.	SSB	3	S=3	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF VICTOZA, OZEMPIC, RYBELSUS, BYETTA, BYDUREON, BYDUREON BCISE OR TRULICITY IN THE PREVIOUS 120 DAYS
DIABETES	TRULICITY	DULAGLUTIDE	0.75MG/0.5	PEN INJCTR	SUBCUTANE.	SSB	2	S=2	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	TRULICITY	DULAGLUTIDE	1.5 MG/0.5	PEN INJCTR	SUBCUTANE.	SSB	2	S=2	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	BYETTA	EXENATIDE	10MCG/0.04	PEN INJCTR	SUBCUTANE.	SSB	2	S=2	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	BYETTA	EXENATIDE	5MCG/0.02	PEN INJCTR	SUBCUTANE.	SSB	2	S=2	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	BYDUREON	EXENATIDE MICROSPHERES	2 MG	VIAL	SUBCUTANE.	SSB	2	S=2	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	BYDUREON PEN	EXENATIDE MICROSPHERES	2MG/0.65ML	PEN INJCTR	SUBCUTANE.	SSB	2	S=2	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	BYDUREON BCISE	EXENATIDE MICROSPHERES	2MG/0.85ML	AUTO INJCT	SUBCUTANE.	SSB	2	S=2	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	VICTOZA 3-PAK	LIRAGLUTIDE	0.6 MG/0.1	PEN INJCTR	SUBCUTANE.	SSB	2	S=2	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	ADLYXIN	LIXISENATIDE	10-20 (1)	PEN INJCTR	SUBCUTANE.	SSB	3	S=3	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF VICTOZA, OZEMPIC, RYBELSUS, BYETTA, BYDUREON, BYDUREON BCISE OR TRULICITY IN THE PREVIOUS 120 DAYS

2Q20 Formulary Actions

Drug							Formulary Status Marketplace (HIEX)		Utilization Management Marketplace (HIEX)				
Category	Brand Name	Generic Name	Strength	Dosage Form	Route	Brand Status	Current Status	Action	Current Status	Action	Rationale of Changes	Optional Benefit Exclusion	Client Communication - Commercial/HIEX
DIABETES	ADLYXIN	LIXISENATIDE	20 MCG/0.2	PEN INJCTR	SUBCUTANE.	SSB	3	S=3	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF VICTOZA, OZEMPIC, RYBELSUS, BYETTA, BYDUREON, BYDUREON BCISE OR TRULICITY IN THE PREVIOUS 120 DAYS
DIABETES	OZEMPIC	SEMAGLUTIDE	0.25 OR .5	PEN INJCTR	SUBCUTANE.	SSB	2	S=2	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	RYBELSUS	SEMAGLUTIDE	14 MG	TABLET	ORAL	SSB	2	S=2	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	OZEMPIC	SEMAGLUTIDE	1MG/0.75ML	PEN INJCTR	SUBCUTANE.	SSB	2	S=2	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	RYBELSUS	SEMAGLUTIDE	3 MG	TABLET	ORAL	SSB	2	S=2	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	RYBELSUS	SEMAGLUTIDE	7 MG	TABLET	ORAL	SSB	2	S=2	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	XULTOPHY 100-3.6	INSULIN DEGLUDEC/LIRAGLUTIDE	100-3.6/ML	INSULN PEN	SUBCUTANE.	SSB	2	S=2	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF ONE OF THE FOLLOWING: LANTUS, TOUJEO, LEVEMIR, TRESIBA, VICTOZA, OZEMPIC, RYBELSUS, BYETTA, BYDUREON, BYDUREON BCISE OR TRULICITY IN THE PREVIOUS 120 DAYS
DIABETES	SOLIQUA 100-33	INSULIN GLARGINE/LIXISENATIDE	100-33/ML	INSULN PEN	SUBCUTANE.	SSB	2	S=2	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF ONE OF THE FOLLOWING: LANTUS, TOUJEO, LEVEMIR, TRESIBA, VICTOZA, OZEMPIC, RYBELSUS, BYETTA, BYDUREON, BYDUREON BCISE OR TRULICITY IN THE PREVIOUS 120 DAYS
DIABETES	INVOKANA	CANAGLIFLOZIN	100 MG	TABLET	ORAL	SSB	3	S=3	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF JARDIANCE, SYNJARDY, SYNJARDY XR, FARXIGA, OR XIGDUO XR IN THE PREVIOUS 120 DAYS.
DIABETES	INVOKANA	CANAGLIFLOZIN	300 MG	TABLET	ORAL	SSB	3	S=3	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF JARDIANCE, SYNJARDY, SYNJARDY XR, FARXIGA, OR XIGDUO XR IN THE PREVIOUS 120 DAYS.
DIABETES	INVOKAMET	CANAGLIFLOZIN/METFORMIN HCL	150-1000MG	TABLET	ORAL	SSB	3	S=3	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF JARDIANCE, SYNJARDY, SYNJARDY XR, FARXIGA, OR XIGDUO XR IN THE PREVIOUS 120 DAYS.
DIABETES	INVOKAMET XR	CANAGLIFLOZIN/METFORMIN HCL	150-1000MG	TAB BP 24H	ORAL	SSB	3	S=3	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF JARDIANCE, SYNJARDY, SYNJARDY XR, FARXIGA, OR XIGDUO XR IN THE PREVIOUS 120 DAYS.
DIABETES	INVOKAMET	CANAGLIFLOZIN/METFORMIN HCL	150-500 MG	TABLET	ORAL	SSB	3	S=3	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF JARDIANCE, SYNJARDY, SYNJARDY XR, FARXIGA, OR XIGDUO XR IN THE PREVIOUS 120 DAYS.
DIABETES	INVOKAMET XR	CANAGLIFLOZIN/METFORMIN HCL	150-500 MG	TAB BP 24H	ORAL	SSB	3	S=3	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF JARDIANCE, SYNJARDY, SYNJARDY XR, FARXIGA, OR XIGDUO XR IN THE PREVIOUS 120 DAYS.
DIABETES	INVOKAMET	CANAGLIFLOZIN/METFORMIN HCL	50-1000 MG	TABLET	ORAL	SSB	3	S=3	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF JARDIANCE, SYNJARDY, SYNJARDY XR, FARXIGA, OR XIGDUO XR IN THE PREVIOUS 120 DAYS.
DIABETES	INVOKAMET XR	CANAGLIFLOZIN/METFORMIN HCL	50-1000 MG	TAB BP 24H	ORAL	SSB	3	S=3	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF JARDIANCE, SYNJARDY, SYNJARDY XR, FARXIGA, OR XIGDUO XR IN THE PREVIOUS 120 DAYS.
DIABETES	INVOKAMET	CANAGLIFLOZIN/METFORMIN HCL	50MG-500MG	TABLET	ORAL	SSB	3	S=3	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF JARDIANCE, SYNJARDY, SYNJARDY XR, FARXIGA, OR XIGDUO XR IN THE PREVIOUS 120 DAYS.
DIABETES	INVOKAMET XR	CANAGLIFLOZIN/METFORMIN HCL	50MG-500MG	TAB BP 24H	ORAL	SSB	3	S=3	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF JARDIANCE, SYNJARDY, SYNJARDY XR, FARXIGA, OR XIGDUO XR IN THE PREVIOUS 120 DAYS.
DIABETES	FARXIGA	DAPAGLIFLOZIN PROPANEDIOL	10 MG	TABLET	ORAL	SSB	2	S=2	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	FARXIGA	DAPAGLIFLOZIN PROPANEDIOL	5 MG	TABLET	ORAL	SSB	2	S=2	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	XIGDUO XR	DAPAGLIFLOZIN/METFORMIN HCL	10-1000 MG	TAB BP 24H	ORAL	SSB	2	S=2	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A

2Q20 Formulary Actions

Drug							Formulary Status Marketplace (HIEX)		Utilization Management Marketplace (HIEX)				
Category	Brand Name	Generic Name	Strength	Dosage Form	Route	Brand Status	Current Status	Action	Current Status	Action	Rationale of Changes	Optional Benefit Exclusion	Client Communication - Commercial/HIEX
DIABETES	XIGDUO XR	DAPAGLIFLOZIN/METFORMIN HCL	10MG-500MG	TAB BP 24H	ORAL	SSB	2	S=2	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	XIGDUO XR	DAPAGLIFLOZIN/METFORMIN HCL	2.5-1000MG	TAB BP 24H	ORAL	SSB	2	S=2	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	XIGDUO XR	DAPAGLIFLOZIN/METFORMIN HCL	5 MG-500MG	TAB BP 24H	ORAL	SSB	2	S=2	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	XIGDUO XR	DAPAGLIFLOZIN/METFORMIN HCL	5MG-1000MG	TAB BP 24H	ORAL	SSB	2	S=2	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	QTERN	DAPAGLIFLOZIN/SAXAGLIPTIN HCL	10 MG-5 MG	TABLET	ORAL	SSB	3	S=3	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF JANUVIA, JANUMET, JANUMET XR, FARXIGA, XIGDUO XR, JARDIANCE, SYNJARDY, OR SYNJARDY XR IN THE PAST 120 DAYS
DIABETES	QTERN	DAPAGLIFLOZIN/SAXAGLIPTIN HCL	5 MG-5 MG	TABLET	ORAL	SSB	3	S=3	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF JANUVIA, JANUMET, JANUMET XR, FARXIGA, XIGDUO XR, JARDIANCE, SYNJARDY, OR SYNJARDY XR IN THE PAST 120 DAYS
DIABETES	TRIJARDY XR	EMPAGLIFLOZ/LINAGLIP/METFORMIN	10-5-1000	TAB BP 24H	ORAL	SSB	3	S=3	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF JANUVIA, JANUMET, JANUMET XR, FARXIGA, XIGDUO XR, JARDIANCE, SYNJARDY, OR SYNJARDY XR IN THE PAST 120 DAYS
DIABETES	TRIJARDY XR	EMPAGLIFLOZ/LINAGLIP/METFORMIN	12.5-2.5MG	TAB BP 24H	ORAL	SSB	3	S=3	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF JANUVIA, JANUMET, JANUMET XR, FARXIGA, XIGDUO XR, JARDIANCE, SYNJARDY, OR SYNJARDY XR IN THE PAST 120 DAYS
DIABETES	TRIJARDY XR	EMPAGLIFLOZ/LINAGLIP/METFORMIN	25-5-1000	TAB BP 24H	ORAL	SSB	3	S=3	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF JANUVIA, JANUMET, JANUMET XR, FARXIGA, XIGDUO XR, JARDIANCE, SYNJARDY, OR SYNJARDY XR IN THE PAST 120 DAYS
DIABETES	TRIJARDY XR	EMPAGLIFLOZ/LINAGLIP/METFORMIN	5-2.5-1000	TAB BP 24H	ORAL	SSB	3	S=3	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF JANUVIA, JANUMET, JANUMET XR, FARXIGA, XIGDUO XR, JARDIANCE, SYNJARDY, OR SYNJARDY XR IN THE PAST 120 DAYS
DIABETES	JARDIANCE	EMPAGLIFLOZIN	10 MG	TABLET	ORAL	SSB	2	S=2	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	JARDIANCE	EMPAGLIFLOZIN	25 MG	TABLET	ORAL	SSB	2	S=2	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	GLYXAMBI	EMPAGLIFLOZIN/LINAGLIPTIN	10 MG-5 MG	TABLET	ORAL	SSB	2	C=3	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF JANUVIA, JANUMET, JANUMET XR, FARXIGA, XIGDUO XR, JARDIANCE, SYNJARDY, OR SYNJARDY XR IN THE PAST 120 DAYS NOTE: CURRENT MEMBERS WILL BE GRANDFATHERED UNTIL 1/1/2021.
DIABETES	GLYXAMBI	EMPAGLIFLOZIN/LINAGLIPTIN	25 MG-5 MG	TABLET	ORAL	SSB	2	C=3	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF JANUVIA, JANUMET, JANUMET XR, FARXIGA, XIGDUO XR, JARDIANCE, SYNJARDY, OR SYNJARDY XR IN THE PAST 120 DAYS NOTE: CURRENT MEMBERS WILL BE GRANDFATHERED UNTIL 1/1/2021.
DIABETES	SYNJARDY XR	EMPAGLIFLOZIN/METFORMIN HCL	10-1000 MG	TAB BP 24H	ORAL	SSB	2	S=2	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	SYNJARDY	EMPAGLIFLOZIN/METFORMIN HCL	12.5-1000	TABLET	ORAL	SSB	2	S=2	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A

2Q20 Formulary Actions

Drug							Formulary Status Marketplace (HIEX)		Utilization Management Marketplace (HIEX)				
Category	Brand Name	Generic Name	Strength	Dosage Form	Route	Brand Status	Current Status	Action	Current Status	Action	Rationale of Changes	Optional Benefit Exclusion	Client Communication - Commercial/HIEX
DIABETES	SYNJARDY XR	EMPAGLIFLOZIN/METFORMIN HCL	12.5-1000	TAB BP 24H	ORAL	SSB	2	S=2	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	SYNJARDY	EMPAGLIFLOZIN/METFORMIN HCL	12.5-500MG	TABLET	ORAL	SSB	2	S=2	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	SYNJARDY XR	EMPAGLIFLOZIN/METFORMIN HCL	25-1000 MG	TAB BP 24H	ORAL	SSB	2	S=2	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	SYNJARDY	EMPAGLIFLOZIN/METFORMIN HCL	5 MG-500MG	TABLET	ORAL	SSB	2	S=2	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	SYNJARDY	EMPAGLIFLOZIN/METFORMIN HCL	5MG-1000MG	TABLET	ORAL	SSB	2	S=2	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	SYNJARDY XR	EMPAGLIFLOZIN/METFORMIN HCL	5MG-1000MG	TAB BP 24H	ORAL	SSB	2	S=2	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	STEGLATRO	ERTUGLIFLOZIN PIDOLATE	15 MG	TABLET	ORAL	SSB	3	S=3	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF JARDIANCE, SYNJARDY, SYNJARDY XR, FARXIGA, OR XIGDUO XR IN THE PREVIOUS 120 DAYS
DIABETES	STEGLATRO	ERTUGLIFLOZIN PIDOLATE	5 MG	TABLET	ORAL	SSB	3	S=3	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF JARDIANCE, SYNJARDY, SYNJARDY XR, FARXIGA, OR XIGDUO XR IN THE PREVIOUS 120 DAYS
DIABETES	SEGLUROMET	ERTUGLIFLOZIN/METFORMIN	2.5-1000MG	TABLET	ORAL	SSB	3	S=3	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF JARDIANCE, SYNJARDY, SYNJARDY XR, FARXIGA, OR XIGDUO XR IN THE PREVIOUS 120 DAYS.
DIABETES	SEGLUROMET	ERTUGLIFLOZIN/METFORMIN	2.5-500 MG	TABLET	ORAL	SSB	3	S=3	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF JARDIANCE, SYNJARDY, SYNJARDY XR, FARXIGA, OR XIGDUO XR IN THE PREVIOUS 120 DAYS.
DIABETES	SEGLUROMET	ERTUGLIFLOZIN/METFORMIN	7.5-1000MG	TABLET	ORAL	SSB	3	S=3	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF JARDIANCE, SYNJARDY, SYNJARDY XR, FARXIGA, OR XIGDUO XR IN THE PREVIOUS 120 DAYS.
DIABETES	SEGLUROMET	ERTUGLIFLOZIN/METFORMIN	7.5-500 MG	TABLET	ORAL	SSB	3	S=3	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF JARDIANCE, SYNJARDY, SYNJARDY XR, FARXIGA, OR XIGDUO XR IN THE PREVIOUS 120 DAYS.
DIABETES	STEGLUJAN	ERTUGLIFLOZIN/SITAGLIPTIN	15MG-100MG	TABLET	ORAL	SSB	3	S=3	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF JANUVIA, JANUMET, JANUMET XR, FARXIGA, XIGDUO XR, JARDIANCE, SYNJARDY, OR SYNJARDY XR IN THE PAST 120 DAYS
DIABETES	STEGLUJAN	ERTUGLIFLOZIN/SITAGLIPTIN	5 MG-100MG	TABLET	ORAL	SSB	3	S=3	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF JANUVIA, JANUMET, JANUMET XR, FARXIGA, XIGDUO XR, JARDIANCE, SYNJARDY, OR SYNJARDY XR IN THE PAST 120 DAYS
ENDOCRINE DISORDER - FERTILITY	TADALAFIL	TADALAFIL	10 MG	TABLET	ORAL	GENERIC	1	S=1	QL,ST	D=ST S=QL	Low Net Cost Strategy		N/A
ENDOCRINE DISORDER - FERTILITY	TADALAFIL	TADALAFIL	20 MG	TABLET	ORAL	GENERIC	1	S=1	QL,ST	D=ST S=QL	Low Net Cost Strategy		N/A
ENDOCRINE DISORDER - OTHER	ACTHAR	CORTICOTROPIN	80 UNIT/ML	VIAL	INJECTION	SSB	4	S=4	PA	C=PA	Clinical/Safety Strategy	Non-Self Administered Drug (NSA)	N/A
ENDOCRINE DISORDER - OTHER	INCRELEX	MECASERMIN	10 MG/ML	VIAL	SUBCUTANE.	SSB	4	S=4	PA	C=PA	Clinical/Safety Strategy		N/A
HEMATOLOGICAL DISORDERS	REBLOZYL	LUSPATERCEPT-AAMT	25 MG	VIAL	SUBCUTANE.	SSB	4	S=4	PA	C=PA	Clinical/Safety Strategy	Non-Self Administered Drug (NSA)	N/A

2Q20 Formulary Actions

Drug							Formulary Status Marketplace (HIEX)		Utilization Management Marketplace (HIEX)				
Category	Brand Name	Generic Name	Strength	Dosage Form	Route	Brand Status	Current Status	Action	Current Status	Action	Rationale of Changes	Optional Benefit Exclusion	Client Communication - Commercial/HIEX
HEMATOLOGICAL DISORDERS	REBLOZYL	LUSPATERCEPT-AAMT	75 MG	VIAL	SUBCUTANE.	SSB	4	S=4	PA	C=PA	Clinical/Safety Strategy	Non-Self Administered Drug (NSA)	N/A
INFECTIOUS DISEASE - VIRAL	HARVONI	LEDIPASVIR/SOFOSBUVIR	45MG-200MG	TABLET	ORAL	SSB	4	S=4	PA	C=PA	Clinical/Safety Strategy		N/A
INFECTIOUS DISEASE - VIRAL	HARVONI	LEDIPASVIR/SOFOSBUVIR	90MG-400MG	TABLET	ORAL	GENERIC/MSB	4	S=4	PA	C=PA	Clinical/Safety Strategy		N/A
INFECTIOUS DISEASE - VIRAL	EPCLUSA	SOFOSBUVIR/VELPATASVIR	400-100 MG	TABLET	ORAL	GENERIC/MSB	4	S=4	PA	C=PA	Clinical/Safety Strategy		N/A
INFLAMMATORY DISEASE	HYALGAN	HYALURONATE SODIUM	10 MG/ML	VIAL	INTRAARTIC	SSB	3	S=3	PA	C=PA	Clinical/Safety Strategy		N/A
INFLAMMATORY DISEASE	MULTIPLE BRAND NAMES	HYALURONATE SODIUM	10 MG/ML	SYRINGE	INTRAARTIC	SSB	3	S=3	PA	C=PA	Clinical/Safety Strategy		N/A
INFLAMMATORY DISEASE	GELSYN-3	HYALURONATE SODIUM	16.8MG/2ML	SYRINGE	INTRAARTIC	SSB	3	S=3	PA	C=PA	Clinical/Safety Strategy		N/A
INFLAMMATORY DISEASE	ORTHOVISC	HYALURONATE SODIUM	30 MG/2 ML	SYRINGE	INTRAARTIC	SSB	3	S=3	PA	C=PA	Clinical/Safety Strategy		N/A
INFLAMMATORY DISEASE	DUROLANE	HYALURONATE SODIUM, STABILIZED	60 MG/3 ML	SYRINGE	INTRAARTIC	SSB	3	S=3	PA	C=PA	Clinical/Safety Strategy		N/A
INFLAMMATORY DISEASE	MONOVISC	HYALURONATE SODIUM, STABILIZED	88 MG/4 ML	SYRINGE	INTRAARTIC	SSB	3	S=3	PA	C=PA	Clinical/Safety Strategy		N/A
INFLAMMATORY DISEASE	HYMOVIS	HYALURONATE,MOD.,NON-CROSSLINK	24 MG/3 ML	SYRINGE	INTRAARTIC	SSB	3	S=3	PA	C=PA	Clinical/Safety Strategy		N/A
INFLAMMATORY DISEASE	SYNVISC	HYLAN G-F 20	16MG/2ML	SYRINGE	INTRAARTIC	SSB	3	S=3	PA	C=PA	Clinical/Safety Strategy		N/A
INFLAMMATORY DISEASE	SYNVISC-ONE	HYLAN G-F 20	48 MG/6 ML	SYRINGE	INTRAARTIC	SSB	3	S=3	PA	C=PA	Clinical/Safety Strategy		N/A
LOWER GASTROINTESTINAL DISORDERS - OTHER	GATTEX	TEDUGLUTIDE	5 MG	KIT	SUBCUTANE.	SSB	4	S=4	PA	C=PA	Clinical/Safety Strategy		N/A
MISCELLANEOUS AGENTS	SPINRAZA	NUSINERSEN SODIUM/PF	12MG/5ML	VIAL	INTRATHEC.	SSB	4	S=4	PA	C=PA	Clinical/Safety Strategy	Non-Self Administered Drug (NSA)	N/A
NEOPLASTIC DISEASE	BELEODAQ	BELINOSTAT	500 MG	VIAL	INTRAVEN.	SSB	4	S=4	PA	C=PA	Clinical/Safety Strategy	Non-Self Administered Drug (NSA)	N/A
NEOPLASTIC DISEASE	AVASTIN	BEVACIZUMAB	25 MG/ML	VIAL	INTRAVEN.	SSB	4	S=4	PA	C=PA	Trade Relations Strategy	Non-Self Administered Drug (NSA)	N/A

2Q20 Formulary Actions

Drug							Formulary Status Marketplace (HIEX)		Utilization Management Marketplace (HIEX)				
Category	Brand Name	Generic Name	Strength	Dosage Form	Route	Brand Status	Current Status	Action	Current Status	Action	Rationale of Changes	Optional Benefit Exclusion	Client Communication - Commercial/HIEX
NEOPLASTIC DISEASE	MVASI	BEVACIZUMAB-AWWB	25 MG/ML	VIAL	INTRAVEN.	SSB	4	S=4	PA	C=PA	Trade Relations Strategy	Non-Self Administered Drug (NSA)	N/A
NEOPLASTIC DISEASE	ZIRABEV	BEVACIZUMAB-BVZR	25 MG/ML	VIAL	INTRAVEN.	SSB	4	S=4	PA	C=PA	Trade Relations Strategy	Non-Self Administered Drug (NSA)	N/A
NEOPLASTIC DISEASE	BEXAROTENE	BEXAROTENE	75 MG	CAPSULE	ORAL	GENERIC	4	S=4	PA	C=PA	Clinical/Safety Strategy		N/A
NEOPLASTIC DISEASE	CAPECITABINE	CAPECITABINE	150 MG	TABLET	ORAL	GENERIC	4	S=4	PA,QL	D=QL C=PA	Clinical/Safety Strategy		N/A
NEOPLASTIC DISEASE	CAPECITABINE	CAPECITABINE	500 MG	TABLET	ORAL	GENERIC	4	S=4	PA,QL	D=QL C=PA	Clinical/Safety Strategy		N/A
NEOPLASTIC DISEASE	IMFINZI	DURVALUMAB	120 MG/2.4	VIAL	INTRAVEN.	SSB	4	S=4	PA	C=PA	Clinical/Safety Strategy	Non-Self Administered Drug (NSA)	N/A
NEOPLASTIC DISEASE	IMFINZI	DURVALUMAB	500MG/10ML	VIAL	INTRAVEN.	SSB	4	S=4	PA	C=PA	Clinical/Safety Strategy	Non-Self Administered Drug (NSA)	N/A
NEOPLASTIC DISEASE	BRAFTOVI	ENCORAFENIB	50 MG	CAPSULE	ORAL	SSB	4	S=4	PA,QL	D=QL C=PA	Clinical/Safety Strategy		N/A
NEOPLASTIC DISEASE	BRAFTOVI	ENCORAFENIB	75 MG	CAPSULE	ORAL	SSB	4	S=4	PA,QL	D=QL C=PA	Clinical/Safety Strategy		N/A
NEOPLASTIC DISEASE	YERVOY	IPILIMUMAB	50 MG/10ML	VIAL	INTRAVEN.	SSB	4	S=4	PA	C=PA	Clinical/Safety Strategy	Non-Self Administered Drug (NSA)	N/A
NEOPLASTIC DISEASE	NERLYNX	NERATINIB MALEATE	40 MG	TABLET	ORAL	SSB	4	S=4	PA	C=PA	Clinical/Safety Strategy		N/A
NEOPLASTIC DISEASE	HERCEPTIN	TRASTUZUMAB	150 MG	VIAL	INTRAVEN.	SSB	4	S=4	PA	C=PA	Trade Relations Strategy	Non-Self Administered Drug (NSA)	N/A
NEOPLASTIC DISEASE	HERCEPTIN	TRASTUZUMAB	440 MG	VIAL	INTRAVEN.	SSB	4	S=4	PA	C=PA	Trade Relations Strategy	Non-Self Administered Drug (NSA)	N/A
NEOPLASTIC DISEASE	KANJINTI	TRASTUZUMAB-ANNS	150 MG	VIAL	INTRAVEN.	SSB	4	S=4	PA	C=PA	Trade Relations Strategy	Non-Self Administered Drug (NSA)	N/A
NEOPLASTIC DISEASE	KANJINTI	TRASTUZUMAB-ANNS	420 MG	VIAL	INTRAVEN.	SSB	4	S=4	PA	C=PA	Trade Relations Strategy	Non-Self Administered Drug (NSA)	N/A
NEOPLASTIC DISEASE	OGIVRI	TRASTUZUMAB-DKST	150 MG	VIAL	INTRAVEN.	SSB	4	S=4	PA	C=PA	Trade Relations Strategy	Non-Self Administered Drug (NSA)	N/A
NEOPLASTIC DISEASE	OGIVRI	TRASTUZUMAB-DKST	420 MG	VIAL	INTRAVEN.	SSB	4	S=4	PA	C=PA	Trade Relations Strategy	Non-Self Administered Drug (NSA)	N/A

2Q20 Formulary Actions

Drug							Formulary Status Marketplace (HIEX)		Utilization Management Marketplace (HIEX)				
Category	Brand Name	Generic Name	Strength	Dosage Form	Route	Brand Status	Current Status	Action	Current Status	Action	Rationale of Changes	Optional Benefit Exclusion	Client Communication - Commercial/HIEX
NEOPLASTIC DISEASE	HERCEPTIN HYLECTA	TRASTUZUMAB-HYALURONIDASE-OYSK	600-10000	VIAL	SUBCUTANE.	SSB	4	S=4	PA	C=PA	Trade Relations Strategy	Non-Self Administered Drug (NSA)	N/A
NEOPLASTIC DISEASE	TRAZIMERA	TRASTUZUMAB-QYYP	420 MG	VIAL	INTRAVEN.	SSB	4	S=4	PA	C=PA	Trade Relations Strategy	Non-Self Administered Drug (NSA)	N/A
NEOPLASTIC DISEASE	MARQIBO	VINCRISTINE SULFATE LIPOSOMAL	FNL 5MG/31	KIT	INTRAVEN.	SSB	4	S=4	PA	C=PA	Clinical/Safety Strategy	Non-Self Administered Drug (NSA)	N/A
OTHER DRUGS	MEPSEVII	VESTRONIDASE ALFA-VJBK	10 MG/5 ML	VIAL	INTRAVEN.	SSB	4	S=4	PA	C=PA	Clinical/Safety Strategy	Non-Self Administered Drug (NSA)	N/A
OTHER DRUGS	MOZOBIL	PLERIXAFOR	24MG/1.2ML	VIAL	SUBCUTANE.	SSB	4	S=4	PA	C=PA	Clinical/Safety Strategy	Non-Self Administered Drug (NSA)	N/A
OTHER DRUGS	ZAVESCA	MIGLUSTAT	100 MG	CAPSULE	ORAL	MSB/ GENERIC	4	S=4	PA	C=PA	Clinical/Safety Strategy		N/A
OTHER RESPIRATORY DISORDERS	OFEV	NINTEDANIB ESYLATE	100 MG	CAPSULE	ORAL	SSB	4	S=4	PA	C=PA	Clinical/Safety Strategy		N/A
OTHER RESPIRATORY DISORDERS	OFEV	NINTEDANIB ESYLATE	150 MG	CAPSULE	ORAL	SSB	4	S=4	PA	C=PA	Clinical/Safety Strategy		N/A
PAIN MANAGEMENT - ANALGESICS	NURTEC ODT	RIMEGEPANT SULFATE	75 MG	TAB RAPDIS	ORAL	SSB	3	S=3	PA	C=PA	Clinical/Safety Strategy		N/A
PARKINSONS DISEASE	ZELAPAR	SELEGILINE HCL	1.25 MG	TAB RAPDIS	ORAL	SSB	3	S=3	QL	A=ST S=QL	Low Net Cost Strategy		ST: TRIAL OF GENERIC SELEGILINE CAPSULES OR TABLETS IN THE PREVIOUS 120 DAYS

2Q20 Formulary Actions

Drug							Formulary Status Medicaid		Utilization Management Medicaid				
Category	Brand Name	Generic Name	Strength	Dosage Form	Route	Brand Status	Current Status	Action	Current Status	Action	Rationale of Changes	Optional Benefit Exclusion	Client Communication - Standard Medicaid
ALLERGY	AZELASTINE HCL	AZELASTINE HCL	205.5 MCG	SPRAY/PUMP	NASAL	GENERIC	NC	S=NC	QL,ST	D=ST S=QL	Low Net Cost Strategy		N/A
ALLERGY	OLOPATADINE HCL	OLOPATADINE HCL	0.6 %	SPRAY/PUMP	NASAL	GENERIC	F	S=F	QL,ST	D=ST S=QL	Low Net Cost Strategy		N/A
ASTHMA AND COPD	FASENRA	BENRALIZUMAB	30 MG/ML	SYRINGE	SUBCUTANE.	SSB	NC	S=NC	PA	C=PA	Clinical/Safety Strategy	Non-Self Administered Drug (NSA)	N/A
ASTHMA AND COPD	FASENRA PEN	BENRALIZUMAB	30 MG/ML	AUTO INJCT	SUBCUTANE.	SSB	NC	S=NC	PA	C=PA	Clinical/Safety Strategy		N/A
ASTHMA AND COPD	DUPIXENT	DUPILUMAB	200MG/1.14	SYRINGE	SUBCUTANE.	SSB	NC	S=NC	PA	C=PA	Clinical/Safety Strategy		N/A
ASTHMA AND COPD	NUCALA	MEPOLIZUMAB	100 MG	VIAL	SUBCUTANE.	SSB	NC	S=NC	PA	C=PA	Clinical/Safety Strategy	Non-Self Administered Drug (NSA)	N/A
ASTHMA AND COPD	NUCALA	MEPOLIZUMAB	100 MG/ML	SYRINGE	SUBCUTANE.	SSB	NC	S=NC	PA	C=PA	Clinical/Safety Strategy		N/A
ASTHMA AND COPD	NUCALA	MEPOLIZUMAB	100 MG/ML	AUTO INJCT	SUBCUTANE.	SSB	NC	S=NC	PA	C=PA	Clinical/Safety Strategy		N/A
ASTHMA AND COPD	CINQAIR	RESLIZUMAB	10 MG/ML	VIAL	INTRAVEN.	SSB	NC	S=NC	PA	C=PA	Clinical/Safety Strategy	Non-Self Administered Drug (NSA)	N/A
ASTHMA AND COPD	DUPIXENT	DUPILUMAB	300 MG/2ML	SYRINGE	SUBCUTANE.	SSB	NC	S=NC	PA	C=PA	Clinical/Safety Strategy		N/A
BEHAVIORAL HEALTH - OTHER	EMSAM	SELEGILINE	12MG/24HR	PATCH TD24	TRANSDERM.	SSB	NC	S=NC	QL	A=ST S=QL	Low Net Cost Strategy		ST: TRIAL OF PHENELZINE, TRANYLCYPROMINE, OR MARPLAN IN THE PREVIOUS 120 DAYS
BEHAVIORAL HEALTH - OTHER	EMSAM	SELEGILINE	6 MG/24 HR	PATCH TD24	TRANSDERM.	SSB	NC	S=NC	QL	A=ST S=QL	Low Net Cost Strategy		ST: TRIAL OF PHENELZINE, TRANYLCYPROMINE, OR MARPLAN IN THE PREVIOUS 120 DAYS
BEHAVIORAL HEALTH - OTHER	EMSAM	SELEGILINE	9 MG/24 HR	PATCH TD24	TRANSDERM.	SSB	NC	S=NC	QL	A=ST S=QL	Low Net Cost Strategy		ST: TRIAL OF PHENELZINE, TRANYLCYPROMINE, OR MARPLAN IN THE PREVIOUS 120 DAYS
CARDIOVASCULAR DISEASE - LIPID IRREGULARITY	NEXLETOL	BEMPEDOIC ACID	180 MG	TABLET	ORAL	SSB	NC	S=NC	PA	C=PA	Clinical/Safety Strategy		N/A
CARDIOVASCULAR DISEASE - LIPID IRREGULARITY	JUXTAPID	LOMITAPIDE MESYLATE	10 MG	CAPSULE	ORAL	SSB	F	S=F	PA	C=PA	Clinical/Safety Strategy		N/A
CARDIOVASCULAR DISEASE - LIPID IRREGULARITY	JUXTAPID	LOMITAPIDE MESYLATE	20 MG	CAPSULE	ORAL	SSB	F	S=F	PA	C=PA	Clinical/Safety Strategy		N/A

2Q20 Formulary Actions													
Drug							Formulary Status Medicaid		Utilization Management Medicaid				
Category	Brand Name	Generic Name	Strength	Dosage Form	Route	Brand Status	Current Status	Action	Current Status	Action	Rationale of Changes	Optional Benefit Exclusion	Client Communication - Standard Medicaid
CARDIOVASCULAR DISEASE - LIPID IRREGULARITY	JUXTAPID	LOMITAPIDE MESYLATE	30 MG	CAPSULE	ORAL	SSB	F	S=F	PA	C=PA	Clinical/Safety Strategy		N/A
CARDIOVASCULAR DISEASE - LIPID IRREGULARITY	JUXTAPID	LOMITAPIDE MESYLATE	40 MG	CAPSULE	ORAL	SSB	F	S=F	PA	C=PA	Clinical/Safety Strategy		N/A
CARDIOVASCULAR DISEASE - LIPID IRREGULARITY	JUXTAPID	LOMITAPIDE MESYLATE	5 MG	CAPSULE	ORAL	SSB	F	S=F	PA	C=PA	Clinical/Safety Strategy		N/A
CARDIOVASCULAR DISEASE - LIPID IRREGULARITY	JUXTAPID	LOMITAPIDE MESYLATE	60 MG	CAPSULE	ORAL	SSB	F	S=F	PA	C=PA	Clinical/Safety Strategy		N/A
CARDIOVASCULAR DISEASE - LIPID IRREGULARITY	NIACIN ER	NIACIN	1000 MG	TAB ER 24H	ORAL	GENERIC	F	S=F	ST	D=ST	Low Net Cost Strategy		N/A
CARDIOVASCULAR DISEASE - LIPID IRREGULARITY	NIACIN ER	NIACIN	500 MG	TAB ER 24H	ORAL	GENERIC	F	S=F	ST	D=ST	Low Net Cost Strategy		N/A
CARDIOVASCULAR DISEASE - LIPID IRREGULARITY	NIACIN ER	NIACIN	750 MG	TAB ER 24H	ORAL	GENERIC	F	S=F	ST	D=ST	Low Net Cost Strategy		N/A
CARDIOVASCULAR DISEASE - LIPID IRREGULARITY	PRALUENT PEN	ALIROCUMAB	150 MG/ML	PEN INJCTR	SUBCUTANE.	SSB	NC	S=NC	PA	C=PA	Clinical/Safety Strategy		N/A
CARDIOVASCULAR DISEASE - LIPID IRREGULARITY	PRALUENT PEN	ALIROCUMAB	75 MG/ML	PEN INJCTR	SUBCUTANE.	SSB	NC	S=NC	PA	C=PA	Clinical/Safety Strategy		N/A
CARDIOVASCULAR DISEASE - LIPID IRREGULARITY	REPATHA SURECLICK	EVOLOCUMAB	140 MG/ML	PEN INJCTR	SUBCUTANE.	SSB	NC	S=NC	PA	C=PA	Clinical/Safety Strategy		N/A
CARDIOVASCULAR DISEASE - LIPID IRREGULARITY	REPATHA SYRINGE	EVOLOCUMAB	140 MG/ML	SYRINGE	SUBCUTANE.	SSB	NC	S=NC	PA	C=PA	Clinical/Safety Strategy		N/A

2Q20 Formulary Actions

Drug							Formulary Status Medicaid		Utilization Management Medicaid				
Category	Brand Name	Generic Name	Strength	Dosage Form	Route	Brand Status	Current Status	Action	Current Status	Action	Rationale of Changes	Optional Benefit Exclusion	Client Communication - Standard Medicaid
CARDIOVASCULAR DISEASE - LIPID IRREGULARITY	REPATHA PUSHTRONEX	EVOLOCUMAB	420 MG/3.5	WEAR INJCT	SUBCUTANE.	SSB	F	S=F	PA	C=PA	Clinical/Safety Strategy		N/A
DERMATOLOGY - ACNE	ARAZLO	TAZAROTENE	0.045 %	LOTION	TOPICAL	SSB	NC	S=NC	AGE	A=ST S=AGE	Low Net Cost Strategy		ST: TRIAL OF 1 OF THE FOLLOWING GENERIC TOPICALS: TAZAROTENE, TRETINOIN, OR ADAPALENE (GEL, CREAM, LOTION, OR SOLUTION) REQUIRED IN THE PAST 120 DAYS
DERMATOLOGY - ANTIINFECTIVE	DOUBLE ANTIBIOTIC	BACITRACIN/POLYMYXIN B SULFATE	500-10K/G	OINT. (G)	TOPICAL	GENERIC	F	C=NC	NONE	NONE	Low Net Cost Strategy	Class O	N/A
DERMATOLOGY - ANTIINFECTIVE	KETOCONAZOLE	KETOCONAZOLE	2 %	FOAM	TOPICAL	GENERIC	F	C=NC	NONE	A=ST	Low Net Cost Strategy		ST: TRIAL OF KETOCONAZOLE 2% CREAM OR SHAMPOO IN THE PREVIOUS 120 DAYS
DERMATOLOGY - ANTIINFECTIVE	XOLEGEL	KETOCONAZOLE	2 %	GEL (GRAM)	TOPICAL	SSB	NC	S=NC	NONE	A=ST	Low Net Cost Strategy		ST: TRIAL OF KETOCONAZOLE 2% CREAM OR SHAMPOO IN THE PREVIOUS 120 DAYS
DERMATOLOGY - ANTIINFLAMMATORY	PENNSAID	DICLOFENAC SODIUM	2.00%	SOLN PK(G)	TOPICAL	SSB	NC	S=NC	ST	C=ST			ST: TRIAL OF GENERIC DICLOFENAC GEL OR DROPS IN THE PREVIOUS 120 DAYS
DERMATOLOGY - ANTIINFLAMMATORY	PENNSAID	DICLOFENAC SODIUM	20MG/G(2%)	SOL MD PMP	TOPICAL	SSB	NC	S=NC	ST	C=ST	Low Net Cost Strategy		ST: TRIAL OF GENERIC DICLOFENAC GEL OR DROPS IN THE PREVIOUS 120 DAYS
DERMATOLOGY - MISCELLANEOUS	TARGRETIN	BEXAROTENE	1 %	GEL (GRAM)	TOPICAL	SSB	F	S=F	PA	C=PA	Clinical/Safety Strategy		N/A
DERMATOLOGY - MISCELLANEOUS	LIDOCAINE	LIDOCAINE	5 %	OINT. (G)	TOPICAL	GENERIC	F	S=F	QL,ST	D=ST S=QL	Low Net Cost Strategy		N/A
DERMATOLOGY - PSORIASIS/ECZEMA	TALTZ AUTOINJECTOR	IXEKIZUMAB	80 MG/ML	AUTO INJCT	SUBCUTANE.	SSB	F	S=F	PA	C=PA	Clinical/Safety Strategy		N/A
DERMATOLOGY - PSORIASIS/ECZEMA	TALTZ SYRINGE	IXEKIZUMAB	80 MG/ML	SYRINGE	SUBCUTANE.	SSB	F	S=F	PA	C=PA	Clinical/Safety Strategy		N/A

2Q20 Formulary Actions

Drug							Formulary Status Medicaid		Utilization Management Medicaid				
Category	Brand Name	Generic Name	Strength	Dosage Form	Route	Brand Status	Current Status	Action	Current Status	Action	Rationale of Changes	Optional Benefit Exclusion	Client Communication - Standard Medicaid
DERMATOLOGY - PSORIASIS/ECZEMA	COSENTYX PEN (2 PENS)	SECUKINUMAB	150 MG/ML	PEN INJCTR	SUBCUTANE.	SSB	F	S=F	PA	C=PA	Clinical/Safety Strategy		N/A
DERMATOLOGY - PSORIASIS/ECZEMA	COSENTYX SYRINGE	SECUKINUMAB	150 MG/ML	SYRINGE	SUBCUTANE.	SSB	F	S=F	PA	C=PA	Clinical/Safety Strategy		N/A
DIABETES	RIOMET ER	METFORMIN HCL	500 MG/5ML	SUS ER REC	ORAL	SSB	NC	S=NC	PA	D=PA A=ST	Low Net Cost Strategy		ST: TRIAL OF METFORMIN IR TABLETS/SOLUTION OR ER TABLETS IN THE PREVIOUS 120 DAYS
DIABETES	TANZEUM	ALBIGLUTIDE	30MG/0.5ML	PEN INJCTR	SUBCUTANE.	SSB	NC	S=NC	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF TRULICITY, VICTOZA, OZEMPIC, OR RYBELSUS IN THE PREVIOUS 120 DAYS
DIABETES	TANZEUM	ALBIGLUTIDE	50MG/0.5ML	PEN INJCTR	SUBCUTANE.	SSB	NC	S=NC	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF TRULICITY, VICTOZA, OZEMPIC, OR RYBELSUS IN THE PREVIOUS 120 DAYS
DIABETES	BYETTA	EXENATIDE	10MCG/0.04	PEN INJCTR	SUBCUTANE.	SSB	NC	S=NC	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF TRULICITY, VICTOZA, OZEMPIC, OR RYBELSUS IN THE PREVIOUS 120 DAYS
DIABETES	BYETTA	EXENATIDE	5MCG/0.02	PEN INJCTR	SUBCUTANE.	SSB	NC	S=NC	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF TRULICITY, VICTOZA, OZEMPIC, OR RYBELSUS IN THE PREVIOUS 120 DAYS
DIABETES	BYDUREON	EXENATIDE MICROSPHERES	2 MG	VIAL	SUBCUTANE.	SSB	NC	S=NC	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF TRULICITY, VICTOZA, OZEMPIC, OR RYBELSUS IN THE PREVIOUS 120 DAYS
DIABETES	BYDUREON PEN	EXENATIDE MICROSPHERES	2MG/0.65ML	PEN INJCTR	SUBCUTANE.	SSB	NC	S=NC	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF TRULICITY, VICTOZA, OZEMPIC, OR RYBELSUS IN THE PREVIOUS 120 DAYS
DIABETES	BYDUREON BCISE	EXENATIDE MICROSPHERES	2MG/0.85ML	AUTO INJCT	SUBCUTANE.	SSB	NC	S=NC	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF TRULICITY, VICTOZA, OZEMPIC, OR RYBELSUS IN THE PREVIOUS 120 DAYS
DIABETES	ADLYXIN	LIXISENATIDE	10-20 (1)	PEN INJCTR	SUBCUTANE.	SSB	NC	S=NC	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF TRULICITY, VICTOZA, OZEMPIC, OR RYBELSUS IN THE PREVIOUS 120 DAYS
DIABETES	ADLYXIN	LIXISENATIDE	20 MCG/0.2	PEN INJCTR	SUBCUTANE.	SSB	NC	S=NC	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF TRULICITY, VICTOZA, OZEMPIC, OR RYBELSUS IN THE PREVIOUS 120 DAYS
DIABETES	SOLIQUA 100-33	INSULIN GLARGINE/LIXISENATIDE	100-33/ML	INSULN PEN	SUBCUTANE.	SSB	F	S=F	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF ONE OF THE FOLLOWING: BASAGLAR, TRESIBA, TRULICITY, OZEMPIC, RYBELSUS, OR VICTOZA IN THE PREVIOUS 120 DAYS
DIABETES	FARXIGA	DAPAGLIFLOZIN PROPANEDIOL	10 MG	TABLET	ORAL	SSB	NC	S=NC	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF STEGLATRO, SEGLUROMET, INVOKANA, INVOKAMET OR INVOKAMET XR IN THE PREVIOUS 120 DAYS
DIABETES	FARXIGA	DAPAGLIFLOZIN PROPANEDIOL	5 MG	TABLET	ORAL	SSB	NC	S=NC	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF STEGLATRO, SEGLUROMET, INVOKANA, INVOKAMET OR INVOKAMET XR IN THE PREVIOUS 120 DAYS
DIABETES	XIGDUO XR	DAPAGLIFLOZIN/METFORMIN HCL	10-1000 MG	TAB BP 24H	ORAL	SSB	NC	S=NC	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF STEGLATRO, SEGLUROMET, INVOKANA, INVOKAMET OR INVOKAMET XR IN THE PREVIOUS 120 DAYS
DIABETES	XIGDUO XR	DAPAGLIFLOZIN/METFORMIN HCL	10MG-500MG	TAB BP 24H	ORAL	SSB	NC	S=NC	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF STEGLATRO, SEGLUROMET, INVOKANA, INVOKAMET OR INVOKAMET XR IN THE PREVIOUS 120 DAYS
DIABETES	XIGDUO XR	DAPAGLIFLOZIN/METFORMIN HCL	2.5-1000MG	TAB BP 24H	ORAL	SSB	NC	S=NC	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF STEGLATRO, SEGLUROMET, INVOKANA, INVOKAMET OR INVOKAMET XR IN THE PREVIOUS 120 DAYS
DIABETES	XIGDUO XR	DAPAGLIFLOZIN/METFORMIN HCL	5 MG-500MG	TAB BP 24H	ORAL	SSB	NC	S=NC	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF STEGLATRO, SEGLUROMET, INVOKANA, INVOKAMET OR INVOKAMET XR IN THE PREVIOUS 120 DAYS

2Q20 Formulary Actions

Drug							Formulary Status Medicaid		Utilization Management Medicaid				
Category	Brand Name	Generic Name	Strength	Dosage Form	Route	Brand Status	Current Status	Action	Current Status	Action	Rationale of Changes	Optional Benefit Exclusion	Client Communication - Standard Medicaid
DIABETES	XIGDUO XR	DAPAGLIFLOZIN/METFORMIN HCL	5MG-1000MG	TAB BP 24H	ORAL	SSB	NC	S=NC	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF STEGLATRO, SEGLUROMET, INVOKANA, INVOKAMET OR INVOKAMET XR IN THE PREVIOUS 120 DAYS
DIABETES	QTERN	DAPAGLIFLOZIN/SAXAGLIPTIN HCL	10 MG-5 MG	TABLET	ORAL	SSB	NC	S=NC	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF STEGLATRO, SEGLUROMET, INVOKANA, INVOKAMET OR INVOKAMET XR IN THE PREVIOUS 120 DAYS
DIABETES	QTERN	DAPAGLIFLOZIN/SAXAGLIPTIN HCL	5 MG-5 MG	TABLET	ORAL	SSB	NC	S=NC	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF STEGLATRO, SEGLUROMET, INVOKANA, INVOKAMET OR INVOKAMET XR IN THE PREVIOUS 120 DAYS
DIABETES	TRIJARDY XR	EMPAGLIFLOZ/LINAGLIP/METFORMIN	10-5-1000	TAB BP 24H	ORAL	SSB	NC	S=NC	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF STEGLATRO, SEGLUROMET, INVOKANA, INVOKAMET OR INVOKAMET XR IN THE PREVIOUS 120 DAYS
DIABETES	TRIJARDY XR	EMPAGLIFLOZ/LINAGLIP/METFORMIN	12.5-2.5MG	TAB BP 24H	ORAL	SSB	NC	S=NC	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF STEGLATRO, SEGLUROMET, INVOKANA, INVOKAMET OR INVOKAMET XR IN THE PREVIOUS 120 DAYS
DIABETES	TRIJARDY XR	EMPAGLIFLOZ/LINAGLIP/METFORMIN	25-5-1000	TAB BP 24H	ORAL	SSB	NC	S=NC	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF STEGLATRO, SEGLUROMET, INVOKANA, INVOKAMET OR INVOKAMET XR IN THE PREVIOUS 120 DAYS
DIABETES	TRIJARDY XR	EMPAGLIFLOZ/LINAGLIP/METFORMIN	5-2.5-1000	TAB BP 24H	ORAL	SSB	NC	S=NC	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF STEGLATRO, SEGLUROMET, INVOKANA, INVOKAMET OR INVOKAMET XR IN THE PREVIOUS 120 DAYS
DIABETES	JARDIANCE	EMPAGLIFLOZIN	10 MG	TABLET	ORAL	SSB	NC	S=NC	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF STEGLATRO, SEGLUROMET, INVOKANA, INVOKAMET OR INVOKAMET XR IN THE PREVIOUS 120 DAYS
DIABETES	JARDIANCE	EMPAGLIFLOZIN	25 MG	TABLET	ORAL	SSB	NC	S=NC	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF STEGLATRO, SEGLUROMET, INVOKANA, INVOKAMET OR INVOKAMET XR IN THE PREVIOUS 120 DAYS
DIABETES	GLYXAMBI	EMPAGLIFLOZIN/LINAGLIPTIN	10 MG-5 MG	TABLET	ORAL	SSB	F	S=F	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	GLYXAMBI	EMPAGLIFLOZIN/LINAGLIPTIN	25 MG-5 MG	TABLET	ORAL	SSB	F	S=F	QL,ST	D=ST S=QL	Trade Relations Strategy		N/A
DIABETES	SYNJARDY XR	EMPAGLIFLOZIN/METFORMIN HCL	10-1000 MG	TAB BP 24H	ORAL	SSB	NC	S=NC	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF STEGLATRO, SEGLUROMET, INVOKANA, INVOKAMET OR INVOKAMET XR IN THE PREVIOUS 120 DAYS
DIABETES	SYNJARDY	EMPAGLIFLOZIN/METFORMIN HCL	12.5-1000	TABLET	ORAL	SSB	NC	S=NC	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF STEGLATRO, SEGLUROMET, INVOKANA, INVOKAMET OR INVOKAMET XR IN THE PREVIOUS 120 DAYS
DIABETES	SYNJARDY XR	EMPAGLIFLOZIN/METFORMIN HCL	12.5-1000	TAB BP 24H	ORAL	SSB	NC	S=NC	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF STEGLATRO, SEGLUROMET, INVOKANA, INVOKAMET OR INVOKAMET XR IN THE PREVIOUS 120 DAYS
DIABETES	SYNJARDY	EMPAGLIFLOZIN/METFORMIN HCL	12.5-500MG	TABLET	ORAL	SSB	NC	S=NC	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF STEGLATRO, SEGLUROMET, INVOKANA, INVOKAMET OR INVOKAMET XR IN THE PREVIOUS 120 DAYS
DIABETES	SYNJARDY XR	EMPAGLIFLOZIN/METFORMIN HCL	25-1000 MG	TAB BP 24H	ORAL	SSB	NC	S=NC	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF STEGLATRO, SEGLUROMET, INVOKANA, INVOKAMET OR INVOKAMET XR IN THE PREVIOUS 120 DAYS
DIABETES	SYNJARDY	EMPAGLIFLOZIN/METFORMIN HCL	5 MG-500MG	TABLET	ORAL	SSB	NC	S=NC	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF STEGLATRO, SEGLUROMET, INVOKANA, INVOKAMET OR INVOKAMET XR IN THE PREVIOUS 120 DAYS
DIABETES	SYNJARDY	EMPAGLIFLOZIN/METFORMIN HCL	5MG-1000MG	TABLET	ORAL	SSB	NC	S=NC	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF STEGLATRO, SEGLUROMET, INVOKANA, INVOKAMET OR INVOKAMET XR IN THE PREVIOUS 120 DAYS
DIABETES	SYNJARDY XR	EMPAGLIFLOZIN/METFORMIN HCL	5MG-1000MG	TAB BP 24H	ORAL	SSB	NC	S=NC	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF STEGLATRO, SEGLUROMET, INVOKANA, INVOKAMET OR INVOKAMET XR IN THE PREVIOUS 120 DAYS
DIABETES	STEGLUJAN	ERTUGLIFLOZIN/SITAGLIPTIN	15MG-100MG	TABLET	ORAL	SSB	NC	S=NC	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF STEGLATRO, SEGLUROMET, INVOKANA, INVOKAMET OR INVOKAMET XR IN THE PREVIOUS 120 DAYS
DIABETES	STEGLUJAN	ERTUGLIFLOZIN/SITAGLIPTIN	5 MG-100MG	TABLET	ORAL	SSB	NC	S=NC	QL,ST	S=QL C=ST	Trade Relations Strategy		ST: TRIAL OF STEGLATRO, SEGLUROMET, INVOKANA, INVOKAMET OR INVOKAMET XR IN THE PREVIOUS 120 DAYS

2Q20 Formulary Actions

Drug							Formulary Status Medicaid		Utilization Management Medicaid				
Category	Brand Name	Generic Name	Strength	Dosage Form	Route	Brand Status	Current Status	Action	Current Status	Action	Rationale of Changes	Optional Benefit Exclusion	Client Communication - Standard Medicaid
ENDOCRINE DISORDER - OTHER	ACTHAR	CORTICOTROPIN	80 UNIT/ML	VIAL	INJECTION	SSB	NC	S=NC	PA	C=PA	Clinical/Safety Strategy	Non-Self Administered Drug (NSA)	N/A
ENDOCRINE DISORDER - OTHER	INCRELEX	MECASERMIN	10 MG/ML	VIAL	SUBCUTANE.	SSB	F	S=F	PA	C=PA	Clinical/Safety Strategy		N/A
HEMATOLOGICAL DISORDERS	REBLOZYL	LUSPATERCEPT-AAMT	25 MG	VIAL	SUBCUTANE.	SSB	NC	S=NC	PA	C=PA	Clinical/Safety Strategy	Non-Self Administered Drug (NSA)	N/A
HEMATOLOGICAL DISORDERS	REBLOZYL	LUSPATERCEPT-AAMT	75 MG	VIAL	SUBCUTANE.	SSB	NC	S=NC	PA	C=PA	Clinical/Safety Strategy	Non-Self Administered Drug (NSA)	N/A
INFECTIOUS DISEASE - VIRAL	HARVONI	LEDIPASVIR/SOFOSBUVIR	45MG-200MG	TABLET	ORAL	SSB	F	S=F	PA	C=PA	Clinical/Safety Strategy		N/A
INFECTIOUS DISEASE - VIRAL	HARVONI	LEDIPASVIR/SOFOSBUVIR	90MG-400MG	TABLET	ORAL	GENERIC/ MSB	F	S=F	PA	C=PA	Clinical/Safety Strategy		N/A
INFECTIOUS DISEASE - VIRAL	EPCLUSA	SOFOSBUVIR/VELPATASVIR	400-100 MG	TABLET	ORAL	GENERIC/ MSB	F	S=F	PA	C=PA	Clinical/Safety Strategy		N/A
INFLAMMATORY DISEASE	HYALGAN	HYALURONATE SODIUM	10 MG/ML	VIAL	INTRAARTIC	SSB	NC	S=NC	PA	C=PA	Clinical/Safety Strategy		N/A
INFLAMMATORY DISEASE	MULTIPLE BRAND NAMES	HYALURONATE SODIUM	10 MG/ML	SYRINGE	INTRAARTIC	SSB	NC	S=NC	PA	C=PA	Clinical/Safety Strategy		N/A
INFLAMMATORY DISEASE	GELSYN-3	HYALURONATE SODIUM	16.8MG/2ML	SYRINGE	INTRAARTIC	SSB	NC	S=NC	PA	C=PA	Clinical/Safety Strategy		N/A
INFLAMMATORY DISEASE	ORTHOVISC	HYALURONATE SODIUM	30 MG/2 ML	SYRINGE	INTRAARTIC	SSB	NC	S=NC	PA	C=PA	Clinical/Safety Strategy		N/A
INFLAMMATORY DISEASE	DUROLANE	HYALURONATE SODIUM, STABILIZED	60 MG/3 ML	SYRINGE	INTRAARTIC	SSB	NC	S=NC	PA	C=PA	Clinical/Safety Strategy		N/A
INFLAMMATORY DISEASE	MONOVISC	HYALURONATE SODIUM, STABILIZED	88 MG/4 ML	SYRINGE	INTRAARTIC	SSB	NC	S=NC	PA	C=PA	Clinical/Safety Strategy		N/A
INFLAMMATORY DISEASE	HYMOVIS	HYALURONATE,MOD.,NON-CROSSLINK	24 MG/3 ML	SYRINGE	INTRAARTIC	SSB	NC	S=NC	PA	C=PA	Clinical/Safety Strategy		N/A
INFLAMMATORY DISEASE	SYNVISC	HYLAN G-F 20	16MG/2ML	SYRINGE	INTRAARTIC	SSB	NC	S=NC	PA	C=PA	Clinical/Safety Strategy		N/A
INFLAMMATORY DISEASE	SYNVISC-ONE	HYLAN G-F 20	48 MG/6 ML	SYRINGE	INTRAARTIC	SSB	NC	S=NC	PA	C=PA	Clinical/Safety Strategy		N/A
LOWER GASTROINTESTINAL DISORDERS - OTHER	GATTEX	TEDUGLUTIDE	5 MG	KIT	SUBCUTANE.	SSB	F	S=F	PA	C=PA	Clinical/Safety Strategy		N/A

2Q20 Formulary Actions

Drug							Formulary Status Medicaid		Utilization Management Medicaid				
Category	Brand Name	Generic Name	Strength	Dosage Form	Route	Brand Status	Current Status	Action	Current Status	Action	Rationale of Changes	Optional Benefit Exclusion	Client Communication - Standard Medicaid
MISCELLANEOUS AGENTS	SPINRAZA	NUSINERSEN SODIUM/PF	12MG/5ML	VIAL	INTRATHEC.	SSB	NC	S=NC	PA	C=PA	Clinical/Safety Strategy	Non-Self Administered Drug (NSA)	N/A
NEOPLASTIC DISEASE	BELEODAQ	BELINOSTAT	500 MG	VIAL	INTRAVEN.	SSB	NC	S=NC	PA	C=PA	Clinical/Safety Strategy	Non-Self Administered Drug (NSA)	N/A
NEOPLASTIC DISEASE	AVASTIN	BEVACIZUMAB	25 MG/ML	VIAL	INTRAVEN.	SSB	NC	S=NC	PA	S=PA		Non-Self Administered Drug (NSA)	N/A
NEOPLASTIC DISEASE	MVASI	BEVACIZUMAB-AWWB	25 MG/ML	VIAL	INTRAVEN.	SSB	NC	S=NC	PA	S=PA		Non-Self Administered Drug (NSA)	N/A
NEOPLASTIC DISEASE	ZIRABEV	BEVACIZUMAB-BVZR	25 MG/ML	VIAL	INTRAVEN.	SSB	NC	S=NC	PA	S=PA		Non-Self Administered Drug (NSA)	N/A
NEOPLASTIC DISEASE	BEXAROTENE	BEXAROTENE	75 MG	CAPSULE	ORAL	GENERIC	F	S=F	PA	C=PA	Clinical/Safety Strategy		N/A
NEOPLASTIC DISEASE	CAPECITABINE	CAPECITABINE	150 MG	TABLET	ORAL	GENERIC	F	S=F	PA,QL	D=QL C=PA	Clinical/Safety Strategy		N/A
NEOPLASTIC DISEASE	CAPECITABINE	CAPECITABINE	500 MG	TABLET	ORAL	GENERIC	F	S=F	PA,QL	D=QL C=PA	Clinical/Safety Strategy		N/A
NEOPLASTIC DISEASE	IMFINZI	DURVALUMAB	120 MG/2.4	VIAL	INTRAVEN.	SSB	NC	S=NC	PA	C=PA	Clinical/Safety Strategy	Non-Self Administered Drug (NSA)	N/A
NEOPLASTIC DISEASE	IMFINZI	DURVALUMAB	500MG/10ML	VIAL	INTRAVEN.	SSB	NC	S=NC	PA	C=PA	Clinical/Safety Strategy	Non-Self Administered Drug (NSA)	N/A
NEOPLASTIC DISEASE	BRAFTOVI	ENCORAFENIB	50 MG	CAPSULE	ORAL	SSB	F	S=F	PA,QL	D=QL C=PA	Clinical/Safety Strategy		N/A
NEOPLASTIC DISEASE	BRAFTOVI	ENCORAFENIB	75 MG	CAPSULE	ORAL	SSB	F	S=F	PA,QL	D=QL C=PA	Clinical/Safety Strategy		N/A
NEOPLASTIC DISEASE	YERVOY	IPILIMUMAB	50 MG/10ML	VIAL	INTRAVEN.	SSB	NC	S=NC	PA	C=PA	Clinical/Safety Strategy	Non-Self Administered Drug (NSA)	N/A
NEOPLASTIC DISEASE	NERLYNX	NERATINIB MALEATE	40 MG	TABLET	ORAL	SSB	NC	S=NC	PA	C=PA	Clinical/Safety Strategy		N/A
NEOPLASTIC DISEASE	HERCEPTIN	TRASTUZUMAB	150 MG	VIAL	INTRAVEN.	SSB	NC	S=NC	PA	S=PA		Non-Self Administered Drug (NSA)	N/A
NEOPLASTIC DISEASE	HERCEPTIN	TRASTUZUMAB	440 MG	VIAL	INTRAVEN.	SSB	NC	S=NC	PA	S=PA		Non-Self Administered Drug (NSA)	N/A
NEOPLASTIC DISEASE	KANJINTI	TRASTUZUMAB-ANNS	150 MG	VIAL	INTRAVEN.	SSB	NC	S=NC	PA	S=PA		Non-Self Administered Drug (NSA)	N/A

2Q20 Formulary Actions

Drug							Formulary Status Medicaid		Utilization Management Medicaid				
Category	Brand Name	Generic Name	Strength	Dosage Form	Route	Brand Status	Current Status	Action	Current Status	Action	Rationale of Changes	Optional Benefit Exclusion	Client Communication - Standard Medicaid
NEOPLASTIC DISEASE	KANJINTI	TRASTUZUMAB-ANNS	420 MG	VIAL	INTRAVEN.	SSB	NC	S=NC	PA	S=PA		Non-Self Administered Drug (NSA)	N/A
NEOPLASTIC DISEASE	OGIVRI	TRASTUZUMAB-DKST	150 MG	VIAL	INTRAVEN.	SSB	NC	S=NC	PA	S=PA		Non-Self Administered Drug (NSA)	N/A
NEOPLASTIC DISEASE	OGIVRI	TRASTUZUMAB-DKST	420 MG	VIAL	INTRAVEN.	SSB	NC	S=NC	PA	S=PA		Non-Self Administered Drug (NSA)	N/A
NEOPLASTIC DISEASE	HERCEPTIN HYLECTA	TRASTUZUMAB-HYALURONIDASE-OYSK	600-10000	VIAL	SUBCUTANE.	SSB	NC	S=NC	PA	S=PA		Non-Self Administered Drug (NSA)	N/A
NEOPLASTIC DISEASE	TRAZIMERA	TRASTUZUMAB-QYYP	420 MG	VIAL	INTRAVEN.	SSB	NC	S=NC	PA	S=PA		Non-Self Administered Drug (NSA)	N/A
NEOPLASTIC DISEASE	MARQIBO	VINCRISTINE SULFATE LIPOSOMAL	FNL 5MG/31	KIT	INTRAVEN.	SSB	NC	S=NC	PA	C=PA	Clinical/Safety Strategy	Non-Self Administered Drug (NSA)	N/A
OTHER DRUGS	MEPSEVII	VESTRONIDASE ALFA-VJBK	10 MG/5 ML	VIAL	INTRAVEN.	SSB	NC	S=NC	PA	C=PA	Clinical/Safety Strategy	Non-Self Administered Drug (NSA)	N/A
OTHER DRUGS	MOZOBIL	PLERIXAFOR	24MG/1.2ML	VIAL	SUBCUTANE.	SSB	NC	S=NC	PA	C=PA	Clinical/Safety Strategy	Non-Self Administered Drug (NSA)	N/A
OTHER DRUGS	ZAVESCA	MIGLUSTAT	100 MG	CAPSULE	ORAL	MSB/ GENERIC	F	S=F	PA	C=PA	Clinical/Safety Strategy		N/A
OTHER RESPIRATORY DISORDERS	OFEV	NINTEDANIB ESYLATE	100 MG	CAPSULE	ORAL	SSB	F	S=F	PA	C=PA	Clinical/Safety Strategy		N/A
OTHER RESPIRATORY DISORDERS	OFEV	NINTEDANIB ESYLATE	150 MG	CAPSULE	ORAL	SSB	F	S=F	PA	C=PA	Clinical/Safety Strategy		N/A
PAIN MANAGEMENT - ANALGESICS	NURTEC ODT	RIMEGEPANT SULFATE	75 MG	TAB RAPDIS	ORAL	SSB	NC	S=NC	PA	C=PA	Clinical/Safety Strategy		N/A
PARKINSONS DISEASE	ZELAPAR	SELEGILINE HCL	1.25 MG	TAB RAPDIS	ORAL	SSB	NC	S=NC	QL	A=ST S=QL	Low Net Cost Strategy		ST: TRIAL OF GENERIC SELEGILINE CAPSULES OR TABLETS IN THE PREVIOUS 120 DAYS

Executive Summaries Tab: 3a

Pharmacy & Therapeutics (P&T) Committee General Consent		
General Considerations	Per Chapter 6 of the Medicare Prescription Drug Benefits Manual, a Part D sponsor's formulary must be developed and reviewed by a P&T committee that meets specific requirements with respect to: membership; conflict of interest; P&T member disclosure to CMS; meeting administration; formulary management; formulary exceptions; and P&T committee role. The P&T Committee must make a reasonable effort to review a new FDA approved drug product (or new FDA approved indication) within 90 days of its release onto the market and will make a decision on each new FDA approved drug product (or new FDA approved indication) within 180 days of its release onto the market, or a clinical justification will be provided if this timeframe is not met. For Medicare Part D, the P&T Committee will follow the CMS-mandated timelines. Formularies must include substantially all drugs in the six protected class categories: immunosuppressant (for prophylaxis of organ transplant rejection), antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic) that are FDA approved by the last CMS specified HPMS formulary upload date for the upcoming contract year. New drugs or newly approved uses for drugs within the six classes that come onto the market after the CMS specified formulary upload date will be subject to an expedited P&T committee review. The expedited review process requires P&T committees to make a decision within 90 days, rather than the normal 180-day requirement. At the end of the 90 day period, these drugs must be added to Part D plan formularies. References: Medicare Prescription Drug Benefit Manual -Chapter 6 - Part D Drugs and Formulary Requirements Section 30	
Tab 3b	Formulary Structure White Paper	2019 Standard Part D Formulary Structure White Paper serves to describe the MedImpact Standard Part D Formularies for 2019. Part D Formularies are available with a number of options to support the structural and operational reporting requirements of the Part D program. Plan Sponsors should use this document to determine which formulary options best meet their needs for the 2019 plan year. Tables below show bucket description and distribuiton of buckets between the three main formulary structures supported by standard.
Tab 3c	Legend	Table listing and explaining short forms and colors used in the material.
Tab 3d	Line-extensions	Line Extensions are new salts, enantiomers or prodrugs of existing drugs. Formulary Placement and Utilization Management decisions for line extensions are aligned with the existing drugs. Most of the line extensions are added to formulary with the utilization management that are approved and applied for existing drugs and placement is brought retrospectively to P&T. Although there are some instances when we bring proposals to P&T for line extensions. For example Xelpros which is a new branded product of the existing generic entity. Drug placements highlighted in green on this tab are line extensions pending the P&T committee's review and approval for prospective formulary placement and utilization management. -Drug placements highlighted in blue represent placement proposals for drugs made by manufacturers that are currently non-participating (i.e. manufacturers who do no have a agreement with CMS to provide discount on brand drugs while medicare benefeciaries are in coverage gap.) and hence non-D eligible. Once they become Part D eligible we will apply the proposed placements.
Tab 3e	New Generics	Formulary Placement and Utilization Management decisions for new generics are mostly made the week the drug is available in the drug file. Utilization Managment is utilized from applied and approved reference brand names. Placement proposals are brought retrospectively to P&T for review and approval.
Tab 3f	New FDA approved drugs	Formulary placement and utilization management decisions on new drugs are based on cost, clinical and rebate related implications. If a new drug meets the specialty cost threshold (>$670/month) it's placed on formulary at the next effective date (usually the Saturday after the drug is available in the drug file). Placement for newly FDA approved drugs that do not meet specialty are brought to P&T for review and approval. Drug placements highlighted in green on this tab are line extensions pending the P&T committee's review and approval for prospective formulary placement and utilization management. Drug placements highlighted in blue represent placement proposals for drugs made by manufacturers that are currently non-participating labelers (i.e. manufacturers who do not have an agreement with CMS to provide discount on brand drugs while Medicare beneficiaries are in coverage gap.) and are therefore not eligible for Part D coverage. When the drugs become Part D eligible we will apply the proposed placements and utilization management.

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Tab 3g	Proposed/Updated Utilization Management Edits	This tab displays any quantity limits, prior authorization and step therapy restrictions applied to line extensions, new generics and any utilization management edits proposed for new drugs. Additionally, this tab provides updates to any existing utilization mangement edits or criteria.
Tab 3h	Expedited Review	This tab is reserved for any high impact drugs or protected class drugs (PCD) released the week of P&T and expeditious review is warranted.
Tab 3i	Other Formulary Changes	This tab includes some formulary enhancements and CMS approved negative changes (E.x. brand generic offsets).
Tab 3j	New FDA approved indications	CMS requires a review of all new indications for drugs on formulary to determine if any changes in placement or utilization management are necessary. New indications are reviewed by Drug Information and changes to formulary status or existing prior authorization criteria as a result are summarized here. For prior authorization (PA) criteria update details refer to the Drug Information documents.

TABLE 1		
2020 Bucket	**Content**	*** Please refer to Standard Part D White Paper for details on each bucket**
G-L, G-M, G-H, G-PPM, G-PPH, G-NP, G-VH, G-PPVH, G-L-STAR, G-M-STAR, G-INS, G-INSP, G-VACC, G-X, G-SHORTAGE, INS-X	Generics	
B-L, B-M, B-H, B-VACC, B-INS, B-INSP, B-PP, B-MS, B-NP, B-SHORTAGE, BMSREB-GH, BMSREB-GL, INS-REBGH	Brands	
S-L, S-M, S-PPL, S-PPM, S-MS, S-NP, S-X, S-MSREB, S-SHORTAGE	Specialty (>$670 per month)	
Advantage	**Plus Closed**	**Plus Open**
Buckets	**Adding to Advantage Buckets**	**Adding to Advantage and Plus Closed Buckets**
G-L, G-M, G-H, G-VH, B-L, B-INS, B-M, B-VACC, S-L, S-M	G-PPM, G-PPH, G-PPVH, B-H, B-PP, S-PPL, S-PPM	G-NP, B-MS, S-MS, S-NP, SL-NP

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2020 Standard Part D Formulary Structure White Paper

Updated February 14th, 2019

INTRODUCTION

This document serves to describe the MedImpact Standard Part D Formularies for 2020. Part D Formularies are available with a number of options to support the structural and operational reporting requirements of the Part D program. Plan Sponsors should use this document to determine which formulary options best meet their needs for the 2020 plan year.

Please note that tremendous strategic, clinical, and operational effort goes into making our Standard Part D Formularies valuable, effective, operationally sound, and CMS-compliant. Significant annual changes in CMS processes and requirements, levied under extremely aggressive time frames, result in formulary process evolution each and every year to meet and exceed CMS mandates. As a result of the significant work involved in creating the available options for the MedImpact Standard Part D Formularies for each plan year, deviations from the options outlined in this document are not possible for the 2020 Medicare plan year. MedImpact is proud to offer our Part D Standard Formulary offerings to you as an integral component of a successful 2020 CMS contract year.

MEDIMPACT PART D STANDARD FORMULARY MAIN OPTIONS

At the highest level, MedImpact has 2 Standard Part D Formularies to consider:

MedImpact Advantage Formulary – The Advantage formulary is a net cost-focused formulary with significantly greater restrictions. It is intended for a closed formulary design. The Advantage formulary is often used when greater cost control is desired.

MedImpact Plus Formulary – The Plus formulary is designed for broader access and is intended for a closed formulary design under a variety of different tier structures. The Plus formulary is often used in situations where offering more generous beneficiary access to drug coverage is desired.

In order to reduce "two of class" issues and to better streamline our formularies, we will continue to apply a MedImpact custom therapeutic classification to our 2020 Part D formularies. The MedImpact custom therapeutic classification is based on a modification of the AHFS classification scheme and is intended to meet CMS formulary guidance requirements for the 2020 plan year.

Please note that the drugs with PA Type 2 (PA Required with New Starts Only), ST Type 1 (Step Therapy), or ST Type 2 (Step Therapy withNew Starts Only) will have a look back of 120 days in most cases, to identifymembers considered "currently taking" a drug. This look back will allow sequential 30 and 90 days fills.

For Advantage plans continuing with the Advantage option in 2020, please note that the Standard Advantage Part D offering will contain less formulary agents. This is being done to contain costs and remain competitive in the market place.

YOUR 2020 PART D STANDARD FORMULARY

MedImpact Standard Part D Formularies will offer a variety of options for the 2020 CMS contract year. Starting with Section 3 of the 2020 Part D Implementation Questionnaire (IQ), please select your preferred Standard Formulary Type and tier structure from our formulary options.

Similar to 2019, we will be utilizing a modular approach to our formularies that categorizes the drugs within "buckets". MedImpact will collectively place the drugs in each bucket into the appropriate tier levels based on the plan sponsor's chosen benefit design. Our bucket naming convention is also similar to 2019.

Distinctions will be seen between Generic, Brand, and Specialty drug bucketing represented by the letters G, B, and S with subcategories for each, which offers the potential for different tier positioning (if applicable). Please refer to the table below that outlines the descriptions of the 2020 formulary structure and formulary options with examples of drug bucket placement.

Based on CMS CY2019 Plan Benefit Package (PBP) Software and Formulary Submission titled: Appendix C Formulary proposed 2019 Tier Model. *"The optional 5th or 6th tier can be used as an excluded-drug-only or for other meaningful offerings such as $0 vaccine-only tier, Select Care or Select Diabetes Drugs."*

MedImpact will provide an optional tier to place select drugs in any desired combinations. For example:

(1) STAR drugs
AND/OR
(2) Select Insulins
AND/OR
(3) Vaccines

SUPPLEMENTAL FORMULARY OPTIONS

As in previous years, we will continue to offer several formulary/benefit options within your MedImpact Standard Part D Formularies for 2020. Please refer to previous CMS communications and 2020 Formulary Instructions for more details regarding these various options. The options include:

- **OTC**
  MedImpact will define a standard subset of cost-effective **Over-The-Counter** drugs for each formulary that can be optionally covered by your plan based upon specific CMS-defined coverage rules.

- **HI**
  MedImpact will define a standard subset of drugs that may be used as an optional **Home Infusion Carve-out** for MAPD plans as defined by CMS guidelines.

- **FFF**
  MedImpact will define a standard set of **Free First Fill** drugs that may be used in conjunction with this optional benefit as defined by CMS guidelines.

- **GC**
  MedImpact Standard Part D Formularies will support **Gap Coverage** by ***tier*** for 2020. This choice is made through your plan bid; no formulary supplemental files are required.
- **ENH (also known as CMS Exclude Supplemental File)**
  MedImpact will define a standard set of drugs which are not Part D eligible that may be covered under a supplemental benefit. For 2020, this list will include ***generic*** Viagra 25mg, 50 mg, and 100mg tablets with a quantity limit of 6 tablets per 30 days.

NEW for 2020

- **Partial Non-Extended Days' Supply (Partial NDS)**

MedImpact Standard Part D Formularies will expand the Partial Non-Extended Days' Supply offering for 2020 to include specialty drugs, select opioids, and/or select benzodiazepines. Plan sponsors are required to submit to CMS on their bid which tiers will contain drugs that are limited to a one-month supply. Since opioids and benzodiazepines are disseminated throughout various tiers, plan sponsors selecting to apply partial Non-Extended Days' Supply to benzodiazepines and/or opioids will need to indicate this for all formulary tiers on the bid.

STANDARD FORMULARY REFERENCE TABLES

2020 MedImpact Standard Part D Formulary Bucket Structure

Drug Bucket	Content	Description
G-L	Low Cost Generics	A subset of generic drugs which carry a preferred designation, generally costing less than $10 per 30 days.
G-L-STAR	Low Cost STAR Generics	Low cost generic drugs which include select hypertension, oral diabetes, and hyperlipidemia drugs.
G-M	Medium Cost Generics	Available Generic drugs, generally costing between $10 and $50 per 30 days.
G-M-STAR	Medium Cost STAR Generics	Medium cost generic drugs which include select hypertension, oral diabetes, and hyperlipidemia drugs.
G-H	High Cost Generics	Generic drugs generally costing more than $50 per 30 days.
G-VH	Other Generics	Generic drugs with a high price in comparison to other generics within the class designated to be up tiered for plans utilizing non-preferred drug tier.
G-X	Non Formulary Generics for PEM clients	Exclusion of specified generic drugs involved with the Patent Exclusivity Management (PEM) program. Claims will deny with the following POS message: "IF CLAIM FOR GENERIC PRODUCT DENIES FOR NON-FORMULARY, PLEASE DISPENSE BRAND %%%%%%. USE DAW 9" Generic will process on generic tier with PA override. This bucket to be used in conjunction with bucket BMSREB-GH or BMSREB-GL. For clients that select not to participate in PEM, these drugs will be placed in the high cost generic tier.

G-INS	Generic Insulins	Tier 5 or 6 option for select generic insulin products.
G-VACC	Generic Vaccines	Tier 5 or 6 option for select generic vaccine products.
G-PPM	Generic Plus Medium	Available Generic drugs on the Plus formulary only, generally costing between $10 and $50 per 30 days
G-PPH	Generic Plus High Cost	Generic drugs on the Plus formulary only, with a high price in comparison to its corresponding multisource brand counterpart or other generics within the class, generally costing more than $50 per 30 days.
B-L	Preferred Brand Drugs	Brand drugs which carry a preferred designation based on net cost and preferential rebate contract discounts.
B-M	Other Brands	Other formulary brand drugs.
B-H	Non Preferred Brand Drugs	Non Preferred brand drugs only available on Plus Plans.
B-PP	Plus Formulary Preferred Brands	Brand drugs which carry a preferred designation based on net cost which make placement on a Plus formulary only at preferred brand copay (including rebate considerations) financially advantageous to the Plan versus placement at non-preferred brand copay.
BMSREB-GL	Multisource Brands in Generic tier	Preferred multisource brand (MSB) drugs placed on a generic tier corresponding to bucket G-L. These specified MSB drugs allow for continued rebate reimbursement and allow for the MSB drug to remain on all formularies. Used in conjunction with bucket G-X. For clients that select not to participate in PEM, these drugs will be placed in the preferred brand tier.

BMSREB-GH	Multisource Brands in Generic tier	Preferred multisource brand (MSB) drugs placed on a generic tier corresponding to bucket G-H. These specified MSB drugs allow for continued rebate reimbursement and allow for the MSB drug to remain on all formularies. Used in conjunction with bucket G-X. For clients that select not to participate in PEM, these drugs will be placed in the preferred brand tier.
B-INS	Brand Insulins	Tier 5 or 6 option for select brand insulin products.
B-VACC	Brand Vaccines	Tier 5 or 6 option for select brand vaccine products.
S-L	Specialty Generics	Generic drugs that meet the CMS designation for Specialty tier.
S-PPL	Specialty Generic Plus	Generic drugs on the Plus formulary only, which meet the CMS designation for Specialty tier.
S-M	Specialty Brands	Brand drugs that meet the CMS designation for Specialty tier.
S-PPM	Specialty Brand Plus Only	Brand drugs on the Plus formulary only, which meet the CMS designation for Specialty tier.
S-X	Excluded Specialty Generics	Exclusion of specified generic drugs involved with the Patent Exclusivity Management (PEM) program. Claims will deny with the following POS message: "IF CLAIM FOR GENERIC PRODUCT DENIES FOR NON-FORMULARY, PLEASE DISPENSE BRAND %%%%%%. USE DAW 9" For clients that select not to participate in PEM, these drugs will be placed in the same tier as generic specialty drugs.
OTC-B	Special OTC agents - Both	Special OTC agents covered on all formularies if OTC is selected as a supplemental formulary option

2020 FORMULARY STRUCTURE ADVANTAGE FORMULARY

2020 Tier Structure	2020 Option	2020 Tier Label					
		Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Tier 6
ADVANTAGE							
Blue Shading* = CMS Tier label to be used for PBP Bid Submission							
ALL GENERICS AT SAME TIER							
1 Tier	A	•Generic •Preferred Brand •Other Brand •Specialty Drugs					
2 Tier	A	Generic*	Brand*				
		•Generic •Specialty Generic	•Preferred Brand •Other Brand •Specialty Brand				
3 Tier	A	Generic*	Brand*	Specialty*			
		•Generic	•Preferred Brand •Other Brand	•Specialty Tier			
4 Tier	A	Generic*	Preferred Brand*	Non-Preferred Brand*	Specialty*		
		•Generic	•Preferred Brand	•Other Brand	•Specialty Tier		
LOW COST GENERICS PREFERRED (<$10)							
5 Tier	A	Preferred Generic*	Generic*	Preferred Brand*	Non-Preferred Brand*	Specialty*	
		•Low-Cost Generic	•Medium-Cost Generic •High-Cost Generic	•Preferred Brand	•Other Brand	•Specialty Tier	
6 Tier	A	Preferred Generic*	Generic*	Preferred Brand*	Non-Preferred Brand*	Specialty*	Optional*
		•Low-Cost Generic	•Medium-Cost Generic •High-Cost Generic	•Preferred Brand	•Other Brand	•Specialty Tier	•Optional STAR drugs Vaccines Select insulins
LOW & MEDIUM COST GENERICS PREFERRED (<$50)							
5 Tier	B	Preferred Generic*	Generic*	Preferred Brand*	Non-Preferred Brand*	Specialty*	
		•Low-Cost Generic •Medium-Cost Generic	•High-Cost Generic	•Preferred Brand	•Other Brand	•Specialty Tier	
6 Tier	B	Preferred Generic*	Generic*	Preferred Brand*	Non-Preferred Brand*	Specialty*	Optional*
		•Low-Cost Generic •Medium-Cost Generic	•High-Cost Generic	•Preferred Brand	•Other Brand	•Specialty Tier	•Optional STAR drugs Vaccines Select insulins
OTHER GENERICS NON-PREFERRED							
5 Tier	C	Preferred Generic*	Generic*	Preferred Brand*	Non-Preferred Drug*	Specialty*	
		•Low-Cost Generic	•Medium-Cost Generic •High-Cost Generic	•Preferred Brand	• Other Generic • Other Brand	•Specialty Tier	
6 Tier	C	Preferred Generic*	Generic*	Preferred Brand*	Non-Preferred Drug*	Specialty*	Optional*
		•Low-Cost Generic	•Medium-Cost Generic •High-Cost Generic	•Preferred Brand	• Other Generic • Other Brand	•Specialty Tier	•Optional STAR drugs Vaccines Select insulins
LOW & MEDIUM COST GENERICS PREFERRED & OTHER GENERICS NON-PREFERRED							
4 Tier	B	Preferred Generic*	Preferred Brand*	Non-Preferred Drug*	Specialty*		
		•Low-Cost Generic •Medium-Cost Generic •High-Cost Generic	•Preferred Brand	• Other Generic • Other Brand	•Specialty Tier		

Formulary Structure Example 1: Advantage: 5 Tier B, OTC - No

Tier	Description	Drug Buckets
1	Preferred Generic	G-L, G-M, G-INS, G-VACC
2	Generic	G-H
3	Preferred Brand	B-L, B-INS, B-VACC
4	Non-Preferred Brand	B-M
5	Specialty Tier	S-L, S-M

PLUS CLOSED FORMULARY

2020 Tier Structure	2020 Option	2020 Tier Label					
		Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Tier 6
PLUS CLOSED							
Blue Shading* = CMS Tier label to be used for PBP Bid Submission							
ALL GENERICS AT SAME TIER							
1 Tier	A	•Generic •Preferred Brand •Other Brand •Specialty Drugs					
4 Tier	A	Generic*	Preferred Brand*	Non-Preferred Brand*	Specialty*		
		•Generic	•Preferred Brand	•Non-Preferred Brand •Other Brand	•Specialty Tier		
LOW COST GENERICS PREFERRED (<$10)							
5 Tier	A	Preferred Generic*	Generic*	Preferred Brand*	Non-Preferred Brand*	Specialty*	
		•Low-Cost Generic	•Medium-Cost Generic •High-Cost Generic	•Preferred Brand	•Non-Preferred Brand •Other Brand	•Specialty Tier	
6 Tier	A	Preferred Generic*	Generic*	Preferred Brand*	Non-Preferred Brand*	Specialty*	Optional*
		•Low-Cost Generic	•Medium-Cost Generic •High-Cost Generic	•Preferred Brand	•Non-Preferred Brand •Other Brand	•Specialty Tier	•Optional STAR drugs Vaccines Select insulins
LOW & MEDIUM COST GENERICS PREFERRED (<$50)							
5 Tier	B	Preferred Generic*	Generic*	Preferred Brand*	Non-Preferred Brand*	Specialty*	
		•Low-Cost Generic •Medium-Cost Generic	•High-Cost Generic	•Preferred Brand	•Non-Preferred Brand •Other Brand	•Specialty Tier	
6 Tier	B	Preferred Generic*	Generic*	Preferred Brand*	Non-Preferred Brand*	Specialty*	Optional*
		•Low-Cost Generic •Medium-Cost Generic	•High-Cost Generic	•Preferred Brand	•Non-Preferred Brand •Other Brand	•Specialty Tier	•Optional STAR drugs Vaccines Select insulins
OTHER GENERICS NON-PREFERRED							
4 Tier	B	Preferred Generic*	Preferred Brand*	Non-Preferred Drug*	Specialty*		
		•Low-Cost Generic •Medium-Cost Generic •High-Cost Generic	•Preferred Brand	•Other Generic •Non-Preferred Brand •Other Brand	•Specialty Tier		
5 Tier	C	Preferred Generic*	Generic*	Preferred Brand*	Non-Preferred Drug*	Specialty*	
		•Low-Cost Generic	•Medium-Cost Generic •High-Cost Generic	•Preferred Brand	•Other Generic •Non-Preferred Brand •Other Brand	•Specialty Tier	
	D	Preferred Generic*	Preferred Brand*	Non-Preferred Drug*	Specialty*	Optional*	
		•Low-Cost Generic •Medium-Cost Generic •High-Cost Generic	•Preferred Brand	•Other Generic •Non-Preferred Brand •Other Brand	•Specialty Tier	•Optional STAR buckets Vaccines Insulins	
6 Tier	C	Preferred Generic*	Generic*	Preferred Brand*	Non-Preferred Drug*	Specialty*	Optional*
		•Low-Cost Generic	•Medium-Cost Generic •High-Cost Generic	•Preferred Brand	•Other Generic •Non-Preferred Brand •Other Brand	•Specialty Tier	•Optional STAR drugs Vaccines Select insulins

Formulary Structure Example 2: Plus Closed: 6 Tier B, Star Buckets in Optional tier, OTC – No

Tier	Description	Drug Buckets
1	Preferred Generic	G-L, G-M, G-PPM, G-INS, G-VACC
2	Generic	G-H, G-PPH
3	Preferred Brand	B-L, B-PP, B-INS, B-VACC
4	Non-Preferred Brand	B-M, B-H
5	Specialty Tier	S-L, S-M, S-PPL, S-PPM
6	Optional Tier	G-L STAR, G-M STAR

Formulary Structure Example 3: Plus Closed: 5 Tier C, OTC - No

Tier	Description	Drug Buckets
1	Preferred Generic	G-L
2	Generic	G-M, G-H, G-PPH, , G-PPM, G-INS, G-VACC
3	Preferred Brand	B-L, B-PP, B-INS, B-VACC
4	Non-Preferred Drug	B-M, B-H, G-VH, G-PPVH
5	Specialty Tier	S-L, S-M, S-PPL, S-PPM

PART D LEGEND

Formulary Actions	Prescribing Guidelines
NC = No Change	AGE = Age Restriction
Grey = Not Applicable	QL = Quantity Limit
Green = Add with P&T Committee Approval	HRM PA = High Risk Medication
Blue = Add with P&T approval pending CMS eligibility due to labeler status	PA, BvD = Payment Determination
Formulary Placement	PA, TIRF = Payment Determination
G-L = Low Cost Formulary Generics	ST = Step Therapy
G-M = Formulary Generics	PA = Prior Authorization
G-H = High Cost Generics	PAGL = PA guideline
G-INS = Generic insulin products for Advantage and Plus	
G-INSP= Generic insulin products on Plus formulary only	
G-NP = Non-Preferred Generic	
G-L STAR = Low Cost Generics (Select Generic Statins, Select Generic ACE-I/ARBs, Select Oral Generic Anti-Diabetic drug)	
G-M STAR = Medium Cost Generics (Select Generic Statins, Select Generic ACE-I/ARBs, Select Oral Generic Anti-Diabetic drug)	
G-VH = Very High Cost Generics	
B-L = Formulary Preferred Brand	
B-M = Plus and Advantage Formulary Brand	
B-H = Plus Formulary Brand	
G-PPM, G-PPH, G-PPVH, B-PP, S-PPL, S-PPM = Plus Formulary	
B-NP = Non-Preferred Brand	
B-INSP = Brand insulin products for the Plus formulary only	
S-L = Specialty Generic Drug	
S-M = Specialty Brand Drug	
S-NP = Specialty Non-Preferred Drug	
G-VACC, B-VACC = Vaccines	
B-INS = Brand insulin products for the Advantage and Plus	
B-MS*, S-MS* = Multi-source Brand	
OTC-L-A, OTC-L-P, OTC-L-B = OTC Adv, Plus or Both (zero copay), if plan participates in OTC supplemental coverage	
BMSREB-GL, BMSREB-GH = Brand PEM Drug	
SMSREB = Specialty Brand PEM Drug	
INS-REBGH = Insulin Brand PEM Drug	
S-X = Specialty Generic PEM Drug	
G-X = Generic PEM Drug	
INS-X = Generic Insulin PEM Drug	
ENH-EDL = Enhanced Drugs	
PEND = Pending	
SL-NP = Specialty Generic Non-Preferred Drug	
NA = Non-Formulary/ Not Covered under D	

* The corresponding multi-source brand for a new generic will be moved to bucket B-MS or S-MS once a CMS proxy for the generic is provided. The generic proxy must have an ANDA (abbreviated new drug application) in compliance with the CMS regulation and 60 day member notification has been given.

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I. Interim Approved Line-Extensions

Drug					Formulary Status	Prescribing Limitations						Notes	Effective Date
						Plus			Advantage				
Brand Name	Generic Name	Strength	Dosage Form	Route	Drug Bucket	PA	ST	QL	PA	ST	QL		
DUPIXENT PEN	DUPILUMAB	300 MG/2 ML	PEN INJCTR	SUBCUTANE.	S-M	DUPILUMAB	NONE	NONE	DUPILUMAB	NONE	NONE	Line extension will follow placement of existing formulary agents	7/18/2020
TOPOTECAN HCL	TOPOTECAN HCL	1 MG/ML	VIAL	INTRAVEN.	S-PPL	NONE	NONE	NONE				Line extension will follow placement of existing formulary agents	7/18/2020
SIRTURO	BEDAQUILINE FUMARATE	20 MG	TABLET	ORAL	S-M	BEDAQUILINE	NONE	NONE	BEDAQUILINE	NONE	NONE	Line extension will follow placement of existing formulary agents	7/25/2020
MIDAZOLAM HCL-0.8% NACL	MIDAZOLAM IN NACL,ISO-OSMOT/PF	100 MG/0.1 L	VIAL	INTRAVEN	G-NP	NONE	NONE	NONE				Line extension will follow placement of existing formulary agents	7/25/2020
ORTIKOS	BUDESONIDE	6 MG	CAPSULE ER	ORAL	S-NP	NONE	NONE	NONE				Line extension will follow placement of existing formulary agents	8/1/2020
ORTIKOS	BUDESONIDE	9 MG	CAPSULE ER	ORAL	S-NP	NONE	NONE	NONE				Line extension will follow placement of existing formulary agents	8/1/2020
SUMATRIPTAN SUCCINATE	SUMATRIPTAN SUCCINATE	6 MG/0.5 ML	CARTRIDGE	SUBCUTANE.	G-VH	NONE	INJECTABLE TRIPTANS	4/28	NONE	INJECTABLE TRIPTANS	4/28	Line extension will follow placement of existing formulary agents	8/1/2020
ENBREL	ETANERCEPT	25 MG/0.5 ML	VIAL	SUBCUT	S-M	ETANERCEPT	NONE	NONE	ETANERCEPT	NONE	NONE	Line extension will follow placement of existing formulary agents	8/8/2020
CYCLOPHOSPHAMIDE	CYCLOPHOSPHAMIDE	200 MG/ML	VIAL	INTRAVEN.	S-L	INFUSIBLE DRUG BVD DETERMINATION	NONE	NONE	INFUSIBLE DRUG BVD DETERMINATION	NONE	NONE	Line extension will follow placement of existing formulary agents	8/15/2020
MYCAPSSA	OCTREOTIDE ACETATE	20 MG	CAPSULE DR	ORAL	S-PPM	OCTREOTIDE - ORAL	NONE	120/30				Line extension will follow placement of existing formulary agents	8/22/2020
UPNEEQ	OXYMETAZOLINE HCL/PF	0.1 %	DROPERETTE	OPHTHALMIC	B-NP	NONE	NONE	NONE				Line extension will follow placement of existing formulary agents	TBD
ZCORT	DEXAMETHASONE	1.5 MG	TAB DS PK	ORAL	G-NP	NONE	NONE	NONE				Line extension will follow placement of existing formulary agents	8/29/2020
VANCOMYCIN HCL	VANCOMYCIN/WATER FOR INJ (PEG)	750 MG/0.15 L	PIGGYBACK	INTRAVEN	NA							Line extension will follow placement of existing formulary agents	8/29/2020
VANCOMYCIN HCL	VANCOMYCIN/WATER FOR INJ (PEG)	1.25 G/250 ML	PIGGYBACK	INTRAVEN	NA							Line extension will follow placement of existing formulary agents	8/29/2020
VANCOMYCIN HCL	VANCOMYCIN/WATER FOR INJ (PEG)	1.75 G/350 ML	PIGGYBACK	INTRAVEN	NA							Line extension will follow placement of existing formulary agents	8/29/2020
KESIMPTA PEN	OFATUMUMAB	20 MG/0.4 ML	PEN INJCTR	SUBCUTANE.	S-M	OFATUMUMAB-SQ	NONE	1.2/28	OFATUMUMAB-SQ	NONE	1.2/28	IR directed placement	9/5/2020
AIRDUO DIGIHALER	FLUTICASONE PROPION/SALMETEROL	55 MCG-14 MCG	AER PW BAS	INHALATION	B-NP	NONE	NONE	1/30				IR directed placement	9/5/2020
AIRDUO DIGIHALER	FLUTICASONE PROPION/SALMETEROL	113 MCG-14 MCG	AER PW BAS	INHALATION	B-NP	NONE	NONE	1/30				IR directed placement	9/5/2020
AIRDUO DIGIHALER	FLUTICASONE PROPION/SALMETEROL	232 MCG-14 MCG	AER PW BAS	INHALATION	B-NP	NONE	NONE	1/30				IR directed placement	9/5/2020
ONUREG	AZACITIDINE	200 MG	TABLET	ORAL	S-M	AZACITIDINE	NONE	14/28	AZACITIDINE	NONE	14/28	PCD with a unique formulation/indication	9/12/2020
ONUREG	AZACITIDINE	300 MG	TABLET	ORAL	S-M	AZACITIDINE	NONE	14/28	AZACITIDINE	NONE	14/28	PCD with a unique formulation/indication	9/12/2020
AKYNZEO	FOSNETUPITANT/PALONOSETRON	235 MG-0.25 MG	VIAL	INTRAVEN.	B-M	NONE	NONE	NONE	NONE	NONE	NONE	Line extension will follow placement of existing formulary agents	9/12/2020
HEMADY	DEXAMETHASONE	20 MG	TABLET	ORAL	B-H	NONE	NONE	NONE				Lower cost/similar drug entity available will move the drug to a non-preferred tier/placement	9/12/2020
INSULIN GLARGINE,HUM.REC.ANLOG	SEMGLEE	100 U/ML	VIAL	SUBCUTANE.	B-NP	NONE	ANTIDIABETIC AGENTS – INSULINS	40/28				IR directed placement	9/12/2020
INSULIN GLARGINE,HUM.REC.ANLOG	SEMGLEE PEN	100 U/ML	INSULIN PEN	SUBCUTANE.	B-NP	NONE	ANTIDIABETIC AGENTS – INSULINS	30/28				IR directed placement	9/12/2020
TRULICITY	DULAGLUTIDE	3 MG/0.5 ML	PEN INJCTR	SUBCUT	B-L	NONE	NONE	2/28	NONE	NONE	2/28	Line extension will follow placement of existing formulary agents	9/19/2020
TRULICITY	DULAGLUTIDE	4.5 MG/0.5 ML	PEN INJCTR	SUBCUT	B-L	NONE	NONE	2/28	NONE	NONE	2/28	Line extension will follow placement of existing formulary agents	9/19/2020
CYSTADROPS	CYSTEAMINE HCL	0.37%	DROPS	OPHTHALMIC	S-PPM	NONE	NONE	NONE				Lower cost/similar drug entity available will move the drug to a non-preferred tier/placement	9/19/2020
GIMOTI	METOCLOPRAMIDE HCL	15 MG/SPRAY	SPRAY/PUMP	NASAL	S-NP	METOCLOPRAMIDE - SPRAY	NONE	NONE				Lower cost/similar drug entity available will move the drug to a non-preferred tier/placement	TBD
MENQUADFI	MENING VAC A,C,Y,W135,C-TET/PF	10 MCG/0.5 ML	VIAL	INTRAMUSC	B-VACC	NONE	NONE	NONE	NONE	NONE	NONE	Line extension will follow placement of existing formulary agents	9/19/2020
ARMONAIR DIGIHALER	FLUTICASONE PROPIONATE	55 MCG	AER PW BAS	INHALATION	B-NP	NONE	INHALED CORTICOSTEROID	1/30				Line extension will follow placement of existing formulary agents	9/26/2020
ARMONAIR DIGIHALER	FLUTICASONE PROPIONATE	113 MCG	AER PW BAS	INHALATION	B-NP	NONE	INHALED CORTICOSTEROID	1/30				Line extension will follow placement of existing formulary agents	9/26/2020
ARMONAIR DIGIHALER	FLUTICASONE PROPIONATE	232 MCG	AER PW BAS	INHALATION	B-NP	NONE	INHALED CORTICOSTEROID	1/30				Line extension will follow placement of existing formulary agents	9/26/2020
OXALIPLATIN	OXALIPLATIN	200 MG/40 ML	VIAL	INTRAVEN.	G-PPH	NONE	NONE	NONE				Line extension will follow placement of existing formulary agents	9/26/2020
POLIVY	POLATUZUMAB VEDOTIN-PIIQ	30 MG	VIAL	INTRAVEN	S-M	POLATUZUMAB VEDOTIN	NONE	NONE	POLATUZUMAB VEDOTIN	NONE	NONE	Line extension will follow placement of existing formulary agents	10/3/2020
XYWAV	SODIUM,CALCIUM,MAG,POT OXYBATE	0.5 G/ML	SOLUTION	ORAL	S-M	SODIUM/CALCIUM/MAG/POT OXYBATE	NONE	540/30	SODIUM/CALCIUM/MAG/POT OXYBATE	NONE	540/30	Clinical and cost information justifies the need for formulary placement with UM	10/3/2020
XERAVA	ERAVACYCLINE DI-HYDROCHLORIDE	100 MG	VIAL	INTRAVEN.	S-NP	NONE	NONE	NONE				Lower cost/similar drug entity available will move the drug to a non-preferred tier/placement	10/10/2020
TRELEGY ELLIPTA	FLUTICASONE/UMECLIDIN/VILANTER	200-62.5	BLST W/DEV	INHALATION	B-L	NONE	NONE	NONE	NONE	NONE	NONE	Line extension will follow placement of existing formulary agents	10/17/2020

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II. Interim Approved First-time Generic

Drug					Formulary Status	Prescribing Limitations						Notes	Effective Date
						Plus			Advantage				
Generic Name	Reference Brand Name	Strength	Dosage Form	Route	Drug Bucket	PA	ST	QL	PA	ST	QL		
METYROSINE	DEMSER	250 MG	CAPSULE	ORAL	S-L	NONE	NONE	NONE	NONE	NONE	NONE	Generic will mirror the placement of brand	8/8/2020
DEFERASIROX	JADENU SPRINKLE	90 MG	GRAN PACK	ORAL	S-L	DEFERASIROX	NONE	NONE	DEFERASIROX	NONE	NONE	Generic will mirror the placement of brand	8/15/2020
DEFERASIROX	JADENU SPRINKLE	180 MG	GRAN PACK	ORAL	S-L	DEFERASIROX	NONE	NONE	DEFERASIROX	NONE	NONE	Generic will mirror the placement of brand	8/15/2020
DEFERASIROX	JADENU SPRINKLE	360 MG	GRAN PACK	ORAL	S-L	DEFERASIROX	NONE	NONE	DEFERASIROX	NONE	NONE	Generic will mirror the placement of brand	8/15/2020
CIPROFLOXACIN-DEXAMETHASONE	CIPRODEX	0.3 %-0.1%	DROPS SUSP	OTIC	G-H	NONE	NONE	NONE	NONE	NONE	NONE	Generic will mirror the placement of brand	8/22/2020
PANTOPRAZOLE SODIUM	PROTONIX	40 MG	GRANPKT DR	ORAL	G-NP	NONE	ANTIULCER AGENTS	60/30				Generic will mirror the placement of brand	8/22/2020
DIMETHYL FUMARATE	TECFIDERA	120 MG	CAPSULE DR	ORAL	S-L	DIMETHYL FUMARATE	NONE	14/7	DIMETHYL FUMARATE	NONE	14/7	IR directed placement	10/10/2020
DIMETHYL FUMARATE	TECFIDERA	240 MG	CAPSULE DR	ORAL	S-L	DIMETHYL FUMARATE	NONE	60/30	DIMETHYL FUMARATE	NONE	60/30	IR directed placement	10/10/2020
PEG3350/SOD SUL/NACL/KCL/ASB/C	MOVIPREP	7.5 G-2.691 G	POWD PACK	ORAL	G-NP	NONE	NONE	NONE				Generic will mirror the placement of brand	9/12/2020
EMTRICITABINE	EMTRIVA	200 MG	CAPSULE	ORAL	G-H	NONE	NONE	NONE	NONE	NONE	NONE	Generic will mirror the placement of brand	9/12/2020
SAPROPTERIN DIHYDROCHLORIDE	KUVAN	100 MG	TABLET SOL	ORAL	S-L	NONE	NONE	NONE	NONE	NONE	NONE	Generic will mirror the placement of brand	9/19/2020
SAPROPTERIN DIHYDROCHLORIDE	KUVAN	500 MG	POWD PACK	ORAL	SL-NP	NONE	NONE	NONE				Generic will mirror the placement of brand	9/19/2020
SAPROPTERIN DIHYDROCHLORIDE	KUVAN	100 MG	POWD PACK	ORAL	SL-NP	NONE	NONE	NONE				Generic will mirror the placement of brand	9/19/2020
TOBRAMYCIN	BETHKIS	300 MG/4 ML	AMPUL-NEB	INHALATION	S-L	NEBULIZER BVD DETERMINATION	NONE	NONE	NEBULIZER BVD DETERMINATION	NONE	NONE	Generic will mirror the placement of brand	9/26/2020
EFAVIRENZ/LAMIVU/TENOFOV DISOP	SYMFI	600 MG-300 MG	TABLET	ORAL	S-L	NONE	NONE	NONE	NONE	NONE	NONE	Generic will mirror the placement of brand	9/26/2020
EFAVIRENZ/LAMIVU/TENOFOV DISOP	SYMFI LO	400 MG-300 MG	TABLET	ORAL	S-L	NONE	NONE	NONE	NONE	NONE	NONE	Generic will mirror the placement of brand	9/26/2020
DICLOFENAC SUBMICRONIZED	ZORVOLEX	35 MG	CAPSULE	ORAL	NA							Marketing Status Mismatch	TBD
DEFERIPRONE	FERRIPROX	500 MG	TABLET	ORAL	S-L	DEFERIPRONE	NONE	NONE	DEFERIPRONE	NONE	NONE	Generic will mirror the placement of brand	10/3/2020
LAPATINIB DITOSYLATE	TYKERB	250 MG	TABLET	ORAL	S-L	LAPATINIB DITOSYLATE	NONE	NONE	LAPATINIB DITOSYLATE	NONE	NONE	Generic will mirror the placement of brand	10/10/2020
DIMETHYL FUMARATE	TECFIDERA	120-240 MG	CAPSULE DR	ORAL	S-L	DIMETHYL FUMARATE	NONE	NONE	DIMETHYL FUMARATE	NONE	NONE	Generic will mirror the placement of brand	10/10/2020
FAVIRENZ-EMTRIC-TENOFOV DISO	ATRIPLA	600-200MG	TABLET	ORAL	S-L	NONE	NONE	NONE	NONE	NONE	NONE	Generic will mirror the placement of brand	10/17/2020
EMTRICITABINE-TENOFOVIR DISOP	TRUVADA	200-300 MG	TABLET	ORAL	S-L	NONE	NONE	NONE	NONE	NONE	NONE	Generic will mirror the placement of brand	10/17/2020
FOSFOMYCIN TROMETHAMINE	MONUROL	3 G	PACKET	ORAL	G-NP	NONE	NONE	NONE				Generic will mirror the placement of brand	10/17/2020

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I. Interim Approved Line-Extensions

Drug					Formulary Status	Prescribing Limitations						Notes	Effective Date
						Plus			Advantage				
Brand Name	Generic Name	Strength	Dosage Form	Route	Drug Bucket	PA	ST	QL	PA	ST	QL		
RUKOBIA	FOSTEMSAVIR TROMETHAMINE	600 MG	TAB ER 12H	ORAL	S-M	NONE	NONE	NONE	NONE	NONE	NONE	PCD with a unique formulation/indication	7/18/2020
FINTEPLA	FENFLURAMINE HCL	2.2 MG/ML	SOLUTION	ORAL	S-M	FENFLURAMINE	NONE	NONE	FENFLURAMINE	NONE	NONE	PCD with a unique formulation/indication	7/18/2020
DOJOLVI	TRIHEPTANOIN	8.3 KCAL/ML	LIQUID	ORAL	S-NP	TRIHEPTANOIN	NONE	NONE				Clinical and cost information justifies the need for formulary placement with UM	7/25/2020
MONJUVI	TAFASITAMAB-CXIX	200 MG	VIAL	INTRAVEN.	S-M	TAFASITAMAB-CXIX	NONE	NONE	TAFASITAMAB-CXIX	NONE	NONE	PCD with a unique formulation/indication	8/15/2020
BAFIERTAM	MONOMETHYL FUMARATE	95 MG	CAPSULE DR	ORAL	S-NP	MONOMETHYL FUMARATE	NONE	120/30				IR directed placement	9/5/2020
BARHEMSYS	AMISULPRIDE	5 MG/2 ML	VIAL	INTRAVEN.	B-NP	NONE	NONE	NONE				Lower cost/similar drug entity available will move the drug to a non-preferred tier/placement	TBD
BREZTRI AEROSPHERE	BUDESONIDE/GLYCOPYR/FORMOTEROL	160 MCG-9 MCG-4.8 MCG	HFA AER AD	INHALATION	B-L	NONE	NONE	NONE	NONE	NONE	NONE	IR directed placement	10/1/2020
BLENREP	BELANTAMAB MAFODOTIN-BLMF	100 MG	VIAL	INTRAVEN.	S-M	BELANTAMAB MAFODOTIN-BLMF	NONE	NONE	BELANTAMAB MAFODOTIN-BLMF	NONE	NONE	PCD with a unique formulation/indication	8/22/2020
EVRYSDI	RISDIPLAM	0.75 MG/ML	SOLN RECON	ORAL	S-M	RISDIPLAM	NONE	NONE	RISDIPLAM	NONE	NONE	Clinical and cost information justifies the need for formulary placement with UM	8/22/2020
INQOVI	DECITABINE/CEDAZURIDINE	35 MG-100 MG	TABLET	ORAL	S-M	DECITABINE/CEDAZURIDINE	NONE	5/28	DECITABINE/CEDAZURIDINE	NONE	5/28	PCD with a unique formulation/indication	8/22/2020
ENSPRYNG	SATRALIZUMAB-MWGE	120 MG/ML	SYRINGE	SUBCUT	S-PPM	SATRALIZUMAB-MWGE	NONE	NONE				Clinical and cost information justifies the need for formulary placement with UM	8/29/2020
VILTEPSO	VILTOLARSEN	250 MG/5ML	VIAL	INTRAVEN	S-NP	VILTOLARSEN	NONE	NONE				Clinical and cost information justifies the need for formulary placement with UM	10/10/2020
ONGENTYS	OPICAPONE	50 MG	CAPSULE	ORAL	B-H	OPICAPONE	NONE	30/30				Clinical and cost information justifies the need for formulary placement with UM	9/12/2020
GAVRETO	PRALSETINIB	100 MG	CAPSULE	ORAL	S-M	PRALSETINIB	NONE	120/30	PRALSETINIB	NONE	120/30	PCD with a unique formulation/indication	9/19/2020
LAMPIT	NIFURTIMOX	30 MG	TABLET	ORAL	B-NP	NONE	NONE	NONE				Clinical information justifies the need for non-formulary placement will move the drug to a non-preferred tier/placement	9/26/2020
LAMPIT	NIFURTIMOX	120 MG	TABLET	ORAL	B-NP	NONE	NONE	NONE				Clinical information justifies the need for non-formulary placement will move the drug to a non-preferred tier/placement	9/26/2020
CONJUPRI	LEVAMLODIPINE MALEATE	2.5 MG	TABLET	ORAL	B-NP	LEVAMLODIPINE MALEATE	NONE	30/30				Lower cost/similar drug entity available will move the drug to a non-preferred tier/placement	TBD
CONJUPRI	LEVAMLODIPINE MALEATE	5 MG	TABLET	ORAL	B-NP	LEVAMLODIPINE MALEATE	NONE	30/30				Lower cost/similar drug entity available will move the drug to a non-preferred tier/placement	TBD

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V. Proposed Utilization Management Edits

1. Updates to Step Therapy Edits

STGD	Action	Proposed Criteria	Notes	Effective Date
ANTIPSYCHOTIC AGENTS	UPDATE	PRIOR CLAIM FOR FORMULARY VERSIONS OF ANY TWO ORAL ANTIPSYCHOTICS: RISPERIDONE, CLOZAPINE TABLET, OLANZAPINE, IMMEDIATE RELEASE QUETIAPINE FUMARATE, ZIPRASIDONE, ARIPIPRAZOLE, OR LATUDA WITHIN THE PAST 365 DAYS.	TR directed placement to add Latuda as a preferred agent	9/1/2020
ANTIPSYCHOTIC AGENTS II	UPDATE	PRIOR CLAIM FOR TWO (2) OF THE FOLLOWING FORMULARY ORAL VERSIONS OF ATYPICAL ANTIPSYCHOTICS (RISPERIDONE, CLOZAPINE, OLANZAPINE, QUETIAPINE, ARIPIPRAZOLE, ZIPRASIDONE, OR LATUDA), SSRI (CITALOPRAM, ESCITALOPRAM, FLUOXETINE, PAROXETINE OR SERTRALINE), SNRI (DESVENLAFAXINE, DULOXETINE OR VENLAFAXINE) WITHIN THE PAST 365 DAYS	TR directed placement to add Latuda as a preferred agent	9/1/2020

2. Updates to Prior Authorization Edits

PAGD	Action	Criteria Field	Notes	Effective Date
ANTI-NAUSEA AGENT BVD DETERMINATION	UPDATE	Exlusion Criteria	UM Change	8/1/2020
APREPITANT BVD DETERMINATION	UPDATE	Exlusion Criteria, Required Medical Information, Coverage Duration	UM Change	8/1/2020
CORTICOSTEROID BVD DETERMINATION	UPDATE	Exlusion Criteria, Other Criteria	UM Change	8/1/2020
CYCLOPHOSPHAMIDE BVD DETERMINATION	UPDATE	Covered Uses, Exlusion Criteria, Coverage Duration, Other Criteria	UM Change	8/1/2020
HEPATITIS B VACCINE BVD DETERMINATION	UPDATE	Exlusion Criteria, Required Medical Information	UM Change	8/1/2020
IMMUNE GLOBULIN BVD DETERMINATION	UPDATE	Exlusion Criteria, Coverage Duration	UM Change	8/1/2020
IMMUNOSUPPRESSANT BVD DETERMINATION	UPDATE	Exlusion Criteria, Other Criteria	UM Change	8/1/2020
INFUSIBLE DRUG BVD DETERMINATION	UPDATE	Exlusion Criteria, Required Medical Information, Coverage Duration	UM Change	8/1/2020
METHOTREXATE BVD DETERMINATION	UPDATE	Exlusion Criteria, Coverage Duration	UM Change	8/1/2020
NEBULIZER BVD DETERMINATION	UPDATE	Exlusion Criteria, Other Criteria	UM Change	8/1/2020

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V. Proposed Utilization Management Edits

NETUPITANT/PALONOSETRON BVD DETERMINATION	UPDATE	Exlusion Criteria, Other Criteria	UM Change	8/1/2020
RABIES VACCINE BVD DETERMINATION	UPDATE	Exlusion Criteria, Other Criteria	UM Change	8/1/2020
ROLAPITANT BVD DETERMINATION	UPDATE	Exlusion Criteria, Other Criteria	UM Change	8/1/2020
TOTAL PARENTERAL NUTRITION AGENT BVD DETERMINATION	UPDATE	Exlusion Criteria	UM Change	8/1/2020
OLAPARIB	UPDATE	Other Criteria	UM Change	11/1/2020
RUCAPARIB	UPDATE	Other Criteria	UM Change	9/1/2020
IXEKIZUMAB	UPDATE	Required Medical Information, Prescriber Restrictions, Other Criteria	UM Change	9/1/2020
SECUKINUMAB	UPDATE	Required Medical Information, Prescriber Restrictions, Other Criteria	UM Change	9/1/2020
CANAKINUMAB	UPDATE	Prescriber Restrictions, Other Criteria	UM Change	9/1/2020
LASMIDITAN	UPDATE	Other Criteria	UM Change /IR Directed Placement	9/1/2020
RIMEGEPANT	UPDATE	Other Criteria	UM Change /IR Directed Placement	9/1/2020
UBROGEPANT	UPDATE	Other Criteria	UM Change /IR Directed Placement	9/1/2020
OLAPARIB	UPDATE	Other Criteria	CMS PA Criteria Concern	8/24/2020
RUCAPARIB	UPDATE	Other Criteria	UM Change	10/1/2020
TOCILIZUMAB IV	UPDATE	Prescriber Restrictions	UM Change	10/1/2020
TOCILIZUMAB SQ	UPDATE	Prescriber Restrictions	UM Change	10/1/2020
ERYTHROPOIESIS STIMULATING AGENTS - ARANESP	UPDATE	Required Medical Information	UM Change	10/1/2020
ERYTHROPOIESIS STIMULATING AGENTS -MIRCERA	UPDATE	Required Medical Information	UM Change	10/1/2020
GUSELKUMAB	UPDATE	Required Medical Information, Prescriber Restrictions	UM Change	10/1/2020
ESKETAMINE	UPDATE	Required Medical Information, Prescriber Restrictions, Coverage Duration, Other Criteria	UM Change	10/1/2020
CANNABIDIOL	UPDATE	Prescriber Restrictions	UM Change	10/1/2020
OLAPARIB	UPDATE	Other Criteria	UM Change/CMS PA Criteria Concern	9/24/2020
IPILIMUMAB	UPDATE	Coverage Duration	UM Change	11/1/2020
GOLIMUMAB IV	UPDATE	Required Medical Information, Coverage Duration, Other Criteria	UM Change	11/1/2020

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VII. Expedited New FDA Approved Drugs - Proposed Actions

Drug					Formulary Status	Prescribing Limitations						Notes	Effective Date
						Plus			Advantage				
Brand Name	Generic Name	Strength	Dosage Form	Route	Drug Bucket	PA	ST	QL	PA	ST	QL		

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VI. Other Formulary Changes

Drug					Formulary Status	Prescribing Limitations						Notes	Effective Date
						Plus			Advantage				
Brand Name	Generic Name	Strength	Dosage Form	Route	Drug Bucket	PA	ST	QL	PA	ST	QL		
NEXLETOL	BEMPEDOIC ACID	180 MG	TABLET	ORAL	B-L	NONE	NONE	30/30	NONE	NONE	30/30	Drug bucket previously B-M, TR directed placement	7/18/2020
REYVOW	LASMIDITAN SUCCINATE	100 MG	TABLET	ORAL	B-L	LASMIDITAN	NONE	8/30	LASMIDITAN	NONE	8/30	Drug bucket previously B-NP, TR directed placement	9/1/2020
REYVOW	LASMIDITAN SUCCINATE	50 MG	TABLET	ORAL	B-L	LASMIDITAN	NONE	4/30	LASMIDITAN	NONE	4/30	Drug bucket previously B-NP, TR directed placement	9/1/2020
NURTEC ODT	RIMEGEPANT SULFATE	75 MG	TAB RAPDIS	ORAL	B-L	RIMEGEPANT	NONE	16/30	RIMEGEPANT	NONE	16/30	Drug bucket previously B-NP, TR directed placement	9/1/2020
UBRELVY	UBROGEPANT	100 MG	TABLET	ORAL	B-L	UBROGEPANT	NONE	16/30	UBROGEPANT	NONE	16/30	Drug bucket previously B-NP, TR directed placement	9/1/2020
UBRELVY	UBROGEPANT	50 MG	TABLET	ORAL	B-L	UBROGEPANT	NONE	16/30	UBROGEPANT	NONE	16/30	Drug bucket previously B-NP, TR directed placement	9/1/2020
FERRIPROX TWICE-A-DAY	DEFERIPRONE	1000 MG	TABS	ORAL	S-M	DEFERIPRONE	NONE	NONE	DEFERIPRONE	NONE	NONE		7/18/2020
NULYTELY	POLYETHYLENE GLYCOL AND POTASSIUM CHLORIDE AND SODIUM BICARBONATE AND SODIUM CHLORIDE	420 GM , 1.48 GM , 5.72 GM , 11.2 GM	SOLR	ORAL	B-MS	NONE	NONE	NONE					7/18/2020
CHARLOTTE 24 FE	ETHINYL ESTRADIOL AND FERROUS FUMARATE AND NORETHINDRONE ACETATE	20 MCG , 75 MG , 1 MG	CHEW	ORAL	G-NP	NONE	NONE	NONE				New Drug Entity	7/25/2020
EPOGEN	EPOETIN ALFA	10000/ML	VIAL	INJECTION	B-L	ERYTHROPOIESIS STIMULATING AGENTS - EPOETIN ALFA	NONE	12/28	ERYTHROPOIESIS STIMULATING AGENTS - EPOETIN ALFA	NONE	12/28	Drug bucket previously B-NP, TR directed placement	8/1/2020
EPOGEN	EPOETIN ALFA	2000/ML	VIAL	INJECTION	B-L	ERYTHROPOIESIS STIMULATING AGENTS - EPOETIN ALFA	NONE	12/28	ERYTHROPOIESIS STIMULATING AGENTS - EPOETIN ALFA	NONE	12/28	Drug bucket previously B-NP, TR directed placement	8/1/2020
EPOGEN	EPOETIN ALFA	20000/2ML	VIAL	INJECTION	B-L	ERYTHROPOIESIS STIMULATING AGENTS - EPOETIN ALFA	NONE	12/28	ERYTHROPOIESIS STIMULATING AGENTS - EPOETIN ALFA	NONE	12/28	Drug bucket previously B-NP, TR directed placement	8/1/2020
EPOGEN	EPOETIN ALFA	20000/ML	VIAL	INJECTION	S-L	ERYTHROPOIESIS STIMULATING AGENTS - EPOETIN ALFA	NONE	12/28	ERYTHROPOIESIS STIMULATING AGENTS - EPOETIN ALFA	NONE	12/28	Drug bucket previously S-NP, TR directed placement	8/1/2020
EPOGEN	EPOETIN ALFA	3000/ML	VIAL	INJECTION	B-L	ERYTHROPOIESIS STIMULATING AGENTS - EPOETIN ALFA	NONE	12/28	ERYTHROPOIESIS STIMULATING AGENTS - EPOETIN ALFA	NONE	12/28	Drug bucket previously B-NP, TR directed placement	8/1/2020
EPOGEN	EPOETIN ALFA	4000/ML	VIAL	INJECTION	B-L	ERYTHROPOIESIS STIMULATING AGENTS - EPOETIN ALFA	NONE	12/28	ERYTHROPOIESIS STIMULATING AGENTS - EPOETIN ALFA	NONE	12/28	Drug bucket previously B-NP, TR directed placement	8/1/2020
PROGLYCEM	DIAZOXIDE	50 MG/ML	ORAL SUSP	ORAL	B-M	NONE	NONE	NONE	NONE	NONE	NONE	CMS line level review to add brand back onto formulary	1/1/2020
PROTONIX	PANTOPRAZOLE SODIUM	40 MG	GRANPKT DR	ORAL	B-NP	NONE	ANTIULCER AGENTS	60/30				Update QL from 30/30 to 60/30	1/1/2020
XCOPRI	CENOBAMATE	150 MG	TABLET	ORAL	S-M	CENOBAMATE	NONE	60/30	CENOBAMATE	NONE	60/30	Update QL from 30/30 to 60/30, Summer Limited Outlier Justification	1/1/2020
DORYX	DOXYCYCLINE HYCLATE	80 MG	TABLET DR	ORAL	B-NP	NONE	NONE	NONE				New Drug Entity	9/5/2020
LEVONORGESTREL-ETH ESTRADIOL	LEVONORGESTREL/ETHIN.ESTRADIOL	6-5-10	TABLET	ORAL	G-M	NONE	NONE	NONE	NONE	NONE	NONE	New Drug Entity	9/5/2020
BIDIL	ISOSORBIDE DINIT/HYDRALAZINE	20-37.5MG	TABLET	ORAL	B-L	NONE	NONE	NONE	NONE	NONE	NONE	New Drug Entity	9/12/2020
RELAFEN	NABUMETONE	500 MG	TABLET	ORAL	NA							New Drug Entity	9/12/2020
RELAFEN	NABUMETONE	750 MG	TABLET	ORAL	NA							New Drug Entity	9/12/2020
FARXIGA	DAPAGLIFLOZIN PROPANEDIOL	10 MG	TABLET	ORAL	B-NP	NONE	NONE	30/30				Term ST at drug level	10/1/2020
FARXIGA	DAPAGLIFLOZIN PROPANEDIOL	5 MG	TABLET	ORAL	B-NP	NONE	NONE	30/30				Term ST at drug level	10/1/2020
INVOKANA	CANAGLIFLOZIN	100 MG	TABLET	ORAL	B-L	NONE	NONE	60/30	NONE	NONE	60/30	Term ST at drug level	10/1/2020
INVOKANA	CANAGLIFLOZIN	300 MG	TABLET	ORAL	B-L	NONE	NONE	30/30	NONE	NONE	30/30	Term ST at drug level	10/1/2020
INVOKAMET XR	CANAGLIFLOZIN/METFORMIN HCL	150-1000MG	TAB BP 24H	ORAL	B-L	NONE	NONE	60/30	NONE	NONE	60/30	Term ST at drug level	10/1/2020
INVOKAMET	CANAGLIFLOZIN/METFORMIN HCL	150-1000MG	TABLET	ORAL	B-L	NONE	NONE	60/30	NONE	NONE	60/30	Term ST at drug level	10/1/2020
INVOKAMET XR	CANAGLIFLOZIN/METFORMIN HCL	150-500 MG	TAB BP 24H	ORAL	B-L	NONE	NONE	60/30	NONE	NONE	60/30	Term ST at drug level	10/1/2020
INVOKAMET	CANAGLIFLOZIN/METFORMIN HCL	150-500 MG	TABLET	ORAL	B-L	NONE	NONE	60/30	NONE	NONE	60/30	Term ST at drug level	10/1/2020
INVOKAMET XR	CANAGLIFLOZIN/METFORMIN HCL	50-1000 MG	TAB BP 24H	ORAL	B-L	NONE	NONE	60/30	NONE	NONE	60/30	Term ST at drug level	10/1/2020
INVOKAMET	CANAGLIFLOZIN/METFORMIN HCL	50-1000 MG	TABLET	ORAL	B-L	NONE	NONE	60/30	NONE	NONE	60/30	Term ST at drug level	10/1/2020
INVOKAMET XR	CANAGLIFLOZIN/METFORMIN HCL	50MG-500MG	TAB BP 24H	ORAL	B-L	NONE	NONE	60/30	NONE	NONE	60/30	Term ST at drug level	10/1/2020
INVOKAMET	CANAGLIFLOZIN/METFORMIN HCL	50MG-500MG	TABLET	ORAL	B-L	NONE	NONE	120/30	NONE	NONE	120/30	Term ST at drug level	10/1/2020
JARDIANCE	EMPAGLIFLOZIN	10 MG	TABLET	ORAL	B-L	NONE	NONE	30/30	NONE	NONE	30/30	Term ST at drug level	10/1/2020
JARDIANCE	EMPAGLIFLOZIN	25 MG	TABLET	ORAL	B-L	NONE	NONE	30/30	NONE	NONE	30/30	Term ST at drug level	10/1/2020
SYNJARDY XR	EMPAGLIFLOZIN/METFORMIN HCL	10-1000 MG	TAB BP 24H	ORAL	B-L	NONE	NONE	30/30	NONE	NONE	30/30	Term ST at drug level	10/1/2020
SYNJARDY XR	EMPAGLIFLOZIN/METFORMIN HCL	12.5-1000	TAB BP 24H	ORAL	B-L	NONE	NONE	60/30	NONE	NONE	60/30	Term ST at drug level	10/1/2020
SYNJARDY	EMPAGLIFLOZIN/METFORMIN HCL	12.5-1000	TABLET	ORAL	B-L	NONE	NONE	60/30	NONE	NONE	60/30	Term ST at drug level	10/1/2020
SYNJARDY	EMPAGLIFLOZIN/METFORMIN HCL	12.5-500MG	TABLET	ORAL	B-L	NONE	NONE	60/30	NONE	NONE	60/30	Term ST at drug level	10/1/2020
SYNJARDY XR	EMPAGLIFLOZIN/METFORMIN HCL	25-1000 MG	TAB BP 24H	ORAL	B-L	NONE	NONE	30/30	NONE	NONE	30/30	Term ST at drug level	10/1/2020
SYNJARDY	EMPAGLIFLOZIN/METFORMIN HCL	5 MG-500MG	TABLET	ORAL	B-L	NONE	NONE	60/30	NONE	NONE	60/30	Term ST at drug level	10/1/2020
SYNJARDY XR	EMPAGLIFLOZIN/METFORMIN HCL	5MG-1000MG	TAB BP 24H	ORAL	B-L	NONE	NONE	60/30	NONE	NONE	60/30	Term ST at drug level	10/1/2020
SYNJARDY	EMPAGLIFLOZIN/METFORMIN HCL	5MG-1000MG	TABLET	ORAL	B-L	NONE	NONE	60/30	NONE	NONE	60/30	Term ST at drug level	10/1/2020

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SAPHRIS	ASENAPINE MALEATE	10 MG	TAB SUBL	SUBLINGUAL	S-M	NONE	ANTIPSYCHOTIC AGENTS	60/30	NONE	ANTIPSYCHOTIC AGENTS	60/30	Re-assigned as a ST2 agent under the ANTIPSYCHOTIC AGENTS STGD	9/1/2020
SAPHRIS	ASENAPINE MALEATE	2.5 MG	TAB SUBL	SUBLINGUAL	S-M	NONE	ANTIPSYCHOTIC AGENTS	60/30	NONE	ANTIPSYCHOTIC AGENTS	60/30	Re-assigned as a ST2 agent under the ANTIPSYCHOTIC AGENTS STGD	9/1/2020
SAPHRIS	ASENAPINE MALEATE	5 MG	TAB SUBL	SUBLINGUAL	S-M	NONE	ANTIPSYCHOTIC AGENTS	60/30	NONE	ANTIPSYCHOTIC AGENTS	60/30	Re-assigned as a ST2 agent under the ANTIPSYCHOTIC AGENTS STGD	9/1/2020
VRAYLAR	CARIPRAZINE HCL	1.5 MG	CAPSULE	ORAL	S-M	NONE	ANTIPSYCHOTIC AGENTS	30/30	NONE	ANTIPSYCHOTIC AGENTS	30/30	Re-assigned as a ST2 agent under the ANTIPSYCHOTIC AGENTS STGD	9/1/2020
VRAYLAR	CARIPRAZINE HCL	1.5 MG-3MG	CAP DS PK	ORAL	B-M	NONE	ANTIPSYCHOTIC AGENTS	NONE	NONE	ANTIPSYCHOTIC AGENTS	NONE	Re-assigned as a ST2 agent under the ANTIPSYCHOTIC AGENTS STGD	9/1/2020
VRAYLAR	CARIPRAZINE HCL	3 MG	CAPSULE	ORAL	S-M	NONE	ANTIPSYCHOTIC AGENTS	30/30	NONE	ANTIPSYCHOTIC AGENTS	30/30	Re-assigned as a ST2 agent under the ANTIPSYCHOTIC AGENTS STGD	9/1/2020
VRAYLAR	CARIPRAZINE HCL	4.5 MG	CAPSULE	ORAL	S-M	NONE	ANTIPSYCHOTIC AGENTS	30/30	NONE	ANTIPSYCHOTIC AGENTS	30/30	Re-assigned as a ST2 agent under the ANTIPSYCHOTIC AGENTS STGD	9/1/2020
VRAYLAR	CARIPRAZINE HCL	6 MG	CAPSULE	ORAL	S-M	NONE	ANTIPSYCHOTIC AGENTS	30/30	NONE	ANTIPSYCHOTIC AGENTS	30/30	Re-assigned as a ST2 agent under the ANTIPSYCHOTIC AGENTS STGD	9/1/2020
FANAPT	ILOPERIDONE	1 MG	TABLET	ORAL	B-M	NONE	ANTIPSYCHOTIC AGENTS	60/30	NONE	ANTIPSYCHOTIC AGENTS	60/30	Re-assigned as a ST2 agent under the ANTIPSYCHOTIC AGENTS STGD	9/1/2020
FANAPT	ILOPERIDONE	1-2-4-6MG	TAB DS PK	ORAL	B-M	NONE	ANTIPSYCHOTIC AGENTS	NONE	NONE	ANTIPSYCHOTIC AGENTS	NONE	Re-assigned as a ST2 agent under the ANTIPSYCHOTIC AGENTS STGD	9/1/2020
FANAPT	ILOPERIDONE	10 MG	TABLET	ORAL	S-M	NONE	ANTIPSYCHOTIC AGENTS	60/30	NONE	ANTIPSYCHOTIC AGENTS	60/30	Re-assigned as a ST2 agent under the ANTIPSYCHOTIC AGENTS STGD	9/1/2020
FANAPT	ILOPERIDONE	12 MG	TABLET	ORAL	S-M	NONE	ANTIPSYCHOTIC AGENTS	60/30	NONE	ANTIPSYCHOTIC AGENTS	60/30	Re-assigned as a ST2 agent under the ANTIPSYCHOTIC AGENTS STGD	9/1/2020
FANAPT	ILOPERIDONE	2 MG	TABLET	ORAL	B-M	NONE	ANTIPSYCHOTIC AGENTS	60/30	NONE	ANTIPSYCHOTIC AGENTS	60/30	Re-assigned as a ST2 agent under the ANTIPSYCHOTIC AGENTS STGD	9/1/2020
FANAPT	ILOPERIDONE	4 MG	TABLET	ORAL	B-M	NONE	ANTIPSYCHOTIC AGENTS	60/30	NONE	ANTIPSYCHOTIC AGENTS	60/30	Re-assigned as a ST2 agent under the ANTIPSYCHOTIC AGENTS STGD	9/1/2020
FANAPT	ILOPERIDONE	6 MG	TABLET	ORAL	S-M	NONE	ANTIPSYCHOTIC AGENTS	60/30	NONE	ANTIPSYCHOTIC AGENTS	60/30	Re-assigned as a ST2 agent under the ANTIPSYCHOTIC AGENTS STGD	9/1/2020
FANAPT	ILOPERIDONE	8 MG	TABLET	ORAL	S-M	NONE	ANTIPSYCHOTIC AGENTS	60/30	NONE	ANTIPSYCHOTIC AGENTS	60/30	Re-assigned as a ST2 agent under the ANTIPSYCHOTIC AGENTS STGD	9/1/2020
FAZACLO	CLOZAPINE	100 MG	TAB RAPDIS	ORAL	S-MS	NONE	ANTIPSYCHOTIC AGENTS	90/30				Re-assigned as a ST2 agent under the ANTIPSYCHOTIC AGENTS STGD	9/1/2020
CLOZAPINE ODT	CLOZAPINE	100 MG	TAB RAPDIS	ORAL	G-VH	NONE	ANTIPSYCHOTIC AGENTS	90/30	NONE	ANTIPSYCHOTIC AGENTS	90/30	Re-assigned as a ST2 agent under the ANTIPSYCHOTIC AGENTS STGD	9/1/2020
FAZACLO	CLOZAPINE	12.5 MG	TAB RAPDIS	ORAL	B-MS	NONE	ANTIPSYCHOTIC AGENTS	90/30				Re-assigned as a ST2 agent under the ANTIPSYCHOTIC AGENTS STGD	9/1/2020

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CLOZAPINE ODT	CLOZAPINE	12.5 MG	TAB RAPDIS	ORAL	G-VH	NONE	ANTIPSYCHOTIC AGENTS	90/30	NONE	ANTIPSYCHOTIC AGENTS	90/30	Re-assigned as a ST2 agent under the ANTIPSYCHOTIC AGENTS STGD	9/1/2020
FAZACLO	CLOZAPINE	150 MG	TAB RAPDIS	ORAL	S-MS	NONE	ANTIPSYCHOTIC AGENTS	180/30				Re-assigned as a ST2 agent under the ANTIPSYCHOTIC AGENTS STGD	9/1/2020
CLOZAPINE ODT	CLOZAPINE	150 MG	TAB RAPDIS	ORAL	G-VH	NONE	ANTIPSYCHOTIC AGENTS	180/30	NONE	ANTIPSYCHOTIC AGENTS	180/30	Re-assigned as a ST2 agent under the ANTIPSYCHOTIC AGENTS STGD	9/1/2020
FAZACLO	CLOZAPINE	200 MG	TAB RAPDIS	ORAL	S-MS	NONE	ANTIPSYCHOTIC AGENTS	120/30				Re-assigned as a ST2 agent under the ANTIPSYCHOTIC AGENTS STGD	9/1/2020
CLOZAPINE ODT	CLOZAPINE	200 MG	TAB RAPDIS	ORAL	S-L	NONE	ANTIPSYCHOTIC AGENTS	120/30	NONE	ANTIPSYCHOTIC AGENTS	120/30	Re-assigned as a ST2 agent under the ANTIPSYCHOTIC AGENTS STGD	9/1/2020
FAZACLO	CLOZAPINE	25 MG	TAB RAPDIS	ORAL	B-MS	NONE	ANTIPSYCHOTIC AGENTS	90/30				Re-assigned as a ST2 agent under the ANTIPSYCHOTIC AGENTS STGD	9/1/2020
CLOZAPINE ODT	CLOZAPINE	25 MG	TAB RAPDIS	ORAL	G-VH	NONE	ANTIPSYCHOTIC AGENTS	90/30	NONE	ANTIPSYCHOTIC AGENTS	90/30	Re-assigned as a ST2 agent under the ANTIPSYCHOTIC AGENTS STGD	9/1/2020
VERSACLOZ	CLOZAPINE	50 MG/ML	ORAL SUSP	ORAL	S-M	NONE	ANTIPSYCHOTIC AGENTS	540/30	NONE	ANTIPSYCHOTIC AGENTS	540/30	Re-assigned as a ST2 agent under the ANTIPSYCHOTIC AGENTS STGD	9/1/2020
XYLON 10	HYDROCODONE/IBUPROFEN	10MG-200MG	TABLET	ORAL	G-NP	NONE	NONE	NONE				New Drug Entity	10/10/2020
EPINEPHRINE	EPINEPHRINE	1 MG/ML	VIAL	INJECTION	G-L	NONE	NONE	NONE	NONE	NONE	NONE	New Drug Entity	10/10/2020

Negative Change Requests (NCR) - Maintenance changes

Drug					Formulary Status	Prescribing Limitations						Notes	Effective Date
						Plus			Advantage				
Brand Name	Generic Name	Strength	Dosage Form	Route	Drug Bucket	PA	ST	QL	PA	ST	QL		
DIFFERIN	ADAPALENE	0.10%	GEL (GRAM)	TOPICAL	NA							No longer Part D Eligible	12/1/2020
DEXTROSE IN WATER	DEXTROSE 20 % IN WATER	20%	IV SOLN	INTRAVEN.	NA							No longer Part D Eligible	12/1/2020
EXELDERM	SULCONAZOLE NITRATE	1%	SOLUTION	TOPICAL	NA							No longer Part D Eligible	12/1/2020
VIMOVO	NAPROXEN/ESOMEPRAZOLE MAG	375 MG-20 MG	TAB IR DR	ORAL	S-MS	NONE	NONE	60/30				Drug bucket previously S-PPM, brand/generic offset	12/1/2020
VIMOVO	NAPROXEN/ESOMEPRAZOLE MAG	500 MG-20 MG	TAB IR DR	ORAL	S-MS	NONE	NONE	60/30				Drug bucket previously S-PPM, brand/generic offset	12/1/2020
KARBINAL ER	CARBINOXAMINE MALEATE	4 MG/5 ML	SUS ER 12H	ORAL	NA							No longer Part D Eligible	12/1/2020
ACIPHEX SPRINKLE	RABEPRAZOLE SODIUM	10 MG	CAP DR SPR	ORAL	NA							No longer Part D Eligible	12/1/2020
ACIPHEX SPRINKLE	RABEPRAZOLE SODIUM	5 MG	CAP DR SPR	ORAL	NA							No longer Part D Eligible	12/1/2020
RANITIDINE HCL	RANITIDINE HCL	15 MG/ML	SYRUP	ORAL	NA							FDA requested market withdrawal	12/1/2020

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IV. New FDA Approved Indications

Drug		Formulary Status		Prescribing Limitations				New (Expanded) Indications	Previous Indications
		Plus/Advantage		Plus		Advantage			
Brand Name	Generic Name	Current	Action	Current	Action	Current	Action		

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Medicare 4Q20 P&T Actions

Santa Clara Family Health Plan™

SANTA CLARA FAMILY HEALTH PLAN

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Medicare P&T Actions 4Q20

Category	Drug	Formulary Change
New Drugs	Rukobia 600mg ER tablet	Added (Tier 2)
	Fintepla 2.2mg/mL solution	Added (Tier 2) with PA
	Monjuvi 200mg vial	Added (Tier 2) with PA
	Breztri Aerosphere 160-9-4.8mcg	Added (Tier 2)
	Blenrep 100mg vial	Added (Tier 2) with PA
	Evrysdi 0.75mg/mL solution	Added (Tier 2) with PA
	Inqovi 35-100mg tablet	Added (Tier 2) with PA & QL
	Gavreto 100mg capsule	Added (Tier 2) with PA & QL

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Medicare P&T Actions 4Q20

Category	Drug	Formulary Change
Line Extensions	Dupixent 300mg/2mL pen	Added (Tier 2) with PA
	Sirturo 20mg tablet	Added (Tier 2) with PA
	Sumatriptan 6mg/0.5mL cartridge	Added (Tier 1) with ST & QL
	Enbrel 25mg/0.5mL vial	Added (Tier 2) with PA
	Cyclophosphamide 200mg/mL vial	Added (Tier 1) with PA
	Kesimpta 20mg/0.4mL pen	Added (Tier 2) with PA & QL
	Onureg 200mg, 300mg tablet	Added (Tier 2) with PA & QL
	Akynzeo 235mg-0.25mg vial	Added (Tier 2)
	Trulicity 3mg/0.5mL, 4.5mg/0.5mL pen	Added (Tier 2)
	Menquadfi 10mcg/0.5mL vial	Added (Tier 2)
	Polivy 30mg vial	Added (Tier 2) with PA
	Xywav 0.5g/mL solution	Added (Tier 2) with PA & QL
	Trelegy Ellipta 200-62.5-25mcg	Added (Tier 2)

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Medicare P&T Actions 4Q20

Category	Drug	Formulary Change
New Generics	Metyrosine 250mg capsule	Added (Tier 1)
	Deferasirox 90mg, 180mg, 360mg granules	Added (Tier 1) with PA
	Ciprofloxacin-Dexamethasone 0.3%-0.1% otic drops	Added (Tier 1)
	Dimethyl Fumarate 120mg, 240mg, 120-240mg capsule	Added (Tier 1) with PA
	Emtricitabine 200mg capsule	Added (Tier 1)
	Sapropterin Dihydrochloride 100mg soluble tablet	Added (Tier 1)
	Tobramycin 300mg/4mL ampule (neb)	Added (Tier 1) with PA
	Efavirenz-Lamivudine-Tenofovir 400-300-300mg, 600-300-300mg tablet	Added (Tier 1)
	Efavirenz-Emtricitabine-Tenofovir 600-200-300mg tablet	Added (Tier 1)
	Emtricitabine-tenofoir 200-300mg tablet	Added (Tier 1)
	Deferiprone 500mg tablet	Added (Tier 1) with PA
	Lapatinib Ditosylate 250mg tablet	Added (Tier 1) with PA

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Medicare P&T Actions 4Q20

Category	Drug	Formulary Change
Other Formulary Changes (Positive)	Reyvow 50mg, 100mg tablet	Added (Tier 2) with PA & QL
	Nurtec ODT 75mg tablet	Added (Tier 2) with PA & QL
	Ubrelvy 50mg, 100mg tablet	Added (Tier 2) with PA & QL
	Ferriprox 1000mg tablet	Added (Tier 2) with PA
	Epogen 2000/mL, 3000/mL, 4000/mL, 10000/mL, 20000/2mL vial	Added (Tier 2) with PA & QL
	Epogen 20000/mL vial	Added (Tier 1) with PA & QL
	Proglycem 50mg/mL suspension	Added (Tier 2)
	Levonorgestrel-Ethinyl Estradiol 6-5-10 tablet	Added (Tier 1)
	Bidil 20-37.5mg tablet	Added (Tier 2)
	Epinephrine 1mg/ml vial	Added (Tier 1)
	Invokana 100mg, 300mg tablet	ST removed
	Invokamet 50-500mg, 50-1000mg, 150-500mg, 150-1000mg IR & XR tablet	ST removed
	Jardiance 10mg, 25mg tablet	ST removed
	Synjardy 5-500mg, 5-1000mg, 12.5-500mg, 12.5-1000mg tablet	ST removed
	Synjardy 5-1000mg, 10-1000mg, 12.5-1000mg, 25-1000mg XR tablet	ST removed
	Xcopri 150mg tablet	QL updated (from 30/30 to 60/30)

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Santa Clara Family Health Plan™

Medical Benefit Drug Prior Authorization Grid

The following drugs require prior authorization for all Santa Clara Family Health Plan members. Additional required actions, restrictions, or limits on use are indicated in the right column.

Abbreviations used in this document include:

ST: Step Therapy
PA: Prior Authorization

Brand	Generic	Necessary Actions, Restrictions, or Limits on Use
ANTIEMETICS (ASSOCIATED WITH CANCER CHEMOTHERAPY)		
Cinvanti	Aprepitant	PA
Emend IV	Fosaprepitant	PA
Aloxi	Palonosetron	PA
Akynzeo IV	Fosnetupitant/Palonosetron	PA
ANTIHEMOPHILIC AGENTS		
Hemlibra	Emicizumab-kxwh	PA
CAR-T CELL IMMUNOTHERAPY		
Yescarta	Axicabtagene ciloleucel	PA
Tecartus	Brexucabtagene autoleucel	PA
Kymriah	Tisagenlecleucel	PA
ERYTHROPOIESIS STIMULATING AGENTS		
Aranesp	Darbepoetin alfa	PA, ST: Retacrit
Epogen, Procrit	Epoetin alfa	PA, ST: Retacrit
Retacrit	Epoetin alfa-epbx	PA
Mircera	Methoxy polyethylene glycol-epoetin beta	PA, ST: Retacrit
COLONY STIMULATING FACTORS		
Neupogen	Filgrastim	PA, ST: Zarxio or Nivestym
Neulasta, Neulasta Onpro	Pegfilgrastim	PA, ST: Fulphila, ~~or~~ Udenyca, Ziextenzo, or Nyvepria
Granix	Tbo-filgrastim	PA, ST: Zarxio or Nivestym
Leukine	Sargramostim	PA, ST: Zarxio, Nivestym, Fulphila, ~~or~~ Udenyca, Ziextenzo, or Nyvepria
GAUCHER DISEASE		
Cerezyme	Imiglucerase	PA
Elelyso	Taliglucerase alfa	PA
Vpriv	Velaglucerase alfa	PA

Brand	Generic	Necessary Actions, Restrictions, or Limits on Use
HEREDITARY ANGIOEDEMA		
Berinert, Cinryze, Haegarda	C1 esterase inhibitor, human	PA
Ruconest	C1 esterase inhibitor, recombinant	PA
Kalbitor	Ecallantide	PA
Firazyr	Icatibant	PA
Takhzyro	Lanadelumab-flyo	PA
IV IMMUNOGLOBULIN (IVIG)		
Asceniv, Bivigam, Carimune NF, Cutaquig, Cuvitru, Flebogamma DIF, Gamastan, Gamastan S/D, Gammagard, Gammagard S/D, Gammaked, Gammaplex, Gamunex-C, Hizentra, Hyqvia, Octagam, Panzyga, Privigen, Xembify	Immune globulin, Immune globulin lyophilized, Immune globulin non-lyophilized	PA
MULTIPLE SCLEROSIS		
Tysabri	Natalizumab	PA
Ocrevus	Ocrelizumab	PA
NEUROMUSCULAR BLOCKING AGENTS		
Dysport	AbobotulinumtoxinA	PA
Xeomin	IncobotulinumtoxinA	PA
Botox	OnabotulinumtoxinA	PA
Myobloc	RimabotulinumtoxinB	PA
OPHTHALMIC AGENTS		
Beovu	Brolucizumab-dbll	PA
Eylea	Aflibercept	PA
Lucentis	Ranibizumab	PA
Luxturna	Voretigene neparvovec-rzyl	PA
OSTEOPOROSIS OR BONE MODIFIERS		
~~Prolia, Xgeva~~	~~Denosumab~~	~~PA~~
Boniva IV	Ibandronate sodium ~~(IV)~~	PA
Aredia	Pamidronate disodium	PA
Reclast, Zometa	Zoledronic acid	PA
PULMONARY HYPERTENSION		
Flolan, Veletri	Epoprostenol	PA
Remodulin IV	Treprostinil ~~(injection)~~	PA

Brand	Generic	Necessary Actions, Restrictions, or Limits on Use
RESPIRATORY		
Aralast NP, Glassia, Prolastin-C, Zemaira	α-1 proteinase inhibitor	PA
Fasenra	Benralizumab	PA
Nucala	Mepolizumab	PA
Xolair	Omalizumab	PA
Synagis	Palivizumab	PA
Cinqair	Reslizumab	PA
RHEUMATOLOGY/IMMUNOSUPPRESSANTS		
Orencia IV	Abatacept	PA
Humira, Cyltezo, Abrilada, Amjevita, Hyrimoz, Hadlima, Hulio	Adalimumab, Adalimumab-adbm, Adalimumab-afzb, Adalimumab-atto, Adalimumab-adaz, Adalimumab-bwwd, Adalimumab-fkjp	Pharmacy Benefit Only
Cimzia	Certolizumab pegol	Pharmacy Benefit Only
Enbrel, Erelzi, Eticovo	Etanercept, Etanercept-szzs, Etanercept-ykro	Pharmacy Benefit Only
Simponi Aria	Golimumab	PA
Tremfya	Guselkumab	PA
Remicade	Infliximab	PA, ST: Inflectra, Renflexis, ~~or~~ Ixifi, or Avsola
Inflectra, Renflexis, Ixifi, Avsola	Infliximab-dyyb, Infliximab-abda, Infliximab-qbtx, Infliximab-axxq	PA
Taltz	Ixekizumab	Pharmacy Benefit Only
Rituxan, Rituxan Hycela	Rituximab, Rituximab/hyaluronidase	PA, ST: Truxima or Ruxience
Truxima, Ruxience	Rituximab-abbs, Rituximab-pvvr	PA
Actemra IV	Tocilizumab ~~IV~~	PA
Stelara IV	Ustekinumab ~~IV~~	PA
Entyvio	Vedolizumab	PA

Brand	Generic	Necessary Actions, Restrictions, or Limits on Use
MISCELLANEOUS		
Exondys 51	Eteplirsen	PA
Spinraza	Nusinersen	PA
Onpattro	Patisiran	PA
Krystexxa	Pegloticase	PA
Nplate	Romiplostim	PA
Radicava	Edaravone	PA
Zolgensma	Onasemnogene abeparvovec-xioi	PA
Tepezza	Teprotumumab-trbw	PA
Vyepti	Eptinezumab-jjmr	PA
UNCLASSIFIED		
Unclassified drugs and biologics		PA

DRAFT

Santa Clara Family Health Plan™

Pharmacy & Therapeutics Committee

MEDI-CAL FORMULARY & PRIOR AUTHORIZATION

2020 SCFHP Medi-Cal Formulary Changes

Formulary Change	Rationale	BCR Date	Effective Date	Approved
Added Trulicity 3mg/0.5ml and 4.5mg/0.5ml to formulary with QL 0.5/7 days and ST to look for 5/180 days of metformin	New strengths of Trulicity available	9/25/2020	9/1/2020	L. Nakahira
Added budesonide/formoterol inhaler to formulary	Align with updated 2020 GINA treatment guideline recommendations	10/23/2020	10/1/2020	L. Nakahira
Added Semglee vial and pen to formulary with QL 1.5/day	New insulin glargine product	10/29/2020	9/1/2020	L. Nakahira
Changed QL on ibandronate 150mg tablet to 1/30 days	Formulary clean-up	10/29/2020	8/1/2020	L. Nakahira
Changed ST on Spiriva HandiHaler and Spiriva Respimat to look for 5/180 days of any of the following: fluticasone/salmeterol, ipratropium/albuterol nebulizer solution, Combivent Respimat, Atrovent HFA, ipratropium nebulizer solution, or budesonide/formoterol	Include newly added budesonide/formoterol in ST	10/29/2020	10/1/2020	L. Nakahira

Medi-Cal Updates

Santa Clara Family Health Plan™

SANTA CLARA FAMILY HEALTH PLAN

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CDL COMPARISON

SAC Medi-Cal Updates

Notice Date	Drug	Summary of Change to FFS CDL	SAC Formulary Status	Proposed Action
09/20	Rituximab-ABBS (Truxima)	Drug Added Code 1 Restriction Added (Cancer)	Non-Formulary	No Action
09/20	Trastuzumab-PKRB (Herzuma)	Drug Added Code 1 Restriction Added (Cancer)	Non-Formulary	No Action
09/20	Nelarabine (Arranon)	Code 1 Restriction Added (Cancer)	Non-Formulary	No Action
09/20	Topotecan HCL (Hycamtin)	Code 1 Restriction Added (Cancer)	Non-Formulary	No Action
09/20	Palbociclib (Ibrance)	Drug Added (tablets)	Non-Formulary	No Action
09/20	Linagliptin/Metformin ER (Jentadueto XR)	Drug Added	Non-Formulary	No Action
09/20	Empagliflozin/Linagliptin (Glyxambi)	Drug Added	Non-Formulary	No Action
09/20	Empagliflozin/Linagliptin/Metformin (Trijardy XR)	Drug Added	Non-Formulary	No Action
09/20	Empagliflozin/Metformin (Synjardy)	Drug Added	Formulary, Step Therapy Quantity Limit (1-2/day)	No Action
09/20	Dabigatran Etexilate Mesylate (Pradaxa)	Drug Added	Non-Formulary	No Action

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CDL COMPARISON

SAC Medi-Cal Updates

Notice Date	Drug	Summary of Change to FFS CDL	SAC Formulary Status	Proposed Action
09/20	Diazepam (Valtoco)	Drug Added Code 1 Restriction (Acute Epilepsy) Age Restriction (6 years and older) Quantity Limit (10 cartons/year)	Non-Formulary	No Action
09/20	Glucagon Nasal (Basqimi)	Drug Added Limited to 2 per fill & 2 fills per year	Non-Formulary	No Action
09/20	Celecoxib (Celebrex)	Code 1 Restrictions Removed (RA, AS, JA with DMARD)	Formulary Quantity Limit (1-2/day)	No Action
09/20	Diclofenac (Voltaren)	Code 1 Restrictions Removed (arthritis)	Formulary	No Action
09/20	Diflunisal (Dolobid)	Code 1 Restrictions Removed (arthritis)	Non-Formulary	No Action
09/20	Fenoprofen (Nalfon)	Code 1 Restrictions Removed (arthritis)	Non-Formulary	No Action
09/20	Flurbiprofen (Ansaid)	Code 1 Restrictions Removed (arthritis)	Formulary	No Action
09/20	Ibuprofen (Motrin)	Step Therapy Removed	Formulary	No Action
09/20	Indomethacin (Indocin)	Step Therapy Removed	Formulary	No Action

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CDL COMPARISON

SAC Medi-Cal Updates

Notice Date	Drug	Summary of Change to FFS CDL	SAC Formulary Status	Proposed Action
09/20	Olodaterol HCL (Striverdi Respimat)	Drug Added	Non-Formulary	No Action
09/20	Tiotropium BR/Olodaterol HCL (Stiolto Respimat)	Drug Added	Non-Formulary	No Action
09/20	Tiotropium Bromide Inh (Spiriva Respimat)	Drug Added	Formulary, Step Therapy Quantity Limit (1/month)	No Action
10/20	Pralsetinib (Gavreto)	Drug Added Code 1 Restriction Added (Cancer)	Non-Formulary	No Action
10/20	Baloxavir Marboxil (Xofluxa)	Drug Added (TAR if < 12yoa)	Formulary Quantity Limit (2/fill)	No Action
10/20	Cyproheptadine	Drug Added	Formulary	No Action
10/20	Mupirocin (Bactroban)	Drug Added	Formulary	No Action
10/20	Segesterone/E. Estradiol (Annovera)	Drug Added (Limit to 1 per fill & 2 fills per year)	Non-Formulary	No Action
10/20	Ubrogepant (Ubrelvy)	Drug Added Treatment Authorization Request	Non-Formulary	No Action
10/20	Ondansetron (Zofran)	Drug Added (4mg/5mL liquid)	Formulary Quantity Limit (100mL/month)	No Action

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SAC Medi-Cal Updates

Notice Date	Drug	Summary of Change to FFS CDL	SAC Formulary Status	Proposed Action
10/20	Aspirin	Drug Added (81mg chewable tab)	Formulary	No Action
10/20	Meloxicam (Mobix)	Code 1 Restriction Removed (arthritis) Step Therapy Removed	Formulary	No Action
10/20	Nabumetone (Relafen)	Code 1 Restriction Removed (arthritis) Step Therapy Removed	Formulary	No Action
10/20	Naproxen (Naprosyn)	Step Therapy Removed	Formulary	No Action
10/20	Piroxicam (Feldene)	Code 1 Restriction Removed (arthritis) Step Therapy Removed	Non-Formulary	No Action
10/20	Salsalate (Disalcid)	Code 1 Restriction Removed (arthritis)	Formulary	No Action
10/20	Sulindac (Clinoril)	Code 1 Restriction Removed (arthritis) Step Therapy Removed	Formulary	No Action
10/20	Tolmetin (Tolectin)	Code 1 Restriction Removed (arthritis) Step Therapy Removed	Non-Formulary	No Action
10/20	Ezetimibe (Zetia)	Code 1 Restriction Removed (lipid-lowering)	Formulary Quantity Limit (1/day)	No Action
10/20	Cefdinir (Omnicef)	Age Restriction Removed (liquid)	Formulary	No Action

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SAC Medi-Cal Updates

Notice Date	Drug	Summary of Change to FFS CDL	SAC Formulary Status	Proposed Action
10/20	Divalproex Sodium (Depakote)	Age Restriction Removed	Formulary	No Action
10/20	Divalproex Sodium (Depakote ER)	Age Restriction Removed	Formulary, Step Therapy	No Action
11/20	Clonazepam (Klonopin)	Quantity Limit Changed (90 tabs/month)	Formulary Quantity Limit (4/day)	No Action
11/20	Diazepam (Valium)	Age Restriction Added (2 yoa+ only) Code 1 Restriction Removed (CP, AS, SCD) (tablets)	Formulary Quantity Limit (4/day)	No Action
11/20	Diazepam (Valium)	Age Restriction Added (2 yoa+ only) (vial, syringe, cartridge)	Non-Formulary	No Action
11/20	Diazepam (Valtoco)	Code 1 Restriction Added (epilepsy) Age Restriction Added (6 yoa+ only) Quantity Limit Added (20 doses/year)	Non-Formulary	No Action
11/20	Flurazepam (Dalmane)	Quantity Limit Added (60 caps/month)	Formulary	No Action
11/20	Lorazepam (Ativan)	Quantity Limit Changed (60 tabs/month)	Formulary Quantity Limit (3/day)	No Action
11/20	Temazepam (Restoril)	Quantity Limit Added (60 caps/month)	Formulary	No Action
11/20	Triazolam (Halcion)	Quantity Limit Added (60 tabs/month)	Formulary Quantity Limit (2/day)	No Action

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CDL COMPARISON

SAC Medi-Cal Updates

Notice Date	Drug	Summary of Change to FFS CDL	SAC Formulary Status	Proposed Action
11/20	Belantmab Mafodotin-blmf (Blenrep)	Drug Added Code 1 Restriction Added (Cancer)	Non-Formulary	No Action
11/20	Blinatumomab (Blincyto)	Drug Added Code 1 Restriction Added (Cancer)	Non-Formulary	No Action
11/20	Carfilzomib (Kyprolis)	Drug Added Code 1 Restriction Added (Cancer)	Non-Formulary	No Action
11/20	Ripretinib (Qinlock)	Drug Added Code 1 Restriction Added (Cancer)	Non-Formulary	No Action
11/20	Talimogene Laherparepvec (Imlygic)	Drug Added Code 1 Restriction Added (Cancer)	Non-Formulary	**Add to Medical Benefit**
11/20	Acyclovir (Zovirax)	Code 1 Restriction Removed (herpes genitalis, herpes zoster)	Formulary	No Action
11/20	Valacyclovir (Valtrex)	Code 1 Restriction Removed (herpes genitalis, herpes zoster)	Formulary Quantity Limit (2-4/day)	No Action
11/20	Chlordiazepoxide (Librax)	Drug Added Quantity Limit (30 caps/month)	Formulary Quantity Limit (4/day)	No Action
11/20	Ramelteon (Rozerem)	Quantity Limit Changed (60 tabs/month) Age Restriction Added (18 yoa + only)	Non-Formulary	No Action
11/20	Zolpidem (Ambien)	Quantity Limit Added (60 tabs/month)	Formulary Quantity Limit (1/day)	No Action

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Santa Clara Family Health Plan™

Medical Benefit Drug Prior Authorization Grid

The following drugs require prior authorization for all Santa Clara Family Health Plan members. Additional required actions, restrictions, or limits on use are indicated in the right column.

Abbreviations used in this document include:

ST: Step Therapy
PA: Prior Authorization

Brand	Generic	Necessary Actions, Restrictions, or Limits on Use
ANTIEMETICS (ASSOCIATED WITH CANCER CHEMOTHERAPY)		
Cinvanti	Aprepitant	PA
Emend IV	Fosaprepitant	PA
Aloxi	Palonosetron	PA
Akynzeo IV	Fosnetupitant/Palonosetron	PA
ANTIHEMOPHILIC AGENTS		
Hemlibra	Emicizumab-kxwh	PA
CAR-T CELL IMMUNOTHERAPY		
Yescarta	Axicabtagene ciloleucel	PA
Tecartus	Brexucabtagene autoleucel	PA
Kymriah	Tisagenlecleucel	PA
ERYTHROPOIESIS STIMULATING AGENTS		
Aranesp	Darbepoetin alfa	PA, ST: Retacrit
Epogen, Procrit	Epoetin alfa	PA, ST: Retacrit
Retacrit	Epoetin alfa-epbx	PA
Mircera	Methoxy polyethylene glycol-epoetin beta	PA, ST: Retacrit
COLONY STIMULATING FACTORS		
Neupogen	Filgrastim	PA, ST: Zarxio or Nivestym
Neulasta, Neulasta Onpro	Pegfilgrastim	PA, ST: Fulphila, ~~or~~ Udenyca, Ziextenzo, or Nyvepria
Granix	Tbo-filgrastim	PA, ST: Zarxio or Nivestym
Leukine	Sargramostim	PA, ST: Zarxio, Nivestym, Fulphila, ~~or~~ Udenyca, Ziextenzo, or Nyvepria
GAUCHER DISEASE		
Cerezyme	Imiglucerase	PA
Elelyso	Taliglucerase alfa	PA
Vpriv	Velaglucerase alfa	PA

Brand	Generic	Necessary Actions, Restrictions, or Limits on Use
HEREDITARY ANGIOEDEMA		
Berinert, Cinryze, Haegarda	C1 esterase inhibitor, human	PA
Ruconest	C1 esterase inhibitor, recombinant	PA
Kalbitor	Ecallantide	PA
Firazyr	Icatibant	PA
Takhzyro	Lanadelumab-flyo	PA
IV IMMUNOGLOBULIN (IVIG)		
Asceniv, Bivigam, Carimune NF, Cutaquig, Cuvitru, Flebogamma DIF, Gamastan, Gamastan S/D, Gammagard, Gammagard S/D, Gammaked, Gammaplex, Gamunex-C, Hizentra, Hyqvia, Octagam, Panzyga, Privigen, Xembify	Immune globulin, Immune globulin lyophilized, Immune globulin non-lyophilized	PA
MULTIPLE SCLEROSIS		
Tysabri	Natalizumab	PA
Ocrevus	Ocrelizumab	PA
NEUROMUSCULAR BLOCKING AGENTS		
Dysport	AbobotulinumtoxinA	PA
Xeomin	IncobotulinumtoxinA	PA
Botox	OnabotulinumtoxinA	PA
Myobloc	RimabotulinumtoxinB	PA
OPHTHALMIC AGENTS		
Beovu	Brolucizumab-dbll	PA
Eylea	Aflibercept	PA
Lucentis	Ranibizumab	PA
Luxturna	Voretigene neparvovec-rzyl	PA
OSTEOPOROSIS OR BONE MODIFIERS		
~~Prolia, Xgeva~~	~~Denosumab~~	~~PA~~
Boniva IV	Ibandronate sodium ~~(IV)~~	PA
Aredia	Pamidronate disodium	PA
Reclast, Zometa	Zoledronic acid	PA
PULMONARY HYPERTENSION		
Flolan, Veletri	Epoprostenol	PA
Remodulin IV	Treprostinil ~~(injection)~~	PA

Brand	Generic	Necessary Actions, Restrictions, or Limits on Use
RESPIRATORY		
Aralast NP, Glassia, Prolastin-C, Zemaira	α-1 proteinase inhibitor	PA
Fasenra	Benralizumab	PA
Nucala	Mepolizumab	PA
Xolair	Omalizumab	PA
Synagis	Palivizumab	PA
Cinqair	Reslizumab	PA
RHEUMATOLOGY/IMMUNOSUPPRESSANTS		
Orencia IV	Abatacept	PA
Humira, Cyltezo, Abrilada, Amjevita, Hyrimoz, Hadlima, Hulio	Adalimumab, Adalimumab-adbm, Adalimumab-afzb, Adalimumab-atto, Adalimumab-adaz, Adalimumab-bwwd, Adalimumab-fkjp	Pharmacy Benefit Only
Cimzia	Certolizumab pegol	Pharmacy Benefit Only
Enbrel, Erelzi, Eticovo	Etanercept, Etanercept-szzs, Etanercept-ykro	Pharmacy Benefit Only
Simponi Aria	Golimumab	PA
Tremfya	Guselkumab	PA
Remicade	Infliximab	PA, ST: Inflectra, Renflexis, ~~or~~ Ixifi, or Avsola
Inflectra, Renflexis, Ixifi, Avsola	Infliximab-dyyb, Infliximab-abda, Infliximab-qbtx, Infliximab-axxq	PA
Taltz	Ixekizumab	Pharmacy Benefit Only
Rituxan, Rituxan Hycela	Rituximab, Rituximab/hyaluronidase	PA, ST: Truxima or Ruxience
Truxima, Ruxience	Rituximab-abbs, Rituximab-pvvr	PA
Actemra IV	Tocilizumab ~~IV~~	PA
Stelara IV	Ustekinumab ~~IV~~	PA
Entyvio	Vedolizumab	PA

Brand	Generic	Necessary Actions, Restrictions, or Limits on Use
MISCELLANEOUS		
Exondys 51	Eteplirsen	PA
Spinraza	Nusinersen	PA
Onpattro	Patisiran	PA
Krystexxa	Pegloticase	PA
Nplate	Romiplostim	PA
Radicava	Edaravone	PA
Zolgensma	Onasemnogene abeparvovec-xioi	PA
Tepezza	Teprotumumab-trbw	PA
Vyepti	Eptinezumab-jjmr	PA
UNCLASSIFIED		
Unclassified drugs and biologics		PA

DRAFT

New or Revised Criteria

	Brand	Generic	Q4 2020 Comments
1	Protopic ointment	tacrolimus	Revised – added tacrolimus 0.1% ointment for 16 years of age or older, tacrolimus 0.03% no age limits
2	Non-formulary		Revised - removed “For requests reviewed prior to 1/1/2020, approve until 12/31/2020”

Annual Review

	Brand	Generic	Q4 2020 Comments
1	Zarxio	filgrastim-SNDZ	Annual review - no change
2	Norditropin Flexpro	somatropin	Annual review - no change

Santa Clara Family Health Plan

tacrolimus ointment
PROTOPIC

DRUG PRIOR AUTHORIZATION REQUEST CRITERIA

Generic	Brand	HICL	GPID	ROUTE
TACROLIMUS	**PROTOPIC**	**20974**	**12289 – 0.03% OINTMENT** **12302 – 0.1% OINTMENT**	**TOPICAL**

Prior Authorization Required

Authorization Criteria:

Nonfacial/Nonintertriginous affected areas

1. Diagnosis of atopic dermatitis/eczema; **and**
2. Tried and failed two medium or high potency topical steroids; **and**
3. One of the following:
   a. Tacrolimus 0.1% ointment: 16 years of age or older; **or**
   b. Tacrolimus 0.03% ointment: no age limit

Facial/Intertriginous affected areas (excluding around eyes)

1. Diagnosis of atopic dermatitis/eczema; **and**
2. Tried and failed one low potency topical steroid; **and**
3. One of the following:
   a. Tacrolimus 0.1% ointment: 16 years of age or older; **or**
   b. Tacrolimus 0.03% ointment: no age limit

Around or on the eyelids

1. Diagnosis of atopic dermatitis/eczema around or on the eyelids; **and**
2. Quantity requested does not exceed 30 grams per month; **and**
3. One of the following:
   a. Tacrolimus 0.1% ointment: 16 years of age or older; **or**
   b. Tacrolimus 0.03% ointment: no age limit

Approval period:

- Approve by **GPID** for 12 months.

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Denial Language:

D1. Approval requires you to try and fail two medium or high potency topical steroids: Fluocinolone 0.01% (cream, solution, oil), fluocinolone 0.03% (cream, ointment), mometasone 0.1% (cream, ointment), triamcinolone 0.025% (cream, ointment, lotion), triamcinolone 0.05% (ointment), triamcinolone 0.1% (cream, ointment, lotion), triamcinolone 0.5% (cream, ointment), betamethasone dipropionate 0.05% cream, betamethasone dipropionate-augmented 0.05% (cream, ointment, lotion), fluocinonide 0.05% (cream, ointment, solution, gel).
D2. Approval requires you to try and fail one low potency topical steroid: Hydrocortisone butyrate 0.1% (ointment, solution), hydrocortisone 0.5% (cream, ointment, lotion), hydrocortisone 1% (cream, ointment, gel, solution, lotion, spray), hydrocortisone 2% lotion, hydrocortisone 2.5% (cream, ointment, solution, lotion), hydrocortisone 10% gel, alclometasone 0.05% (cream, ointment), prednicarbate 0.1% (cream, ointment).

FDA Approved Indications:

- Tacrolimus Ointment, both 0.03% and 0.1% for adults, and only 0.03% for children aged 2 to 15 years, is indicated as second-line therapy for the short-term and non-continuous chronic treatment of moderate to severe atopic dermatitis in non-immunocompromised adults and children who have failed to respond adequately to other topical prescription treatment for atopic dermatitis, or when whose treatments are not advisable.

Definition:

- Intertriginous area is any area where two areas of skin touch or rub each other (e.g. skin folds, underneath breasts, axilla, groin area, between fingers)

References:

- Valeant Pharmaceuticals North America LLC. Elidel package insert. Bridgewater, NJ. Revised 12/2017.
- Fougera Pharmaceuticals Inc. Tacrolimus package insert. Melville, NY. Revised 10/2017.
- Eichenfield LF, Tom WL, Berger TG, et al. Guidelines of care for the management of atopic dermatitis: section 2. Management and treatment of atopic dermatitis with topical therapies. J Am Acad Dermatol 2014; 71:116.

Version	Date	P&T Approval	Comments/Changes
1	02/15/2019	03/21/2019	DN Created; P&T Approved 1Q2019
2	03/11/2020	04/30/2020	DN Revised criteria for around or on the eyelids to add "Quantity requested does not exceed 30 grams per month." P&T Approved 1Q2020
3	12/08/2020	PENDING Q4 2020	DN Revised: added age limits – Tacrolimus 0.1% ointment for 16 years of age or older, Tacrolimus 0.03% ointment no age limits

Santa Clara Family Health Plan™

non-formulary
NF

DRUG PRIOR AUTHORIZATION REQUEST CRITERIA

Non-Formulary

Authorization Criteria:

1. The requested drug is being prescribed for an FDA approved indication or supported in established and nationally recognized compendia; **and**

2. Dose does not exceed FDA label or medically accepted dose based on age and indication supported in established and nationally recognized compendia; **and**

3. Request was submitted with chart notes and/or labs that provide supporting clinical information for the requested drug; **and**

4. Chart notes document ***one*** of the following:

    a. Trial and failure of at least *two* formulary alternatives with the same mechanism of action;
    (Note: If two drugs with a similar mechanism of action are not available on the formulary, the member must have tried two alternative formulary drugs that are medically acceptable to treat the member's condition) or
    b. An explanation of why the formulary alternative drugs would not be as effective in treating the member's condition and/or would cause the member to have adverse effects not expected with the requested drug; or
    c. If the requested drug is a non-formulary combination drug where the separate components are on formulary, the member must have tried the individual drugs AND an alternative formulary drug (if available).

Approval Period:

- Maintenance drugs: 12 months
    - ~~For requests reviewed prior to 1/1/2020, approve until 12/31/2020~~
- Non-maintenance and specialty drugs: 6 months
- Self-administered hormonal contraceptives: 12 months

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Denial Language:

D1. SCFHP's Non-Formulary Criteria was not met. Your doctor did not submit chart notes stating that you have tried or cannot use the covered drugs.

Approval requires you to try and fail two of the following covered drugs: <drug1, drug2>.
Approval requires you to try and fail the following covered drug: <drug>.

Rationale for Clinical Intent:
To ensure appropriate use and duration of formulary alternatives available.

References:

- Department of Health Care Services All Plan Letter 18-019: Family Planning Services Policy for Self-Administered Hormonal Contraceptives
- Title 42 United States Code, Sections 1396a(a)23(B) and 1396d(a)(4)(C)
- Medi-Cal Managed Care Boilerplate contract , Exhibit A, Attachment 9, Access and Availability
- Title 22, California Code of Regulations, Section 51200
- SB 999
- HSC Section 1367.25(d)(1)
- Medi-Cal Provider Manual, Family Planning section, Contraceptives
- BPC Section 4064.5(f)(2)

Version	Date	P&T	Comments/Changes
1	08/19/2016	09/15/2016	DH Created; P&T Approved 3Q2016
2	12/07/2017	12/14/2017	DN Deleted "or clinically appropriate" from Approval Period; P&T Approved 4Q2017
3	6/11/2018	06/21/2018	DN Updated Approval Period from 4 months to 6 months; P&T Approved 2Q2018
4	12/13/2018 12/28/2018 (JL Interim Approval)	06/20/2019	TO Added approval period for self-administered hormonal contraceptives in compliance with APL18-019; P&T Approved 2Q2019
5	11/25/2019	12/19/2019	DN Updated Approval Period from 6 months to 12 months for maintenance drugs. For non-maintenance and specialty drugs, approve for 6 months; P&T Approved 4Q2019
6	11/28/2020	PENDING Q4 2020	DH Revised: removed "For requests reviewed prior to 1/1/2020, approve until 12/31/2020"

Santa Clara Family Health Plan™

somatropin
NORDITROPIN FLEXPRO

DRUG PRIOR AUTHORIZATION REQUEST CRITERIA

Generic	Brand	HICL	GPID	ROUTE
SOMATROPIN	**NORDITROPIN FLEXPRO**	**2824**	**24145 – 5 MG/1.5 ML** **24146 – 10 MG/1.5 ML** **24147 – 15 MG/1.5 ML**	**SUBCUTANEOUS**

Prior Authorization Required

Initial Authorization Criteria:

Pediatric growth hormone deficiency (GHD), Noonan syndrome, or Turner syndrome

1. Prescribed by or in consultation with an endocrinologist or a pediatric endocrinologist; **and**
2. Chart notes document diagnosis of pediatric GHD, Noonan syndrome, *or* Turner syndrome; **and**
3. Confirmation of open epiphyses (growth plates) in patients more than 12 years of age; **and**
4. Patient's height is greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender.

Prader-Willi syndrome (PWS)

1. Prescribed by or in consultation with an endocrinologist or a pediatric endocrinologist; **and**
2. Chart notes document diagnosis of Prader-Willi syndrome; **and**
3. Documentation of growth failure.

Short stature born small for gestational age (SGA)

1. Prescribed by or in consultation with an endocrinologist or a pediatric endocrinologist; **and**
2. Chart notes document diagnosis of small stature born small for SGA; **and**
3. Confirmation of open epiphyses (growth plates) in patients more than 12 years of age; **and**
4. Patient has no catch-up growth by age 2 to 4 years; **and**
5. Patient's height is greater than or equal to 2 SD below the mean height for normal children of the same age and gender.

Adult onset growth hormone deficiency (GHD)

1. Prescribed by or in consultation with an endocrinologist; **and**

2. Chart notes document diagnosis of GHD; **and**

3. Confirmation of diagnosis with an appropriate growth hormone provocative test (i.e., insulin tolerance test (ITT), GHRH+arginine test (GHRH+ARG), arginine test (ARG), glucagon test); **and**

4. Labs provided show low IGF-1 level.

Adult onset growth hormone deficiency (GHD) due to hypopituitarism

1. Prescribed by or in consultation with an endocrinologist; **and**

2. Chart notes document diagnosis of GHD associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary disease, hypothalamic disease, surgery, radiation therapy, or trauma; **and**

3. Labs provided show low IGF-1 level.

Childhood onset growth hormone deficiency (GHD) continuing into adulthood

1. Prescribed by or in consultation with an endocrinologist; **and**

2. Chart notes document diagnosis of childhood onset GHD continuing into adulthood; **and**

3. Re-confirmation of GH deficiency with an appropriate growth hormone provocative test (i.e., insulin tolerance test (ITT), GHRH+arginine test (GHRH+ARG), arginine test (ARG), glucagon test) after discontinuation of growth hormone treatment for at least 1 month.

Reauthorization Criteria:

Pediatric GHD, Noonan syndrome, Turner syndrome, or short stature born SGA

1. Prescribed by or in consultation with an endocrinologist or a pediatric endocrinologist; **and**

2. Chart notes document one of the following:
    a. Growth velocity of ≥2 cm over the previous year of treatment; *or*
    b. Patient has not reached 50th percentile for target height following growth hormone therapy.

Prader-Willi syndrome

1. Prescribed by or in consultation with an endocrinologist or pediatric endocrinologist; **and**

2. Chart notes document a positive response to therapy.

Adult onset growth hormone deficiency (GHD)

1. Prescribed by or in consultation with an endocrinologist; **and**

2. Chart notes and labs document improvement or stabilization of IGF-1 level.

Childhood onset growth hormone deficiency (GHD) continuing into adulthood

3. Prescribed by or in consultation with an endocrinologist; **and**

4. Chart notes document a positive response to therapy.

Approval period:

- Approve by **HICL** for 12 months *or* as clinically appropriate

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Initial Authorization Denial Language:

D1. Norditropin Flexpro for pediatric growth hormone deficiency requires all of the following: therapy initiated by or in consultation with an endocrinologist or pediatric endocrinologist; chart notes document diagnosis; confirmation of open epiphyses (growth plates) in patients more than 12 years of age; and patient's height is greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender.
D2. Norditropin Flexpro for Noonan syndrome requires all of the following: therapy initiated by or in consultation with an endocrinologist or pediatric endocrinologist; chart notes document diagnosis; confirmation of open epiphyses (growth plates) in patients more than 12 years of age; and patient's height is greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender.
D3. Norditropin Flexpro for Turner syndrome requires all of the following: therapy initiated by or in consultation with an endocrinologist or pediatric endocrinologist; chart notes document diagnosis; confirmation of open epiphyses (growth plates) in patients more than 12 years of age and patient's height is greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender.
D4. Norditropin Flexpro for Prader-Willi syndrome requires all of the following: therapy initiated by or in consultation with an endocrinologist or pediatric endocrinologist; chart notes document diagnosis and growth failure.
D5. Norditropin Flexpro for short stature born small for gestational age requires all of the following: therapy initiated by or in consultation with an endocrinologist or pediatric endocrinologist; chart notes document diagnosis; patient's epiphyses is not closed (as confirmed by radiograph of the wrist and hand); patient has no catch-up growth by age 2 to 4 years; and patient's height is greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender.
D6. Norditropin Flexpro for adult growth hormone deficiency alone requires all of the following: therapy initiated by or in consultation with an endocrinologist; chart notes document diagnosis; confirmation of diagnosis with an appropriate growth hormone provocative test (i.e., insulin tolerance test (ITT), GHRH+arginine test (GHRH+ARG), arginine test (ARG), glucagon test); and labs provided show low IGF-1.
D7. Norditropin Flexpro for adult growth hormone deficiency due to hypopituitarism requires all of the following: therapy initiated by or in consultation with an endocrinologist; chart notes document diagnosis of GHD associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary disease, hypothalamic disease, surgery, radiation therapy, or trauma; and labs provided show low IGF-1.
D8. Norditropin Flexpro for childhood onset growth hormone deficiency continuing into adulthood requires all of the following: therapy initiated by or in consultation with an endocrinologist; chart notes document diagnosis; and re-confirmation of growth hormone deficiency with an appropriate growth hormone provocative test (i.e., insulin tolerance test (ITT), GHRH+arginine test (GHRH+ARG), arginine test (ARG), glucagon test) after discontinuation of growth hormone treatment for at least 1 month.

Reauthorization Denial Language:

D1. Norditropin Flexpro for pediatric growth hormone deficiency requires all of the following: therapy initiated by or in consultation with an endocrinologist or pediatric endocrinologist; chart notes document

one of the following: (1) growth velocity of ≥2 cm over the previous year of treatment, or (2) patient has not reached 50th percentile for target height following growth hormone therapy.
D2. Norditropin Flexpro for Noonan syndrome requires all of the following: therapy initiated by or in consultation with an endocrinologist or pediatric endocrinologist; chart notes document one of the following: (1) growth velocity of ≥2 cm over the previous year of treatment, or (2) patient has not reached 50th percentile for target height following growth hormone therapy.
D3. Norditropin Flexpro for Turner syndrome requires all of the following: therapy initiated by or in consultation with an endocrinologist or pediatric endocrinologist; chart notes document one of the following: (1) growth velocity of ≥2 cm over the previous year of treatment, or (2) patient has not reached 50th percentile for target height following growth hormone therapy.
D4. Norditropin Flexpro for short stature born small for gestational age requires all of the following: therapy initiated by or in consultation with an endocrinologist or pediatric endocrinologist; chart notes document one of the following: (1) growth velocity of ≥2 cm over the previous year of treatment, or (2) patient has not reached 50th percentile for target height following growth hormone therapy.
D5. Norditropin Flexpro for adult growth hormone deficiency requires all of the following: therapy initiated by or in consultation with an endocrinologist; chart notes and labs document improvement or stabilization of IGF-1 level.
D6. Norditropin Flexpro for childhood onset growth hormone deficiency continuing into adulthood requires all of the following: therapy initiated by or in consultation with an endocrinologist; chart notes document a positive response to therapy.

FDA Approved Indications:
- Pediatric: Treatment of children with growth failure due to growth hormone deficiency (GHD), short stature associated with Noonan syndrome, short stature associated with Turner syndrome and short stature born SGA with no catch-up growth by age 2 to 4 years, growth failure due to Prader-Willi syndrome (PWS)
- Adult: Treatment of adults with either adult onset or childhood onset GHD

Dosing:
- Norditropin should be administered subcutaneously
- Pediatric GHD: 0.024 to 0.034 mg/kg/day, 6 to 7 times a week
- Noonan Syndrome: Up to 0.066 mg/kg/day
- Turner Syndrome: Up to 0.067 mg/kg/day
- Prader-Willi Syndrome: Up to 0.034 mg/kg/day
- SGA: Up to 0.067 mg/kg/day
- Adult GHD: 0.004 mg/kg/day to be increased as tolerated to not more than 0.016 mg/kg/day after approximately 6 weeks, or a starting dose of approximately 0.2 mg/day (range, 0.15 to 0.30 mg/day) increased gradually every 1 to 2 months by increments of approximately 0.1 to 0.2 mg/day

References:

- Novo Nordisk Inc. Norditropin package insert. Plainsboro, NJ. Revised February 2018.
- American Association of Clinical Endocrinologists. Medical Guidelines for Clinical Practice for Growth Hormone Use in Growth Hormone-Deficient Adults and Transition Patients. 2009 Update.
- Mark E. Molitch, David R. Clemmons, Saul Malozowski, George R. Merriam, Mary Lee Vance; Evaluation and Treatment of Adult Growth Hormone Deficiency: An Endocrine Society Clinical Practice Guideline. 2011; 96 (6): 1587-1609. doi: 10.1210/jc.2011-0179.

Version	Date	P&T Approval	Comments/Changes
1	04/01/2019	06/20/2019	TO Created; P&T Approved 2Q2019
2	10/07/2019	12/19/2019	TO Added criteria for Prader-Willi syndrome; P&T Approved 4Q2019
3	11/28/2020	PENDING 4Q2020	DN Annual Reviewe

Santa Clara Family Health Plan™

filgrastim-sndz
ZARXIO

DRUG PRIOR AUTHORIZATION REQUEST CRITERIA

Generic	Brand	HICL	GPID	ROUTES
FILGRASTIM-SNDZ	**ZARXIO**	**41814**	**38083 – 300 MCG/0.5 ML** **38082 – 480 MCG/0.8 ML**	**SUBCUTANEOUS** **INTRAVENOUS**

Prior Authorization Required

Authorization Criteria:

1. Prescribed by or in consultation with an oncologist or a hematologist; **and**
2. Request is for *any* ***one*** of the following diagnoses; **and**
    a. Prevention of febrile neutropenia in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever; or
    b. Prevention of febrile neutropenia in patients with acute myeloid leukemia (AML) receiving induction or consolidation chemotherapy treatment; or
    c. Prevention or treatment of febrile neutropenia and/or neutropenia-related clinical sequelae in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation; or
    d. Mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis; or
    e. Symptomatic congenital neutropenia; or
    f. Symptomatic cyclic neutropenia; or
    g. Symptomatic idiopathic neutropenia.
3. Requested dose does not exceed 24 mcg/kg/day.

Approval period:

- Approve by **GPID** for 12 months.

For Internal Use Only

Denial Language:

D1. This drug must be prescribed by or in consultation with an oncologist or hematologist.

FDA Approved Indications:

- Decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever.
- Reduce the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with acute myeloid leukemia (AML).
- Reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT).
- Mobilize autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis.
- Reduce the incidence and duration of sequelae of severe neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia.

References:

- Sandoz Inc. Zarxio package insert. Princeton, NJ. Revised April 2016.
- Filgrastim, G-CSF. In: Clinical Pharmacology [database on the Internet]. Tampa (FL): Gold Standard; publication year [revision date: 4/17/2015]. Available from: www.clinicalpharmacology.com. Subscription required to view.
- National Comprehensive Cancer Network, Inc. The NCCN Clinical Practice Guidelines in Oncology. Myeloid Growth Factors. (Version 2.2016).

Version	Date	P&T	Comments/Changes
1	10/14/2016	12/15/2016	TO Created; P&T Approved 4Q2016
2	12/07/2017	12/14/2017	DN Deleted “or as clinically appropriate” from Approval Period; P&T Approved 4Q2017
3	12/04/2018	12/13/2018	DN Annual Review; P&T Approved 3Q2018
4	11/26/2019	12/19/2019	DN Annual Review; P&T Approved 4Q2019
5	11/28/2020	PENDING Q4 2020	DN Annual Review

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Pharmacy & Therapeutics Committee

NEW DRUGS AND CLASS REVIEWS

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Tardive Dyskinesia Drug Review

Kristine Zhang, PharmD
PGY-2 Administration Pharmacy Resident

Tardive Dyskinesia

A hyperkinetic movement disorder that appears with a delayed onset

- Usually after prolonged use of dopamine receptor-blocking agents (e.g., antipsychotics, metoclopramide)
- Symptoms: chorea, athetosis, dystonia, akathisia

The need for drugs to control symptoms of TD should be carefully assessed

- Symptoms are often mild and not sufficiently bothersome to require treatment
- Few therapies have produced more than a slight to moderate benefit in clinical practice
- Prevention, early detection, and management of potentially reversible causes are the cornerstones of treatment

Tardive Dyskinesia Management

Pharmacologic interventions in patients with a diagnosis of TD

- Benzodiazepines
- Botulinum toxin injections
- Vesicular monoamine transporter 2 (VMAT2) inhibitors
  - **Valbenazine***, tetrabenazine, **deutetrabenazine***

*** FDA-approved**

Liang TW, Tarsy D. Tardive dyskinesia: prevention, prognosis, and treatment. UpToDate website. Updated Nov 2020. Accessed Dec 6, 2020.
Treatment of tardive syndromes: summary of evidence-based guideline for clinicians. America Academy of Neurology 2013. https://www.aan.com/Guidelines/home/GetGuidelineContent/613.
Bhidayasiri et al. Evidence-based guideline: treatment of tardive syndromes: report of the Guideline Development Subcommittee of the American Academy of Neurology. Neurology. 2013;81(5):463-9. DOI: 10.1212/WNL.0b013e31829d86b6.

VMAT2 Inhibitors

May be considered for patients with **disturbing and intrusive TD not amenable to other therapies**

Agent	Dosing	Current Status	Strength	Cost per 30 DS+	Utilization past 6 mo	Proposed Action
valbenazine (Ingrezza)	Initial 40mg daily, may increase as needed after 1 week; max 80mg daily	NF	40mg tab	$7,176	5 claims (25%)	**No Change**
			80mg tab	$8,080	15 claims (75%)*	
deutetra-benazine (Austedo)	Initial 6mg BID, may increase weekly in 6 mg / day increments; max 48mg/day	NF	6mg tab	12 mg/day: $4,503	0 claims (0%)	**No Change**
			9mg tab	18 mg/day: $5,065		
			12mg tab	24 mg/day: $6,753 48 mg/day: $13,507		

*5 unique members during last 6 months

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COVID-19 Vaccine Information and Payment

Kristine Zhang, PharmD

PGY-2 Administration Pharmacy Resident

COVID-19 Vaccines

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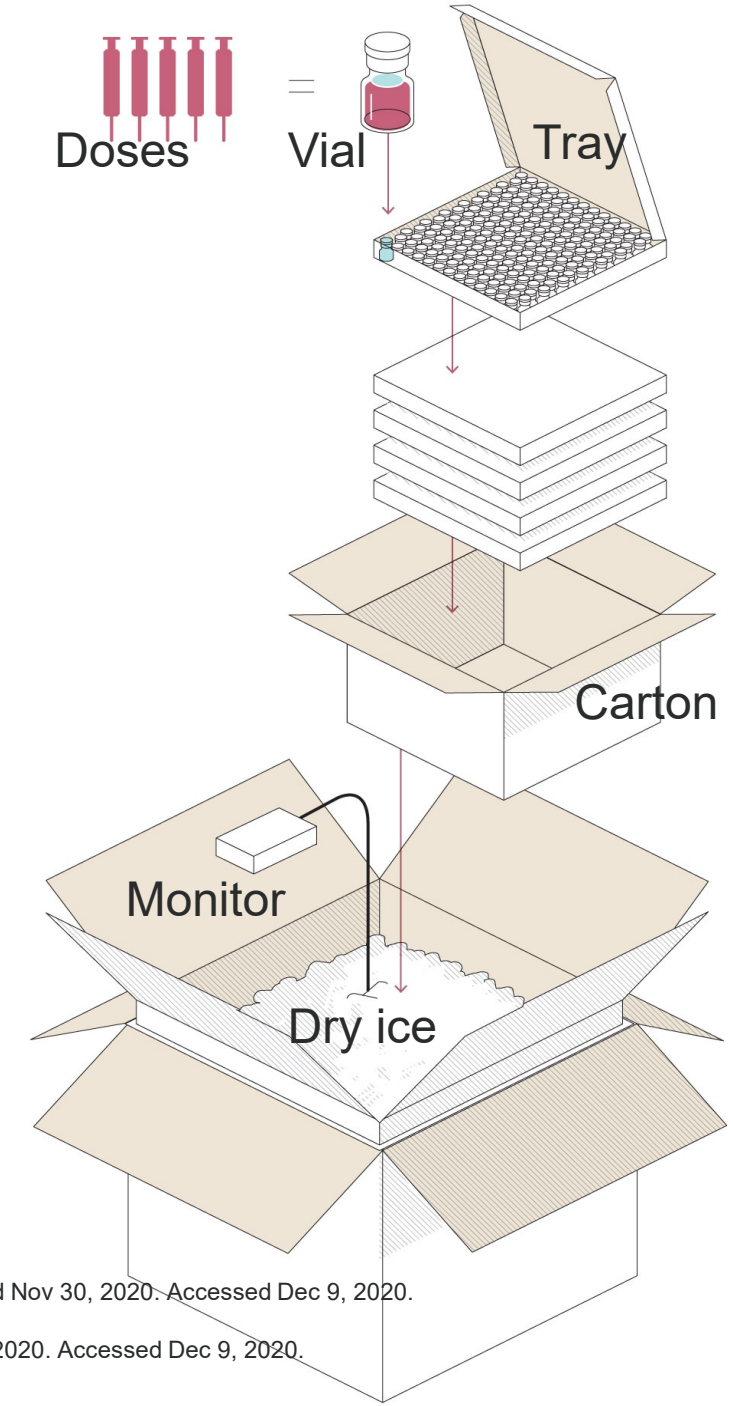
	Pfizer – BioNTech	Moderna	AstraZeneca – Oxford
Efficacy	95%	94.1%	Range from 62-90%
Type	mRNA-based	mRNA-based	Adenovirus vector
Approval	First	Second	Third
Storage requirements	Ultra-cold freezer (-70*C, -94*F) for up to 6 months. Dry-ice chest for up to 30 days w/ replenishments. Standard fridge for up to 5 days	Standard freezer for up to 6 months. Standard fridge for up to 30 days. Room temp for up to 12 hours.	Standard fridge for at least 6 months.
Estimated cost per dose	$20	$15-25	$4
Administration	2 doses, 3 weeks apart	2 doses, 4 weeks apart	2 doses, 4 weeks apart
Production capacity	Up to 50 million doses for global distribution by end of 2020. Up to 1.3 billion doses in 2021.	20 million doses for US by end of 2020. 500 million to 1 billion doses globally in 2021.	Up to 3 billion doses in 2021.

Jibilian I. Here's how the top 3 coronavirus vaccines compare when it comes to efficacy, cots, and more. Business Insider website. Published Dec 7, 2020. Accessed Dec 9, 2020. https://www.businessinsider.com/how-covid-vaccines-compare-cost-astrazeneca-oxford-pfizer-biontech-moderna-2020-11.
Johnson CY and Steckelberg A. What you need to know about the Pfizer, Moderna, and AstraZeneca vaccines. The Washington Post website. Published Nov 30, 2020. Accessed Dec 9, 2020. https://www.washingtonpost.com/health/2020/11/17/covid-vaccines-what-you-need-to-know/?arc404=true.

Shipment of Pfizer Vaccine

1. Frozen vaccine is packaged into 2mL **glass vials**, each holding **5 doses**.
2. One **tray** holds 195 vials. Up to 5 trays fit into a carton.
3. The vaccine **cartons** are surrounded by 50 pounds of **dry-ice** pellets.
4. A GPS temperature **monitor** is placed in each **shipment**. The vaccine must be kept below -70*C.

Total capacity per shipment: 4,875 doses



Johnson CY and Steckelberg A. What you need to know about the Pfizer, Moderna, and AstraZeneca vaccines. The Washington Post website. Published Nov 30, 2020. Accessed Dec 9, 2020. https://www.washingtonpost.com/health/2020/11/17/covid-vaccines-what-you-need-to-know/?arc404=true.
Herper M. COVID-19 vaccine from Pfizer and BioNTeech is strongly effective, early data from large trial indicate. STAT news website. Published Nov 9, 2020. Accessed Dec 9, 2020. https://www.statnews.com/2020/11/09/covid-19-vaccine-from-pfizer-and-biontech-is-strongly-effective-early-data-from-large-trial-indicate/.

COVID-19 Vaccine Unknowns and Limitations

Vaccine safety and efficacy

- Role in prevention of severe cases
- Role for those previously infected
- Duration of immunity
- Willingness of public to accept the vaccine

Storage and distribution

Mainly with Pfizer's vaccine

- Shortages of dry ice and pharmaceutical-grade glass for ultra-cold temperatures
- Limited storage duration vs. shipments of large quantities
- Transportation methods and duration
- Equal distribution and access, especially to rural areas with fewer resources
- Potential use of both vaccines in different settings, requiring additional planning

Johnson CY and Steckelberg A. What you need to know about the Pfizer, Moderna, and AstraZeneca vaccines. The Washington Post website. Published Nov 30, 2020. Accessed Dec 9, 2020. https://www.washingtonpost.com/health/2020/11/17/covid-vaccines-what-you-need-to-know/?arc404=true.
Herper M. COVID-19 vaccine from Pfizer and BioNTeech is strongly effective, early data from large trial indicate. STAT news website. Published Nov 9, 2020. Accessed Dec 9, 2020. https://www.statnews.com/2020/11/09/covid-19-vaccine-from-pfizer-and-biontech-is-strongly-effective-early-data-from-large-trial-indicate/.
Ducharme J. Why you may not be able to get Pfizer's frontrunner COVID-19 vaccine. TIME website. Published Nov 13, 2020. Accessed Dec 9, 2020. https://time.com/5911543/pfizer-vaccine-cold-storage/.

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CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Coverage and Reimbursement of COVID-19 Vaccines, Vaccine Administration, and Cost Sharing under Medicaid, the Children's Health Insurance Program, and Basic Health Program

CMS Vaccine and Administration Coverage

- To receive free supplies of the COVID-19 vaccine(s), all sites of care receiving and administering the vaccine **must sign an agreement** with the US government
  - Under the agreement, all providers **must vaccinate individuals regardless of insurance coverage** and are prohibited from charging vaccine recipients
  - Once Emergency Use Authorization (EUA) or approval of each vaccine is received from the FDA, states should alert Medicaid providers to the new published CPT codes for reporting of immunizations
- Medicare payment rates for administration (will be geographically adjusted):

Vaccine Type	Administration Fee
Single dose	$28.39
≥2 doses: • Initial dose(s) • Final dose	 $16.94 $28.39

CMS Adults Vaccine and Administration Coverage

- Under the **Families First Coronavirus Response Act (FFCRA)**, state and territorial Medicaid programs may receive a **temporary 6.2% increase** in the Federal Medical Assistance Percentage (FMAP; must meet specific qualification criteria)

Adults covered under traditional Medicaid

During the PHE	Outside the PHE
Coverage of vaccine administration is mandatory for **most* beneficiaries without cost sharing** during any quarter for which the state/territory claims the temporary FMAP increase. *Not required for certain beneficiaries receiving limited benefit packages	Coverage of ACIP-recommended vaccinations **without cost sharing** will be mandatory for adults enrolled in an **Alternative Benefit Plan** or beneficiaries **exempt** from cost sharing (e.g., most children <18, most pregnant women, etc.). For other adult Medicaid beneficiaries, states **may opt to impose cost sharing.**

CMS Children Vaccine and Administration Coverage

Children covered under Medicaid

- In general, coverage of vaccine administration for ACIP-recommended vaccines is **mandatory** for Medicaid-enrolled children **under age 21** who are eligible for the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit.
  - For children **through age 18** specifically, these vaccines are provided **without cost sharing** through the Vaccines for Children (VFC) program.

During the PHE	Outside the PHE
Same as for adults	Medicaid will cover administration of the **VFC-covered** vaccines. States **may impose cost sharing** on 19- and 20-year-olds who are not enrolled in an Alternative Benefit Plan.

CMS Vaccine and Administration Reimbursement

- **No reimbursement for the vaccine** while initial vaccine supply is federally purchased
- **States have significant discretion** in determining vaccine **administration reimbursement** rates paid to qualified providers, but are encouraged to use a uniform billing standard and review their payment policies

	During the PHE			Outside the PHE		
Population	**Coverage**	**Cost sharing**	**Reimbursement**	**Coverage**	**Cost sharing**	**Reimbursement**
Adults covered under traditional Medicaid	Mandatory	None	State-established reimbursement rates	**Mandatory** in states receiving extra 1% FMAP for preventive services as described in section 1905(b); optional for others	**None** in states receiving extra 1% FMAP for preventive services as described in section 1905(b); otherwise at **state option** for certain populations	**State-established** reimbursement rates
Children covered under Medicaid				**Mandatory**	**None** for individuals under age 18; at **state option** for individuals ages 19 and 20	**State-established** reimbursement rates; **VFC** implications for individuals under age 18

Asthma Review

DECEMBER 17TH, 2020

Santa Clara Family Health Plan™

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Changes in Asthma Management

Global Initiative for Asthma (GINA)

*"For safety, GINA **no longer** recommends treatment of asthma in adolescents and adults with **SABA alone**. Instead, to reduce their risk of serious exacerbations, all adults and adolescents with asthma **should receive either symptom-driven (in mild asthma) or daily inhaled corticosteroid (ICS)-containing treatment**."*

GINA 2019: a fundamental change in asthma management

Treatment of asthma with short-acting bronchodilators alone is no longer recommended for adults and adolescents

Helen K. Reddel[1], J. Mark FitzGerald[2], Eric D. Bateman[3], Leonard B. Bacharier[4], Allan Becker[5], Guy Brusselle[6], Roland Buhl[7], Alvaro A. Cruz[8], Louise Fleming[9], Hiromasa Inoue[10], Fanny Wai-san Ko[11], Jerry A. Krishnan[12], Mark L. Levy[13], Jiangtao Lin[14], Søren E. Pedersen[15], Aziz Sheikh[16], Arzu Yorgancioglu[17] and Louis-Philippe Boulet[18]

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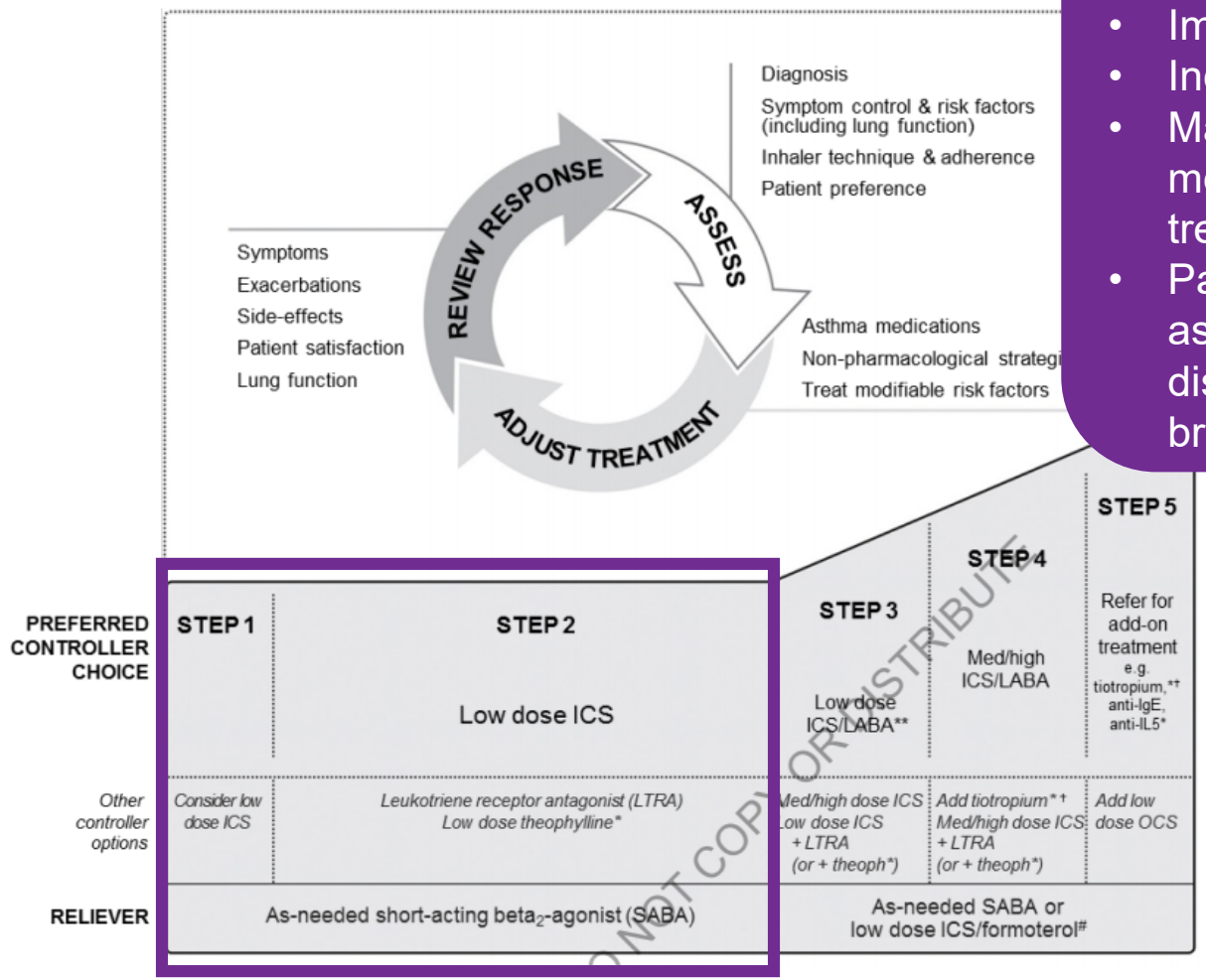
GINA 2018: Outdated Recommendations

Box 7. Stepwise approach to asthma treatment



Why change recommendations?

- Improve safety
- Increase adherence
- Maintain consistent messaging across treatment steps
- Pathophysiology of asthma (not simply a disease of bronchoconstriction)

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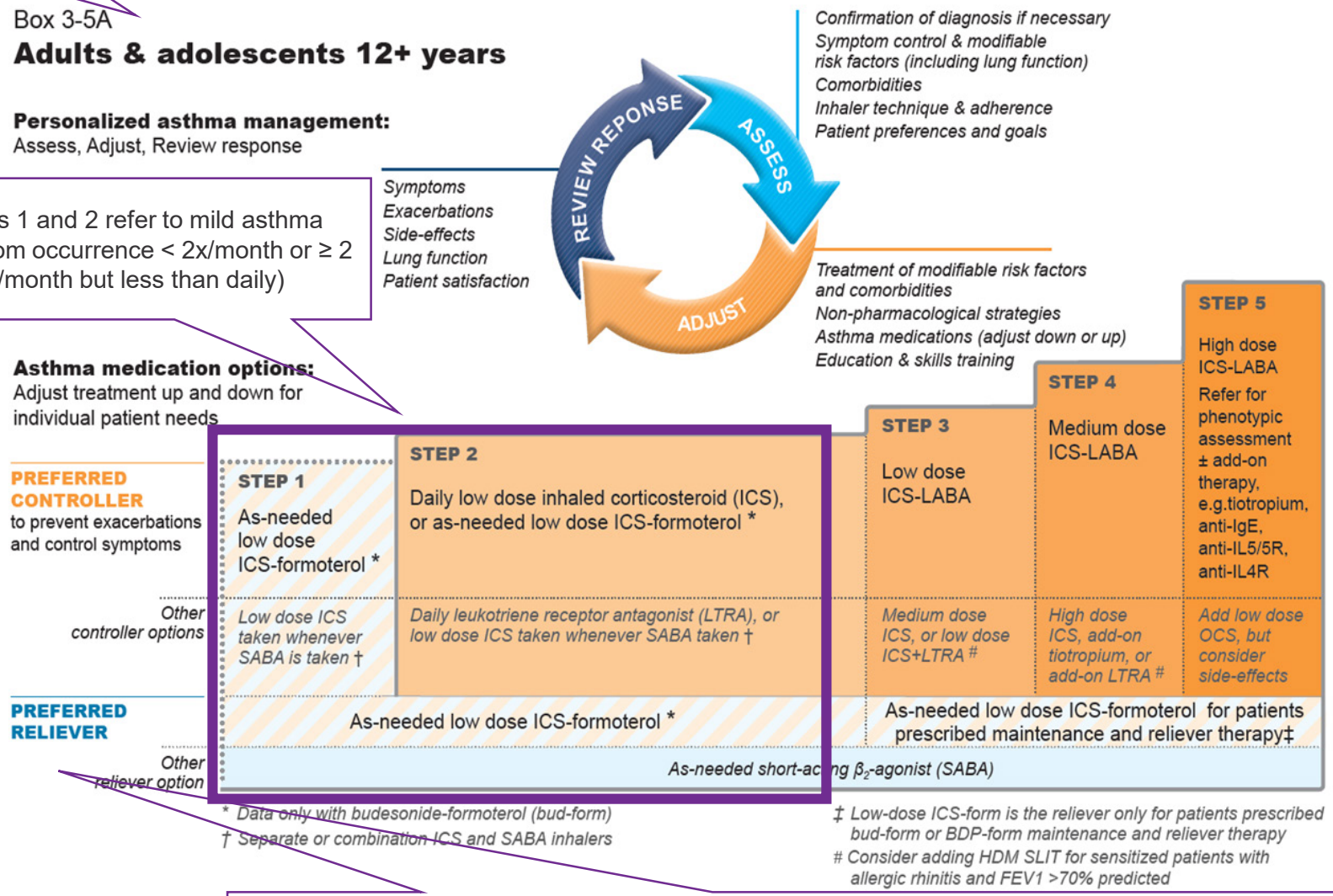
GINA 2019/2020: What's New?

Note that this major update is specific to ages 12 years and older.



Steps 1 and 2 refer to mild asthma (symptom occurrence < 2x/month or ≥ 2 x/month but less than daily)

The preferred reliever is *low-dose* ICS-formoterol **PRN**

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Comparison of Reliever Treatments

SABA-only

- Increased risk of asthma-related hospitalizations
- Increased risk of asthma-related death

ICS-formoterol

- Decreased severe exacerbations
- Decreased hospital visits
- Decreased mortality

ICS-formoterol can be considered both a controller AND a reliever medication (GINA Evidence Grade A)

SYGMA1, SYGMA2, Novel START, and PRACTICAL

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Comparison of ICS-LABA Inhalers

Brand	Components		Inhaler Type	Indication		Limitation of Use	Comments
	ICS	LABA		Asthma	COPD		
Advair Diskus	fluticasone propionate	salmeterol	DPI	X (4 yr+)	X	Not for relief of acute bronchospasm	Salmeterol has a slower onset of action and would not be appropriate for rescue relief
Advair HFA			MDI	X (12 yr+)			
Airduo Digihaler			DPI, app-enabled	X (12 yr+)			
Airduo Respiclick			DPI	X (12 yr+)			
Wixela Inhub			DPI	X (4 yr+)	X		
Breo Ellipta	fluticasone furoate	vilanterol	DPI	X (18 yr+)	X		Not yet studied for rescue treatment; peak levels reached within 10 min
Dulera	mometasone	formoterol	MDI	X (5 yr+)			Not yet studied for rescue treatment
Symbicort	budesonide		MDI (DPI available abroad)	X (6 yr+)	X		Formoterol has fast onset of action (similar to albuterol) with the added advantage of long duration of action

DPI: dry powder inhaler; ICS: inhaled corticosteroid; LABA: long-acting beta-agonist; MDI: metered-dose inhaler

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Costs

Drug	Dosing	Cost/Unit (AWP unless otherwise specified)	Cost/30 Days
Advair HFA (fluticasone/salmeterol) 45/21, 115/21, 230/21 mcg (12-g canister = 120 actuations)	2 inhalations BID	$31.71/gram (45-21 mcg; 12-g inhaler) $39.39/gram (115-21 mcg; 12-g inhaler) $51.81/gram (230-21; 12-g inhaler)	$380-$622
Advair Diskus (fluticasone/salmeterol) 100/50, 250/50, 500/50 mcg (pack of 60 blisters)	1 inhalation BID	MAC = $2.49/blister (100-50 mcg) MAC = $2.60/blister (250-50 mcg) MAC = $3.33/blister (500-50 mcg)	$149-$199
Wixela Inhub (generic for **Advair Diskus** [fluticasone/salmeterol]) 100/50, 250/50, 500/50 mcg (pack of 60 blisters)	1 inhalation BID	MAC = $2.49/blister (100-50 mcg) MAC = $2.60/blister (250-50 mcg) MAC = $3.33/blister (500-50 mcg)	$149-$199
Airduo Digihaler (fluticasone/salmeterol) 55/14, 113/14, 232/14 mcg/actuation (each inhaler = 60 actuations)	1 inhalation BID	$478.80/inhaler (55-14 and 113-14 mcg) $538.80/inhaler (232-14 mcg)	$479-$539
Airduo Respiclick (fluticasone/salmeterol) 55/14, 113/14, 232/14 mcg/actuation (each inhaler = 60 actuations)		MAC = $97.14/inhaler (55-14 mcg and 232-14 mcg) MAC = $101.73/inhaler (113-14 mcg)	$97-$102
Dulera (mometasone/formoterol) **50/5**,100/5, 200/5 mcg (13-g canister = 120 actuations)	2 inhalations BID	$28.74/gram (all inhalers)	$374
Breo Ellipta (fluticasone/vilanterol) 100/25 mcg, 200/25 mcg (pack of 60 blisters; 2 blisters per dose)	1 inhalation once daily	$7.24/blister (60-blister pack)	$434
Symbicort (budesonide/formoterol) **80/4.5**, 160/4.5 mcg (10.2-g canister = 120 actuations)	2 inhalations BID	$34.56/gram (80-4.5 mcg) $39.50/gram (160-4.5 mcg)	$353-$403
Note: *"Low-dose" formulations of ICS-formoterol are in* ***red*** *font.*			

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3Q20 Utilization

Drug	Utilizers	Rx Count	Paid Amount	Avg Cost/Rx	Formulary
Advair HFA	7	15	$6,771	$451.40	NF
fluticasone/salmeterol diskus Wixela Inhub (Advair Diskus)	761	1,362	$282,603	$207.49	Formulary Quantity Limit (1 inhaler/month)
Airduo Digihaler	0	0	---	---	NF
fluticasone/salmeterol respiclick (Airduo Respiclick)	79	130	$14,680	$112.92	Formulary Quantity Limit (1 inhaler/month)
Dulera	28	65	$21,206	$326.25	NF
Breo Ellipta	5	13	$4,908	$377.54	NF
budesonide/formoterol (Symbicort)	58	121	$38,661	$319.51	Formulary Quantity Limit (1 inhaler/month)

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Proposed Actions

Products	Action
Advair HFA	No change. Remains non-formulary. Approve by exception only.
fluticasone/salmeterol Wixela Inhub (generic Advair Diskus)	No change. Remains formulary with quantity limit.
Airduo Digihaler	No change. Remains non-formulary. Approve by exception only.
fluticasone/salmeterol (generic Airduo Respiclick)	No change. Remains formulary with quantity limit.
Dulera	No change. Remains non-formulary. Approve by exception only.
Breo Ellipta	No change. Remains non-formulary. Approve by exception only.
budesonide/formoterol (generic Symbicort)	No change. Remains formulary with quantity limit.

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Orladeyo (berotralstat) Drug Review

DECEMBER 17TH, 2020

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Orladeyo (berotralstat)

Approval Date	December 3, 2020 *(US launch anticipated end of December 2020)*
Manufacturer	BioCryst
Drug Class	Plasma kallikrein inhibitor
Indication	Prevention of attacks of hereditary angioedema (HAE) in adults and pediatric patients 12 years and older.
Dosing	150mg capsule PO once daily with food
Safety	Well-tolerated. Common AE include abdominal pain, vomiting, diarrhea, back pain, and gastroesophageal reflux disease.
Place in Therapy	First oral plasma kallikrein inhibitor and the first oral non-steroid treatment approved for long-term HAE prophylaxis

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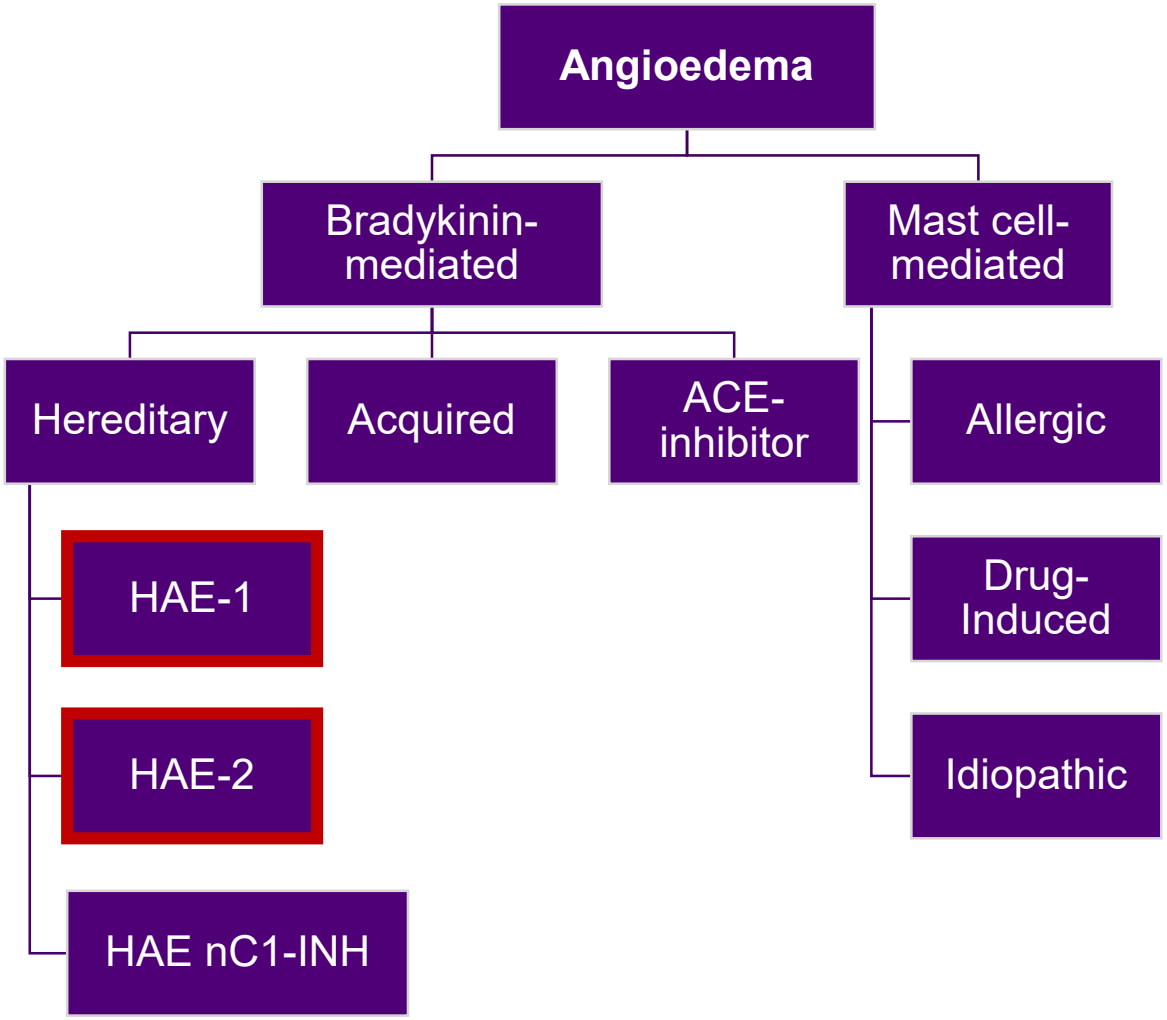
Introduction to Hereditary Angioedema (HAE)

HAE is a genetic disorder caused by a deficiency in C1 inhibitor (C1-INH) and characterized by severe, recurrent episodes of edema



HAE-1: hereditary angioedema due to C1 inhibitor deficiency
HAE-2: hereditary angioedema due to C1 inhibitor dysfunction
HAE nC1-INH: hereditary angioedema with normal C1 inhibitor levels

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Background

Epidemiology

Autosomal dominant inheritance (but 25% of cases due to *de novo* mutations)

Affects about 1:50,000 = ~8,000 Americans

Childhood onset (mean age: 10 years), worsens around puberty

Clinical Presentation

HAE attacks: recurrent, severe episodes of angioedema

- Occur unpredictably
- Variable frequency (average: q1-2 wks)
- Prolonged (gradually resolve over 2-5 days)
- Affect subcutaneous and submucosal tissues (commonly skin and abdomen)
- Laryngeal attacks are life-threatening

Diagnosis

Relies on measurements of C4 concentrations and quantitative and functional analyses of C1-INH

Diagnostic delays are common (roughly >10 years)

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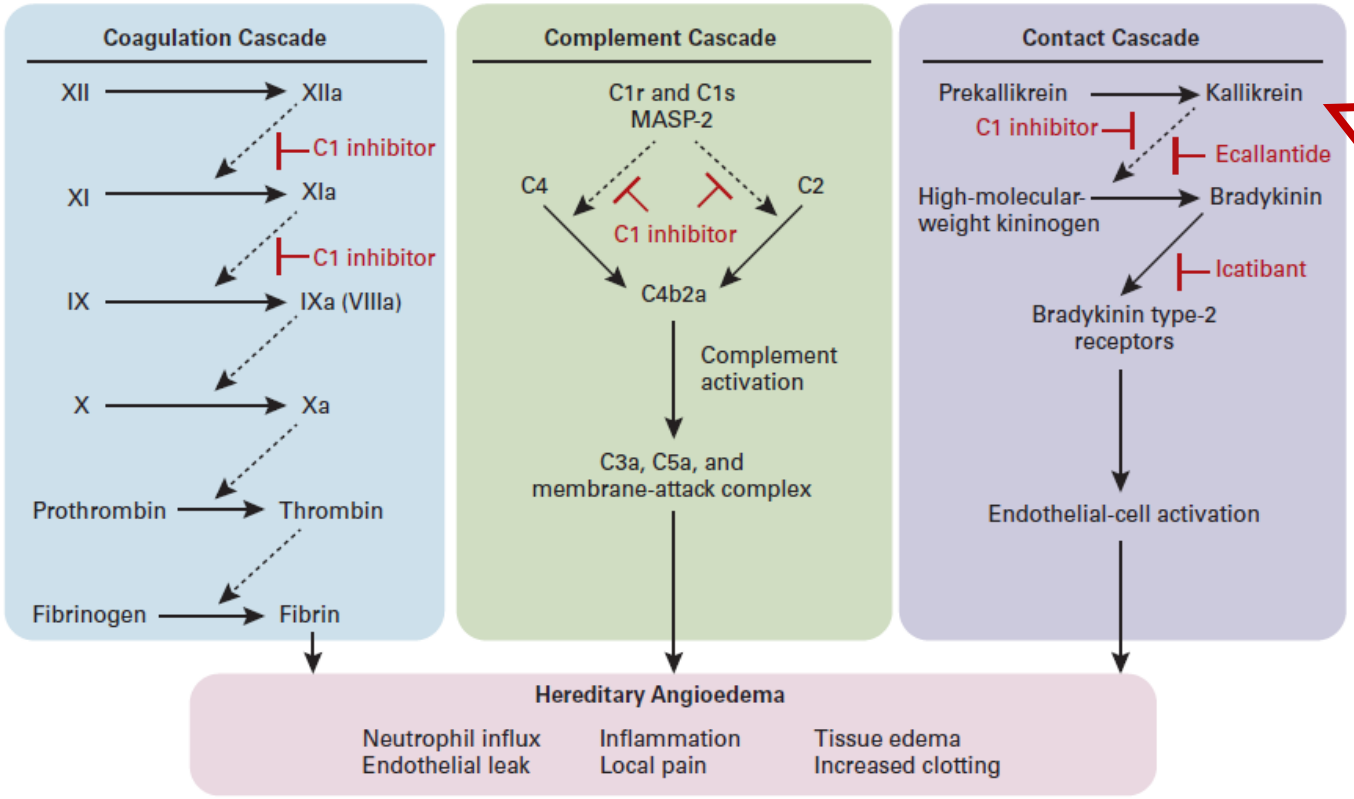
Pathophysiology

Figure 1. Dysregulation of Coagulation, Complement, and Contact Cascades in Hereditary Angioedema[2]



C1 inhibitor controls activation in the coagulation, complement, and contact cascades, and all 3 cascades are dysregulated in hereditary angioedema. Replacement of C1 inhibitor restores homeostasis. Ecallantide and icatibant specifically inhibit the contact cascade but have no direct effect on the complement or coagulation cascade. Dashed arrows indicate enzyme-cleavage steps, and T bars points of inhibition.
MASP-2 indicates mannose-binding lectin–associated serine protease 2.
Reprinted with permission from Morgan BP. *N Engl J Med.* 2010;363:581-583.

Orladeyo is an oral plasma kallikrein inhibitor that works by blocking bradykinin production

Image: Lumry WR. Am J Manag Care. 2013;19:S103-S110.
Figure does not capture all agents used for HAE treatment (e.g. Takhzyro).

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Overview of Treatment Options

Drug Class	Mechanism	Drug	Indication		Route	Comments
			Acute Treatment	Prophylaxis		
Plasma-derived C1-INH	Inhibit bradykinin production by C1-INH repletion	**Berinert**	✓		IV	• Risk of blood-borne infection and thromboembolic events • Depends on plasma supply
		Cinryze	Off-label	✓	IV	
		Haegarda		✓	SC	
Recombinant C1-INH		**Ruconest**	✓	Off-label	IV	• Shorter $t_{1/2}$ than plasma C1-INH
Bradykinin B_2 receptor antagonist	Blocks bradykinin activity	**Firazyr** (icatibant)	✓		SC	• Injection site reactions
Kallikrein inhibitors	Inhibit bradykinin production	**Kalbitor** (ecallantide)	✓		SC (NSA)	• BBW: anaphylaxis • Requires healthcare provider administration
		Takhzyro (lanadelumab)		✓	SC	• RTA as SC push (both Cinryze and Haegarda require reconstitution and infusion)
		Orladeyo (berotralstat)		✓	PO	
Androgens	Increase C1-INH levels (unknown mechanism)	Danazol		✓	PO	• Possesses other indications • Serious side effect profile • Needs routine monitoring • Not option for pediatrics or pregnancy

Notes:
Table not inclusive of older (read: non-HAE-specific) agents that were traditionally used for acute treatment (e.g. fresh frozen plasma) or prophylaxis (e.g. antifibrinolytics).
*Attacks require immediate treatment; as such, **all** agents listed in the table above **can be self-administered** with the exception of Kalbitor.*

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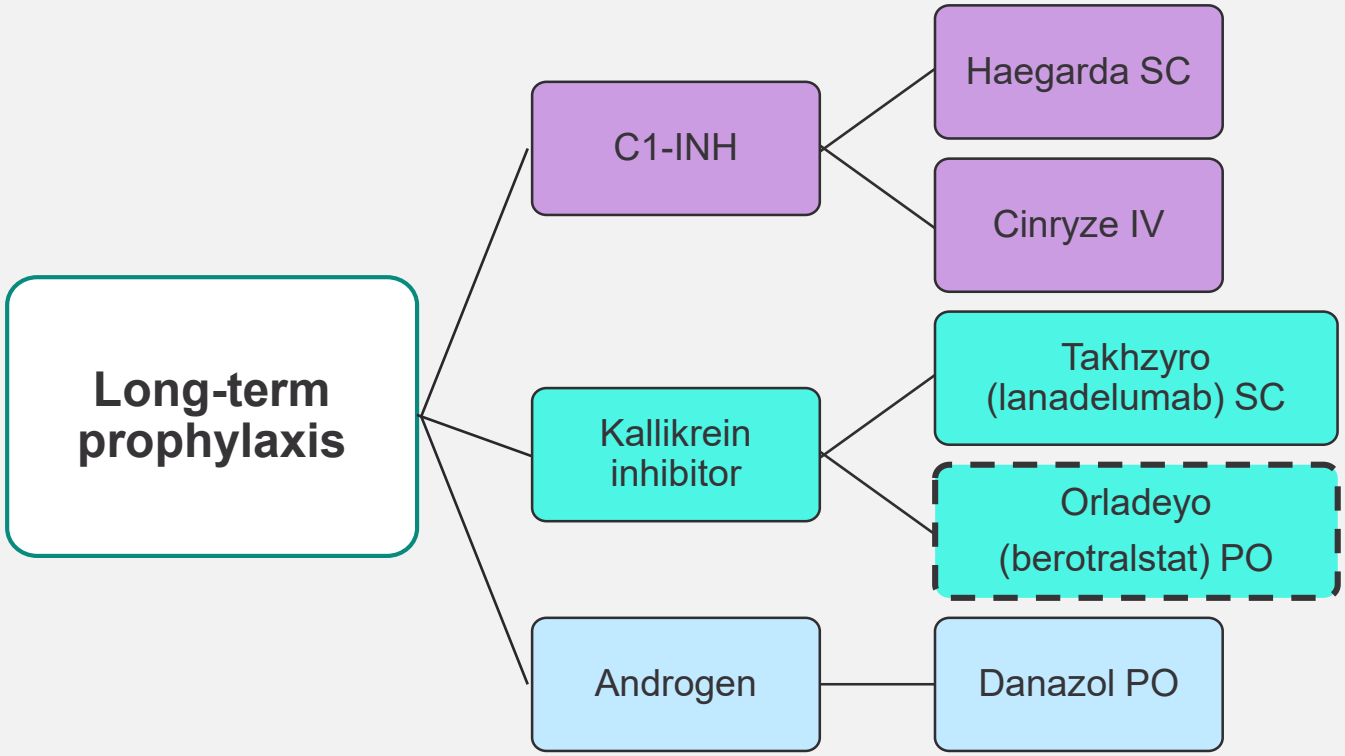
BBW: black box warning; C1-INH: C1 esterase inhibitor; RTA: ready to administer

Treatment Guidelines: Prophylactic Management



- Prophylaxis should be **considered in all severely symptomatic** patients, taking into account the following: disease burden (attack frequency and severity), location of attacks, availability of resources, quality of life, patient preference
- Androgens not recommended for ages <16 years and pregnancy
- Patients should **NOT** be required to fail androgen as a prerequisite to obtaining C1-INH (HAEA MAB position statement)

WAO: World Allergy Organization; EAACI: European Academy of Allergy and Clinical Immunology; US HAEA MAB: US Hereditary Angioedema Association Medical Advisory Board; AAAAI/ACAAI/JCAAI: American Academy/American College/Joint Council of Allergy, Asthma, & Immunology

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Comparative Efficacy

LONG-TERM PROPHYLAXIS				
	Cinryze	**Haegarda**	**Takhzyro** (lanadelumab)	**Orladeyo** (berotralstat)
Status	Approved	Approved	Approved	Approved
Pivotal Trial	CHANGE Study[b]	COMPACT Study[b]	HELP Study	APeX-2
Duration	12 weeks (per arm)/ 24 weeks	16 weeks (per arm)/ 32 weeks	26 weeks	24 weeks
N	24	90	125	121
Study Population	≥6 years; ≥2 attacks/month	≥12 years; ≥2 attacks/month	≥12 years; ≥1 attack/month	≥12 years; ≥2 attacks/month
Treatment Arms	• Placebo • **1000 units IV Q3-4 days[c]**	• Placebo • 40 IU/kg SC 2x/wk • **60 IU/kg SC 2x/wk**	• Placebo • 150mg SC Q4wk • **300mg SC Q4wk** • **300mg SC Q2wk**	• Placebo • 110 mg PO QD[d] • **150 mg PO QD**
Reduction in Attack Rate[e]	51%	84%[f]	73-87%	44%

Notes: *The table provides an indirect comparison across pivotal trials. The recommended doses per FDA-approved labeling are bolded in* ***purple*** *font within the treatment arms section.*

[b]crossover design; [c]label states that doses up to 2,500 units may be considered; [d]dose no longer being pursued—efficacy data is for 150 mg dose; [e]versus placebo; [f]with recommended labeled dose of 60 IU/kg

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Costs

Drug	Drug Class	Dosing Regimen		Cost/Unit	Cost/28 Days (Adult)
		Pediatric	Adult		
Orladeyo (berotralstat) 110mg, 150mg capsule	Kallikrein inhibitor	***Product pricing not available***			
Takhzyro (lanadelumab) 300 mg/2 mL vial		300 mg SC every 2 weeks[a]		AWP: $13,639.26/mL ($27,278.52/vial)	$54,557
Cinryze 500 unit (lyophilized) vial	Plasma-derived C1-INH	6-11 years: 500 units (max 1,000) IV Q3-4 days	≥12 years: 1,000 units (max 2,500[b]) IV Q3-4 days	AWP: $6.62/unit ($3,310.55/vial)	$52,960-$132,400[c]
Haegarda 2000, 3000 unit (lyophilized) vials		≥12 years: 60 units/kg SC Q3-4 days		AWP: $1.16/unit	$55,680[c,d]
Danazol 50, 100, 200 mg capsules	Androgen	Initial dosing for adults:[e] 200 mg PO 2-3 times daily[f]		MAC: $1.98/50 mg $2.29/100 mg $4.37/200 mg	$245-$367

Note: *All prophylactic products may be self-administered.*

[a]*Well-controlled patients may be considered for dosing every 4 weeks*

[b]*Doses up to 2,500 units (not to exceed 100 units/kg) q3-4 days may be considered based on patient response*

[c]*Assuming twice weekly administration*

[d]*Based on body weight of 70 kg, rounded to nearest vial size*

[e]*Pediatric efficacy and safety not established*

[f]*Maintenance: after favorable initial response, decrease dosage by ≤50% at intervals of 1-3 months or longer if attack frequency dictates. If an attack occurs, increase the dosage by up to 200 mg/day.*

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Key Conclusions and Policy Recommendations for Prophylactic Agents for HAE

ICER found that prophylaxis with either C1-INH or Takhzyro resulted in fewer/less severe HAE attacks and improved quality of life, but notes that all agents exceed cost-effectiveness thresholds (but calculations are highly dependent on baseline frequency of attacks, among other variables)

ICER Policy Recommendations	MedImpact Recommendations
Diagnosis: May consider laboratory-based confirmation (includes measurements of complement levels) or physician attestation	☑ Diagnostic confirmation based on complement testing
Indication (prophylaxis): May consider thresholds for starting long-term prophylaxis that may include attack frequency, attack severity, and/or amount of on-demand therapy used, but there are no authoritative guidelines that identify parameters for initiating prophylaxis	⊘ No required attack threshold based on lack of justification from consensus guidelines
Prescriber: By or in consultation with HAE specialist or other specialties (e.g. allergy/immunology, pulmonology) in cases where specialists are not readily accessible	☑ Allergist/immunologist or hematologist
Quantity limits: Payers may wish to consider a coverage cap based on weight-based dosing. This is particularly relevant for Haegarda, which uses a weight-based dosing scheme. Although Cinryze dosing is not generally weight-based (a fixed dose of 1,000-2,500 units per dose is recommended), the package labeling lists 100 units/kg as a maximum dosage. Dosing for Takhzyro is fixed.	☑ QL in place for Cinryze and Takhzyro based on maximum dosing recommendations ⊘ No QL implemented for Haegarda

At this time, there is no indication that ICER will be updating their assessments on prophylactic HAE therapies to include discussion of berotralstat

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Proposed Actions

Products	Action
Orladeyo (berotralstat)	No change. Remains non-formulary. Approve by exception only.
Takhzyro (lanadelumab)	No change. Remains non-formulary. Approve by exception only.
Haegarda	No change. Remains non-formulary. Approve by exception only.
Cinryze	No change. Remains non-formulary. Approve by exception only.

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4Q20: New & Expanded Indications

DECEMBER 17TH, 2020

Santa Clara Family Health Plan™

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New and Expanded Indications

Drug	New/Expanded Indication	Other/Previous Indications
Epidiolex (cannabidiol)	July 31, 2020: Treatment of seizures associated with tuberous sclerosis complex (TSC) in patients 1 year and older	Lennox-Gastaut syndrome (LGS), Dravet syndrome (DS)
Spravato (esketamine)	July 31, 2020: In conjunction with an oral antidepressant, for the treatment of depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior	In conjunction with an oral antidepressant, for the treatment of treatment-resistant depression (TRD) in adults
Tremfya (guselkumab)	July 13, 2020: Active psoriatic arthritis (PsA)	Moderate-to-severe plaque psoriasis (PP) who are candidates for systemic therapy or phototherapy
Simponi Aria (golimumab)	Sept 30, 2020: Polyarticular juvenile idiopathic arthritis (PJIA) in patients 2 years of age older Sept 30, 2020: Psoriatic arthritis (PsA) in patients 2 years of age and older	Rheumatoid arthritis (RA) with methotrexate, adults Ankylosing spondylitis (AS), adults Psoriatic arthritis (PsA), adults

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Proposed Actions

Products	Action
Epidiolex (cannabidiol)	No change. Remains non-formulary. Approve by exception only.
Spravato (esketamine)	No change. Remains non-formulary. Approve by exception only.
Tremfya (guselkumab)	No change. Remains non-formulary. Approve by exception only.
Simponi Aria (golimumab)	No change. Remains non-formulary. Approve by exception only.

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4Q20 P&T

Anemia in CKD (roxadustat)

OCTOBER 16, 2020

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Background

Epidemiology

- Nearly 37 million American Adults have chronic kidney disease (CKD)
- 15% of patients with CKD have anemia

Complications of Anemia in CKD

- Reduced quality of life
- Increased risk of:
  - Cardiovascular events
  - Hospitalizations
  - Mortality

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ESA=erythropoiesis-stimulating agent

Background

Causes of Anemia in CKD:

- Reduced kidney production of erythropoietin
- Functional iron deficiency (FID) mediated by hepcidin

CKD Stage	Kidney Function Description	GFR (ml/min per 1.73 m^2)	Prevalence of CKD based on stage (%)	Prevalence of Anemia based on stage (%)	Hb <10 g/dL based on stage (%)
Stage 3	Moderate decreased GFR	30-59	6.4	17.4	5.6
Stage 4	Severe decreased GFR	15-29	0.37	50.3	11
Stage 5	Kidney failure	<15 non-dialysis	0.13	53.4	27.2
		dialysis*	0.16	85.2	--

*Approximately 10% are on peritoneal dialysis and 90% on hemodialysis

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CKD=chronic kidney disease; GFR=glomerular filtration rate; Hb=hemoglobin

KDIGO Clinical Practice Guideline for Anemia in CKD (2012)

	CKD 3	CKD 4	CKD 5
Diagnosis of Anemia	• Hb <13 g/dL in males • Hb <12 g/dL in females		
TSAT ≤30% and ferritin ≤500 mcg/L			
Iron therapy	• Balance the potential benefits of minimizing transfusions, ESA therapy and anemia-related symptoms against risk of harm with iron therapy • **NDD-CKD:** IV/oral iron • **DD-CKD:** IV iron preferred		
ESA therapy – **Initiation**	• When Hb is <10 g/dL, initiate ESA based on individual rate of Hb decline, prior response to iron, risk of needing transfusions, risks related to ESAs and presence of anemia-related symptoms		
ESA therapy – **Maintenance**	• Dose to achieve a Hb <11.5 g/dL		
Transfusions	• Initiate when ESA is ineffective or when ESA risks outweigh benefits • Try to avoid in patients eligible for organ transplant		

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CKD=chronic kidney disease; DD=dialysis dependent; ESA=erythropoiesis-stimulating agent; Hb=hemoglobin; KDIGO=Kidney Disease Improving Global Outcomes; NDD=non-dialysis dependent; TSAT=transferrin saturation

Erythropoietin-Stimulating Agents

ESAs	• **Epogen** (epoetin alfa), **Procrit** (epoetin alfa), **Retacrit** (epoetin alfa-epbx); **Aranesp** (darbepoetin alfa); **Mircera** (methoxy polyethylene glycol-epoetin beta)
MOA	• Stimulates production of red blood cells
Administration	• SQ or IV, typically TIW
Use	• Approximately 14% of patients in the U.S. were on an ESA before initiating dialysis
Limitations	• Hyporesponsiveness is seen in around 10–30% of patients on dialysis • Functional iron deficiency often occurs in patients

	Per label:
	• Appropriate iron stores are required for effective treatment with ESAs
	• **NDD-CKD:** If the hemoglobin level exceeds 10 g/dL, reduce or interrupt the dose of ESA, and use the lowest dose of ESA sufficient to reduce the need for RBC transfusions
	• **DD-CKD:** If the hemoglobin level approaches or exceeds 11 g/dL, reduce or interrupt the dose of ESA
	ALERT: US Boxed Warning
	• **Warning:** Erythropoiesis-stimulating agents (ESAs) increase the risk of death, MI, stroke, venous thromboembolism, thrombosis of vascular access and tumor progression or recurrence.
	• **Chronic kidney disease:**
	  • In controlled trials, patients experienced greater risks for death, serious adverse cardiovascular reactions, and stroke when administered ESAs to target a hemoglobin level of greater than 11 g/dL.
	  • No trial has identified a hemoglobin target level, ESA dose, or dosing strategy that does not increase these risks.
	  • Use the lowest dose sufficient to reduce the need for RBC transfusions.

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Roxadustat

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Roxadustat

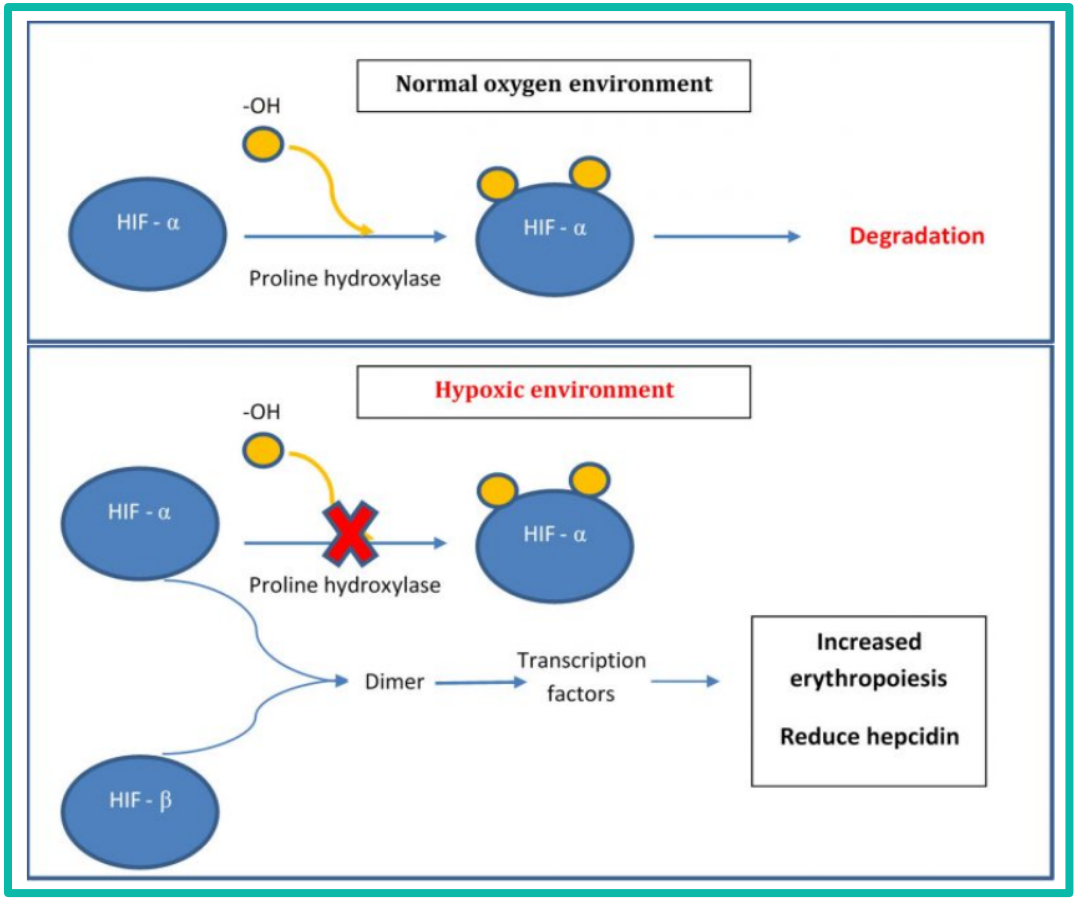
PDUFA Date: December 20, 2020

Manufacturer: Fibrogen/AstraZeneca

Proposed indication: Treatment of anemia of CKD in adult non-dialysis dependent (NDD) and dialysis dependent (DD) patients

Studied dosing: Orally three times weekly with titration based on hemoglobin levels as needed

MOA: Hypoxia-inducible factor prolyl hydroxylase (HIF-PH) inhibitor



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DRUG PIPELINE

HIF-PH Inhibitors

Generic Name	Manufacturer	Route	Phase	Status
vadadustat	Akebia	Oral	Phase 3	Possible FDA filing in 2021
daprodustat	GlaxoSmithKline	Oral	Phase 3	Phase 3 data anticipated 12/2020

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PIVOTAL PHASE 3 TRIALS

Study Design

Non-Dialysis Dependent

OLYMPUS
roxadustat vs. placebo

- **Key inclusion criteria:** CKD Stage 3-5, Hb <10 g/dL, Ferritin ≥50 ng/mL, TSAT≥15%, no ESA within 6 weeks
- **Treatment**: 1:1 randomization
- **Starting dose:** 70 mg TIW; then adjusted to maintain Hb 10-12 g/dL

ANDES
roxadustat vs. placebo

- **Key inclusion criteria:** CKD Stage 3-5, Hb <10 g/dL, Ferritin ≥30 ng/mL, TSAT≥5%, no ESA within 12 weeks
- **Treatment**: 2:1 randomization
- **Starting dose:** 45 to <70 kg=70 mg TIW ***or*** 70 to 160 kg=100 mg TIW; then adjusted to maintain Hb 10-12 g/dL

ALPS
roxadustat vs. placebo

- **Key inclusion criteria:** CKD Stage 3-5, Hb <10 g/dL, Ferritin ≥30 ng/mL, TSAT≥5%, no ESA within 12 weeks
- **Treatment**: 2:1 randomization
- **Starting dose:** 45 to <70 kg=70 mg TIW ***or*** 70 to 160 kg=100 mg TIW; then adjusted to maintain Hb 10-12 g/dL

Dialysis Dependent

ROCKIES
roxadustat vs. EPO

- **Key inclusion criteria:** HD/PD/ID; Hb <12 g/dL if on ESA ***or*** Hb <10 g/dL if not on ESA for ≥4 weeks ***or*** Mircera for ≥8 weeks before the first visit; Ferritin ≥100 ng/mL, TSAT≥20%
- **Treatment**: 1:1 randomization
- **Starting dose:** roxadustat dose based on prior EPO dose ***or*** if EPO naïve based on weight TIW ***or*** EPO TIW in EPO group; then adjusted to maintain Hb 10-12 g/dL

SIERRAS
roxadustat vs. EPO

- **Key inclusion criteria:** HD/PD/ID; DD: Hb ≥9 to ≤12 g/dL if on ESA ≥8 weeks ***or*** ID: Hb ≥8.5 to ≤12 g/dL if on ESA ≥4 weeks; Ferritin ≥100 ng/mL, TSAT≥20%
- **Treatment**: 1:1 randomization
- **Starting dose:** roxadustat dose based on prior EPO TIW ***or*** EPO TIW in EPO group; then adjusted to maintain Hb 10-12 g/dL

HIMALAYAS
roxadustat vs. EPO

- **Key inclusion criteria:** ID; Hb ≤10 g/dL; on an ESA ≤3 weeks within the past year; Ferritin ≥100 ng/mL, TSAT≥20%
- **Treatment**: 1:1 randomization
- **Starting dose:** roxadustat dose based on weight (<70 kg=70 mg TIW ***or*** 70 to 160 kg=100 mg TIW) ***or*** EPO TIW in EPO group; then adjusted to maintain Hb 10-12 g/dL

EPO=epoetin; ESA=erythropoiesis-stimulating agent; DD=dialysis dependent; HD=hemodialysis; Hb = hemoglobin; ID=incident dialysis; PD=peritoneal dialysis; TSAT=transferrin saturation; TIW=three times weekly

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PIVOTAL PHASE 3 TRIALS

Primary and Secondary Endpoints

Non-Dialysis Dependent

OLYMPUS
roxadustat (N=1,393) vs. **placebo** (N=1,388)

- **1º endpoint:** Mean CFB in Hb averaged over Weeks 28–52
- **Key 2º endpoints**: Proportion of patients achieving Hb response[a] within 24 weeks at 2 consecutive visits without rescue therapy[b], time with Hb ≥10 g/dL over Weeks 28–52, CFB in LDL at Week 24, time to rescue therapy, AEs

ANDES
roxadustat (N=616) vs. **placebo** (N=306)

- **1º endpoint:** Mean CFB in Hb averaged over Weeks 28–52
- **Key 2º endpoints:** Proportion of patients achieving Hb response[a] within 24 weeks at 2 consecutive visits without rescue therapy[b], CFB in Hb over Weeks 28–36 with censoring for rescue therapy, CFB in LDL over Weeks 12–28, time to rescue therapy, AEs over 52 weeks

ALPS
roxadustat (N=391) vs. **placebo** (N=203)

- **1º endpoint:** Mean CFB in Hb averaged over Weeks 28–52
- **Key 2º endpoints**: CFB in LDL over Weeks 12–28, time to use of rescue therapy, AEs

Dialysis Dependent

ROCKIES
roxadustat (N=1,068) vs. **EPO** (N=1,065)

- **1º endpoint:** Mean CFB in Hb averaged over Weeks 28–52
- **Key 2º endpoints**: Proportion of patients with total time with Hb ≥10 g/dL at Weeks 28–52, LSM CFB in Hb with baseline hsCRP >ULN at Weeks 28–52, monthly, time to rescue therapy, AEs

SIERRAS
roxadustat (N=370) vs. **EPO** (N=371)

- **1º endpoint:** Mean CFB in Hb averaged over Weeks 28–52
- **Key 2º endpoints:** Mean CFB in Hb averaged over Weeks 28–36, without rescue therapy[b], proportion of patients with Hb ≥10 g/dL over Weeks 28–52, mean CFB in Hb averaged over Weeks 18–24 in patients with baseline hs-CRP>ULN, AEs

HIMALAYAS
roxadustat (N=522) vs. **EPO** (N=521)

- **1º endpoint**: Mean CFB in Hb averaged over Weeks 28–52
- **Key 2º endpoints**: Proportion of patients achieving Hb response[a] within 24 weeks at 2 consecutive visits without rescue therapy[b], AEs

AE = adverse event; CFB = change from baseline; Hb = hemoglobin; hs-CRP = high-sensitivity c-reactive protein
LDL = low density lipoprotein; LSM = least squares mean; ULN = upper limit of normal; EPO=epoetin
[a]defined as Hb ≥11.0 g/dL and Hb increase from baseline by ≥1.0 g/dL in patients with baseline Hb >8.0 g/dL, or an increase in Hb by ≥2.0 g/dL in patients with baseline Hb ≤8.0 g/dL
[b]blood/RBC transfusion, ESA use, and IV iron for NDD patients and RBC transfusion or ESA use for DD patients

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Patient Population

Phase 3 CKD Non-Dialysis Dependent Pool				
OLYMPUS	**ANDES**	**ALPS**	**NDD Pooled**	
N=2,761	N=922	N=594	**roxadustat**	**Placebo**
			N=2,391	N=1,886

Phase 3 CKD Dialysis Dependent Pool				
ROCKIES	**SIERRAS**	**HIMALAYAS**	**DD Pooled**	
N=2,106	N=741	N=1,043	**roxadustat**	**EPO**
			N=1,943	N=1,947
Incident Dialysis (ID): Prespecified sub-group of the DD patient population (patients new to dialysis [2 weeks to ≤4 months prior to randomization])				
N=1,530				

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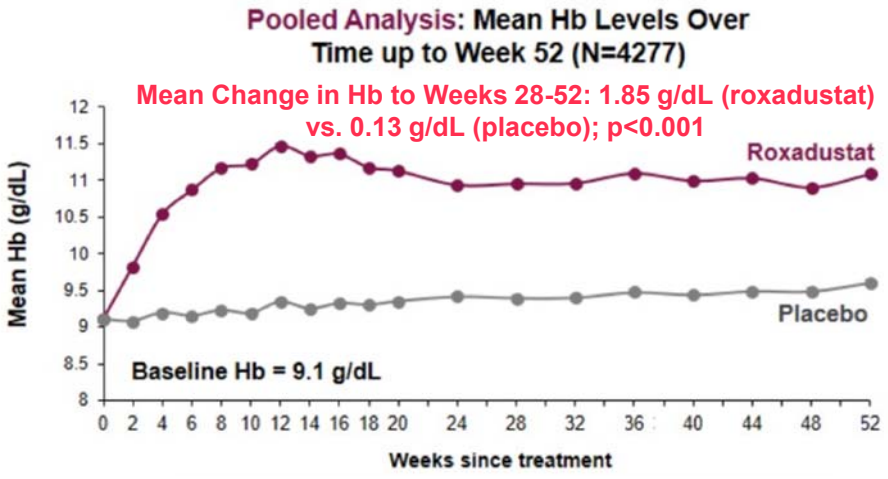
DD=dialysis dependent; EPO=epoetin; NDD=non-dialysis dependent

Pooled Efficacy Results



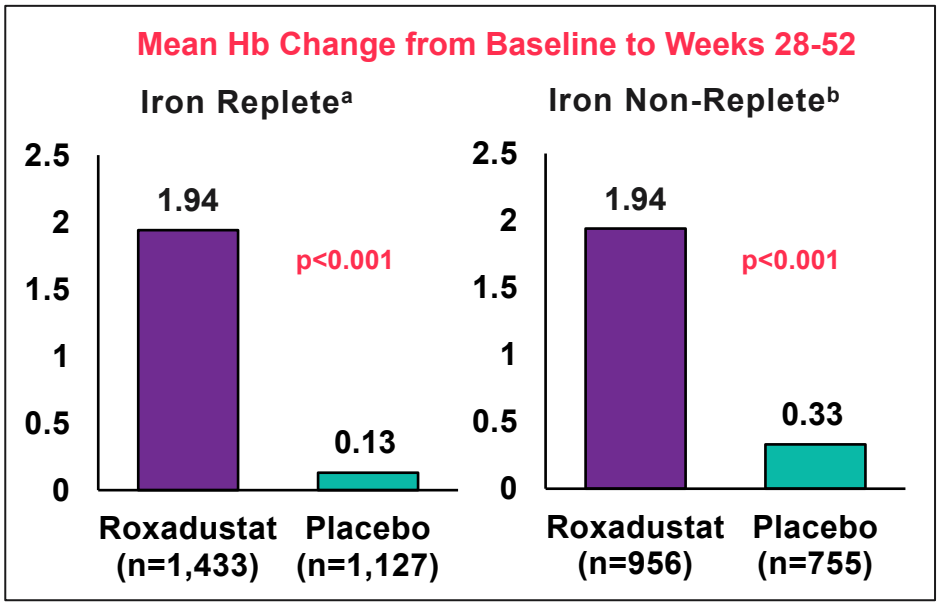
Summary

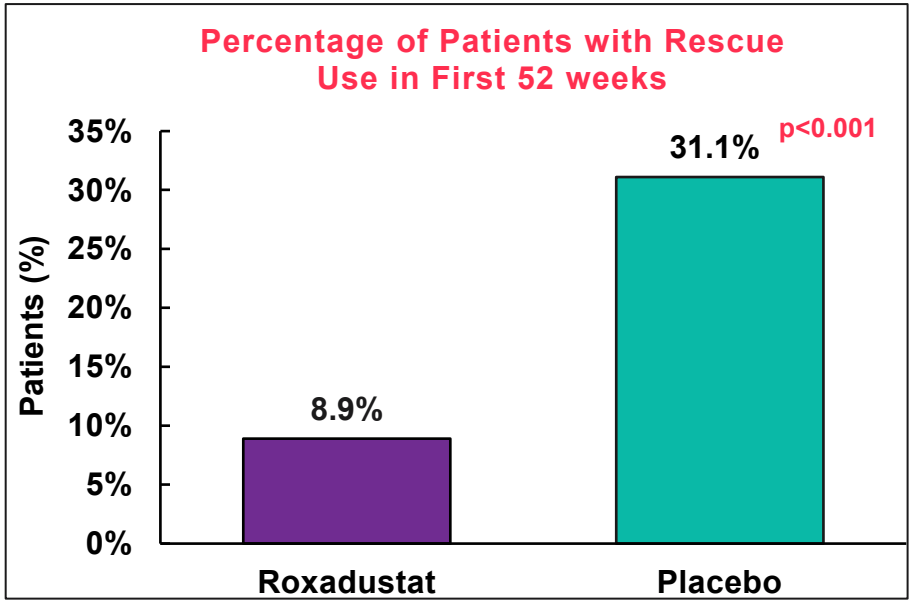
Primary endpoint:

- Roxadustat was statistically superior to placebo in improvement of Hb; p<0.001

Secondary endpoints:

- Greater improvement in Hb from baseline regardless of iron status
- Lower rate of RBC transfusions required
- Decrease in rate of rescue therapy required
- Mean LDL treatment difference of -19.83 mg/dL; p<0.001
- Less decline in eGFR from baseline to Week 52 (treatment difference: 1.6 mL/min/1.73 $m^{2;}$ p<0.001)





[a]TSAT≥20% and ferritin ≥100 ng/mL; [b]TSAT <20% and ferritin <100 ng/mL
NDD=non-dialysis dependent; eGFR=estimated glomerular filtration rate; Hb=hemoglobin; LDL=low-density lipoprotein; RBC=red blood cell transfusions
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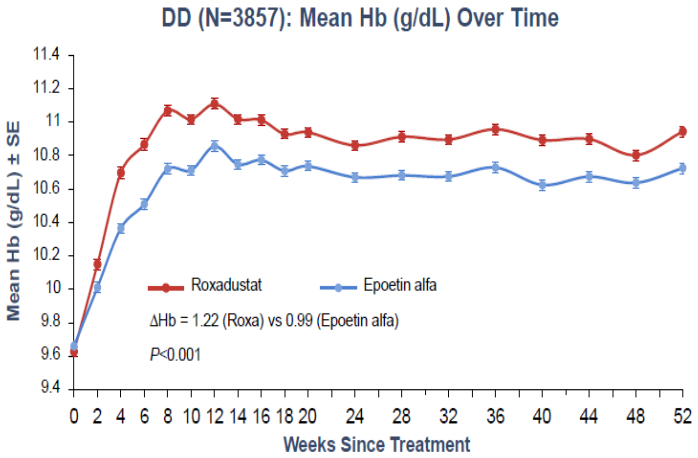
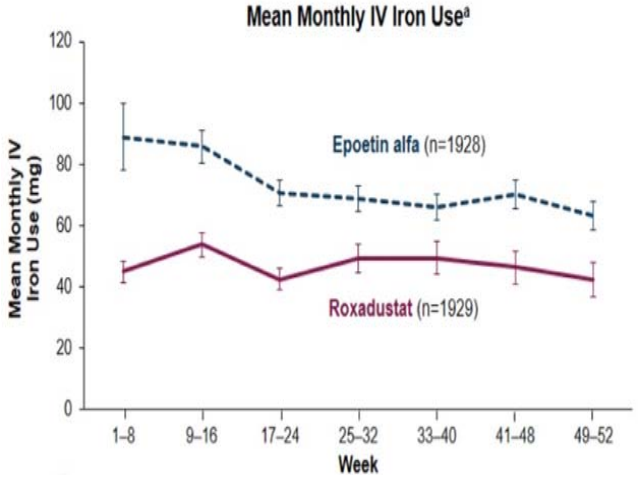
Pooled Efficacy Results

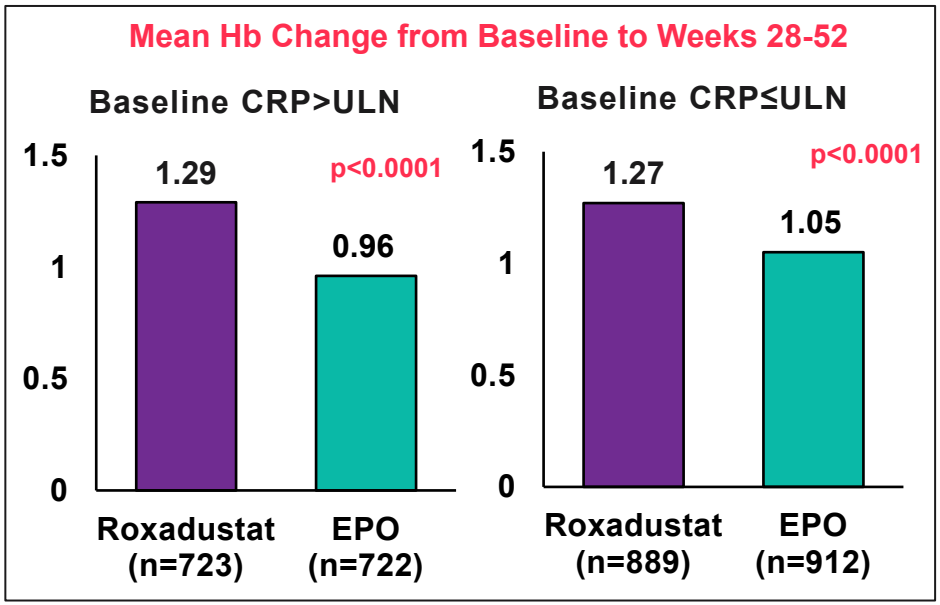


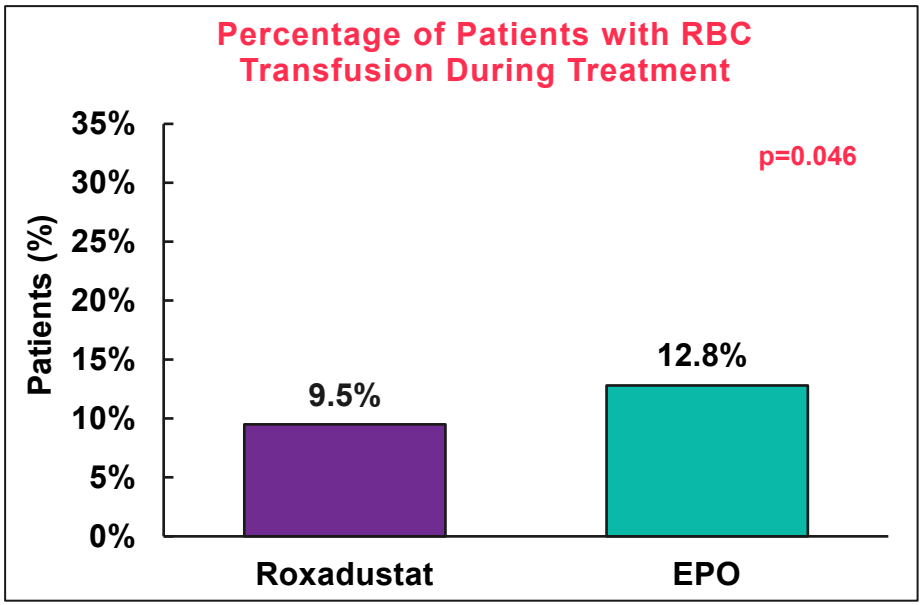
Summary

Primary endpoint:
- Roxadustat was statistically superior to epoetin alfa in improvement of Hb

Secondary endpoints:
- Less monthly IV iron use
- Higher Hb increase in patients with inflammation (CRP >ULN) and in patients without inflammation
- Lower rate of RBC transfusions







DD=dialysis dependent; CRP=c-reactive protein; EPO= epoetin alfa; Hb=hemoglobin; IV= intravenous; ULN=upper limit of normal; RBC=red blood cell transfusions

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NON-DIALYSIS AND DIALYSIS DEPENDENT PATIENT POPULATION

Pooled Cardiovascular Safety Results

Key safety endpoints

Time to first MACE

- MACE (Major Adverse Cardiovascular Events) include: all-cause mortality, myocardial infarction, and stroke

Time to first MACE+

- MACE+ include: MACE, unstable angina requiring hospitalization, and congestive heart failure requiring hospitalization

Time to all-cause mortality

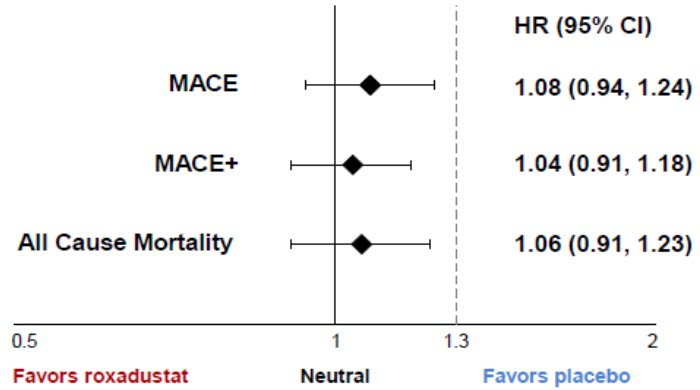
Non-Dialysis Dependent

- Risks of MACE, MACE+, and all-cause mortality in roxadustat patients were comparable to placebo

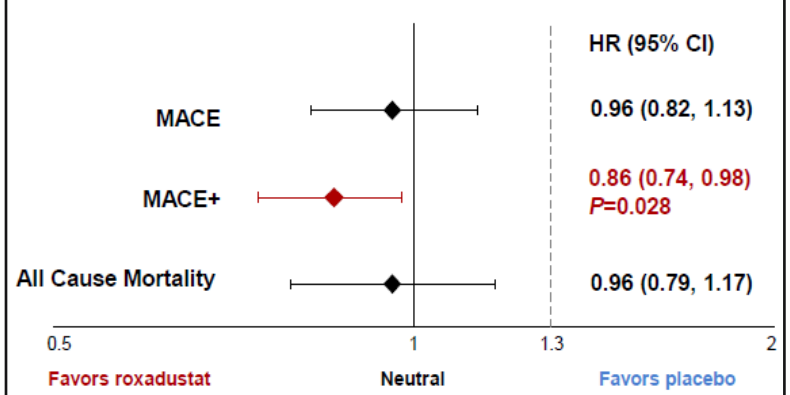
Dialysis Dependent

- Risks of MACE and all-cause mortality in roxadustat patients were not increased compared to those for patients receiving EPO
- Risk of MACE+ was 14% lower in roxadustat-treated patients than in those receiving EPO

Time to Event Endpoints Using Cox Model ITT Analysis (n=4,270)



Time to Event Endpoints Using Cox Model (n=3,880)



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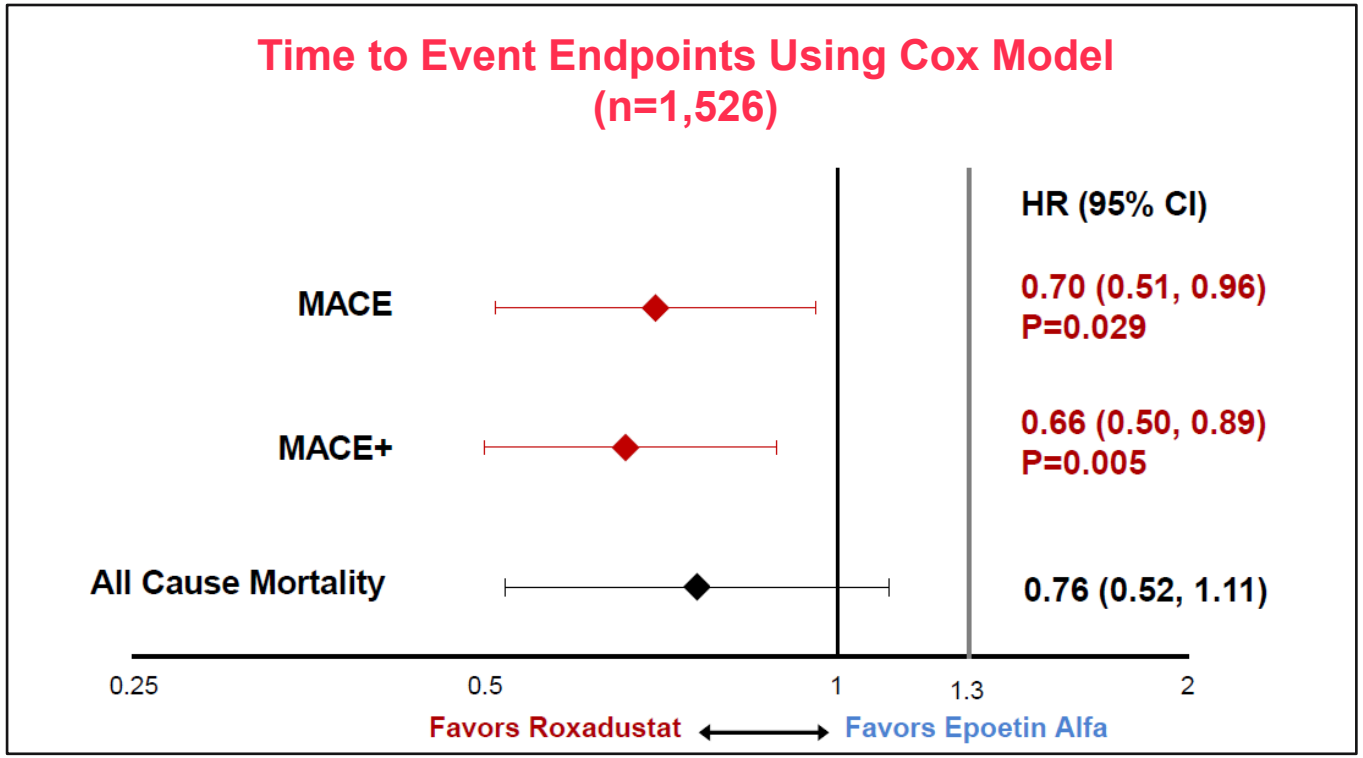
Cardiovascular Safety Analysis

Incident Dialysis: Sub-group of the DD patient population and defined as patients new to dialysis (2 weeks to ≤4 months prior to randomization)

- Risk of MACE was 30% lower in roxadustat-treated patients than in epoetin alfa
- A trend towards lower all-cause mortality relative to epoetin alfa in incident dialysis patients



MACE: all-cause mortality, myocardial infarction, and stroke
MACE+: MACE, unstable angina requiring hospitalization, and congestive heart failure requiring hospitalization

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Business Considerations

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Cost

Drug	Adult Starting Dose	Cost/Unit	Cost per Year*
roxadustat	***Under review by FDA for anemia in CKD indication***		
Procrit (epoetin alfa) SDV: 2,000, 3,000, 4,000, 10,000, 40,000 Units/mL MDV: 20,000 Units/2 mL and 20,000 Units/mL	**NDD/DD**: 50 to 100 Units/kg IV/SQ 3 times weekly	$64.15 - 1,282.80/mL (parity)	$16,166 - 32,332
Epogen (epoetin alfa) SDV: 2,000, 3,000, 4,000, 10,000 Units/mL MDV: 20,000 Units/2 mL and 20,000 Units/mL	**NDD/DD:** 50 to 100 Units/kg IV/SQ 3 times weekly	$39.79 - 397.92/mL (parity)	$10,027 - 20,054
Aranesp (darbepoetin alfa) SDV: 25, 40, 60, 100, 200, and 300 mcg/1 mL SD-prefilled syringes: 10 mcg/0.4 mL, 25 mcg/0.42 mL, 40 mcg/0.4 mL, 60 mcg/0.3 mL, 100 mcg/0.5 mL, 150 mcg/0.3 mL, 200 mcg/0.4 mL, 300 mcg/0.6 mL, and 500 mcg/1 mL	**NDD:** 0.45 mcg/kg IV/SQ at 4 week intervals	Vials: $232.20 – 1,857.60/mL Syringes: $232.20-4,644/mL (parity)	NDD: $3,511
	DD: 0.45 mcg/kg IV/SQ weekly OR 0.75 mcg/kg IV/SQ every 2 weeks		DD: $11,703 - 14,043
Retacrit (epoetin alfa-epbx; biosimilar to Epogen/Procrit) SDV: 2,000, 3,000, 4,000, 10,000, 40,000 Units/mL MDV: 20,000 Units/2 mL and 20,000 Units/mL	**NDD/DD:** 50 to 100 Units/kg IV/SQ 3 times weekly	$26.47 - 529.44/mL (parity)	$6,670 - 13,341
Mircera (methoxy polyethylene glycol-epoetin beta) SD-prefilled syringes: 30, 50, 75, 100, 120, 150, 200 mcg, and 250 mcg in 0.3 mL solution, 360 mcg in 0.6 mL	**NDD/DD:** 0.6 mcg/kg IV/SQ once every two weeks	$346.17 - 2,307.80/mL (parity)	$11,631
*Pricing based on 70 kg patient			

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DD=dialysis dependent; IV=intravenous; MDV=multi-dose vials; NDD=non-dialysis dependent; SD=single dose; SDV=single dose vials; SQ=subcutaneous

Clinical Considerations

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External Reviewer

Roxadustat

…Roxadustat could become first-line for the treatment of anemia in CKD…discovery of roxadustat will revolutionize the treatment strategy for renal anemia.

- Patients with end stage renal disease (ESRD) **on hemodialysis are likely to remain on ESAs** because they receive the medication during dialysis therapy. However, patients with CKD not on dialysis or patients with **ESRD on home dialysis modality, will likely be switched to roxadustat due to easier administration** at home (orally) and will be able to avoid going to center for infusion.
- Comparison to current agents: Both agents **appear to be as effective with very similar safety profiles**.
- Advantages: can be **given orally**, has higher reduction of baseline in the hepcidin level (associated with greater iron availability) and reduction from baseline in the total cholesterol level. Disadvantages: **Hyperkalemia and metabolic acidosis** occurred more frequently in the roxadustat group than in the placebo group.
- Patients appropriate for roxadustat would have: poor response to ESA, refractory anemia due to elevation of inflammation, patient with needle phobia, patients with iron overload. Patients inappropriate include: poor compliance to medications
- …**Safety data was appropriate**, however, **hyperkalemia, metabolic acidosis and upper respiratory infection occurred at a higher frequency** in the roxadustat groups. Also, since hypoxia-inducible factor (HIF) pathways regulate or interact with many biologic processes, there is concern about non-erythropoietic adverse effects, **including increased risk of cancer, thrombosis, cardiovascular disease, progression of diabetic retinopathy, and CKD**, among others, which will **require long-term follow-up** of treated patients.
- If appropriate response to roxadustat to stabilize hemoglobin and to prevent blood product transfusion, management of mild to moderate hyperkalemia and metabolic acidosis should not prevent the use of roxadustat.

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External Reviewer

Therapeutic Designation

- Yes. Clinical trials showed oral roxadustat was non-inferior to parenteral epoetin alfa as therapy for anemia in Chinese patients undergoing dialysis with CKD

Utilization Management

Indication/Diagnosis:

- eGFR less than 60 corresponding to stages 3, 4, or 5:
  - Yes. The documentation of anemia in **CKD stage III-IV-V** is necessary prior to initiation of roxadustat.
- Hemoglobin of less than 10 g/dL or patients to have a hemoglobin less than 12 g/dL if on dialysis and were on an ESA:
  - Yes. The goals of therapy of anemia in CKD are using roxadustat are **similar to Kidney Disease Improving Global Outcomes** (KDIGO) guidelines recommendation.

Prescriber: Yes. It is **appropriate** to limit prescribing of roxadustat to a nephrologist.

Approval duration: **12 months** limitation and reassessment is **reasonable**.

Renewal criteria: In patients with increased dose of roxadustat without raising hemoglobin **greater than 10 g/dL**, reassessment and evaluation for roxadustat resistance and to rule out other anemia etiologies may be required.

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Key Takeaways

Decision Date	Manufacturer	Drug Class	Proposed Indication	Studied Dosing
December 20, 2020	Fibrogen & AstraZeneca	Hypoxia-inducible factor prolyl hydroxylase (HIF-PH) inhibitor	Treatment of anemia of CKD in adult patients on dialysis and not on dialysis	orally three times weekly with titration based on hemoglobin levels as needed

- **Efficacy:** Roxadustat was statistically superior to placebo and to epoetin alfa in improvement of Hb
- **Safety:**
  - Generally well-tolerated with hyperkalemia, metabolic acidosis and upper respiratory infection occurring more in patients treated with roxadustat
  - In the NDD-CKD patients, risks of MACE, MACE+, and all-cause mortality in roxadustat patients were comparable to placebo.
  - In the DD-CKD patients, the risk of MACE and all-cause mortality for roxadustat was similar to epoetin; however, patients on roxadustat had significant 14% reduction in MACE+ events compared to epoetin.
- **Place in therapy:**
  - Roxadustat offers a new mechanism of action and an oral alternative to the currently available injectable ESA products.
  - With its statistically better results in improving hemoglobin, reducing iron and transfusion requirements compared to epoetin alfa, roxadustat may experience a rapid uptake.
  - Roxadustat is expected to compete with ESAs and face additional competition with other HIF-PH inhibitors currently in development.
  - Future studies are still needed to determine the long-term efficacy and safety effects of roxadustat.
- **Utilization Management:**
  - Similar to the ESAs, which are currently managed with PAs, will propose a PA for the first oral HIF-PHI to promote appropriate use.

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ESA=erythropoiesis-stimulating agent; DD=dialysis dependent; MACE (Major Adverse Cardiovascular Events) include: all-cause mortality, myocardial infarction, and stroke; MACE+: MACE, unstable angina requiring hospitalization, and congestive heart failure requiring hospitalization; NDD=non-dialysis dependent

Therapeutic Designations

Market Basket: Agents for the treatment of anemia in non-dialysis and dialysis dependent CKD		
Drug Name	**Therapeutic Designation**	**Rationale**
roxadustat	Novel—**NEW**	Unique place in therapy with a new mechanism of action to treat anemia in CKD, offering a new oral option unlike the ESA injectables
Aranesp (darbepoetin alfa)	Equivalent	Similar place in therapy
Epogen (epoetin alfa)	Equivalent	
Procrit (epoetin alfa)	Equivalent	
Retacrit (epoetin alfa-epbx)	Equivalent	
Mircera (methoxy polyethylene glycol-epoetin beta)	Equivalent	

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Questions?

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4Q20 P&T

Systemic Lupus Erythematosus (SLE) Review

OCTOBER 16, 2020

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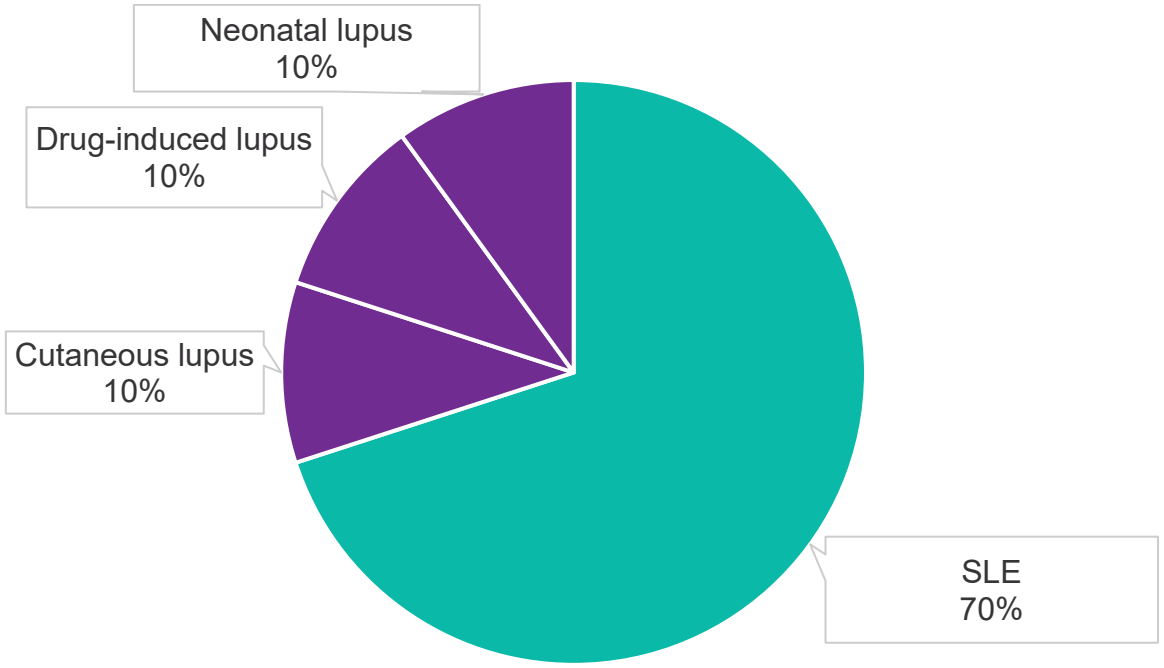
Background.

- Systemic lupus erythematosus (SLE) is a chronic, multisystem, inflammatory autoimmune disorder characterized by systemic inflammation and tissue damage in the affected organs of the body
  - May affect the skin, joints, kidneys, lungs, brain, and blood vessels

- SLE is the most common form of lupus and is marked by periods of recurrent flares and spontaneous remission



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Background.

Epidemiology	• Approximately 1.5 million Americans have some form of lupus, with an estimated prevalence of 20 to 150 cases per 100,000 individuals • 9 out of 10 people living with lupus are women • Higher incidence among people of African, Hispanic, or Asian descent • Median age of disease onset is between 16-55
Etiology	• The etiology of SLE is unknown but is speculated to be multifactorial • Literature suggests genetic, hormonal, immunologic and environmental factors are involved
Pathogenesis	• Many clinical manifestations of SLE are mediated by the production of pathogenic autoantibodies resulting in the abnormal release of inflammatory mediators and immune complexes

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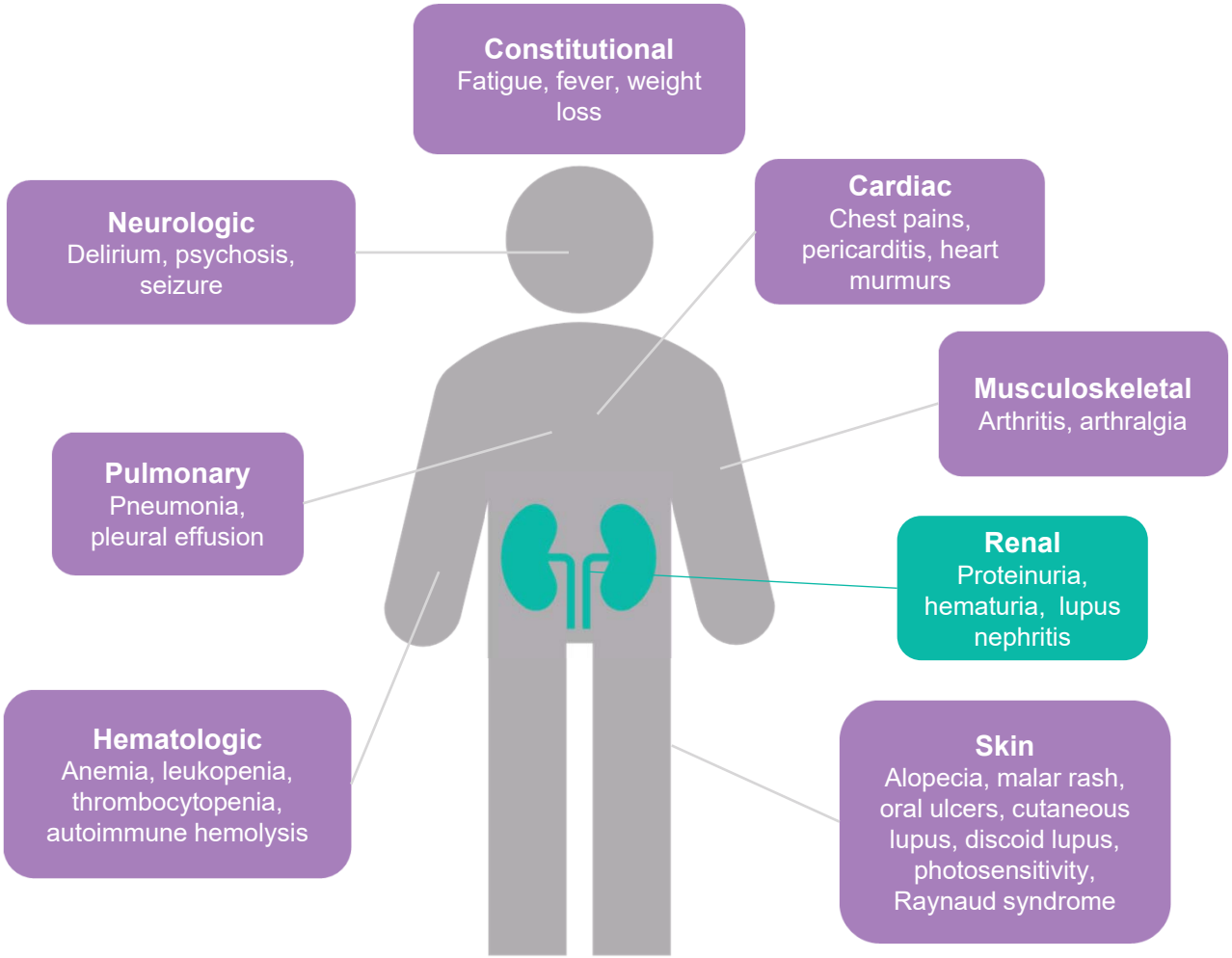
Clinical presentation.



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A disease with many faces: diagnosis.

- Diagnosis of SLE is challenging due to variability in disease presentation.
- Clinicians utilize signs and symptoms in conjunction with supportive lab tests after excluding differential diagnoses.
- Several classification criteria have been developed to categorize patients for entry criteria in clinical trials
  - 1997 American College of Rheumatology (ACR)
  - 2012 Systemic Lupus International Collaborating Clinics (SLICC)
  - 2019 European League Against Rheumatism/American College of Rheumatology (EULAR/ACR)
- According to the 2016 American Academy of Family Physicians (AAFP), SLE may be diagnosed if patients meets 4 of the 11 ACR classification criteria
- The 1999 ACR guidelines recommend referral to a rheumatologist is SLE is suspected to confirm diagnosis

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Old classification criteria.

1997 American College of Rheumatology (ACR) criteria

- SLE classified if 4 out of 11 criteria met
- **Criteria**:
  - Malar rash
  - Photosensitivity
  - Discoid rash
  - Oral ulcers
  - Arthritis
  - Serositis
  - Renal disorder
  - Neurological disorder
  - Hematological disorder
  - Abnormal ANA titer
  - Immunologic disorders

2012 Systemic Lupus International Collaborating Clinics (SLICC) criteria

- SLE classified if 4 out of 17 criteria met[a]
- **Clinical criteria**:
  - Acute cutaneous lupus
  - Chronic cutaneous lupus
  - Nonscarring alopecia
  - Oral/nasal ulcers
  - Joint disease
  - Serositis
  - Renal
  - Neurological
  - Hemolytic anemia
  - Leukopenia/lymphopenia
  - Thrombocytopenia
- **Immunologic criteria**:
  - ANA
  - Anti-dsDNA
  - Anti-Smith
  - Antiphospholipid
  - Low complement
  - Direct coombs test

[a] For the SLICC criteria, a patient is classified as having SLE if 4 of the clinical and immunologic criteria are met, including at least 1 clinical criterion and 1 immunologic criterion. Alternatively, a patient is classified as having SLE if a biopsy-proven nephritis compatible with SLE in the presence of ANAs or anti-dsDNA antibodies.

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New classification criteria.

2019 EULAR/ACR criteria

- Entry criterion: ANA at a titer > 1:80 on Hep-2 cells or an equivalent positive test
- At least 1 clinical criterion required to classify SLE.

Clinical criteria		Weight
Constitutional	Fever	2
Hematologic	Leukopenia	3
	Thrombocytopenia	4
	Autoimmune hemolysis	4
Neuropsychiatric	Delirium	2
	Psychosis	3
	Seizure	5
Mucocutaneous	Nonscarring alopecia	2
	Oral ulcers	2
	Subacute cutaneous or discoid lupus	4
	Acute cutaneous lupus	6
Serosal	Pleural or pericardial effusion	5
	Acute pericarditis	6
Musculoskeletal	Joint involvement	6
Renal	Proteinuria >0.5 g per 24 hours	4
	Renal biopsy Class II or V lupus nephritis	8
	Renal biopsy Class III or IV lupus nephritis	10
Immunological criteria		Weight
Antiphospholipid antibodies	Anti-cardiolipin or anti-beta-2GP1 or lupus anticoagulant	2
Complement proteins	Low C3 or low C4	3
	Low C3 and low C4	4
SLE-specific antibodies	Anti-dsDNA or anti-Smith	6

A total score of ≥10 and ≥1 clinical criterion are required to classify SLE.

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Treatment.

- Goals of therapy: reduce disease activity, prevent organ damage, minimize drug toxicity, and ensure long-term survival

2016 AAFP Primary Care Approach to Diagnosis and Management of SLE

Medications	Indications	Dosage
Azathioprine (Imuran)	Lupus nephritis, severe SLE	1.5 – 2 mg/kg per day
Belimumab (Benlysta)*	SLE	10 mg/kg IV per day
Cyclophosphamide	Lupus nephritis, severe SLE	1 – 3 mg/kg per day
Glucocorticoids	Low dose: SLE w/o major organ damage High dose: cerebritis, lupus nephritis, refractory conditions, thrombocytopenia	Low dose: ≤ 10 mg prednisone per day High dose: 40 – 60 mg prednisone per day
Hydroxychloroquine (Plaquenil)	Long-term protective effect on SLE-related organ damage	200 – 400 mg per day
Methotrexate	Arthritis, cutaneous lupus, serositis, severe SLE	7.5 – 25 mg per week
Mycophenolate (CellCept)	Lupus nephritis, refractory SLE	2 – 3 g per day
NSAIDs	Lupus joint pain	Depends on preparation
Rituximab (Rituxan)	Refractory severe SLE	Two 1 g doses IV, two weeks apart

SLE = systemic lupus erythematosus, IV = intravenously; NSAIDs = nonsteroidal anti-inflammatory drugs
**Benlysta first monoclonal antibody FDA-approved for treatment of SLE*

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Anifrolumab

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ANIFROLUMAB

Product overview.

Approval Date	Expected filing December 2020
Manufacturer	AstraZeneca
Proposed Indication	Treatment of moderate to severe active autoantibody-positive SLE
Mechanism of action	Human monoclonal antibody that binds to subunit 1 of the Type 1 interferon (IFN) receptor, blocking activity of all Type I IFN
Proposed Dosing	300 mg intravenously every 4 weeks

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Proposed mechanism of action.

IFN therapy has been shown to induce autoimmune effects, such as lupus-like syndromes

Clinical evidence supports the involvement of Type I IFN pathway in SLE

Serum IFNα is increased in patients with SLE and associated with high anti-DNA autoantibody levels

Anifrolumab is a human IgG1κ monoclonal antibody that binds to the interferon-α receptor (IFNAR) which prevents binding of type I interferons (IFNs)

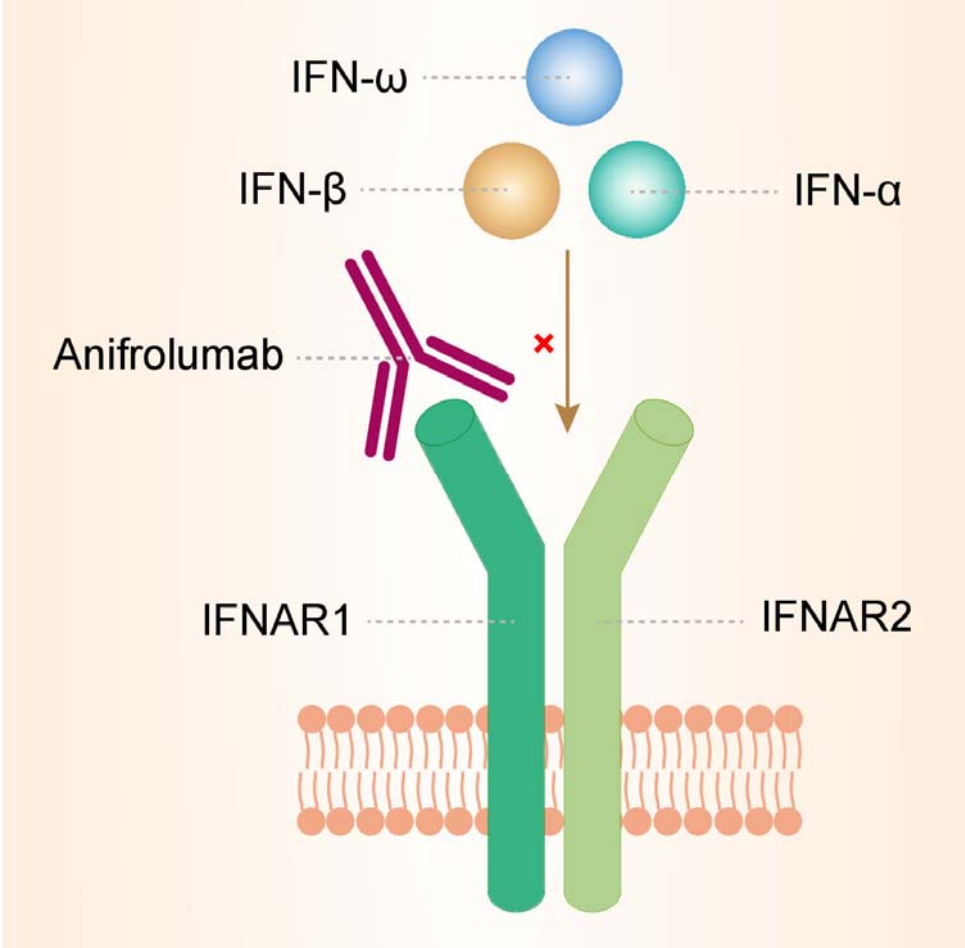

Image from: https://www.creativebiolabs.net/anifrolumab-overview.htm

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Trial design.

- 2 phase 3, multicenter, randomized, double-blind, placebo-controlled trials

	TULIP-1	TULIP-2
Primary Endpoint	Number of patients who achieved an SRI(4) at week 52	Number of patients who achieved a BICLA response at week 52
Intervention	• 150 mg IV every 4 weeks from Week 0 to Week 48 for a total of 13 doses • 300mg IV every 4 weeks from Week 0 to Week 48 for a total of 13 doses • Placebo - IV every 4 weeks from Week 0 to Week 48 for a total of 13 doses	• 300 mg IV every 4 weeks from Week 0 to Week 48 for a total of 13 doses • Placebo - IV every 4 weeks from Week 0 to Week 48 for a total of 13 doses
Inclusion	• Adults age 18-70 years old with active moderate to severe SLE (defined as ACR revised criteria) receiving standard of care (prednisone, antimalarials, etc.) • Seropositive (ANA or anti-dsDNA or anti-Smith antibodies) • SLEDAI-2K score of ≥ 6 • Severe disease activity in ≥ 1 organs or moderate disease activity in ≥ 2 organs measured by BILAG-2004 • PGA score of ≥ 1	
Exclusion	• Active severe lupus nephritis or neuropsychiatric SLE	

SLE = systemic lupus erythematosus; SRI[4] = SLE Responder Index ≥ 4; BICLA = British Isles Lupus Assessment Group-based Composite Lupus Assessment; IV = intravenously; ACR = American College of Rheumatology 1982 revised classification criteria; ANA = antinuclear antibodies; SLEDAI-2K = Systemic Lupus Erythematosus Disease Activity Index 2000; BILAG-2004 = British Isles Lupus Assessment Group 2004 Index; PGA = Physician Global Assessment

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SLE indexes.

Disease Activity

Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI-2K)

British Isles Lupus Assessment Group 2004 Index (BILAG-2004)

Systemic Lupus Erythematosus Responder Index (SRI)

- ≥ 4-point reduction of SLEDAI-2K score from baseline
- No more than 1 new BILAG-2004 B
- No worsening in PGA
- No use of restricted medications
- No discontinuation of investigational product

British Isles Lupus Assessment Group Based Composite Lupus Assessment (BICLA)

- Improvement in all BILAG-2004 A and BILAG-2004 B at baseline with no worsening in other organ systems (1 new A or > 1 new B)
- No worsening SLEDAI-2K
- No worsening PGA
- No use of restricted medication
- No discontinuation of investigational product

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Baseline characteristics.

	TULIP-1		TULIP-2	
Characteristic	**Placebo (N = 184)**	**Anifrolumab (N = 180)**	**Placebo (N = 182)**	**Anifrolumab (N = 180)**
Age (yr)	41.0 (12.3)	42.0 (12.0)	41.1 (11.5)	43.1 (12.0)
Female sex no. (%)	171 (93)	165 (92)	170 (93.4)	168 (93.3)
SLEDAI-2K Global Score	11.5 (3.5)	11.3 (4.0)	11.5 (3.9)	11.4 (3.6)
BILAG-2004 ≥ 1 A item	84 (46)	93 (52)	95 (52.2)	81 (45.0)
BILAG-2004 no A item and ≥ 2 B items	84 (46)	79 (44)	78 (42.9)	91 (50.6)
PGA scores	1.8 (0.4)	1.9 (0.4)	1.8 (0.4)	1.7 (0.4)
High type I IFNGS	151 (82)	148 (82)	151 (83.0)	150 (83.3)
Baseline treatment for SLE				
Oral corticosteroid (OCS)	153 (83)	150 (83)	151 (83.0)	141 (78.3)
OCS ≥ 10 mg/day	102 (55)	103 (69)	83 (45.6)	87 (48.3)
Antimalarial agent	134 (73)	124 (69)	133 (73.1)	119 (66.1)
Immunosuppressant agent	94 (51)	85 (47)	86 (47.3)	88 (48.9)

SLEDAI-2K = Systemic Lupus Erythematosus Disease Activity Index 2000; BILAG-2004 = British Isles Lupus Assessment Group 2004 Index; PGA = Physician Global Assessment; IFNGS = interferon gene signature

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TULIP-2 efficacy.

Primary and Key Secondary Efficacy End Points				
End Point	**Placebo (N=182)**	**Anifrolumab (N=180)**	**Difference (95% CI)**	**Adjusted P Values**
Primary endpoint				
BICLA response at week 52	57/182 (31.5)	86/180 (47.8)	16.3 (6.3 to 26.3)	0.001
Key secondary endpoints				
BICLA response at week 52 in patients with a high IFNGS	46/151 (30.7)	72/15 (48.0)	17.3 (6.5 to 28.2)	0.002
Glucocorticoid reduction to target dose, sustained from week 40 to week 52[a]	25/83 (30.2)	45/87 (51.5)	21.2 (6.8 to 35.7)	0.01
≥50% Reduction in CLASI activity from baseline to week 12[b]	10/40 (25.0)	24/49 (49.0)	24.0 (4.3 to 43.6)	0.04
≥50% Reduction in both swollen and tender joints from baseline to week 52[c]	34/90 (37.5)	30/71 (42.2)	4.7 (–10.6 to 20.0)	0.55
Annualized flare rate through week 52[d]	0.64	0.43	0.67 (0.48 to 0.94)	0.08

BICLA = British Isles Lupus Assessment Group-based compile lupus assessment; CLASI = Cutaneous Lupus Erythematosus Disease Area and Severity Index; CI = confidence interval; IFGNS = interferon gene signature

[a]Reduction in glucocorticoids to < 7.5 mg/day in patients with baseline oral corticosteroids > 10 mg/day prednisone or equivalent. [b]CLASI response was characterized by a ≥ 50% reduction in CLASI activity score from baseline to week 12 in patients with CLASI activity score ≥10 at baseline. [c]Response was characterized by > 50% reduction in swollen and tender joint counts from baseline to week 52 in patients with ≥ 6 swollen and ≥ 6 tender joints at baseline. [d]A flare was defined as ≥1 new BILAG-2004 A item or ≥2 new BILAG-2004 B items compared with the previous visit.

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TULIP-2 safety.

AE category, n (%)	Anifrolumab (N = 180)	Placebo (N = 182)
Any AE	159 (88.3)	153 (84.1)
Serious AE	15 (8.3)	31 (17.0)
Death	1 (0.6)	0
AE leading to discontinuation of intervention	5 (2.8)	13 (7.1)
AE of special interest		
Herpes zoster	13 (7.2)	2 (1.1)
Non-opportunitistic serious infections	5 (2.8)	10 (5.5)
Influenza	4 (2.2)	6 (3.3)
Tuberculosis	3 (1.7)	0
Major adverse cardiovascular event	1 (0.6)	0
Cancer	0	1 (0.5)
Serious AE occurring in ≥ 2 patients in the trial		
Pneumonia	3 (1.7)	7 (3.8)
Gastroenteritis, viral	2 (1.1)	0
Worsening of SLE	1 (0.6)	6 (3.3)
Radius fracture	0	2 (1.1)

AE = adverse event

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TULIP-2 safety.

Adverse Events with Frequency >5% in the Anifrolumab Group		
AE category, n (%)	**Anifrolumab 300 mg (N = 180)**	**Placebo (N = 182)**
Upper respiratory tract infection	39 (21.7)	18 (9.9)
Nasopharyngitis	28 (15.6)	20 (11.0)
Infusion-related reaction	25 (13.9)	14 (7.7)
Bronchitis	22 (12.2)	7 (3.8)
Urinary tract infection	20 (11.1)	25 (13.7)
Herpes zoster	13 (7.2)	2 (1.1)
Sinusitis	12 (6.7)	9 (4.9)
Arthralgia	10 (5.6)	6 (3.3)
Back pain	10 (5.6)	3 (1.6)
Cough	10 (5.6)	6 (3.3)

AE = adverse events

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Rheumatologist

Diagnosis	**What is your approach to diagnosing SLE? Do you utilize classification criteria, such as the American College of Rheumatology (ACR) criteria in clinical practice?** My approach includes evaluation of clinical symptoms and serologic markers. I do utilize the American College of Rheumatology (ACR) classification criteria as a guideline but also adjust for its limitation in certain clinical circumstances (e.g. lupus nephritis confirmed by tissue biopsy as the only manifestation of this disease).
	For patients suspected to have SLE, how often is anti-body testing ordered to confirm diagnosis? Antibody testing is always ordered to confirm diagnosis in patients suspected to have SLE.
	What is your approach to treating patients with SLE? When would you prescribe the use of monoclonal antibodies, such as belimumab (Benlysta)? Treatment selection depends on the patient's clinical manifestations of SLE. Systemic steroids are used initially for rapid control of the inflammatory response. Non-steroidal anti-inflammatory drugs, antimalarials, methotrexate, leflunomide, azathioprine, and mycophenolate mofetil are considered first line agents. Benlysta's use will vary depending on the patient's specific circumstances and tolerance/contraindications to each first-line agent. Monoclonal antibodies, such as belimumab (Benlysta), are not first-line agents and should be used for those patients who have tried and failed first line treatments or have a contraindication to first line agents.
	Do you utilize global indexes (such as SLEDAI-2K, BILAG-2004, or PGA) to determine baseline disease activity? Are these routinely utilized in clinical practice? I do not utilize global indexes (such as SLEDAI-2K, BILAG-2004, or PGA) to determine baseline disease activity. I am unable to comment on the routine use of these indexes by other providers. Global indexes are considered supplemental tools to clinical evaluation that are not required by clinical practice guidelines to determine baseline disease activity, but rather can be used as an additional tool if desired.
anifrolumab	**Given the results of the TULIP trials, do you see anifrolumab as having high clinical value in the SLE space?** Yes. The results of the TULIP trials are promising as they suggest objective improvement of disease activity across many clinical domains, reductions in the glucocorticoid dose, and a decreased risk of flaring when compared to placebo treated patients.

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Rheumatologist

anifrolumab	**Where do you see anifrolumab fitting in the current SLE treatment landscape? a. In what type of patients would you recommend prescribing anifrolumab?** Based on the available data from the TULIP-1 and TULIP-2 trials, I will fit the use of anifrolumab in patients that have failed first line agents or in those that have been unable to decrease their glucocorticoid dose.
	Do you believe anifrolumab would compete with belimumab (Benlysta) for the treatment of active auto-antibody positive SLE in patients taking standard of care? When would you prescribe anifrolumab over belimumab? Would you consider them as equivalent in the treatment of SLE? Yes. I believe anifrolumab will directly compete with belimumab for the treatment of active auto-antibody positive SLE in patients taking standard of care. I will not consider them equivalents as they have a different mechanism of action and most likely different efficacy for specific clinical manifestations of this disease. Based on data thus far, it is not clear when anifrolumab should be used over belimumab. Data suggest they perform quite similarly in patients. One exception to this would be that the data thus far suggests that Benlysta performs slightly better for patients with arthritis symptoms.
Utilization management	**Would it be appropriate to limit prescribing to a rheumatologist? Alternatively, would it be reasonable for primary care physicians to prescribe anifrolumab?** Yes. It will be appropriate to limit prescribing of anifrolumab to a rheumatologist. The American College of Rheumatology Position Statement in regards to patient access to biologics states: "The use of biologics should be supervised and carried out by specially trained physicians and advanced practitioners. These experts have the required knowledge, training and experience to properly handle and administer biologic agents and monitor for adverse reactions." It would not be reasonable for primary care physicians to prescribe anifrolumab.
	Is a positive autoantibody test an appropriate criterion for the initial use of anifrolumab? Yes. A positive autoantibody test is an appropriate criterion for the initial use of anifrolumab.

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EXTERNAL REVIEW

Rheumatologist

Utilization management	**Would it be appropriate to implement other criteria such as patient is currently receiving standard of care (e.g., corticosteroids, antimalarials, or immunosuppressive) and patient does not have severe active lupus nephritis or severe active central nervous system lupus, similar to the inclusion and exclusion criteria in the clinical trial?** No. It would not be appropriate to implement other criteria such as the patient is currently receiving standard of care (e.g., corticosteroids, antimalarials, or immunosuppressive). Some patients cannot take standard of care interventions for multiple patient-specific reasons. However, appropriate documentation of trial/failure or contraindication may be requested as part of the criteria. Using the same inclusion and exclusion criteria as in the clinical trials is not appropriate due to the heterogeneity of this disease and the need to customize treatment for each individual. The American College of Rheumatology Position Statement in regards to patient access to biologics/small molecules states: "Access to therapy should not be tied to disease activity measures used exclusively in research trials that are not a part of routine clinical practice."
	How would you assess clinical improvement/benefit in a patient taking anifrolumab? What type of assessment (test, scores, or documentation) would you require? Provider documentation of clinical improvement should suffice as proof of therapeutic benefit. As indicated above, every patient is different regarding clinical manifestations of SLE. Therefore, clinical documentation indicating improvement in the patient's clinical status and disease manifestations would suffice.
	What are appropriate renewal criteria for anifrolumab? a. Would it be appropriate to require improvement of disease activity (measured by BILAG-2004 or PGA) for the continued use of anifrolumab? No. The American College of Rheumatology Position Statement in regards to patient access to biologics/small molecules states: "Access to therapy should not be tied to disease activity measures used exclusively in research trials that are not a part of routine clinical practice."

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Key Takeaways.

Efficacy
• Anifrolumab did not meet the primary endpoint in TULIP-1; however, it demonstrated superiority versus placebo in reducing disease activity in TULIP-2 • Patients in the anifrolumab group were more likely to see reductions in glucocorticoid dose and severity of skin lesions
Safety
• The most common AE experienced in the anifrolumab group was upper respiratory tract infection. • A higher incidence of herpes zoster occurred among patients in the anifrolumab group compared to the placebo group • One death due to pneumonia occurred in the anifrolumab group.
Place in Therapy
• Biologics are mainstay therapies in the treatment of rheumatic diseases and have only recently been approved for use in the SLE space. • Benlysta (belimumab) is currently the only FDA-approved monoclonal antibody indicated for the treatment of SLE. • If approved, anifrolumab would be the second human monoclonal antibody FDA-approved for the treatment of SLE.

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Voclosporin

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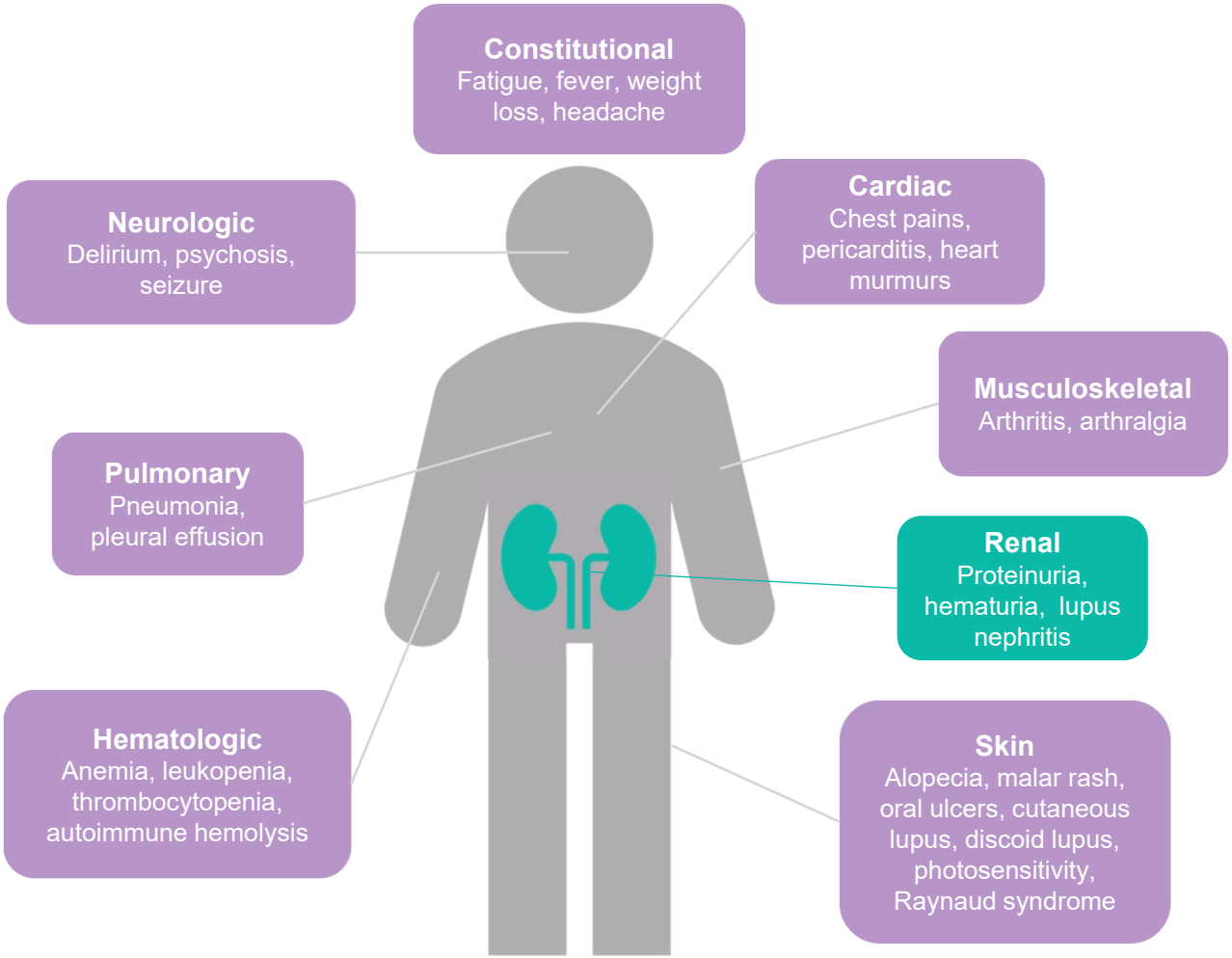
LUPUS NEPHRITIS

Clinical presentation.



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Background.

Epidemiology	• An estimated total of 50–60% of SLE patients will develop LN during the first 10 years of their disease • Up to 10% of patients with LN will develop end-stage renal disease • Time course for the development of LN varies with gender, age, and ethnicity
Etiology	• LN occurs when immune complexes (anti-dsDNA or anti-DNA antibodies) form immune deposit that bind to parts of the glomerulus within the kidney
Pathogenesis	• Depending on where immune complex deposit in the glomerulus, results in glomerulonephritis, hematuria, proteinuria, and acute kidney injury • ~10% of patients with LN develop end-stage renal disease

Diagnosis: 2012 ACR Lupus Nephritis Guidelines

- Persistent proteinuria > 0.5 g per day or > 3+ by dipstick, and/or
- Cellular casts (red blood cells, hemoglobin, granular, tubular, or mixed), or
- Renal biopsy demonstrating immune complex-mediated glomerulonephritis compatible with LN

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Clinical presentation and treatment.

2003 International Society of Nephrology/Renal Pathology Society (ISN/RPS) classification criteria

Class		Clinical Feature	Treatment
Class I: Minimal mesangial LN		Asymptomatic	Not indicated
Class II: Mesangial Proliferative LN		Hematuria and/or proteinuria	
Class III: Focal LN (< 50% glomeruli)	Class III (A) = active lesions	Hematuria, proteinuria, hypertension, decreased eGFR	Induction: Cyclophosphamide + glucocorticoids **OR** Mycophenolate mofetil + glucocorticoids Maintenance: Mycophenolate mofetil **OR** Azathioprine +/- low dose glucocorticoids Refractory: Rituximab **OR** Calcineurin inhibitors + glucocorticoids
	Class III (A/C) = active and chronic lesions		
	Class III (C) = chronic lesions		
Class IV: Diffuse LN (>50% glomeruli)	Class IV (S) = segmental	Hematuria, proteinuria, hypertension, decreased eGFR, nephrotic syndrome	
	Class IV (G) = global		
	Class IV (A) = active lesions		
	Class IV (A/C) = active and chronic lesions		
	Class IV (C) = chronic lesions		
Class V: Membranous LN		Nephrotic syndrome	Induction: Mycophenolate mofetil + prednisone Maintenance: mycophenolate mofetil OR azathioprine
Class VI: Advanced Sclerosed LN (≥ 90% glomeruli)		Progressive renal dysfunction	Renal replacement therapy

VOCLOSPORIN

Product overview.

PDUFA	Anticipated January 22, 2021
Manufacturer	Aurinia Pharmaceuticals
Proposed Indication	Lupus nephritis
Mechanism of action	Voclosporin is a high-potency, novel calcineurin inhibitor with a dual mechanism of action. By inhibiting calcineurin, it blocks IL-2 expression and T-cell mediated immune responses, while stabilizing podocytes in the kidneys.
Proposed Dosing	23.7 mg orally twice daily

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VOCLOSPORIN

Trial design.

	AURA-LV*	AURORA-1	AURORA-2**

Primary Endpoint	• Number of patients achieving renal response (UPCR ≤0.5 mg/mg) at week 52, and all the following:
	  • eGFR ≥60 mL/min/1.73m2 or no confirmed decrease from baseline in eGFR of ≥20%,
	  • Presence of sustained, low dose steroid (≤10 mg prednisone from week 44-52), and
	  • No rescue medications		

Intervention	• Voclosporin 23.7 mg orally twice daily • Voclosporin 23.7 mg orally twice daily until week 2, then 39.5 mg orally twice daily • Placebo 3 capsules orally twice daily until week 2, then 5 capsules orally twice daily	• Voclosporin 23.7 mg orally twice daily + mycophenolate mofetil 2 g daily + oral corticosteroids • Placebo 3 capsules orally twice daily + mycophenolate mofetil 2 g daily + oral corticosteroids	
Inclusion€	• Adults age 18 to 75 years old with diagnosis of SLE (ACR criteria) • Kidney biopsy result within 2 years prior to screening indicating Class III, IV-S, IV-G (alone or in combination with Class V), or Class V LN with a doubling or greater increase of UPCR within the last 6 months to a minimum of ≥1.5 mg/mg for Class III/IV or to a minimum of ≥2 mg/mg for Class V at screening. Biopsy results over 6 months prior to screening must be reviewed with a medical monitor to confirm eligibility, **OR** • Kidney biopsy result within 6 months prior to screening indicating Class III, IV-S or IV-G (alone or in combination with Class V) LN with a UPCR of ≥1.5 mg/mg at screening, **OR** • Kidney biopsy result within 6 months prior to screening indicating Class V LN and a UPCR of ≥2 mg/mg at screening.		
Exclusion	• eGFR ≤45 mL/min at screening • Clinically significant drug or alcohol abuse, HIV infection, or active tuberculosis (TB)		

UPCR = urine protein/creatinine ratio; eGFR = estimated Glomerular Filtration Rate; SLE = systemic lupus erythematosus; ACR = American college of Rheumatology

AURA-LV primary endpoint evaluated at 24 weeks.AURORA-2 trial still active.*

€Refers to AURORA-1 entry criteria

Proposed mechanism of action.

- Voclosporin is a novel calcineurin inhibitor (CNI) developed as a structural analog of cyclosporin A.
  - It is 4x more potent than cyclosporin A.
- Unlike other CNIs, such as Tacrolimus, voclosporin has consistent dose response resulting in removal of therapeutic drug monitoring

2 mechanisms of actions	Inhibition of calcineurin reduces cytokine activation of T-cells
	Potential disease-modifying podocyte stabilization, which protects against proteinuria

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Baseline characteristics.

	AURA-LV*		AURORA-1	
Characteristic	**Placebo (N = 88)**	**Voclosporin (N = 89)**	**Placebo (N = 178)**	**Voclosporin (N = 179)**
Age, yr – mean (SD)	33.1 (10.0)	31.4 (11.8)	33.6 (11.0)	32.8 (10.93)
Male, n (%)	15 (17%)	13 (14.6%)	26 (14.6%)	18 (10.1%)
Female, n (%)	73 (83%)	76 (85.4%)	152 (85.4%)	161 (89.9%)
Baseline UPCR (mg/mg) – mean (SD)	4.4 (3.6)	5.2 (4.2)	3.9 (2.4)	4.1 (2.7)
Baseline eGFR (mL/min/1.73m^2) – mean (SD)	100 (27)	95 (28)	90 (29)	92 (31)
Biopsy class, n (%)				
Class V	13 (15%)	12 (14%)	25 (14%)	25 (14%)
Class III or V (+/- V)	75 (85%)	77 (87%)	153 (86%)	154 (86%)

yr = year; SD = standard deviation; UPCR = urine protein to creatinine ratio
**Does not include data from the high dose voclosporin group*

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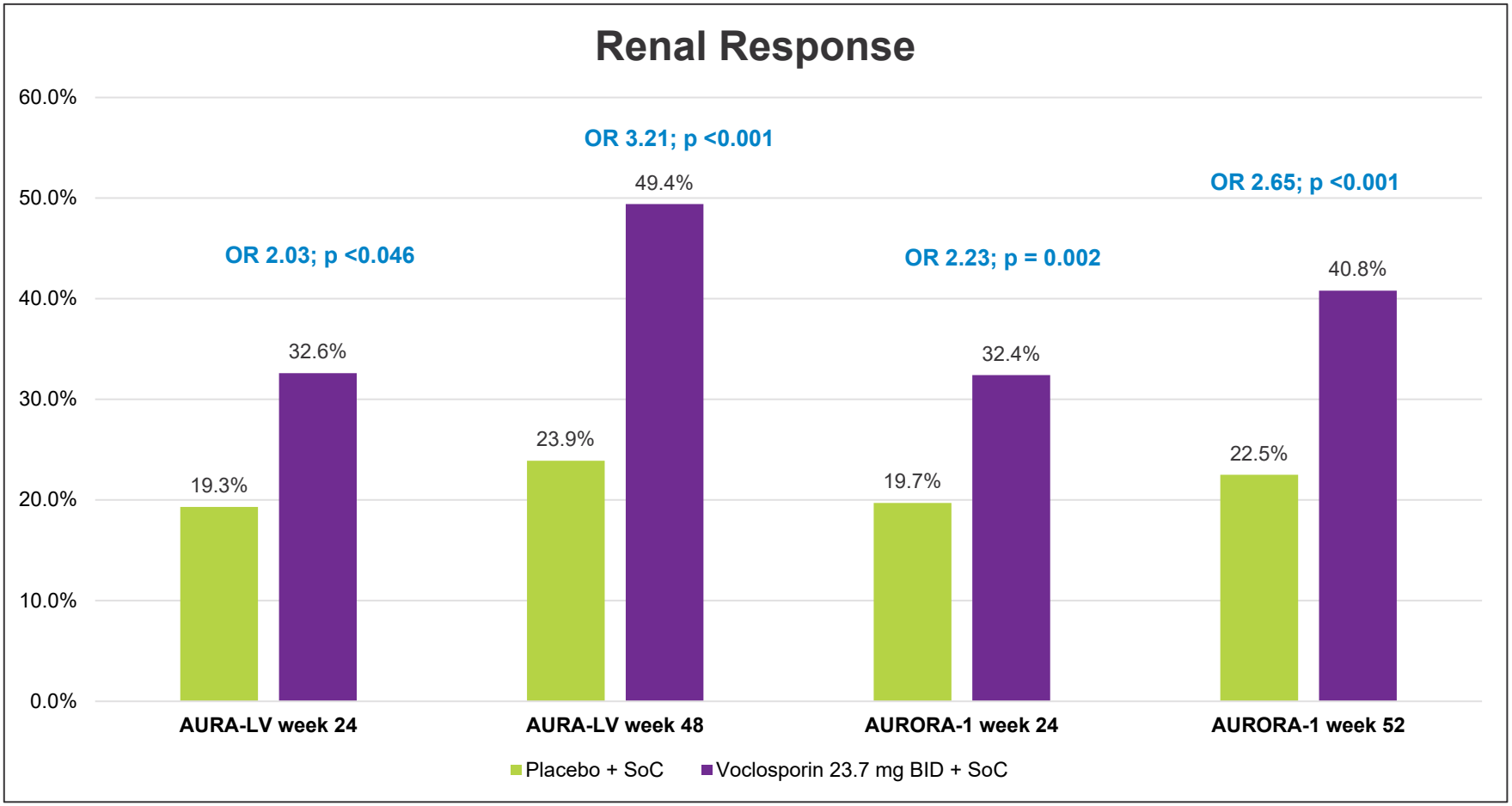
Efficacy.



BID = twice daily; OR = odds ratio; SoC = standard of care (MMF + steroids or IV cyclophosphamide + steroids)

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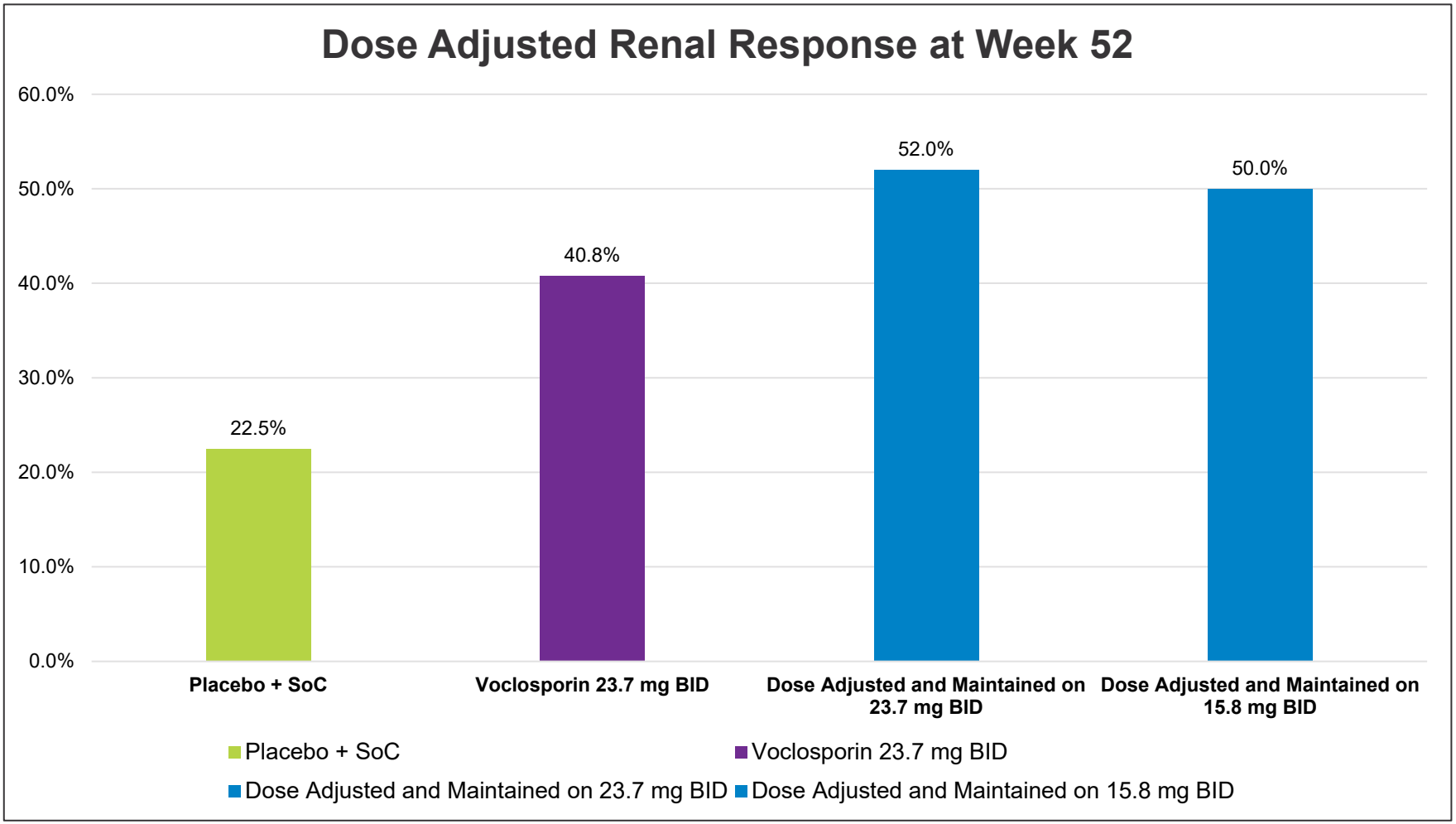
Efficacy.



BID = twice daily; SoC = standard of care (MMF + steroids or IV cyclophosphamide + steroids)

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Safety.

	AURA-LV*		AURORA-1	
AE category, n (%)	**Placebo (N = 88)**	**Voclosporin (N = 89)**	**Placebo (N = 178)**	**Voclosporin (N = 178)**
Any AE	75 (85.2)	82 (92.1)	158 (88.8)	162 (91.0)
Any SAE	14 (15.9)	25 (28.1)	38 (21.3)	37 (20.8)
Any treatment-related AE	15 (17.0)	45 (50.6)	45 (25.3)	80 (44.9)
Any serious treatment-related TEAE	1 (1.1)	4 (4.5)	8 (4.5)	8 (4.5)
Any AE leading to study drug discontinuation	9 (10.2)	16 (18.0)	26 (14.6)	20 (11.2)
Any AE with outcome of death	1 (1.1)	10 (11.2)	5 (2.8)	1 (0.6)

AE = adverse event; SAE = serious adverse event; TEAE = treatment-emergent adverse event
**Does not include data from the high-dose voclosporin group*

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Rheumatologist.

Diagnosis	**What is your approach to diagnosing LN? For patients suspected of having LN, is SLE with evidence of proteinuria enough for a LN diagnosis? If not, what other clinical tests would you consider for diagnosis?** Proteinuria is only used as a screening test for lupus nephritis. Its presence in a patient with SLE is not enough to make a diagnosis. A diagnosis of lupus nephritis requires tissue biopsy for confirmation.
	In your experience, once LN is suspected is a renal biopsy the next step to confirm a LN diagnosis? Yes. A renal biopsy is the next step to confirm a LN diagnosis.
	What is your approach to treating patients with LN? For patient's refractory to induction/maintenance treatment with standard of care, when would you utilize calcineurin inhibitors versus rituximab? I follow the standard of care as delineated on the guidelines from the American College of Rheumatology for the treatment of lupus nephritis which recommends the use of mycophenolate mofetil or cyclophosphamide along with glucocorticoids as initial treatment options. In refractory cases to these drugs, the recommendation is to use rituximab or calcineurin inhibitors in no specific order of selection.
	How often are calcineurin inhibitors utilized in patients with LN refractory to treatment? What proportion of prescribers follow this practice? I am unable to answer this question with objective data. In my clinical experience, rituximab is used more commonly than calcineurin inhibitors in patients with LN refractory to treatment.
	Based on their narrow therapeutic index and nephrotoxicity's, how long should calcineurin inhibitors be used to treat refractory LN? There are no accepted guidelines regarding length of therapy with calcineurin inhibitors to treat refractory LN.
	How is improvement of disease activity of LN measured in practice? Different measures can be used including blood urea nitrogen (BUN)/creatinine levels, quantification of proteinuria, urinalysis, clinical evidence of fluid retention, and frequency/need for dialysis if applicable.
	What prescribers typically treat lupus nephritis patients (e.g., rheumatologists, nephrologists, primary care physicians)? Only rheumatologists and nephrologists typically treat lupus nephritis patients.

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EXTERNAL REVIEW

Rheumatologist.

voclosporin	**Given the results of the AURORA trial, do you see voclosporin as having high clinical value in the LN space?** Yes. The results of the AURORA trial suggest voclosporin will have a high clinical value in the LN space.
	Where do you see voclosporin fitting in the current LN treatment landscape? a. What other lupus nephritis agents share a similar place in therapy as voclosporin'? Based on the results of the Aurora trial, voclosporin may become a standard of care intervention for the management of lupus nephritis. The other drugs in a similar place include mycophenolate mofetil and cyclophosphamide.
	Would you consider voclosporin as equivalent to tacrolimus and cyclosporine in terms of the treatment of LN? No. Based on the results of the AURORA trial, I will consider voclosporin as superior to tacrolimus and cyclosporine when used in combination with mycophenolate mofetil and glucocorticoids in terms of safety and efficacy.
Clinical Trials	**In the clinical trials, renal response was defined as UPCR ≤ 0.5 mg/mg, eGFR ≥ 60 mL/min/1.73m2 or no confirmed decrease from baseline in eGFR of ≥ 20%, presence of sustained, low dose steroid (< 10 mg prednisone from week 44-52) and no use of rescue medications at 52 weeks. Are these criteria for renal response used in clinical practice for patients with LN?** No. Lupus nephritis course/progression and treatment response rate is different for every individual. Even if a patient does not reach any of the parameters used in the trial, the clinical course of lupus nephritis may be worsen if the treatment is discontinued based on this proposed criteria.
Utilization management	**Would it be appropriate to limit the use of voclosporin to patients with an eGFR > 45 mL/min, similar to what was done in the clinical trial?** Yes. It will be appropriate to limit the use of voclosporin to patients with an eGFR greater than 45 mL/min, similar to what was done in the clinical trial. This is recommended as the safety of this drug in patients with an eGFR less than 45 is unknown.

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Rheumatologist.

Utilization management	**Is eGFR or proteinuria or both an appropriate criterion for the initial use of voclosporin? a. If so, what would be an acceptable baseline value for eGFR or proteinuria for LN?** Yes. eGFR or proteinuria or both are an appropriate criterion for the initial use of voclosporin. EGFR less than 60 cc/min or proteinuria greater than 500 mg/24 hours would be an acceptable baseline value for LN.
	Would it be reasonable to limit prescribing to a rheumatologist? Would it be reasonable to limit prescribing to a nephrologist? Would it be reasonable to limit prescribing to a rheumatologist or nephrologist? Alternatively, would it be reasonable for a primary care physician to prescribe voclosporin? It would it be reasonable to limit prescribing to a rheumatologist or nephrologist. It would not be reasonable for a primary care physician to prescribe voclosporin.
	What are appropriate renewal criteria for voclosporin? Documentation of renal response based on clinical parameters (e.g. fluid retention, use of rescue drugs, glucocorticoid dose) and/or laboratory response/lack of progression from patient baseline would be appropriate renewal criteria for voclosporin. **a. Would it be reasonable to require a renal biopsy as a measure of renal response for continued use of voclosporin?** No. This invasive procedure is not commonly used in clinical practice as a measure of renal response. **b. Is it appropriate utilize all components of renal response as defined in the clinical trials for renewal criteria? If they are all not clinically appropriate, what would be an appropriate measure for renal response?** No. Lupus nephritis course/progression and treatment response rate is different for every individual. Application of the strict clinical trials' criteria for common clinical practice is not appropriate. Documentation of renal response based on clinical parameters (e.g. fluid retention, use of rescue drugs, glucocorticoid dose) and/or laboratory response/lack of progression from patient baseline would be an appropriate measure for renal response.

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Key Takeaways.

Efficacy
• Voclosporin was superior to placebo in achieving renal response in patients with active lupus nephritis on standard of care. • Patients in the voclosporin group experienced a faster reduction in urine protein-to-creatinine ratio than compared with placebo.
Safety
• Overall adverse events were similar between voclosporin and placebo with infection being the most common side effect seen in the voclosporin group.
Place in Therapy
• Current treatment for LN consists of induction with IV cyclophosphamide (CYC) or mycophenolate mofetil (MMF) in combination with corticosteroids for 6 months followed by maintenance therapy. However, patients fail to achieve improvement in renal function. • Literature has shown that multitargeted therapy with calcineurin inhibitors (CNI) in combination with MMF to be effective in achieving complete and partial renal response. The use of CNI's is limited in this space due to their toxicities and required therapeutic drug monitoring (TDM). • Voclosporin is a novel CNI that has demonstrated a consistent dose response which could potentially eliminate the need for TDM and would be the first FDA-approved agent indicated specifically for the treatment of LN.

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4Q20 P&T: Prospective Drug Review

Winlevi (clascoterone)

OCTOBER 16, 2020

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Background.

- Acne is a common skin disorder characterized by chronic or recurrent development of skin lesions on the face, neck, trunk, or proximal upper extremities

Epidemiology

- Most prevalent skin condition in the U.S.
- Affects ~80% of the population at some point in life
- Occurs most commonly in adolescents and young adults but may persist into adulthood
- Beginning between the ages of 7-12 years

Etiology

- Most common triggers include:
  - Puberty
  - Hormonal changes in pregnancy or menstruation
  - Use of occlusive cosmetics, cleansers, lotion
  - High humidity, sweating

Pathogenesis

- Acne lesions occur via 4 key factors:
  - Excess sebum production
  - Epithelial hyperkeratinization
  - *Cutibacterium acnes* colonization
  - Inflammation

- Diagnosis of acne vulgaris is by physical examination

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Drug targets.

	Follicular hyperproliferation/ abnormal desquamation	Increased sebum production	*C. Acnes* proliferation	Inflammation
Topical retinoids	✓			✓
Oral retinoids	✓	✓		✓
Azelaic acid	✓		✓	✓
Salicylic acid	✓			
Hormonal therapies	✓	✓		
Oral isotretinoin		✓		✓
Benzoyl peroxide			✓	
Topical/oral antibiotics			✓	✓

All of the above treatment options have a "Level A" strength of recommendation from the American Academy of Dermatology (2016 treatment guidelines) except Salicylic acid, which has a "Level B" strength of recommendation

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Treatment guidelines.

2016 American Academy of Dermatology Acne Vulgaris Guidelines			
	Mild	**Moderate**	**Severe**
1st Line Treatment	• Benzoyl peroxide (BP) • Topical retinoid • Topical combination therapy*	• Topical combination therapy* • Oral antibiotic + topical retinoid + BP • Oral antibiotic + topical retinoid + BP + topical antibiotic	• Oral antibiotic + Topical combination therapy* • Oral isotretinoin
Alternative Treatment	• Add topical retinoid or BP (if not already on) • Consider alternate topical retinoid • Consider topical dapsone	• Alternate combination therapy* • Consider change in oral antibiotic • **Add COC or spironolactone^** • Consider oral isotretinoin	• Consider change in oral antibiotic • **Add COC or spironolactone^** • Consider oral isotretinoin

BP = benzoyl peroxide; COC = combined oral contraceptives
**Topical Combination Therapy = BP + Topical Antibiotic or Topical Retinoid + BP or Topical Retinoid + BP + Topical Antibiotic; may be prescribed as a fixed combination product or as separate component*
^Females

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Winlevi.

Approval Date	August 27, 2020 *(US launch anticipated early 2021)*
Manufacturer	Cassiopea Inc.
Indication	Topical treatment of acne vulgaris in patients 12 years of age and older
Mechanism of action	Clascoterone is an androgen receptor inhibitor. The mechanism of action of Winlevi cream for the topical treatment of acne vulgaris is unknown.
Dosing	Apply a thin layer (~1 gram) to affected area twice daily (morning and evening). Not for ophthalmic, oral or vaginal use.

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Trial design.

	CB-03-01/25 (N = 692)*	CB-03-01/26 (N = 729)*	CB-03-01/27 (N = 599)*
Primary Endpoints	• Proportion of patients achieving IGA success at week 12 • Absolute change from baseline in NILC • ILC at week 12		• All adverse events evaluated at 1, 3, 6, and 9 months • All serious adverse events evaluated at 1, 3, 6, and 9 months
Intervention	• Clascoterone applied to the whole face BID for 12 weeks • Vehicle applied to the whole face BID for 12 weeks		• Clascoterone applied to the face or trunk BID for 9 months • Vehicle applied to the whole face BID for 9 months
Inclusion	• Male and nonpregnant females' patients 9 years or older with moderate to severe AV (grade 3 or 4 on IGA scale) • 30-75 inflammatory lesions or 30-100 noninflammatory lesions		• Participation in either CB-03-01/25 or CB-03-01/26
Exclusion	• Pregnant, lactating, or planning to become pregnant • ≥ 2 facial nodules • Use of topical anti-acne preparations on the face (including OTC acne cleansers or treatments, retinoids, and light treatments) • Use of systemic anti-acne medications (including corticosteroids, antibiotics, spironolactone, and retinoid therapy)		

IGA = Investigators Global Assessment; NILC = Noninflammatory lesion count; ILC = Inflammatory lesion count; BID = twice daily; AV = acne vulgaris; OTC = over the counter;
**CB-03-01/25 and 26 enrolled 19 individuals between 9-11 years; CB-03-01/27 enrolled 10 individuals between 9-11 years*

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Baseline characteristics.

Characteristic	CB-03-01/25*		CB-03-01/26*	
	Clascoterone (N = 353)	Vehicle (N = 355)	Clascoterone (N = 369)	Vehicle (N = 363)
Male, No. (%)	132 (37.4)	140 (39.4)	126 (34.1)	142 (39.2)
Female, No. (%)	221 (62.6)	215 (60.6)	243 (65.9)	221 (60.9)
Age, median (range), y	18 (10-58)	18 (9-50)	18 (10-50)	18 (11-42)
Caucasian, No. (%)	298 (84.4)	297 (83.7)	357 (96.7)	348 (95.9)
IGA score 3 (moderate)	292 (82.7)	291 (82.0)	305 (82.7)	313 (86.2)
IGA score 4 (severe)	61 (17.3)	64 (18.0)	64 (17.3)	50 (13.8)
Mean TLC (SD)	101.5	103.6	105.7	104.6
Mean NILC (SD)	59.1	60.7	62.8	63.3
Mean ILC (SD)	42.4	42.9	42.9	41.3

IGA = Investigators Global Assessment; TLC = total lesion count; NILC = noninflammatory lesion count; ILC = inflammatory lesion count
**ITT population*

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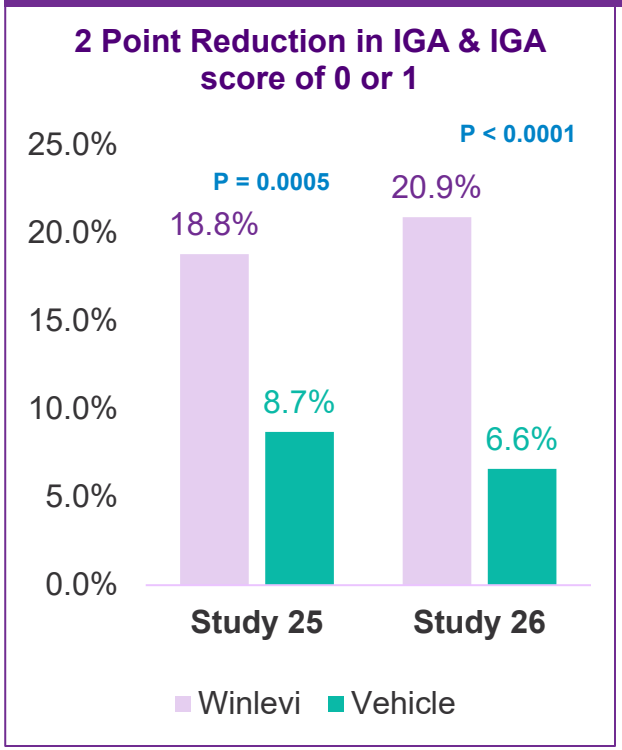
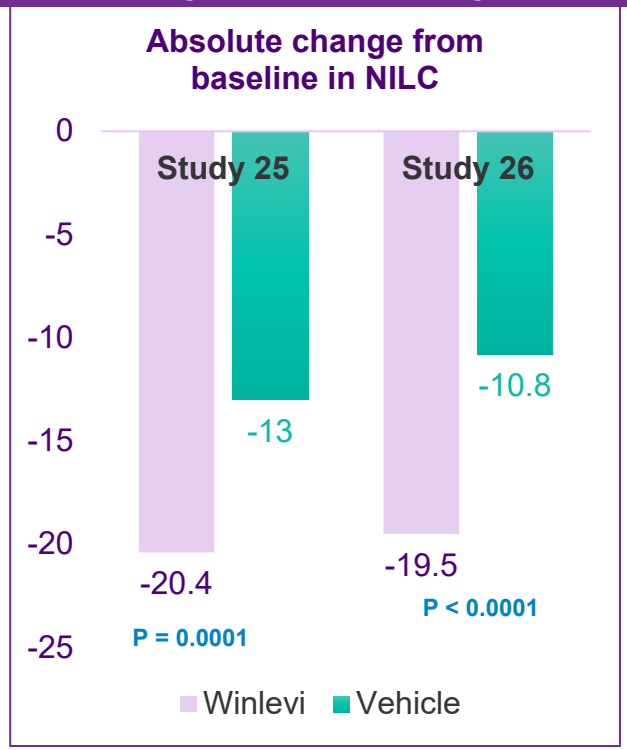
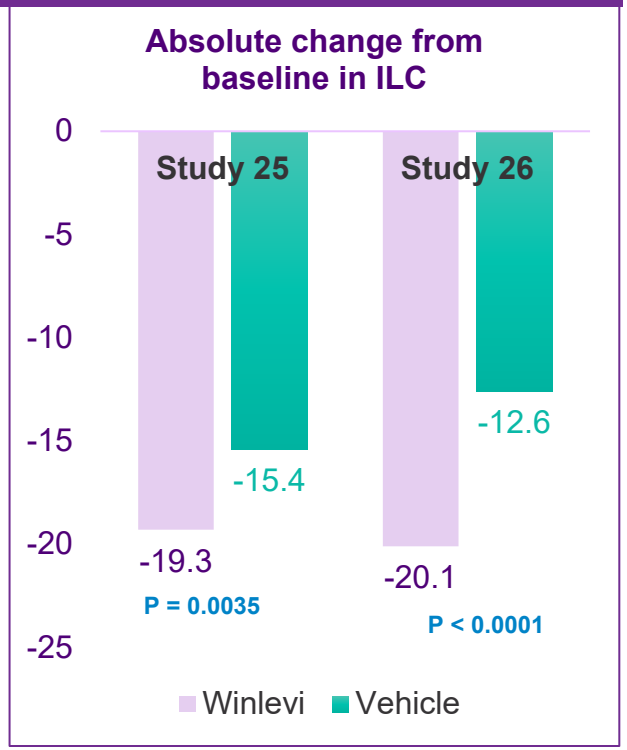
Efficacy.

CB-03-01/25 and 26: Efficacy (Co-Primary Endpoints) ITT (week 12)







IGA = Investigators Global Assessment; NILC = noninflammatory lesion count; ILC = inflammatory lesion count

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Safety.

	CB-03-01/25*		CB-03-01/26*	
	Clascoterone (N = 353)	**Vehicle (N = 355)**	**Clascoterone (N = 369)**	**Vehicle (N = 363)**
Patients experiencing ≥ 1 TEAE	40 (11.3)	41 (11.5)	42 (11.4)	50 (13.8)
Patients experiencing TEAE by severity				
Mild	31 (8.8)	24 (6.8)	32 (8.7)	33 (9.1)
Moderate	9 (2.5)	15 (4.2)	10 (2.7)	16 (4.4)
Severe	0	2 (0.6)	0	1 (0.3)
Patients experience TEAEs				
Serious	0	1 (0.3)	0	1 (0.3)
Related to study drug	4 (1.1)	9 (2.5)	8 (2.2)	13 (3.6)
Leading to study drug discontinuation	3 (0.8)	4 (1.1)	2 (0.5)	8 (2.2)
Most frequent TEAEs				
Nasopharyngitis	6 (1.7)	13 (3.7)	4 (1.1)	7 (1.9)
Headache	2 (0.6)	1 (0.3)	4 (1.1)	3 (0.8)
Oropharyngeal pain	2 (0.6)	1 (0.3)	4 (1.1)	4 (1.1)
Vomiting	2 (0.6)	2 (0.6)	2 (0.5)	1 (0.3)

TEAE = Treatment Emergent Adverse Events
**ITT population*

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Safety.

Incidence of New or Worsening Local Skin Reaction Reported by ≥ 1% of Patients Treated with Winlevi After Day 1 in 12-week Clinical Trials		
	Clascoterone Cream 1% (N = 687[a])	**Vehicle Cream (N = 662[a])**
Edema	25 (3.6%)	23 (3.5%)
Erythema/reddening	84 (12.2%)	101 (15.3%)
Pruritis	52 (7.6%)	55 (8.3%)
Scaling/dryness	72 (10.5%)	68 (10.3%)
Skin atrophy	11 (1.6%)	17 (2.6%)
Stinging/burning	28 (4.1%)	28 (4.2%)
Striae rubrae	17 (2.5%)	10 (1.5%)
Telangiectasia	8 (1.2%)	12 (1.8%)

a. The denominators for calculating the percentage were the 674 of 709 subjects treated with Winlevi cream and 656 of 712 subjects treated with vehicle in both trials who had local skin reaction results reported after Day 1. LSR severity recorded trace, minimal, mild, moderate, or severe. Most were trace/minimal/mild.

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Cost.

Market Basket: Hormonal Acne Vulgaris Agents

Drug	Dosing	Cost/unit	Cost per 28 days
Winlevi (clascoterone1% cream)	Apply one thin layer (~1 gram) to affected area twice daily	***Pricing not available***	
spironolactone (generic for Aldactone) 25 mg, 50 mg 100 mg tablets	50-100 mg orally daily; max 200 mg/day	MAC = $0.11/25 mg MAC = $0.23/50 mg MAC = $0.33/100 mg	$18
Tri-Estarylla, Tri Femynor, Tri-Linyah, Tri-Previfem, Tri-Sprintec, Tri-VyLibra (norgestimate/ethinyl estradiol) 0.180 mg/0.035 mg 0.215 mg/0.035 mg, 0.250 mg/0.035 mg	1 tablet orally daily	MAC = $0.31/tablet	$9
Estrostep Fe*, Tilia Fe, Tri-Legest Fe (norethindrone/ethinyl estradiol) 1 mg/20 mcg, 1 mg/30 mcg, 1 mg/35 mcg, 75 mg ferrous fumarate)		MAC = $1.58/tablet	$44
Beyaz* (drospirenone/ethinyl estradiol/levomefolate) 3 mg/0.02 mg/0.451 mg		MAC = $4.17/tablet	$117
Gianvi, Loryna, Nikki, Yaz* (drospirenone/ethinyl estradiol) 3 mg/0.02 mg		MAC = $0.59/tablet	$17

**multisource brand*
Oral contraceptive agents are FDA-approved for the treatment of acne in women
Spironolactone is used off-label for the treatment of acne

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Key Takeaways.

Approval	Manufacturer	MOA	Indication	Dosing
8/27/2020	Cassiopea Inc.	Androgen receptor inhibitor	Topical treatment of acne vulgaris in patients ≥ 12 years old	Apply a thin layer (~1 gram) to affected area twice daily

Efficacy

- Winlevi proved to be superior to vehicle in the improvement of acne disease severity and the reduction of acne lesions.
- This agent was not used in conjunction with other acne therapies in clinical trials. Therefore, its true efficacy compared to mainstay acne treatments such as benzoyl peroxide or isotretinoin remains to be seen.

Safety

- Winlevi was well tolerated and demonstrated a similar safety profile to that of vehicle in clinical trials.
- It is rapidly metabolized to cortexolone when absorbed, which limits systemic antiandrogen activity as is normally seen with the use of oral contraceptives and spironolactone for acne.

Place in therapy

- Currently available hormonal therapies targeting the androgen pathway are associated with systemic adverse effects and are not suitable for ALL patients with acne.
- Winlevi is a first-in-class androgen receptor inhibitor indicated for the treatment of acne vulgaris in BOTH males and females.

Proposed Actions: will include an age and prescriber edit, as well as a ST through 1st line agents for moderate to severe acne.

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IGA = Investigator Global Assessment; NILC = noninflammatory lesion count; ILC = inflammatory lesion count; TEAE = Treatment Emergent Adverse Events; LSR = local skin reactions; COC = combined oral contraceptives

Therapeutic designations.

Market Basket: Hormonal Acne Vulgaris Agents		
Drug	**Therapeutic Designation**	**Rationale**
Winlevi (clascoterone 1% cream)	Novel—**NEW**	Unique place in therapy; topical antiandrogen that can be used in BOTH males and females
spironolactone (generic for Aldactone)[a]	Equivalent—**NEW**	Similar mechanism of action and used for treatment of acne in females only.
Tri-Estarylla, Tri Femynor, Tri-Linyah, Tri-Previfem, Tri-Sprintec, Tri-VyLibra (norgestimate/ethinyl estradiol)		
Estrostep Fe*, Tilia Fe, Tri-Legest Fe (norethindrone/ethinyl estradiol)		
Beyaz* (drospirenone/ethinyl estradiol/levomefolate)		
Gianvi, Loryna, Nikki, Yaz* (drospirenone/ethinyl estradiol)		
**multisource brand*		

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SSB Acne Agents

Acne agents, topical:

- Azelex (azelaic acid)
- Onexton (clindamycin/benzoyl peroxide)
- Epiduo Forte (adapalene/benzoyl peroxide)
- Neuac (clindamycin/benzoyl peroxide/emol CMB94)
- Nucararxpak (clin-ben-otn-ocsl-oct-oxy-titn)
- Nucaraclinpak (clind/otn/ocsal/o-crl/oxb/titn)

Acne agents, systemic:

- Absorica (isotretinoin)
- Absorica LD (isotretinoin, micronized)

Vitamin A derivatives, topical acne agents:

- Arazlo (tazarotene)
- Fabior (tazarotene)

Vitamin A derivatives:

- Adapalene (adapalene)
- Aklief (trifarotene)
- Altreno (tretinoin)
- Differin (adapalene)
- Retin-A Micropump (tretinoin microspheres)
- Tretin-X (tretinoin/emol 9/skin cleansr1)

Topical antibiotics:

- Amzeeq (minocycline HCl)
- Clindacin PAC/ETZ (clindamycin phos/skin clnsr 19)
- Viabecline (tetracycline HCl)
- Zilxi (minocycline HCl)

Antipsoriatic agents:

- Tazorac (tazarotene)

Tetracyclines, oral:

- Seysara (saracycline HCl)
- Minolira ER (minocycline HCl)
- Doryx (doxycycline HCl)

Keratolytic-Glucocorticoid Combination:

- Vanoxide-HC (benzoyl peroxide/hydrocortisone)

Keratolytics

- Bensal HP/Keralyt Scalp/ Salimez Forte/Ultrasal-ER/Xalix (salicylic acid)
- Inova (benzoyl peroxide/vit e mix)
- Inova 4-1/8-2 (salicylic ac/benzoyl per/vit e)
- Pacnex HP/LP (benzoyl peroxide)
- Salvax Duo Plus (salicylic acid/urea)

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SSB Acne Agents

Rosacea agents, topical:

- Finacea (azelaic acid)
- Mirvaso (brimonidine tartrate)
- Noritate (metronidazole)
- Rhofade (oxymetazoline HCl)
- Rosadan (metronidazole/skin cleanser 23)

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Questions?

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4Q20: New Entities

Duchenne Muscular Dystrophy Review (Viltepso [viltolarsen])

P&T: OCTOBER 16, 2020

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Background

Duchenne muscular dystrophy (DMD):
genetic neuromuscular disorder characterized by progressive muscle degeneration stemming from dystrophin deficiency (less than 3% of normal)

Epidemiology:

- Rare: incidence of 1:3,500-5,000 males globally
- X-linked recessive inheritance

Diagnosis/Pathogenesis:

- Diagnosis confirmed by genetic testing
- DMD is caused by mutations in *DMD* gene that encodes key protein for muscle fiber structure (i.e. dystrophin)

Clinical presentation:

- Childhood onset, typically between ages 3-5 years
- Delayed motor milestones, speech problems, poor coordination → progressive muscle weakness

Prognosis:

- By age 15: >90% become wheelchair-bound
- By age 30: death, primarily caused by respiratory or cardiac failure

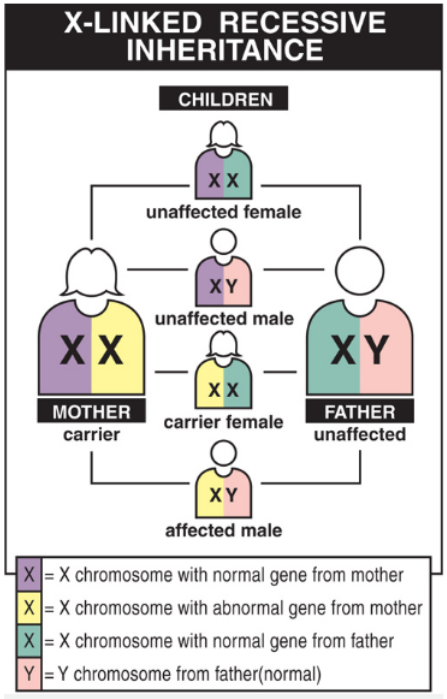

Image:
https://rarediseases.info.nih.gov/diseases/6291/duchenne-muscular-dystrophy

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DMD

Treatment

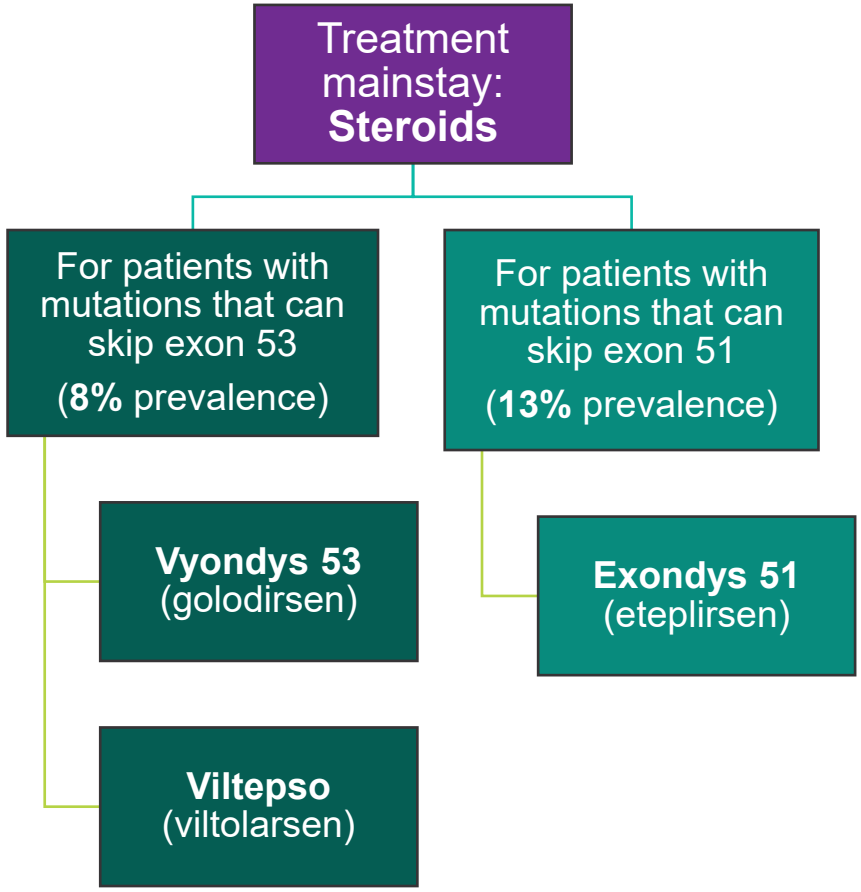
No cure currently exists

Corticosteroids considered for all patients – demonstrated benefits in slowing muscle weakness

- Emflaza (deflazacort): approved in 2017 for DMD
- Other steroids (e.g. prednisone) also used, although off-label

Exon-skipping therapies may be considered for select patients – data suggest that roughly 80% of DMD patients have genotypes amenable to exon skipping

- Three such therapies have FDA approval, collectively providing treatment options for 21% of DMD patients
  - Exondys 51 (eteplirsen): approved in 2016 as the 1st exon skipping treatment for DMD
  - Vyondys 53 (golodirsen)
  - Viltepso (viltolarsen)



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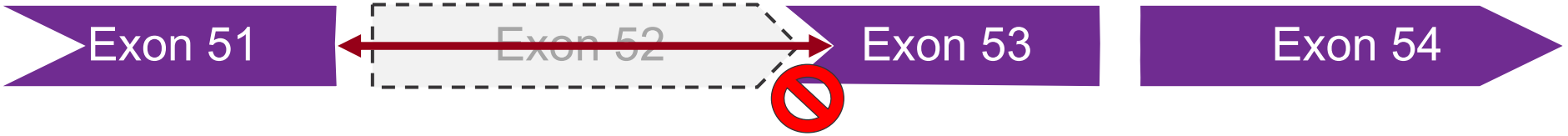
How Do Exon-Skipping Agents Work?

Normal reading frame: functional dystrophin made

Misaligned reading frame (from *DMD* gene mutation): no dystrophin made



Mutations in a specific portion of the DMD gene can be corrected with exon-skipping therapies

Repaired reading frame: truncated, partially functional dystrophin made

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Viltepso (viltolarsen) and Vyondys 53 (golodirsen)

	Viltepso (viltolarsen)	**Vyondys 53** (golodirsen)
FDA Approval and Indication	August 12, 2020	December 12, 2019
	Indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is **amenable to exon 53 skipping**. *This indication is approved under accelerated approval based on an increase in dystrophin production in skeletal muscle observed in patients treated with either Viltepso or Vyondys 53. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial*.	
Drug Class	Antisense oligonucleotide	
How Supplied	250 mg/5 mL single-dose vial	100 mg/2 mL single-dose vial
Dosing and Administration	80 mg/kg given once weekly as an intravenous infusion	30 mg/kg given once weekly as an intravenous infusion

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Study Design & Methods

Pivotal Trial	Viltepso	Vyondys 53
Design	Phase 2, multicenter, two-period • Part 1: DB, PC, dose-finding • Part 2: OL	Phase 1/2, multicenter, two-period • Part 1: DB, PC, dose-titration study • Part 2: OL
Population	Ambulatory males ages **4-9** years with DMD • On stable corticosteroid regimen for at least **3** months • Confirmed *DMD* mutation amenable to skipping exon 53	Ambulatory males ages **6-15** years with DMD • On stable corticosteroid regimen for at least **6** months • Confirmed *DMD* mutation amenable to skipping exon 53
Intervention	Viltepso 80 mg/kg IV once weekly	Vyondys 53 30 mg/kg IV once weekly

Efficacy endpoints	• **Primary:** Change from baseline in dystrophin protein levels (measured as % of levels in healthy subjects) at week 25
	• **Secondary:** gross motor skill assessments (e.g. 6-Minute Walk Test, North Star Ambulatory Assessment)
		• **Primary:**
		  • Change from baseline in dystrophin protein levels (measured as % of levels in healthy subjects) at week 48
		  • 6-Minute Walk Test at week 144

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Efficacy

Viltepso 80 mg/kg	
Patient Number	Dystrophin Levels (% of Normal via Western Blot)
	Change from Baseline to Week 25
1	0.69
2	3.57
3	2.51
4	10.31
5	13.91
6	4.79
7	2.63
8	3.98

Bearing in mind the limited data and differing study designs, Viltepso-treated patients have generally displayed greater increases in dystrophin compared to data for Vyondys 53: Viltepso resulted in a mean increase in dystrophin levels of 5.3% compared to baseline levels versus a mean increase of 0.92% compared to baseline with Vyondys 53. Additionally, Viltepso demonstrated some significant improvements in function tests compared to natural history controls; functional outcomes have not yet been published for Vyondys 53.

Vyondys 53			
Patient Number	Dystrophin Levels (% of Normal via Western Blot) Change from baseline to Week 48	Patient Number	Dystrophin Levels (% of Normal via Western Blot) Change from baseline to Week 48
1	0.01	14	0.06
2	0.01	15	0.07
3	0.01	16	0.37
4	0.08	17	0.97
5	0.09	18	1.55
6	0.09	19	1.05
7	0.25	20	1.69
8	0.95	21	1.66
9	0.48	22	3.99
10	0.92	23	0.25
11	1.49	24	0.88
12	1.84	25	1.22
13	3.15		

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Safety

Parameter	Viltepso	Vyondys 53
Black box warnings	None	None
Contraindications	None	None
Warnings/precautions	• Renal toxicity	• Renal toxicity • Hypersensitivity reactions
Most common adverse reactions (incidence ≥15%)	**N = 16** • URI infection (63%) • injection site reaction (25%) • Cough (19%) • Pyrexia (19%)	**N = 41** • Headache (41%) • Pyrexia (41%) • Fall (29%) • Abdominal pain (27%) • Nasopharyngitis (27%) • Cough (27%) • Vomiting (27%) • Nausea (20%)

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Costs

Indication	Drug	Dosing	AWP Cost/Unit	Annual Cost*
Exon 53 skipping	**Viltepso** (viltolarsen) 250 mg/5 mL SDV	80 mg/kg once weekly via IV infusion	$338.40/mL ($1,692/vial)	$615,888-$2,023,632
	Vyondys 53 (golodirsen) 100 mg/2 mL SDV	30 mg/kg once weekly via IV infusion	$960/mL ($1,920/2mL vial)	$599,040-$2,096,640
Exon 51 skipping	**Exondys 51** (eteplirsen) 100 mg/2 mL, 500 mg/10 mL SDV	30 mg/kg once weekly via IV infusion	$960/mL ($1,920/2mL vial)	$599,040-$2,096,640

Note: *Exon-skipping therapies represent additive costs, as corticosteroids remain the mainstay of DMD treatment.*

**Based on patient weight range between 20-70 kg, not inclusive of facility administration fees or steroid treatment costs, and doses rounded and calculated to nearest vial size*

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Key Takeaways

Drug	Manufacturer	Approved Indication	Approved Dosage
Viltepso (viltolarsen)	Nippon Shinyaku	Indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping.	80 mg/kg IV once weekly
Vyondys 53 (golodirsen)	Sarepta		30 mg/kg IV once weekly

Efficacy

Limited, mostly early-stage data suggest that both therapies can increase dystrophin levels (a surrogate endpoint), but continued approval for their shared indication is contingent upon confirmatory trials and functional outcomes

- Viltepso-treated patients (N=16) demonstrated some improvements/stabilization in motor tests compared to natural history controls; functional outcomes not yet reported for Vyondys 53

Safety

Generally well-tolerated; both require routine monitoring for renal toxicity

Place in Therapy

Viltepso and Vyondys 53 provide treatment options for roughly 8% of the DMD population (whereas Exondys 51 covers about 13%): patients with mutations amenable to exon 53 skipping

- While exon-skipping agents are potentially disease-modifying, they are not curative; all approved exon-skipping treatments require lifelong weekly IV infusions administered by a healthcare professional
- Viltepso and Vyondys 53 will directly compete with one another, and, while Viltepso resulted in higher mean increases in dystrophin compared to Vyondys 53, the clinical benefit of exon-skipping therapy remains to be established (as there is no validated threshold that defines meaningful improvement)
- DMD remains an area of significant unmet clinical need

Utilization Management

Proposing similar management (PA) as existing exon-skipping agents (Exondys 51); updating PAs to align with extra criteria previously approved for Exondys 51 and to include preferred ST given shared place in therapy

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Key Conclusions and Policy Recommendations for Exon-Skipping Therapies (Exondys 51, Vyondys 53)

ICER found that there is "insufficient evidence to judge the net health benefit" of adding exon-skipping therapy compared to steroids and supportive care alone

ICER Policy Recommendations	MedImpact Recommendations
Diagnosis: May reasonably require submission of genetic analysis demonstrating DMD with a mutation amenable to exon-skipping treatment	☑ Diagnostic confirmation based on genetic testing
Age: No clinical justification for age restriction (if treatment is effective, it makes biologic sense to initiate as early as possible)	☑ No age restriction
Severity: Some limit coverage to patients who retain the ability to ambulate. This approach does not align with the view of clinical experts that there is no reason that improvement would not extend to patients who lack ambulation and that improvement in muscle function can be as important to patients who are non-ambulatory as to ambulatory patients.	⊘ Limit to ambulatory patients pending confirmation of clinical benefit
Other criteria: No other criteria suggested	⊘ Prescriber restriction and concurrent use with steroids required within PA
Dosage restriction: Reasonable to restrict coverage to labeled dosing	☑ QL per label
Renewal criteria: There is no reason to require attestation or other renewal criteria for continuing exon-skipping therapy, as some rate of continued clinical decline is expected while on treatment, even if treatment is effective.	⊘ Require attestation of maintenance in or demonstrated less than expected decline in muscle function

At this time, there is no indication that ICER will be updating their assessments to include discussion on Viltepso

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Tanezumab

4Q20 P&T Prospective Drug Review

P&T: OCTOBER 16, 2020

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Background

Osteoarthritis

- Most common form of arthritis
- Leading cause of disability in older adults
- Most frequently affected joints: hands, knees, hips

Epidemiology

- Affects an estimated 300 million people worldwide
  - Roughly 11 million Americans have *moderate-to-severe* disease

Treatment

- **Nonpharmacologic** (e.g. massage therapy, exercise, physical therapy) and **pharmacologic** (oral, topical, intra-articular) treatment options
  - Often used in combination
- Treatment decisions depend on patient preferences and medical status (e.g. comorbidities)

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Pharmacologic Approaches by OA Location

Knee	Recommendation Level	Hip
• NSAIDs (oral/**topical**) • Intra-articular steroids	**Strongly recommended**	• NSAIDs (oral) • Intra-articular steroids
• APAP • Tramadol • Duloxetine • **Topical capsaicin**	**Conditionally recommended**	• APAP • Tramadol • Duloxetine
• Intra-articular Botox • Prolotherapy • Colchicine • Opioids (non-tramadol) • Fish oil • Vitamin D • **Intra-articular hyaluronate**	**Conditionally against**	• Intra-articular Botox • Prolotherapy • Colchicine • Opioids (non-tramadol) • Fish oil • Vitamin D
• Bisphosphonates • Glucosamine • Hydroxychloroquine • MTX • Biologics (TNF, IL-1) • PRP • Stem cell injection • Chondroitin	**Strongly against**	• Bisphosphonates • Glucosamine • Hydroxychloroquine • MTX • Biologics (TNF, IL-1) • PRP • Stem cell injection • Chondroitin • **Intra-articular hyaluronate**

Notes:
The listed order of agents does not imply hierarchy of treatments as treatment options may be used/re-used at various times during the course of a patients' disease.
Bolded agents represent differences between recommendations for knee and hip OA.

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ACR: American College of Rheumatology; AF: Arthritis Foundation; MTX: methotrexate; OA: osteoarthritis; PRP: platelet-rich plasma

Introduction and History of Development: Tanezumab

Decision Date	Manufacturer	Class	Proposed Indication	Dosage under Review
December 2020	Pfizer & Eli Lilly	Nerve growth factor (NGF)-blocking monoclonal antibody*	Pain from moderate-to-severe OA in adults for whom other analgesics are ineffective or not appropriate	2.5 mg SC q8 weeks by HCP

**NGF is released in response to tissue damage to facilitate pain signaling; by blocking NGF, tanezumab disrupts the pain signaling pathway, preventing signals produced in the periphery from reaching the brain*

2010:
- Clinical trials put on hold due to concerns for RPOA

2012:
- Second clinical hold due to concerning sympathetic nervous system data (in animals)

2015:
- Trials resumed contingent upon risk reduction measures

Pre-2015:
- Tanezumab studied as IV (10 mg only) or SC (2.5, 5, 10 mg)

Post-2015: Risk Mitigation Measures:
- Dose restriction: 2.5, 5 mg (both SC)
- Inclusion of patients with inadequate response/intolerance/contraindication to multiple standard analgesics
- Exclusion of patients with certain pre-existing joint conditions
- No chronic concomitant NSAID use (as higher rates of RPOA seen with concurrent use)
- Discontinuation of patients with inadequate pain response to initial doses of tanezumab

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HCP: healthcare professional; RPOA: rapidly progressive OA

Study Designs and Methods

OA Phase 3 Trials (Post-2015)	Studies		
	1056: Schnitzer et al.	**1057: Berenbaum et al.**	**1058**
Design	DB, **PC**, MC (including U.S.), RCT	DB, **PC**, MC (all sites outside U.S.), RCT	DB, **active controlled (NSAIDs)**, MC (including U.S.) RCT
Duration	16 weeks	24 weeks	56 weeks
Population	Adults with OA (hip/knee) who had an inadequate response, who could not tolerate, or who had a contraindication to standard analgesics (i.e. APAP, NSAIDs [*except for Study 1058 where NSAIDs served as the active control*)], tramadol or other opioids)		
Inclusion	• Radiographic confirmation of OA (Kellgren-Lawrence grade ≥2 [minimal]) • Baseline WOMAC* Pain and Physical Function subscale scores, each ≥5 • Baseline PGA-OA scores of fair (3 points), poor (4), or very poor (5)		
Exclusion	• Radiologic evidence of certain joint or bone conditions		
N	698	849	2,996
Co-primary Efficacy Endpoints	Change from baseline to Week **16** in: ***WOMAC* Pain score*** *Mean of scores from 5 individual questions; ranges from 0-10 , where higher scores equate to greater pain* ***WOMAC* Physical Function score*** *Mean of scores from 17 individual questions; ranges from 0-10 , where higher scores equate to greater physical difficulties* ***PGA-OA score*** *Based on one question that asks the patient to rate how they are doing on a given day considering how their disease affects them; scored from 1 (very good) to 5 (very poor)*	Change from baseline to Week **24** in: ***WOMAC* Pain score*** *Mean of scores from 5 individual questions; ranges from 0-10 , where higher scores equate to greater pain* ***WOMAC* Physical Function score*** *Mean of scores from 17 individual questions; ranges from 0-10 , where higher scores equate to greater physical difficulties* ***PGA-OA score*** *Based on one question that asks the patient to rate how they are doing on a given day considering how their disease affects them; scored from 1 (very good) to 5 (very poor)*	Change from baseline to Week **16** in: ***WOMAC* Pain score*** *Mean of scores from 5 individual questions; ranges from 0-10 , where higher scores equate to greater pain* ***WOMAC* Physical Function score*** *Mean of scores from 17 individual questions; ranges from 0-10 , where higher scores equate to greater physical difficulties* ***PGA-OA score*** *Based on one question that asks the patient to rate how they are doing on a given day considering how their disease affects them; scored from 1 (very good) to 5 (very poor)*

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PGA-OA: patient global assessment of OA; WOMAC: Western Ontario and McMasters Universities OA Index; *WOMAC® protected by copyright and confidentiality restrictions that do not permit disclosure to third parties

Efficacy

OA Phase 3 Trials (Post-2015)	Studies								
	1056: Schnitzer et al.			1057: Berenbaum et al.			1058		
Intervention *Tanezumab was dosed every 8 weeks*	• SC tanezumab 2.5 mg at baseline/week 8 • SC tanezumab 2.5 mg at baseline and 5 mg* at week 8 (*forced titration*) • Placebo			• SC tanezumab 2.5 mg at baseline/week 8/week 16 • SC tanezumab 5 mg* at baseline/week 8/week 16 • Placebo			• SC tanezumab 2.5 mg every 8 weeks • SC tanezumab 5 mg* every 8 weeks • NSAID BID (naproxen, diclofenac, or celecoxib)		
Results									
Treatment Arm	**2.5 mg** (n=231)	**2.5/5 mg** (n=233)	**Placebo** (n=232)	**2.5 mg** (n=283)	**5 mg** (n=284)	**Placebo** (n=282)	**2.5 mg** (n=1,002)	**5 mg** (n=998)	**NSAID** (n=996)
WOMAC Pain									
Mean change from baseline	-3.23	-3.37	-2.64	-2.70	-2.85	-2.24	-3.22	-3.33	-3.07
Mean difference vs placebo/NSAID	-0.60 ***P=0.01***	-0.73 ***P=0.002***		-0.46 ***P=0.0088***	-0.62 ***P=0.0006***		-0.15 ***P=0.160***	-0.26 ***P=0.015***	
WOMAC Physical Function									
Mean change from baseline	-3.22	-3.45	-2.56	-2.70	-2.82	-2.11	-3.27	-3.39	-3.08
Mean difference vs placebo/NSAID	-0.66 ***P=0.007***	-0.89 ***P<0.001***		-0.59 ***P=0.0008***	-0.71 ***P<0.0001***		-0.19 ***P=0.069***	-0.31 ***P=0.003***	
PGA-OA									
Mean change from baseline	-0.87	-0.90	-0.65	-0.82	-0.90	-0.72	-0.96	-0.97	-0.94
Mean difference vs placebo/NSAID	-0.22 ***P=0.01***	-0.25 ***P=0.004***		-0.11 ***NS***	-0.19 ***P=0.0051***		-0.02 ***P=0.633***	-0.04 ***P=0.343***	
Note: *Cells in red represent non-significance.*									

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NS: not significant; PGA-OA: patient global assessment of OA; WOMAC: Western Ontario and McMasters Universities OA Index; *dose no longer being pursued

TANEZUMAB

Efficacy

OA Phase 3 Trials (Post-2015)	Studies								
	1056: Schnitzer et al.			1057: Berenbaum et al.			1058		
Intervention *Tanezumab was dosed every 8 weeks*	Only the 2.5 mg strength is being sought for approval at this time. While this dose met all primary endpoints compared to placebo in Study 1056, the 2.5 mg arm only met two of three endpoints in Study 1057 and did not meet any of the efficacy endpoints compared to the NSAID arm in Study 1058.								
Results									
Treatment Arm	**2.5 mg** (n=231)	**2.5/5 mg*** (n=233)	**Placebo** (n=232)	**2.5 mg** (n=283)	**5 mg*** (n=284)	**Placebo** (n=282)	**2.5 mg** (n=1,002)	**5 mg*** (n=998)	**NSAID** (n=996)
WOMAC Pain									
Mean change from baseline	-3.23	-3.37	-2.64	-2.70	-2.85	-2.24	-3.22	-3.33	-3.07
Mean difference vs placebo/NSAID	-0.60 ***P=0.01***	-0.73 ***P=0.002***		-0.46 ***P=0.0088***	-0.62 ***P=0.0006***		-0.15 ***P=0.160***	-0.26 ***P=0.015***	
WOMAC Physical Function									
Mean change from baseline	-3.22	-3.45	-2.56	-2.70	-2.82	-2.11	-3.27	-3.39	-3.08
Mean difference vs placebo/NSAID	-0.66 ***P=0.007***	-0.89 ***P<0.001***		-0.59 ***P=0.0008***	-0.71 ***P<0.0001***		-0.19 ***P=0.069***	-0.31 ***P=0.003***	
PGA-OA									
Mean change from baseline	-0.87	-0.90	-0.65	-0.82	-0.90	-0.72	-0.96	-0.97	-0.94
Mean difference vs placebo/NSAID	-0.22 ***P=0.01***	-0.25 ***P=0.004***		-0.11 ***NS***	-0.19 ***P=0.0051***		-0.02 ***P=0.633***	-0.04 ***P=0.343***	

Note: *Cells in red represent non-significance.*

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NS: not significant; PGA-OA: patient global assessment of OA; WOMAC: Western Ontario and McMasters Universities OA Index; *dose no longer being pursued

Safety: Treatment Period

Safety, n (%)	Studies								
	1056: Schnitzer et al.			1057: Berenbaum et al.			1058		
	2.5 mg (n=231)	2.5/5 mg (n=233)	Placebo (n=232)	2.5 mg (n=283)	5 mg (n=284)	Placebo (n=282)	2.5 mg (n=1,002)	5 mg (n=998)	NSAID (n=996)
All AEs	128 (55.4)	109 (46.8)	115 (49.6)	150 (53.0)	162 (57.0)	155 (55.0)	629 (62.8)	670 (67.1)	601 (60.3)
TEAEs	29 (12.6)	22 (9.4)	24 (10.3)	42 (14.8)	48 (16.9)	40 (14.2)	165 (16.5)	208 (20.8)	158 (15.9)
SAEs	4 (1.7)	4 (1.7)	4 (1.7)	8 (2.8)	9 (3.2)	3 (1.1)	51 (5.1)	80 (8.0)	46 (4.6)
Treatment discontinuations due to AEs	1 (0.4)	3 (1.3)	3 (1.3)	3 (1.1)	4 (1.4)	7 (2.5)	53 (5.3)	88 (8.8)	52 (5.2)
Most common TEAEs (occurring in ≥5% of patients in any treatment group)									
Arthralgia	19 (8.2)	22 (9.4)	29 (12.5)	27 (9.5)	23 (8.1)	34 (12.1)	133 (13.3)	165 (16.5)	117 (11.7)
Nasopharyngitis	12 (5.2)	11 (4.7)	8 (3.4)	31 (11.0)	22 (7.7)	25 (8.9)	57 (5.7)	67 (6.7)	40 (4.0)
Back pain	-	-	-	16 (5.7)	17 (6.0)	15 (5.3)	34 (3.4)	55 (5.5)	35 (3.5)
Headache	-	-	-	15 (5.3)	14 (4.9)	18 (6.4)	56 (5.6)	45 (4.5)	25 (2.5)
Fall	-	-	-	-	-	-	65 (6.5)	53 (5.3)	46 (4.6)
URI	-	-	-	-	-	-	57 (5.7)	45 (4.5)	59 (5.9)
Neurologic TEAEs (occurring in ≥3% of patients in any treatment group)									
Paresthesia	8 (3.5)	3 (1.3)	1 (0.4)	5 (1.8)	12 (4.2)	5 (1.8)	-	-	-

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Joint Safety: Full Study Period (Treatment and Follow-Up)

Tanezumab-treated patients had higher rates of total joint replacements and rapidly progressive OA; the higher dose (5 mg [not being pursued for approval]) was generally associated with a greater incidence of joint safety events than the lower dose (2.5 mg).

Joint Safety Events, n (%)	Studies								
	1056: Schnitzer et al.			1057: Berenbaum et al.			1058		
	2.5 mg (n=231)	2.5/5 mg (n=233)	Placebo (n=232)	2.5 mg (n=283)	5 mg (n=284)	Placebo (n=282)	2.5 mg (n=1,002)	5 mg (n=998)	NSAID (n=996)
Total joint replacements	8 (3.5)	16* (6.9)	4 (1.7)	22 (7.8)	20 (7.0)	19 (6.7)	53 (5.3)	80 (8.0)	26 (2.6)
Normal OA progression	8 (3.5)	17 (7.3)	5 (2.2)	22 (7.8)	19 (6.7)	17 (6.0)	66 (6.6)	79 (7.9)	27 (2.7)
RPOA Type 1	3 (1.3)	1 (0.4)	0	3 (1.1)	5 (1.8)	0	29 (2.9)	49 (4.9)	11 (1.1)
RPOA Type 2	2 (0.9)	0	0	1 (0.4)	3 (1.1)	0	3 (0.3)	14 (1.4)	1 (0.1)
Other joint safety events†	1 (0.4)	0	0	1 (0.4)	1 (0.4)	0	7 (0.7)	8 (0.8)	4 (0.4)

**One patient had 2 joints replaced*
†May include subchondral insufficiency fracture, primary osteonecrosis, or pathologic fracture

Notes: *RPOA Type 1 is defined as significant loss of joint space width ≥2 mm within approximately 1 year, without gross structural failure. Type 2 is defined as abnormal bone destruction or loss, including total or limited collapse of at least 1 subchondral surface, that is not normally present in conventional end-stage OA.*

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RPOA: rapidly progressive OA

External Review: Pertinent Comments

General OA management

- **Assessments:** WOMAC index is valid but generally not used in rheumatology clinical practice. The PGA-OA scale is used.
- **Treatment selection:** **APAP, NSAIDs, and tramadol are used in succession**. Deficits of kidney function and prior history of serious GI bleeding or gastric ulceration are the primary concerns [with] oral NSAIDs…topical NSAIDs are highly effective for patients with OA of the knee…but require recurrent utilization. Duloxetine is on-label for management of OA pain modulation and is particularly useful for OA originating in large weight-bearing joints... duloxetine is under utilized and is very effective for…hip and knee OA pain modulation. Tramadol is useful for patients who do not have other clinical contraindications to opioids. I find NSAIDs, unless contraindicated, are more useful than APAP except in very elderly patients.
- **Unmet needs:** The **pool of patients who cannot find pain relief with the existing arsenal of analgesics is large**…in 2013, estimates of OA of the knee were that 13% of males and 18% of females [were] diagnosed with OA of the knee and that approximately 50% of those patients will require a total knee arthroplasty during their lifetime due to unrelieved pain.

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External Review: Pertinent Comments

Tanezumab

- [It] has been demonstrated to cause RPOA and to increase the incidence of joint replacements…the exclusions which were necessary to mitigate risk in the RCTs are very unlikely to be reproduced exactly [if] the medication is FDA approved…As a rheumatologist, a primary responsibility is to modify the course of the disease for the better. This means preventing joint replacements. Tanezumab increases the risk that a patient will require joint replacement. Any medication which actually has that as a side effect, **should not have any role in therapy for OA unless all non-surgical options have been well and truly exhausted**…but will not be dramatically more effective than the current arsenal of analgesics.

Utilization management

- **PA should be required**
- **Prescribers: Appropriate to restrict prescribing** of this drug to orthopedists, pain specialists, rheumatologists, sports medicine and rehabilitation specialists, and radiologists
- **ST: Appropriate to step tanezumab through other standard analgesics as per clinical trial inclusion criteria**
- **Other criteria:**
  - **Conservative measures** like physical therapy followed by self-management programs and exercise are important adjunctive therapies.
  - Chronic NSAID use is a risk factor for the occurrence of RPOA in patients on tanezumab, and thus it **should be required that the patient not be taking chronic systemic NSAIDs.**
- **Approval duration:** Based upon the studies, **6 months [initial]**
- **Renewal criteria:** A predetermined degree of improvement consistent with the results observed in the trials should be required…radiologic assessments have been reviewed and there is no sign of RPOA

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Key Takeaways

Decision Date	Manufacturer	Class	Proposed Indication	Dosage under Review
December 2020	Pfizer & Eli Lilly	Nerve growth factor-blocking monoclonal antibody	Pain from moderate-to-severe OA in adults for whom other analgesics are ineffective or not appropriate	2.5 mg SC q8 weeks by healthcare provider

Efficacy

The lower dose being pursued (2.5 mg) seemed to be less effective than the higher dose (5 mg); while 2.5 mg met most endpoints compared to placebo, the differences were not clinically remarkable and this tanezumab dose showed no differences in efficacy compared to NSAIDs

Safety

Tanezumab-treated patients had higher rates of joint safety events, including total joint replacements and rapidly progressive OA – will likely be available through a REMS program if approved

Place in Therapy

Could be a first-in-class treatment for OA pain

- While studies to date have not demonstrated it to carry a risk of addiction or misuse, its mixed efficacy, concerning safety data, and requirement for administration by a healthcare provider roughly every two months could relegate it to a treatment option of last resort
- Potential for future indications in cancer-related pain and chronic low back pain

Utilization Management

Proposing PA to promote appropriate use given safety concerns and in anticipation of high cost potential (within a space with multiple OTC and generic options)

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4Q20 P&T: Olanzapine-Samidorphan

OCTOBER 16, 2020

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Olanzapine and samidorphan (OLZ/SAM)

PDUFA:	November 15, 2020
Manufacturer:	Alkermes plc
Proposed Indication:	Schizophrenia and Bipolar I disorder in adults
Drug class:	Atypical antipsychotic and opioid receptor modulator combination
Proposed dosing:	Olanzapine 5, 10, 15, or 20 mg in combination with samidorphan 10 mg orally once daily

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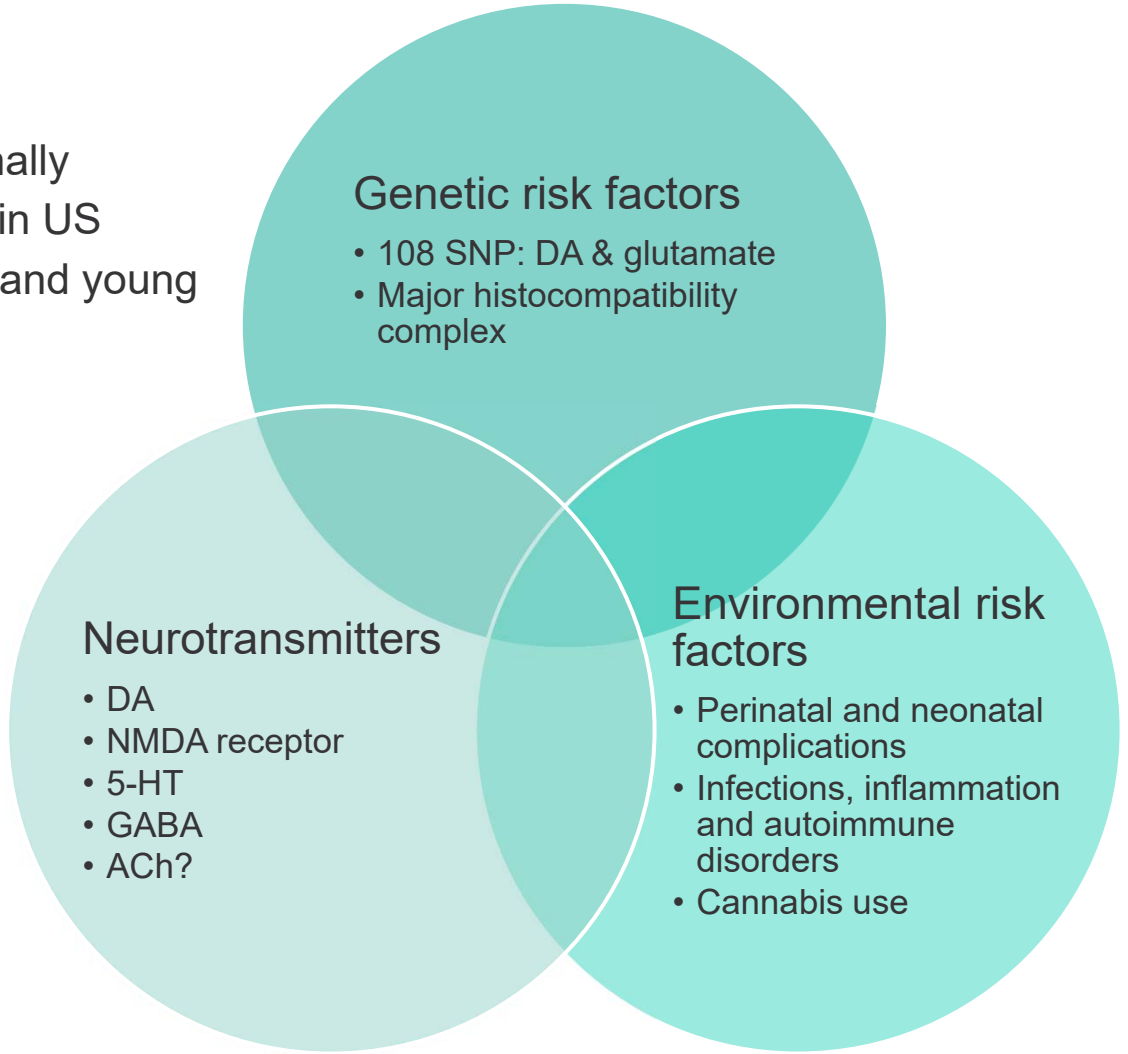
Background

- Epidemiology
  - Prevalence: 1% internationally
    - Estimated 3.5 million in US
  - Age of onset: adolescents and young adults
  - Gender variations
- Higher rates of comorbid diseases
  - Both psychiatric and medical
- Significantly higher mortality rate than general population
- Estimated annual economic burden of ~$156 billion



SNP = single nucleotide polymorphisms; DA = dopamine; NMDA = N-methyl-D-aspartate; 5-HT = serotonin; GABA = gamma-amino-butyric acid; ACh = acetylcholine

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Clinical manifestations

Positive symptoms

- Hallucinations
- Delusions
- Disorganized speech
- Disorganized behavior

Negative symptoms

- Blunted affect
- Alogia
- Avolition
- Anhedonia
- Amotivation

Cognitive symptoms

- Difficulty in maintaining or shifting attention
- Deficits in memory
- Deficits in executive function

Others: Mood/anxiety symptoms, social/occupational dysfunction, and physical manifestations

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Guidelines

	NICE 2014	CSG 2017	APA 2020
First-line	SGA, FGA (in combination with psychological interventions)	SGA, FGA	SGA, FGA
Second-line	SGA, FGA (only if an SGA has already been tried)	SGA, FGA	SGA, FGA, LAIA
Third-line	Clozapine	Clozapine	Clozapine
Fourth-line	Clozapine augmentation	--	Any of the above or augmentation

NICE = National Institute for Health and Care Excellence; CSG = Canadian Schizophrenia Guidelines; APA = American Psychiatric Association; SGA = second generation antipsychotic; FGA = first generation antipsychotic; LAIA = long-acting injectable antipsychotic

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Olanzapine and samidorphan (OLZ/SAM)

olanzapine

- Second-generation (atypical) antipsychotic FDA approved in 1996
- Lower all-cause discontinuation and discontinuation due to lack of efficacy?
- One of the most common limitations of use is secondary weight gain

samidorphan

- Antagonist at μ-opioid receptors and partial agonist at κ- and δ-opioid receptors
- Chemically most similar to naltrexone
- Max opioid blocking at 10 mg, T-max 1 hour, half-life 7-9 hours, metabolized by CYP3A4

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ENLIGHTEN-1 trial

Design	4-week, P3, double-blind, randomized, active- and placebo-controlled study in adults experiencing an active exacerbation of schizophrenia
	Randomized 1:1:1 to OLZ/SAM (10 mg-10 mg or 20 mg-10 mg), olanzapine (10 or 20 mg), or placebo administered orally, once daily
Primary endpoint	Change from baseline in Positive and Negative Syndrome Scale (PANSS) total score at week 4
Secondary endpoints	Change from baseline in CGI-S score, change from baseline in scores on PANSS subscales, the proportion of PANSS responders, and safety evaluations
Inclusion criteria	DSM-5 dx Schizophrenia and met criteria for an acute exacerbation or relapse; PANSS ≥80 with a score ≥4 on at least 3 of the following: delusions, conceptual disorganization, hallucinatory behavior, or suspiciousness/persecution; a CGI-S score ≥4 at baseline; BMI 18-40
Exclusion criteria	Treatment naïve or initiation within past year; h/o OLZ, mesoridazine, chlorpromazine, thioridazine or a LAIA within 6 months; h/o clozapine; h/o inadequate response to OLZ; use of opioid agonists within 14 days or opioid antagonists within 60 days; positive UDS; use of weight-loss meds

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Results

Efficacy endpoints	OLZ/SAM n = 132	OLZ n = 132	Placebo n = 133
PANSS Score, ±SD Baseline Mean change at week 4	 101.8 ± 11.6 -23.7 ± 12.6	 100.6 ± 12.1 -22.4 ±13.6	 102.7 ± 11.9 -19.4 ± 14.8
p value vs placebo	< 0.001	0.004	--
CGI-S Score, ±SD Baseline Mean change at week 4	 5.1 ± 0.7 -1.2 ± 0.9	 5.1 ± 0.7 -1.3 ± 1.0	 5.1 ± 0.7 -0.9 ± 1.0
p value vs placebo	0.002	< 0.001	--
PANSS Responders, n (%)	79 (59.8)	71 (53.8)	51 (38.3)
p value vs placebo	< 0.001	0.015	--

	OLZ/SAM n = 132	OLZ n = 132	Placebo n = 133
Weight, kg Baseline Mean change at week 4 ±SD	 77.9 3.02 ± 3.56	 82.2 2.38 ± 3.65	 76.6 0.24 ± 2.76
Baseline BMI, kg/m2	26.3	27.5	25.9
Baseline BMI ≥30 kg/m2, n (%)	28 (20.9)	46 (34.6)	30 (22.4)

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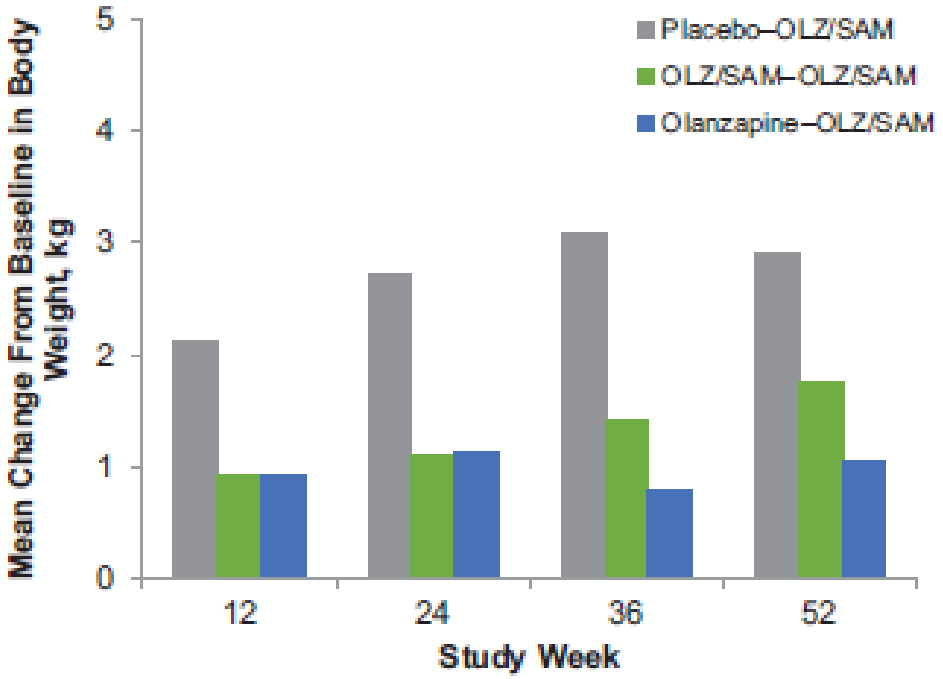
Extension trial

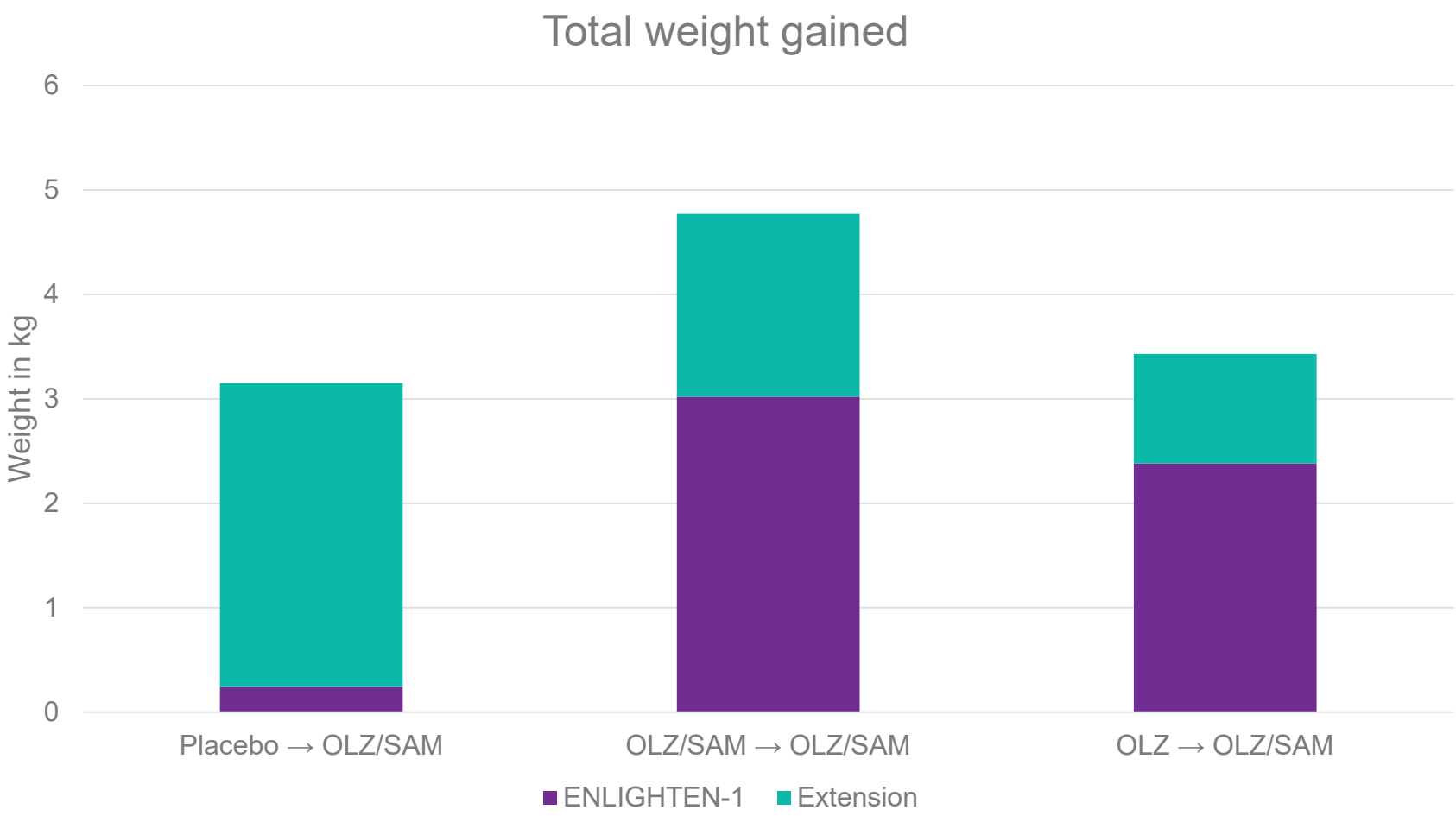
ENLIGHTEN-1

Portion of patients with weight gain ≥ 7% = 27.6% (75/272)

ENLIGHTEN-1	Mean Weight Gain, kg
OLZ/SAM	3.02 ± 3.56
OLZ	2.38 ± 3.65
Placebo	0.24 ± 2.76



ENLIGHTEN-1 plus Extension results



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ENLIGHTEN-2 trial

Design	24-week, phase 3, double-blind, randomized, active-controlled study in adults with stable schizophrenia
	Randomized 1:1 to OLZ/SAM (10 mg-10 mg or 20 mg-10 mg) or olanzapine (10 or 20 mg)
Co-Primary endpoints	Percent change from baseline in body weight
	Proportion of patients with ≥10% weight gain
Secondary endpoints	Proportion of patients with ≥7% weight gain and adverse drug reactions
Inclusion criteria	DSM-5 dx Schizophrenia; BMI 18-30; no hospitalizations for acute exacerbations of schizophrenia within 6 months; maintained a stable body weight (change </= 5%) for at least 3 months
Exclusion criteria	Treatment naïve or initiation of first treatment within past 1 year; h/o treatment resistant schizophrenia, use of olanzapine within 60 days; use of opioid agonists within 14 days or opioid antagonists within 60 days; active substance use disorders

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Results

	OLZ/SAM n = 274	OLZ n = 276	p-value
Mean baseline weight, kg	77.2	77.6	--
Co-Primary Endpoints			
Percent change in body weight, kg, LS mean (SE)	4.21 (0.681)	6.59 (0.668)	0.003
Patients with ≥10% weight gain, %	17.8	29.8	
Secondary Endpoints			
Patients with ≥7% weight gain, %	27.5	42.7	0.001
Mean change in body weight, kg	3.18	5.08	--

Common ADR, %	OLZ/SAM	OLZ
Weight increase	24.8	36.2
Somnolence	21.2	18.1
Dry mouth	12.8	8.0
Increased appetite	10.9	12.3

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Cost

Drug	Strength and Dosage Form	Cost per Unit	Cost per 30 days
olanzapine-samidorphan	olanzapine 5-20 mg with samidorphan 10 mg	TBD	TBD
aripiprazole (**Abilify**)	Tablets: 2mg, 5mg, 10mg, 15gm, 20mg, 30mg Solution: 1mg/mL	MAC = $0.24 - $0.68 MAC = $1.99/mL	$7- $20 $597 - $1,791
clozapine (**Clozaril**)	Tablet: 25 mg, 50 mg, 100 mg, 200 mg ODT: 12.5 mg, 25 mg, 100 mg, 150 mg, 200 mg Versacloz Suspension: 50 mg/1 mL	MAC = $0.49 - $1.69 MAC = $2.23 - $21.95 AWP = $9.62/mL	$44 - $456 $134 - $2,634 $1,732 - $5,195
olanzapine (**Zyprexa**)	Tablet: 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg ODT: 5 mg, 10 mg, 15 mg, 20 mg	MAC = $0.14 - $0.43 MAC = $0.68 - $1.09	$4 - $13 $20 - $110
paliperidone (**Invega**)	ER Tablet: 1.5 mg, 3 mg, 6 mg, 9 mg	MAC = $7.99 - $11.99	$240 - $719
quetiapine (**Seroquel**)	Tablets: 25mg, 50mg, 100mg, 200mg, 300mg, 400mg XR Tablets: 50mg, 150mg, 200mg, 300mg, 400mg	MAC = $0.11 - $0.37 MAC = $0.28 - $0.69	$4 - $22 $8 - $41
risperidone (**Risperdal**)	Tablets: 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, 4 mg Solution: 1mg/mL ODT: 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, 4 mg	MAC = $0.09 - $0.24 MAC = $0.44/mL MAC = $1.15- $3.69	$3 - $29 $79 - $211 $35 - $443
ziprasidone (**Geodon**)	Capsule: 20 mg, 40 mg, 60 mg, 80 mg	MAC = $0.38 - $0.48	$23 - $29
Caplyta (lumateperone)	Capsule: 42 mg	AWP =$52.80	$1,584
Fanapt (iloperidone)	Tablet: 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, 12 mg Tablet dispense pack: 1-2-4-6 mg	AWP = $25.43 - $50.10	$1,526 - $3,006
Latuda (lurasidone)	Tablets: 20mg, 40mg, 60mg, 80mg, 120mg	AWP = $51.34 - $76.63	$1,540 - $3,080
Rexulti (brexpiprazole)	Tablet: 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, 4 mg	AWP = $46.60 (parity)	$1,398
Saphris (asenapine)	SL Tablet: 2.5mg, 5mg, 10mg	AWP = $21.94 - $24.02	$1,316 - $1,441
Secuado (asenapine)	Patch: 3.8 mg, 5.7 mg, 7.6 mg	AWP= $48/patch	$1,440
Vraylar (cariprazine)	Capsules: 1.5 mg, 3 mg, 4.5 mg, 6 mg Capsule dispense pack: 1.5 mg-3 mg	AWP = $49 (parity)	$1,441

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Key Takeaways

PDUFA	Manufacturer	Drug Class	Proposed Indications	Studied Dosing
Nov 15, 2020	Alkermes plc	Atypical antipsychotic and opioid receptor modulator combination	Schizophrenia and Bipolar I disorder	olanzapine 5, 10, 15, or 20 mg with samidorphan 10 mg orally once daily

- **Efficacy:**
  - Addition of samidorphan does not hinder or enhance the antipsychotic efficacy of olanzapine
  - Samidorphan may attenuate some of the weight gain associated with olanzapine, but does not completely prevent any weight gain
- **Safety:**
  - Similar ADR profile to olanzapine with some increase in somnolence and dry mouth
- **Place in therapy:**
  - Likely place in therapy will be for those who are olanzapine naïve
  - More data is needed to establish target populations with most benefit
- **Proposed plan:**
  - Implement PA to establish step therapy and appropriate use

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Questions?

Thank you.

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4Q20: New Entities

Dojolvi (triheptanoin) Review

P&T: OCTOBER 16, 2020

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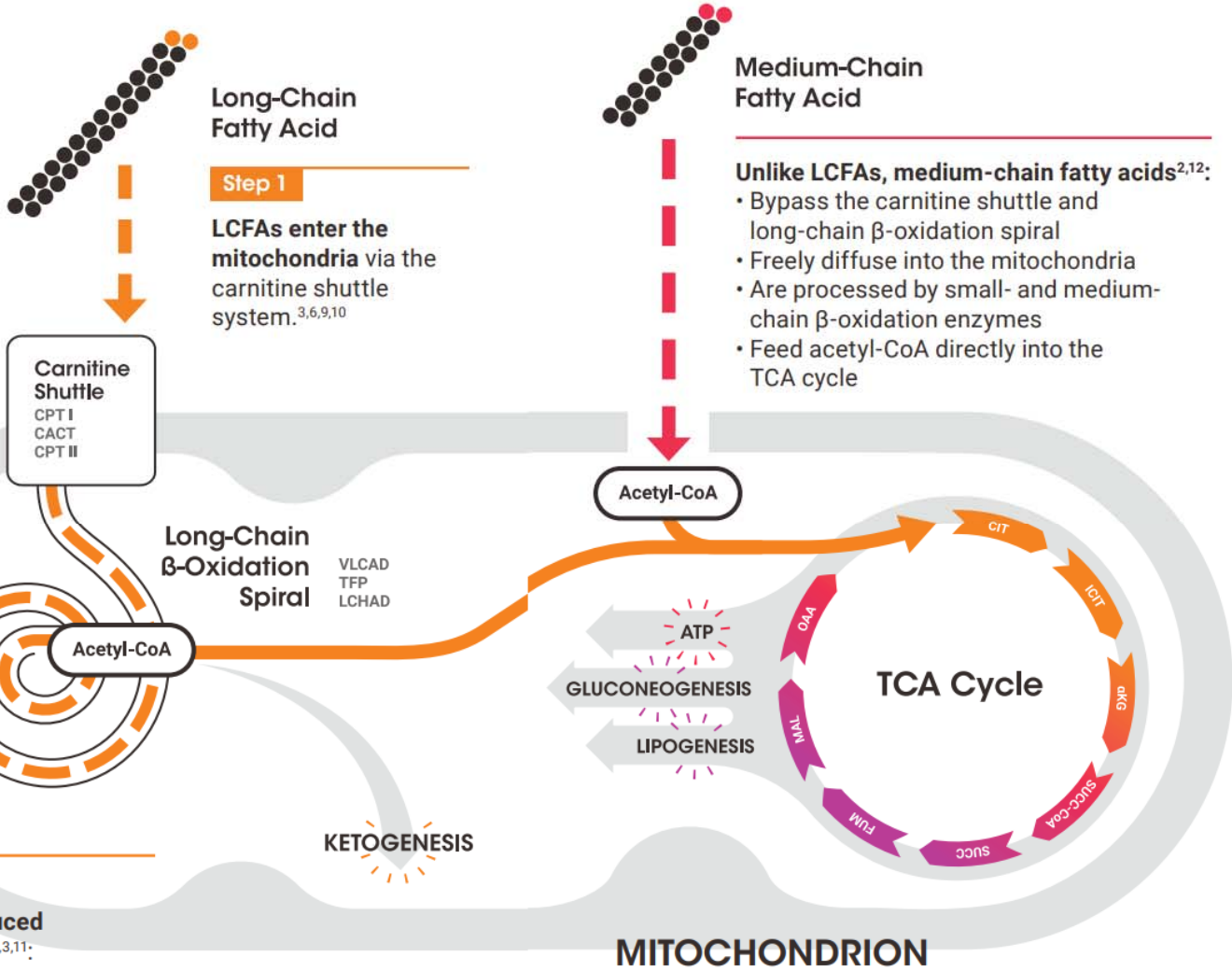
Background

Multiple processes drive healthy fatty acid oxidation

Fatty acids are a major energy source for the heart, skeletal muscle, and liver. This energy is vital during periods of fasting, when glucose is unavailable, and during times of physiological stress.[1-6]

Metabolism of long-chain fatty acids (LCFAs) to support energy production centers around oxidation of acetyl-CoA to CO_2 in the mitochondrial tricarboxylic acid (TCA) cycle.[2,7,8]



Step 2

LCFAs are metabolized by long-chain–specific enzymes in the long-chain β-oxidation spiral.[3,5]

Step 3

Acetyl-CoA is produced and then can either[2,3,11]:
- Divert to the liver for ketogenesis
- Enter the TCA cycle to generate ATP through oxidative phosphorylation

Image from: FAOD in Focus. https://www.faodinfocus.com/hcp/mechanism-of-disease/.

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Background

Long-chain fatty acid oxidation disorders : a group of rare, life-threatening autosomal recessive genetic disorders in which the body is unable to convert long-chain fatty acids into energy

Epidemiology

- Prevalence: affects 2,000-3,500 Americans
- Incidence: roughly 100 births per year have a confirmed LC-FAOD diagnosis

Diagnosis

- Involves measurement of acylcarnitine levels (typically by newborn screening), followed by
- Analysis of enzymatic activity in cultured fibroblasts (if the acylcarnitine profile is abnormal), and
- Genetic testing to determine the underlying molecular defect

Clinical Presentation

- Ranges from severe/life-threatening neonatal cardiomyopathy, hypoglycemia, and hepatomegaly to milder skeletal myopathy and exercise intolerance in adolescents/adults
- Episodic attacks of fatigue and rhabdomyolysis provoked by fatty acid release from endogenous stores, such as during exercise, febrile illness, or fasting
- Sudden death can occur at any point in disease course

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Background

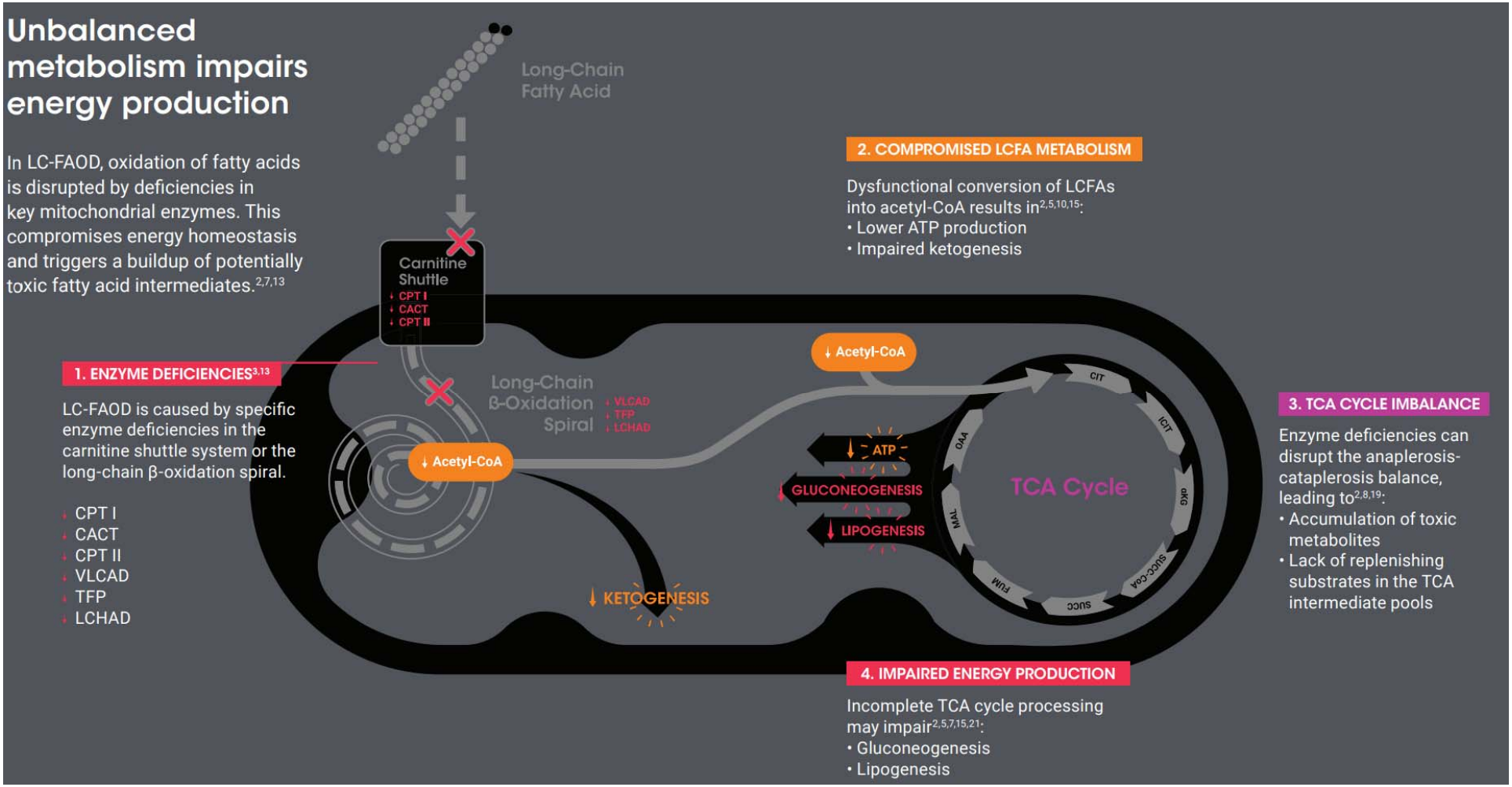

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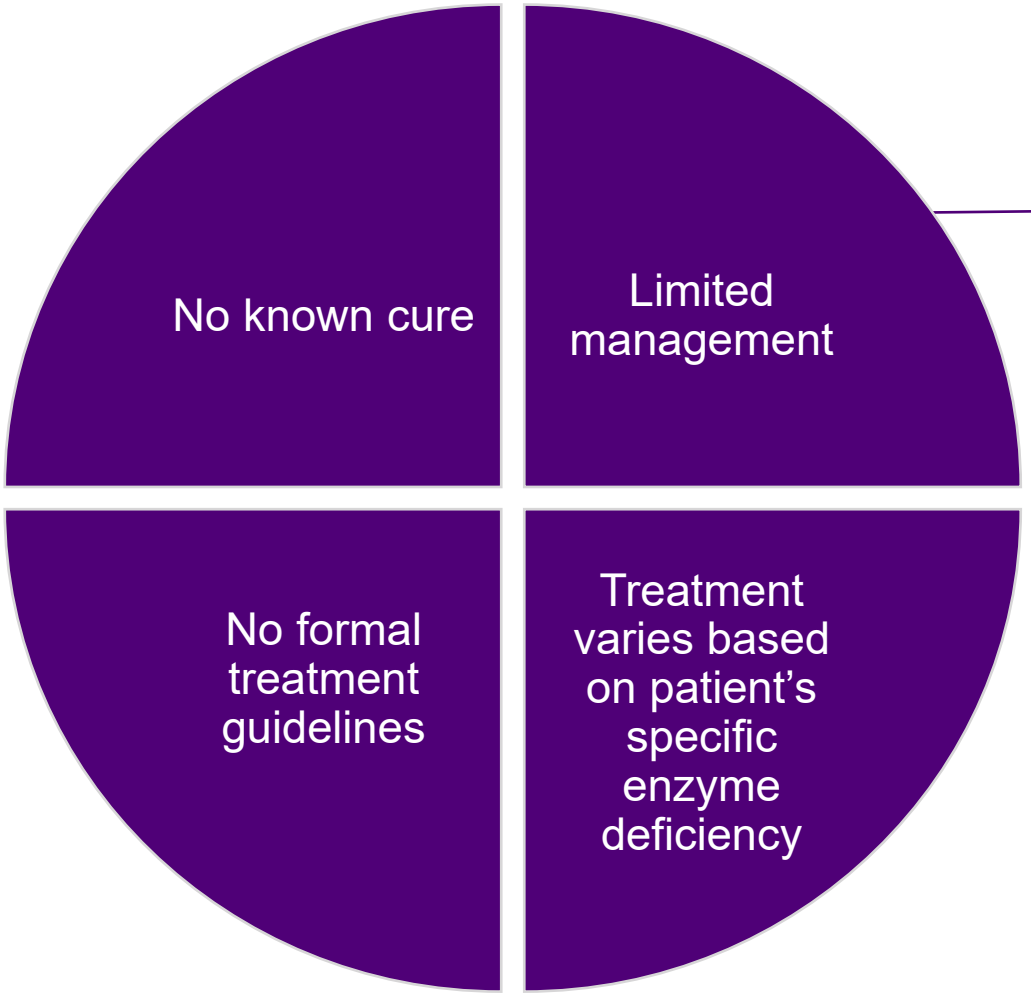
Image from: FAOD in Focus. https://www.faodinfocus.com/hcp/mechanism-of-disease/.

Management



- **Lifestyle approaches**
  - Avoidance of fasting and exercise
- **Dietary strategies**
  - Low-fat/high carbohydrate diets
  - Symptomatic patients are usually supplemented with MCT (OTC preparations are a mixture of **even-carbon** fatty acid chains, mostly C8)

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MCT: medium-chain triglyceride

Dojolvi (triheptanoin)

FDA Approval and Indication

- June 30, 2020: Indicated as a source of calories and fatty acids for the treatment of pediatric and adult patients with molecularly confirmed long-chain fatty acid oxidation disorders (LC-FAOD)

Drug Class/Mechanism

- Synthetic MCT consisting of 3 **odd-chain** 7-carbon (C7) length fatty acids specifically designed to provide a metabolite replacement and energy source

Dosing and Administration

- Up to 35% of the patient's total prescribed daily caloric intake divided into ≥4 doses and given with meals or snacks orally or enterally
- Comes as a 500 mL bottle that supplies 8.3 kcal/mL
- Patients receiving another MCT product should discontinue that product prior to initiating Dojolvi

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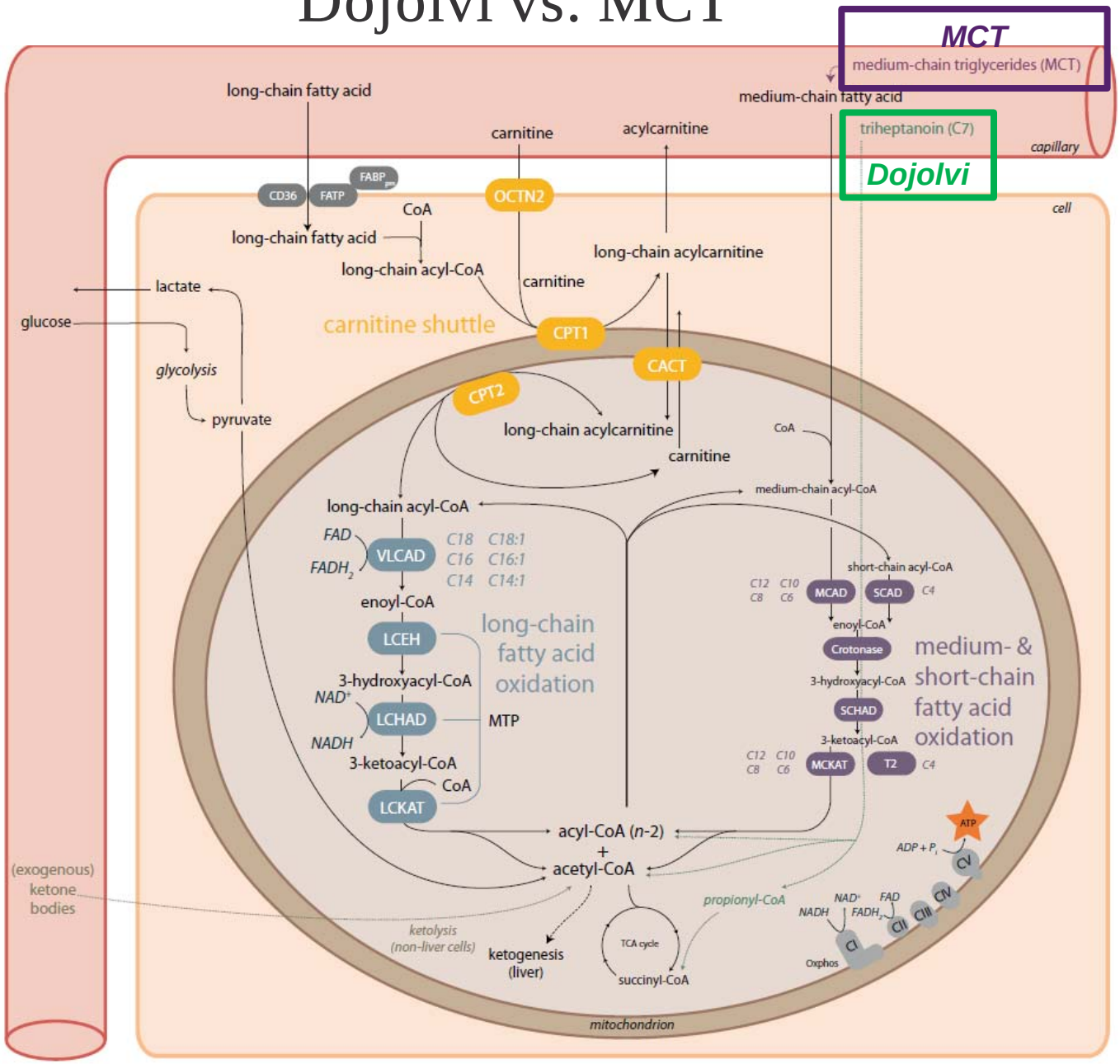
MCT: medium-chain triglyceride

Dojolvi vs. MCT



- **MCT** contains a varied mixture of **even-carbon** fatty acid chains and generates **acetyl-CoA** alone.
- **Dojolvi** contains **odd-numbered carbon** chains and provides substrates for both **acetyl-CoA** (to initiate the TCA cycle) and **propionyl-CoA** (which additionally replenishes TCA cycle substrates in a process known as anaplerosis) to sustain cycle function.

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Image from: Knottnerus S et al. 2018;19:93-106.

Study Design

Design	**Study 3:** Phase 2, 4-month, double-blind, randomized controlled study	
Inclusion	Confirmed diagnosis of LC-FAOD, as evidenced by: **at least one significant episode of rhabdomyolysis** AND **at least two** of the following diagnostic criteria:	1) disease-specific elevations of acylcarnitines on a newborn blood spot or in plasma, 2) low enzyme activity in cultured fibroblasts, or 3) one or more known pathogenic mutations in *CPT2*, *ACADVL*, *HADHA*, or *HADHB*
Exclusion	Anemia (Hgb <10 g/dL), peripheral neuropathy limiting the ability to walk, pregnancy, breastfeeding, and history of MI	

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Results

Intervention	**1:1** Dojolvi (contains 7-carbon chain fatty acids) or trioctanoin (consists of 8-carbon chain fatty acids)
	At baseline, patients had been on low-fat diets supplemented with commercial MCT oil.
	Dosage of study drug was titrated to a protocol-specified target of 20% DCI, whereas the recommended target dosage of Dojolvi is up to 35% of DCI. (The actual mean daily dose achieved was 16% for Dojolvi and 14% for trioctanoin.)
Efficacy Endpoints	Primary outcomes included changes in cardiac function by echocardiogram and exercise tolerance.

Outcome Measure	Dojolvi (n=16)	MCT Oil (n=16)
Change in LVEF from baseline at month 4, mean % (SD)*	2.14 (4.43)	-1.91 (4.16)
Change in TEE from baseline at month 4, mean kg/d (SD)	100.7 (374.7)	-68.1 (323.7)

Note: Only patients with available data were included in each analysis.

**Both baseline values and retest values were within normal range, and changes were within the test/retest variability normally observed in repeated ECHOs. No patients developed cardiomyopathy or had worsening of cardiac function during the trial.*

There were no clinically meaningful differences between the treatment arms.

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DCI: daily caloric intake; LVEF: left ventricular ejection fraction; TEE: total energy expenditure

Safety

- **BBW/Contraindications:** none
- **Warnings/Precautions:**
  - Feeding tube dysfunction
  - Intestinal malabsorption in patients with pancreatic insufficiency
- **Most common adverse events (N = 79, pooled from Studies 1 and 2):**
  - Abdominal pain (60%)
  - Diarrhea (44%)
  - Vomiting (44%)
  - Nausea (14%)
- GI-related adverse reactions led to dose reductions in 35% and 12% of patients in Study 1 (OL, 78 weeks, N=29) and Study 2 (OLE, N=24), respectively.
- Two deaths occurred in Study 2; both were deemed unrelated to Dojolvi and attributed to complications from LC-FAOD
- Commonly reported adverse reactions in Study 3 were similar to those reported in Study 1 and Study 2.
  - Rates of rhabdomyolysis were similar between treatment arms in Study 3: 5 patients experienced 7 events in the Dojolvi group, and 4 patients experienced 7 events in the trioctanoin group.

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OL: open-label; OLE: open-label extension

Costs

Drug	Target Daily Dosage	Cost per Unit	Cost per Year
Dojolvi (triheptanoin) Oral liquid, 100% w/w of tripheptanoin (500 mL bottle)	Up to 35% of the patient's total prescribed daily caloric intake divided into at least four doses and administered with meals or snacks*	AWP = $11.70/mL ($5,850/bottle)	Per the manufacturer: • **Infants:** average net price is $46,000 for the first year of life • **Adults:** average net price will be $138,000 annually
MCT oil	OTC		
** Dojolvi should be given either orally (mixed with semi-solid food or liquids) or enterally via a silicone or polyurethane feeding tube.*			

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Key Takeaways

Drug	Drug Class	Approved Indication	Approved Dosage
Dojolvi (triheptanoin)	MCT, synthetic (odd-chain)	Indicated as a source of calories and fatty acids for the treatment of pediatric and adult patients with molecularly confirmed long-chain fatty acid oxidation disorders (LC-FAOD)	Up to 35% of the patient's total prescribed daily caloric intake

Efficacy

Efficacy data is available for a small set of patients over a limited duration—differences between the treatment arms (Dojolvi vs. MCT oil) were not clinically meaningful in terms of cardiac function and exercise tolerance; FDA noted that some data were of questionable clinical relevance given all patients had normal ECHO evaluations at baseline and changes on repeat testing were within normally observed test/retest variability

Safety

Generally well-tolerated—mostly caused gastrointestinal adverse effects (as can be expected from oil/fat); rates of rhabdomyolysis were similar between treatment arms

Place in Therapy

First FDA-approved agent for treatment of LC-FAOD, a family of rare, life-threatening genetic disorders where the body is unable to convert long-chain fatty acids into energy

- Provides substrates for both acetyl-CoA (to initiate the TCA cycle) and propionyl-CoA (which replenishes TCA cycle intermediates) as opposed to conventional MCT (which only generates acetyl-CoA)
- Essentially offers a pharmaceutical grade alternative to MCT medical food products – may be especially beneficial in those who prove refractory to conventional MCT preparations

Utilization Management

Proposing PA to promote appropriate use and in consideration of substantial cost differential between Dojolvi and conventional MCT oil

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MCT: medium-chain triglyceride; TCA: tricarboxylic acid

Therapeutic Designation

Market Basket: LC-FAOD		
Drug Name	**Therapeutic Designation**	**Rationale**
Dojolvi (triheptanoin)	Novel	Unique place in therapy as sole FDA-approved therapy in this space

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Dojolvi (triheptanoin)

- **Prior Authorization: NEW**
  - **Diagnosis:** LC-FAOD
  - **Other criteria:**
    - Diagnostic confirmation by documentation of at least **two** of the following:
      - 1) disease-specific elevations of acylcarnitines on a newborn blood spot or in plasma,
      - 2) low enzyme activity in cultured fibroblasts, or
      - 3) one or more known pathogenic mutations in *CPT2*, *ACADVL*, *HADHA*, or *HADHB*
    - Patient is symptomatic (e.g. rhabdomyolysis, cardiomyopathy) for LC-FAOD
  - **Prescriber edit:** by or in consultation with gastroenterologist or physician specialist in medical genetics/inherited metabolic disorders
  - **Step therapy:** trial of or contraindication to commercial MCT oil (medical food product)
  - **Duration:** initial: 4 months; renewal: 12 months
  - **Renewal:**
    - Physician attestation of positive clinical response (e.g. improved exercise tolerance) or stabilization of clinical status compared to baseline

Rationale: FDA-approved labeling, clinical trial design, typical management of LC-FAOD; QL not feasible as dosing depends on prescribed daily caloric intake

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LC-FAOD: long-chain fatty acid oxidation disorder; MCT: medium-chain triglyceride

4Q20 P&T: Viloxazine ER

OCTOBER 16, 2020

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Viloxazine Extended-Release (ER)

PDUFA:

- November 8, 2020

Manufacturer:

- Supernus Pharmaceuticals, Inc.

Proposed Indication:

- Attention Deficit Hyperactivity Disorder (ADHD) in children and adolescents

Drug class:

- Serotonin-norepinephrine modulating agent (SNMA)

Proposed dosing:

- 100-400 mg orally once daily

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Background

Epidemiology	Etiology
• Estimated in up to 11% of ages 4-17 years and 4% of adults • More commonly diagnosed in boys (2:1)	• Genetic: 2-8-fold risk if parent or sibling is diagnosed with ADHD • Neurobiology: hypoactivity of dopamine (DA) and norepinephrine (NE) in frontal-subcortical circuits

- Diagnosis
  - A. A persistent pattern of attention and/or hyperactivity-impulsivity that interferes with functioning or development, as characterized by (1) and/or (2):
    1. Inattention – 6 or more symptoms that have persisted for at least 6 months
    2. Hyperactivity and impulsivity – 6 or more symptoms have persisted for at least 6 months
       - a. Symptoms are inconsistent with developmental level, with direct negative impact on social and academic/occupational activities
       - b. Only 5 symptoms are needed for ages 17 years and older
  - B. Several inattentive or hyperactive-impulsive symptoms were present prior to age 12
  - C. Several inattentive or hyperactive-impulsive symptoms are present in 2 or more settings
  - D. There is clear evidence that the symptoms interfere with or reduce the quality of social academic or occupational functioning
  - E. The symptoms do not occur exclusively during the course of schizophrenia or another psychotic disorder and are not better explained by another mental disorder

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Clinical manifestations

Attention

a. Fails to give close attention to details or makes careless mistakes
b. Has difficulty sustaining attention in tasks or play activities
c. Does not seem to listen when spoken to directly
d. Does not follow through on instructions and fails to finish schoolwork, chores or duties in the workplace
e. Has difficulty organizing tasks and activities
f. Avoids, dislikes or is reluctant to engage in tasks that require sustained mental effort
g. Loses things necessary for tasks or activities
h. Is easily distracted by extraneous stimuli
i. Is forgetful in daily activities

Hyperactivity/Impulsivity

a. Often fidgets with or taps hands or feet or squirms in seat
b. Often leaves seat in situations when remaining seated is expected
c. Often runs about or climbs in situations where it is inappropriate
d. Often unable to play or engage in leisure activities quietly
e. Is often “on the go,” acting as if “driven by a motor”
f. Often talks excessively
g. Often blurts out an answer before a question has been completed
h. Often has difficulty waiting his or her turn
i. Often interrupts or intrudes on others

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Guidelines

Level	American Academy of Pediatrics (AAP) 2019	National Institute for Health and Care Excellence (NICE) 2018
First-line	• Ages 4-6: behavior therapy • Ages 6-12: FDA-approved med, along with behavior therapy • Ages 12-18: FDA-approved med, behavior therapy is encouraged	• ≤ 5 years: ADHD-focused parent training • > 5 years: ADHD focused info and support • Adults: MPH or lisdexamfetamine
Second-line	• Ages 4-6: MPH	• ≤ 5 years: meds after second consultant • > 5 years: MPH • Adults: MPH or lisdexamfetamine
Third-line	--	• > 5 years: lisdexamfetamine • Adults: dexamfetamine
Fourth-line	--	• > 5 years: dexamfetamine • Adults: atomoxetine
Fifth-line	--	• > 5 years: atomoxetine or guanfacine

MPH = methylphenidate and dexmethylphenidate

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Viloxazine – What's New?

Bicyclic antidepressant developed in the 1970s

Mechanism of action

- "Selective" NE reuptake inhibitor
- Serotonin receptor modulator

Half-life

- IR vs ER formulation

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Phase 3 trials summary

Design	Randomized, double-blind, placebo-controlled, multicenter, parallel-group study in pediatric patients with DSM-5 diagnosis of ADHD
	P301 and P302: 6-week duration, P303: 8-week duration, P304: 7-week duration
Primary endpoint	Change from baseline to end of study in the ADHD-RS-5 total score • ADHD-RS-5 scale comes in child and adolescent versions with parent and teacher questionnaires • Scoring and interpretation is based on gender and age
Inclusion	P301/303: Age 6-11 years and $\geq$ 20 kg; P302/304: 12-17 years and $\geq$ 35 kg
	ADHD-RS-5 score $\geq$ 28
	Free of ADHD treatment meds for at least 1 week prior
Exclusion	Concurrent major psychiatric or neurologic disorder
	Evidence of suicidality
	BMI greater than 95th percentile for age and gender
	Positive drug screen (amphetamines allowed if taking stimulant)

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Efficacy

Primary endpoint: ADHD-RS-5 total score, change from baseline			
P301, n=477	**100 mg**	**200 mg**	**Placebo**
ADHD-RS-5 total score	-16.6	-17.7	10.9
P-value	0.004	<0.001	--
Effect size	0.54	0.57	--
P303, n=313	**200 mg**	**400 mg**	**Placebo**
ADHD-RS-5 total score	-17.6	-17.5	-11.7
P-value	0.0058	<0.0121	--
Effect size	0.46	0.49	--
P302, n=310	**200 mg**	**400 mg**	**Placebo**
ADHD-RS-5 total score	-16.0	-16.5	-11.4
P-value	0.0232	0.0055	--
Effect size	0.47	0.50	--
P304, n=297	**400 mg**	**600 mg**	**Placebo**
ADHD-RS-5 total score	-18.3	-16.7	-13.2
P-value	0.0082	0.0712	--
Effect size	0.66	--	--

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Safety

	P301	P303	P302	P304
Treatment related AEs reported ≥ 5%	Somnolence, fatigue, decreased appetite, headache, upper abdominal pain		Somnolence, fatigue, decreased appetite, headache, nausea	
Discontinuation rates due to AEs	2.2% - 4.8%		1.9% - 4.1%	4.0% - 5.1%

- **Viloxazine IR history**
  - **Most common adverse effects (AEs):** nausea and vomiting
  - **Other:** dry mouth, dizziness, headache, drowsiness, sleep disturbances, anorexia, heartburn, indigestion, constipation, diarrhea, tremor, dyskinesia, confusion, restlessness, irritability, hypomania and mania, palpitation, tachycardia, increased and decreased blood pressure, pruritus and skin rashes
- **Strattera (children and adolescents)**
  - **Incidence ≥ 5%:** abdominal pain, nausea, vomiting, fatigue, irritability, decreased appetite, headache, somnolence, dizziness

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Cost & Formulary management

Market Basket: ADHD Non-Stimulants				
Drug	**Portfolio/ MedPerform**	**HIEX**	**Medicaid**	**Part D**
atomoxetine (generic for **Strattera**)	F, QL	F, QL	F, QL	G-H, QL
clonidine ER (generic for **Kapvay**)	F, QL	F, QL	F, QL	G-PPVH
guanfacine ER (generic for **Intuniv**)	F, QL	F, QL	F, QL	G-M

Drug	Dosing*	Cost per Unit	Cost per 30 days**
atomoxetine (generic for **Strattera**) 10, 18, 25, 40, 60, 80, 100 mg capsule	Up to 70 kg: 0.5-1.4 mg/kg; max 100 mg/d Greater than 70 kg: 40-100 mg once daily	MAC = $1.99-2.98/capsule	$89
clonidine ER (generic for **Kapvay**) 0.1 mg tablet	0.1-0.4 mg/day once to twice daily	MAC = $0.99/tablet	$30
guanfacine ER (generic for **Intuniv**) 1, 2, 3, 4 mg tablet	Monotherapy: 1-7 mg once daily Adjunctive therapy: 1-4 mg once daily	MAC = $0.34-0.59/tablet	$18

*Pediatric dosing
**Based on max pediatric dosing

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Key takeaways

PDUFA	Manufacturer	Drug Class	Proposed Indication	Studied Dosing
Nov 8, 2020	Supernus Pharmaceuticals, Inc.	Serotonin-norepinephrine modulating agent (SNMA)	ADHD in children and adolescents	100-400 mg orally once daily

- **Efficacy:**
  - Slightly lower effect size (ES) ranging from 0.46-0.66 compared to other commercially available non-stimulants – ES 0.7 for Strattera, Intuniv, and Kapvay
- **Safety:**
  - Generally well-tolerated with substantial clinical use in other countries for years
  - Slightly less GI-related ADRs with ER formulation
- **Place in therapy:**
  - First novel non-stimulant for ADHD in almost a decade
  - Likely to be an option for those with failure or contraindication to other non-stimulants
- **Proposed plan:**
  - UM to align with current non-stimulants for ADHD
  - Management with step therapy appropriate due to anticipated place in therapy

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Questions?

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4Q20 P&T: Prospective Drug Review

vibegron

OCTOBER 16, 2020

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vibegron

- **PDUFA**: December 26, 2020
- **Manufactured by**: Urovant Sciences
- **Proposed indication**: treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency and urinary frequency in adult patients
- **Mechanism of action**: β3 adrenergic receptor agonist, which leads to the relaxation of smooth muscle (detrusor) in the bladder and increases bladder capacity.
- **Proposed dosing**: 75 mg PO once daily

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Overactive Bladder (OAB)

- OAB occurs when the detrusor muscle inappropriately contracts regardless of the amount of urine in the bladder.
- Approximately 17% of the US population experience OAB with prevalence and symptom severity increasing with age.
- Defined as urinary urgency, frequency, and nocturia with (OAB wet) or without (OAB dry) urinary incontinence.

IUGA and ICS: terminology and definitions	
Urinary urgency	Sudden and compelling desire to void that is difficult to defer
Nocturia	Interruption of sleep due to the need to void
Urinary incontinence	Involuntary leakage of urine
Micturition frequency	Up to seven daytime micturition is considered normal

- Diagnosis is based on the presence of above symptoms and the exclusion of conditions that mimic OAB symptoms (e.g. urinary tract infection, bladder stones, bladder cancer, bladder inflammation)

Abbreviations: ICS = international continence society; IUGA = international urogynecological association

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OAB Treatment

- OAB can lead to significant impairments in quality of life (QoL), negatively impacting social activities, occupational activities, and mental health.
- Treatment aimed at improving QoL. The AUA/SUFA 2019 guideline for non-neurogenic bladder recommends the following:

1st line
- Behavioral intervention (e.g. fluid management, pelvic floor muscle training, bladder control strategies)

2nd line
- Oral & transdermal pharmacotherapy:
  - Antimuscarinics (ER > IR)
  - β3 adrenergic agonists

3rd line
- Intra-detrusor Botox injections
- Neuromodulation (PTNS, SNS)

Neurogenic OAB*:
- Viability of behavioral intervention dependent on degree of bladder control and intact bladder sensation
- Antimuscarinics > β3 adrenergic agonists due to limited trial experience in this patient population

**OAB due to brain, spinal cord or nerve issue; recommendations based on literature review and European urology guidelines*

Abbreviations: AUA = American Urological Association; PTNS = peripheral tibial nerve stimulation; SNS = sacral nerve stimulation; SUFA = Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction

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EMPOWUR: trail design & baseline demographics

- Design: double-blind, randomized, placebo and active controlled phase 3 trial

	EMPOWUR (N = 1463)
Duration	12-week randomized period
Intervention	vibegron 75 mg once daily
Control	Placebo or 4 mg tolterodine ER once daily
Inclusion	Adults with OAB (diagnosis at least 3 months prior to trial) 8 or more micturitions per day
Exclusion	Neurological injury or neurodegenerative disease
Co-primary endpoints	CFB in average number of daily micturitions CFB in average number of daily UUI (OAB wet population only)
Secondary endpoints	CFB in average volume voided per micturition
Baseline Demographics	213 patients (14.6%) were previously treated with antimuscarinics and 80 (5.5%) with Myrbetriq. In terms of OAB category; 77% had OAB wet and 23% had OAB dry at baseline.
Abbreviations: CFB = change from baseline; Dx = diagnosed; ER = extended-release; OAB = overactive bladder; UUI = urge urinary incontinence;	

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vibegron: efficacy

	Placebo (N = 520)	Vibegron (N = 526)	Tolterodine ER (N = 417)
Number of micturitions per day			
Baseline	11.8	11.4	11.5
Change from baseline	-1.3	-1.8	-1.6
LSMD vs. placebo	---	-0.5*	-0.3*
Number of UUI episodes per day (OAB wet patients only)			
Baseline	3.5	3.4	3.4
Change from baseline	-1.4	-2.0	-1.8
LSMD vs. placebo	---	-0.6*	-0.4*
Volume voided (mL) per micturition			
Baseline	Mean of 150.5 mL per micturition (NS between groups)		
Change from baseline	+2.2 mL	+23.5 mL	+15.5 mL
LSMD vs. placebo	---	+21.2 mL*	+13.3 mL*

**endpoints where statistically significant compared to placebo*

Abbreviations: ER = extended-release; NS = non-significant; OAB = overactive bladder; UUI = urge urinary incontinence

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Vibegron: safety

- Well-tolerated with similar discontinuation rates due to adverse events between vibegron (1.7%) and placebo (1.1%) groups.
- Mean blood pressure change with vibegron was 1.1/0.8 mm Hg (SBP/DBP) greater than placebo. Incidence of hypertension was identical in both groups (1.7% of patients).

Adverse Event (%)	Placebo (N = 540)	Vibegron (N = 545)
Headache	2.4	4.0
Nasopharyngitis	1.7	2.8
Diarrhea	1.1	2.2
Nausea	1.1	2.2
URTI	0.7	2.0
Constipation	1.3	1.7
Dry mouth	0.9	1.7

- vibegron compared to Myrbetriq:
  - Agents have similar side-effect profiles
  - Respective 52-week extension trials showed similar rates of hypertension
    - 8-11% (Myrbetriq) vs 9% (vibegron)
  - Drug-Drug interactions: Myrbetriq inhibits CYP2D6 unlike vibegron

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Cost: OAB agents

Drug	Dosing	Cost/unit	Cost per 28 days
vibegron 75 mg tablet	75 mg PO once daily	Under review by FDA for OAB	
Myrbetriq (mirabegron) 25 and 50 mg ER tablets	25 mg PO once daily; can increase to 50 mg if needed	AWP = $16.20/tablet	$454
Oxytrol^ (oxybutynin) 3.9 mg/day patch	Apply one patch topically twice weekly	AWP = $101.98/patch	$816
Ditropan (oxybutynin chloride) 5 mg/5 mL oral syrup 5 mg tablets 5, 10, and 15 mg ER tablets	IR: 5 mg PO 2 to 3 times daily ER: 5-10 mg PO once daily; titrate by 5 mg weekly (Max: ER-30 mg/day; IR/Peds-20 mg/day)	MAC = $0.04 to $0.06/mL $0.18/IR tablet $0.38 to $0.48/ER tab	$11 to $34 (syrup) $10 to $20 (IR) $11 to $27 (ER)
Gelnique (oxybutynin chloride) 100 mg/gm (10%) gel	Apply one gram (1 packet or actuation) topically once daily	AWP = $15.82/gram	$443
Detrol (tolterodine tartrate) 1 and 2 mg tablets	IR: 2 mg PO twice daily; can decrease to 1 mg if needed	MAC = $0.88 to $0.89/tablet	$49 to $50 (IR)
Detrol LA (tolterodine tartrate) 2 and 4 mg ER capsules	ER: 4 mg PO once daily; can decrease to 2 mg if needed	MAC = $1.19 to $1.88/capsule	$33 to $53 (ER)

^Oxytrol for Women (3.9 mg/day) is available over-the-counter and costs (AWP) between $2.98 and $3.30 per patch

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Cost: OAB agents continued

Drug	Dosing	Cost/unit	Cost per 28 days
Sanctura (trospium chloride) 20 mg tablets 60 mg ER capsules	IR: 20 mg twice daily ER: 60 mg once daily	MAC = $0.50 to $0.55/tablet $3.97/capsule	$28 to $31 (IR) $111 (ER)
Enablex (darifenacin hydrobromide) 7.5 and 15 mg ER tablets	7.5 mg once daily; can increase to 15 mg if needed	MAC = $3.99 to $4.87/tablet	$112 to $136
Vesicare^ (solifenacin succinate) 5 and 10 mg tablets	5 mg once daily; can increase to 10 mg if needed	MAC = $0.48/tablet	$13
Toviaz (fesoterodine fumarate) 4 and 8 mg ER tablets	4 mg once daily; can increase to 8 mg if needed	AWP = $13.93/tablet	$390

^Vesicare LC (Solifenacin Succinate), a 5 mg/5 mL oral solution, was FDA approved 5/26/20. Pricing is not yet available.

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BOARD CERTIFIED UROLOGIST

External Review: vibegron

Management of OAB	I tend to avoid oxybutynin 5 mg since its dosing schedule is three times daily. I prefer long acting drugs.
	Does treatment paradigm differ for neurogenic OAB? With neurogenic patients, I do not care about conservative measures.
	Combination of antimuscarinic and β3 agonist? Rarely [utilized]. I prefer one drug at a time for the same condition
	Place in therapy for vibegron? With similar efficacy and adverse effect profile to Myrbetriq, it will likely be a matter of which drug is on different formularies and cost.
Utilization management	**vibegron candidate?** Those patients that do not tolerate standard anticholinergic drugs or are at risk for adverse effects.
	β3 agonist step therapy? Most plans require two antimuscarinic trials. Occasionally, only one and some require three.
	Different strategy for neurogenic and non-neurogenic OAB? No. Most plans use the same utilization strategies for both.

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vibegron summary

- If approved, vibegron will join Myrbetriq (mirabegron) as a β3 adrenergic agonist indicated for OAB.

Efficacy:

- Vibegron was found to be superior to placebo
- Efficacy of antimuscarinic and beta-3 adrenergic agonists appear comparable

Safety:

- Vibegron was well tolerated with low discontinuation due to adverse events
- No major concerns for BP changes or incidence of hypertension
- Similar adverse effect profile to Myrbetriq

Utilization management (UM):

- To align with Myrbetriq's approved UM
- When agent comes in ER and IR formulations: ER > IR in US guidelines
- Neurogenic OAB: Antimuscarinics > β3 adrenergic agonists due to limited data of newer agents and based on recommendations in European guidelines

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Thank you. Questions?

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4Q20 P&T: Prospective Drug Review

vericiguat

OCTOBER 16, 2020

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vericiguat

- **PDUFA**: January 21, 2021
- **Manufactured by:** Merck and Bayer
- **Proposed indication**: to reduce the risk of cardiovascular death and hospitalization for HF in adults with HFrEF (NYHA II-IV)
- **Mechanism of action**: soluble guanylate cyclase (sGC) stimulator leading to vasodilation, improved endothelial function and eventually decreased fibrosis and heart remodeling.
- **Proposed dosing**: initiate at 2.5 mg PO QD then titrate to 5 mg and 10 mg in two-week intervals

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Heart Failure Background

- Heart failure (HF) is a common clinical syndrome that results from a structural or functional impairment of ventricular filling or ejection of blood

HFrEF	**EF ≤40%**	**Target population for most randomized controlled trials. Multiple agents indicated to improve CV mortality and/or hospitalization due to HF. A subset of patients may subsequently experienced improved EF and be classified as having HFrecEF.**
HFmrEF	EF 41 to 49%	An intermediate group that can dynamically transition into HFpEF and HFrEF. Treatment pattern for these patients depends on the direction of change in their EF.
HFpEF	EF ≥50%	No drugs have demonstrated mortality or morbidity benefit for this group. Treatment is focused on the management of associated conditions.

- **Prevalence/Incidence:**
  - ~6 million Americans have HF with ~750,000 newly diagnosed per year
  - Prevalence increases with age from 0.8% to 2% in general population to 10-20% in those that are over 70 years old
  - Risk of HF is 20-fold higher in people aged ≥60 years than in younger patients
- **Hospitalization:**
  - Approximately 1 million hospitalizations for HF each year:
    - 1-month readmission rate: 25%, 6-month readmission rate: 50%
  - Accounts for half the healthcare cost associated with HF treatment

Abbreviations: HF = heart failure; HFmrEF = heart failure with midrange ejection fraction; HFpEF = heart failure with preserved ejection fraction; HFrEF = Heart failure with reduced ejection fraction: HFrecEF = heart failure with recovered ejection fraction; RCT = randomized controlled trial

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Heart Failure Background Continued

- **Mortality:**
  - Absolute mortality rate for HF is around 50% within 5-years of diagnosis
  - Mortality rate after a hospitalization for HF at 30-days, 1-year, and 5-years post discharge are 10.4%, 22%, and 42.3%, respectively.

ACCF/AHA stages of HF		NYHA functional classification	
A	At high risk for HF but no structural heart disease or symptoms of HF	**None**	
B	Structural heart disease but without signs or symptoms of HF	**I**	No limitation of physical activity. Ordinary physical activity does not cause symptoms of HF.
C	Structural heart disease with prior or current symptoms of HF	**I**	No limitation of physical activity. Ordinary physical activity does not cause symptoms of HF.
		II	Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity results in symptoms of HF.
		III	Marked limitation of physical activity. Comfortable at rest, but less than ordinary activity causes symptoms of HF.
		IV	Unable to carry on any physical activity without symptoms of HF, or symptoms of HF at rest.
D	Refractory HF requiring specialized interventions	**IV**	Unable to carry on any physical activity without symptoms of HF, or symptoms of HF at rest.

Abbreviations: ACCF = American College of Cardiology Foundation; AHA = American Heart Association; HF = heart failure; NYHA = New York Heart Association

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Guideline Recommendations for HFrEF

- **Stage A**: optimize therapies for underlying cardiovascular disorders (e.g. diabetes, ASCVD, hypertension)
- **Stage B**: initiate ACEi or ARB ± beta-blocker (low-level evidence)
- **Stage C**: initiate ACEi or ARB + beta-blocker; add secondary agents or cardiac devices based on patient characteristics and history

Agent/Class	Patient Scenario	Considerations
Aldosterone antagonists (e.g. spironolactone)	NYHA II-IV; CrCl >30 mL/min; K+ <5.0 mEq/L;	A standard of care for eligible patients (triple therapy = ACEi/ARB/ARNI, BB, and MRA)
Entresto (sacubitril and valsartan)	NYHA II-III; adequate BP	Initiated as first-line in some clinics without ACEi/ARB trial
BiDil (hydralazine and isosorbide dinitrate)	NYHA III-IV; black patients	Poor adherence due to dosing frequency and high risk of adverse events
Corlanor (ivabradine)	NYHA II-III on maximally tolerated BB; HR ≥70 bpm; NSR	Reduces CV death/HF hospitalization only in patients taking <50% of BB target dose
digoxin	NYHA II-IV	Considered a last resort unless indicated due to comorbidities; narrow therapeutic index; decrease HF hospitalization only
Farxiga (dapagliflozin)	NYHA II-IV without CI (e.g. CrCl <30 mL/min)	Considered a SGLT-2 class effect; multiple mechanism theorized; Jardiance may soon have indication (RCT published 8/2020)

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Abbreviations: ACEi = angiotensin-converting enzyme inhibitor; ACCF = American College of Cardiology Foundation; AHA = American Heart Association; ARB = angiotensin receptor blocker; HF = heart failure; ARNI = angiotensin receptor-neprilysin inhibitor; *MRA = mineralocorticoid receptor antagonists; NYHA = New York Heart Association*

VICTORIA: trial design & baseline demographics

- Design: double-blind, randomized, placebo-controlled, time-to-event phase 3 trial

	VICTORIA (N = 5,050)
Intervention	vericiguat 2.5 mg once daily then titrated to 5 mg and 10 mg in two-week intervals (as tolerated by patient)
Inclusion	Adults with HF, EF ≤45% and NYHA class II to IV on standard of care (ACEi, ARB, BB, MRA and/or cardiac devices) BNP ≥300 pg/mL or NT-proBNP ≥ 1000 pg/mL Evidence of worsening HF (hospitalization ≤6 months or intravenous diuretics ≤3 months)
Exclusion	Long-acting nitrates; PDE-5 inhibitors; Adempas (riociguat)
Primary Endpoint	Composite: cardiovascular death or 1st hospitalization for HF
Secondary Endpoints	Components of primary outcome; total hospitalizations for HF events; death from any cause
Baseline Demographics	85.6% had EF <40%; ACEi/ARB (73.4%); ARNI (14.5%); beta-blocker (93.1%); MRA (70.3%); cardiac device (42.4%)

ACEi = angiotensin-converting enzyme inhibitor; ARB = angiotensin receptor blocker; ARNI = angiotensin receptor-neprilysin inhibitor; BB = beta-blocker; BNP = B-type natriuretic peptide; EF = ejection fraction; HF = heart failure; MRA = mineralocorticoid receptor antagonist; NT-proBNP = N-terminal pro-B-type natriuretic peptide; NYHA = New York Heart Association; PDE-5 = phosphodiesterase type 5

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VICTORIA: Efficacy in HFrEF

- Median follow-up was 10.8 months
- Primary Composite Endpoint: cardiovascular death OR first hospitalization for HF

Primary Outcome % (no.)	Vericiguat (N = 2526)	Placebo (N = 2524)	P-value
Composite Endpoint:	35.5% (897)	38.5% (972)	0.02
*CV death^*	8.2% (206)	8.9% (225)	NR
Hospitalization for HF	27.4% (691)	29.6% (747)	NS

^without a preceding hospitalization for HF event

- Secondary outcomes:

Secondary Outcome % (no.)	Vericiguat (N = 2526)	Placebo (N = 2524)	P-value
CV death*	16.4% (414)	17.5% (441)	NS
Total hospitalizations for HF	1223 events	1336 events	0.02
Death from any cause	20.3% (512)	21.2% (534)	NS

*with or without a preceding hospitalization for HF event

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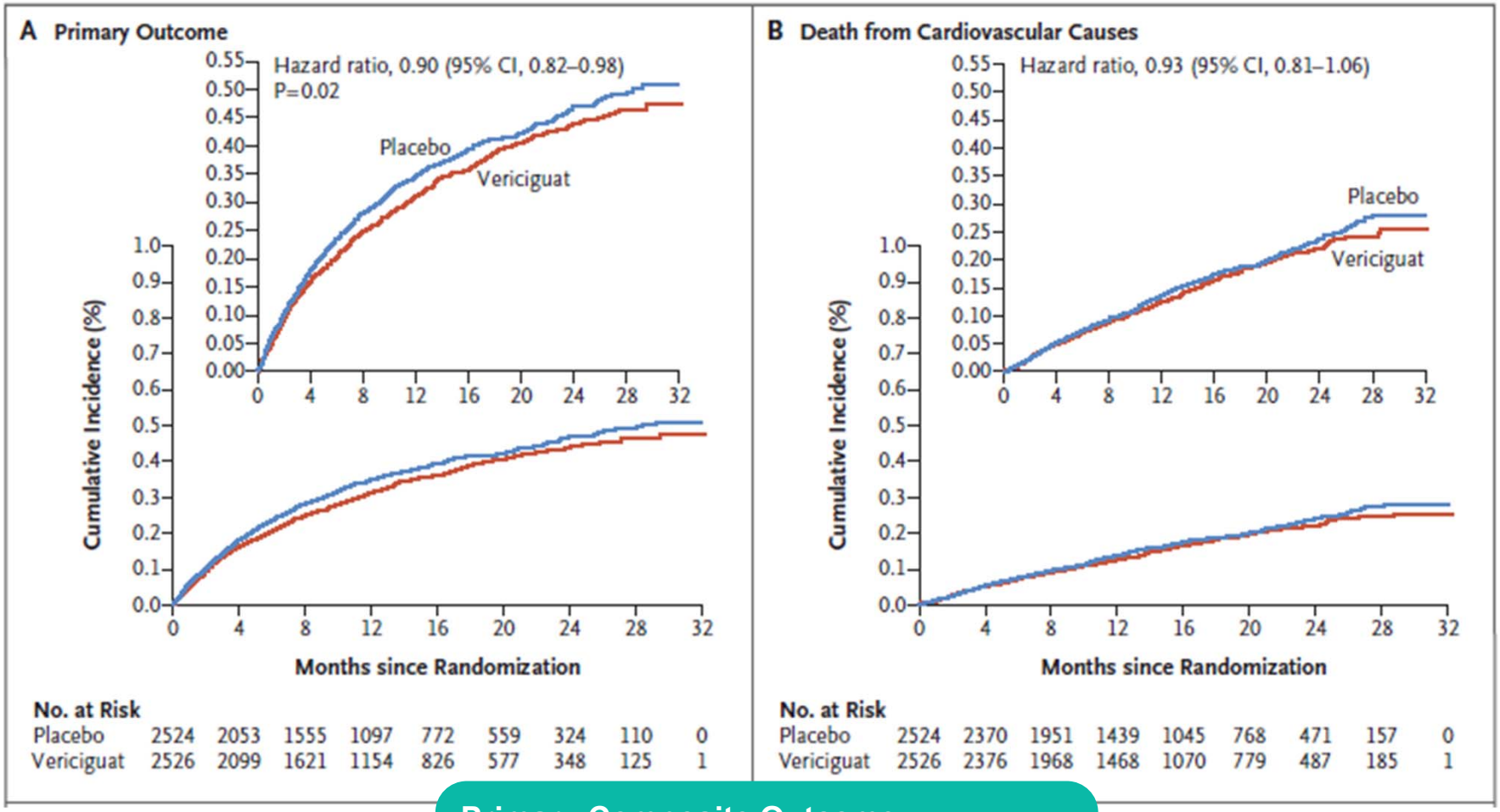
Abbreviations: CV = cardiovascular; HF = heart failure; HFrEF = heart failure reduced ejection fraction; NR = not reported; NS = not significant;

VICTORIA: Efficacy in HFrEF

Image: Armstrong et al. N Engl J Med; 382(20): 1883-93



Primary Composite Outcome:

- Relative risk reduction of 10%
- NNT = 34
- 12-mo, absolute rate reduction = 3.7%^

^Butler et al. Circulation. 2020; 141:717-719

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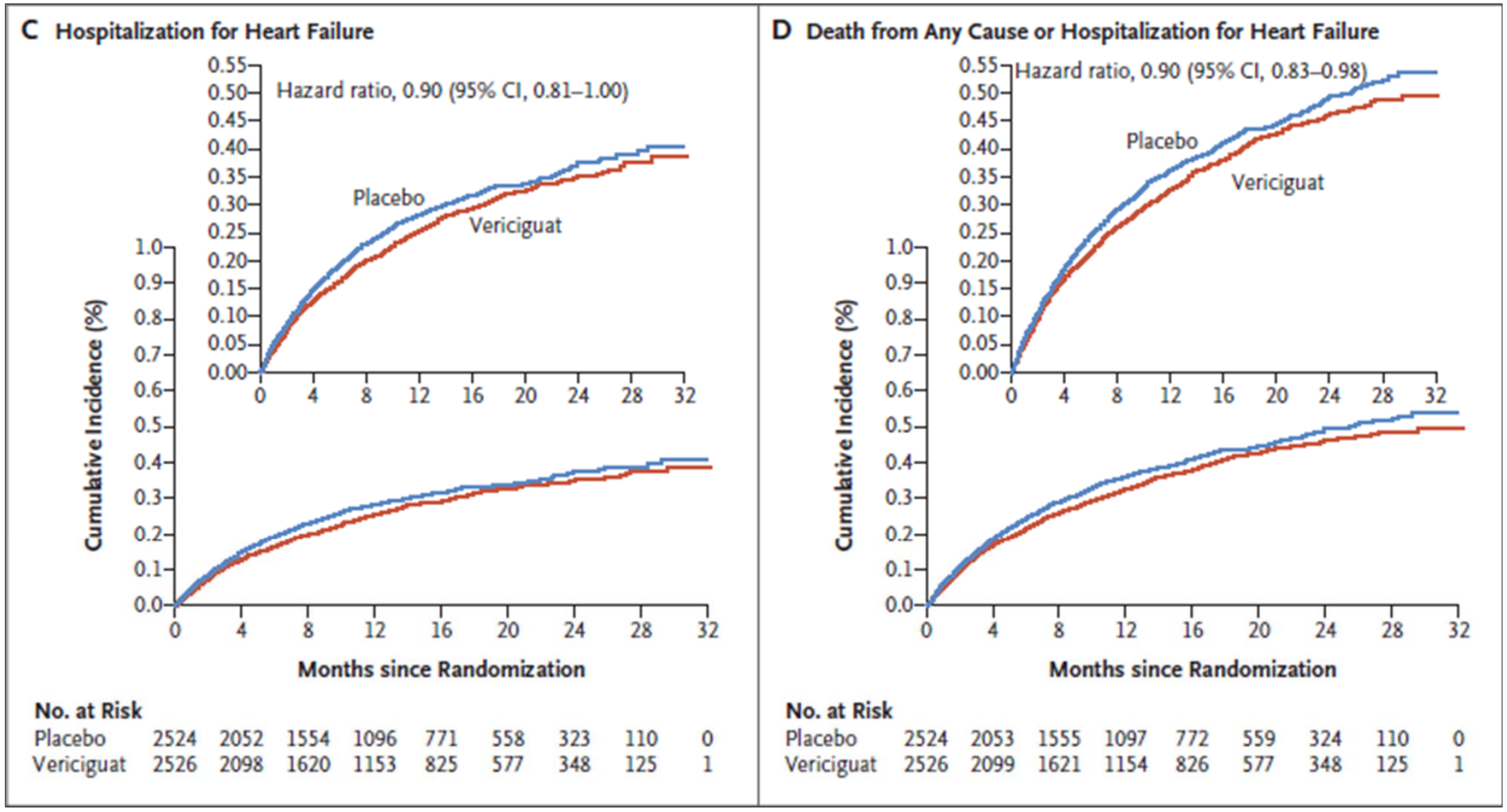
VICTORIA: Efficacy in HFrEF



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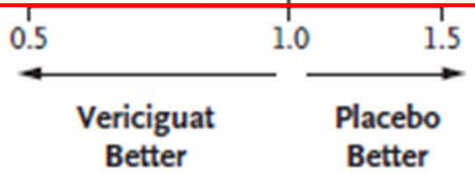
SUBGROUP ANALYSIS

VICTORIA: Efficacy in HFrEF

Age			
<65 yr	290	348	0.81 (0.70–0.95)
≥65 yr	607	624	0.94 (0.84–1.06)
<75 yr	579	669	0.84 (0.75–0.94)
≥75 yr	318	303	1.04 (0.88–1.21)
NT-proBNP level			
Quartile 1 (≤1556.0 pg/ml)	128	161	0.78 (0.62–0.99)
Quartile 2 (>1556.0 to ≤2816.0 pg/ml)	165	201	0.73 (0.60–0.90)
Quartile 3 (>2816.0 to ≤5314.0 pg/ml)	213	257	0.82 (0.69–0.99)
Quartile 4 (>5314.0 pg/ml)	355	302	1.16 (0.99–1.35)
Ejection fraction			
<35%	637	703	0.88 (0.79–0.97)
≥35%	255	265	0.96 (0.81–1.14)
<40%	773	851	0.88 (0.80–0.97)
≥40%	119	117	1.05 (0.81–1.36)



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Indirect comparison of efficacy

- Inclusion criteria for HFrEF trials:
  - Entresto, Farxiga, Jardiance: Hospitalization in the last 12-months OR NT-proBNP ≥600 pg/mL OR BNP ≥100 pg/mL
  - Vericiguat: recent HF decompensation (hospitalization in the last 6-months or IV diuretics in last 3-months) OR NT-proBNP ≥1000 pg/mL OR BNP ≥300 pg/mL
- Median follow-up:

Entresto	Farxiga	Jardiance	vericiguat
27-months	18-months	16-months	11-months

Drug	Primary Outcome (RRR vs. placebo)			Standard therapy at baseline (% of pts)				
	Composite[1]	Rate of CV death[2]	Rate of HF hospitalization	ACE, ARB or ARNI	BB	MRA	Devices (ICD/CRT)	NYHA III or IV
Entresto	20% vs. enalapril	20% vs. enalapril	21% vs. enalapril	Active-control	94%	82%	15%	25%
Farxiga	26%	18%	30%	94%	96%	71%	26%	33%
Jardiance[3]	25%	8%	31%	89%	95%	71%	44%	25%
vericiguat (worsening HF)	10%	NS	NS[4]	88%	93%	70%	42%	41%

[1] *Composite endpoint of CV death OR 1st HF hospitalization OR 1st urgent care visit for HF (Farxiga only)*
[2] with or without a preceding hospitalization for HF event
[3] *Jardiance is not FDA-approved for HFrEF at this time*
[4] *Significant difference in number of hospitalization for HF events. Annualized event rate of 38.3 vs. 42.4 events for vericiguat and placebo groups, respectively.*

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Indirect comparison of efficacy:

Trial	Annualized Event Rate (# of events per 100 patient-years)			
	Outcome	Control	Intervention	Difference
PARADIGM-HF (Entresto vs. enalapril)	Primary composite endpoint[1]	13.2	10.5	2.7
	CV death[2]	7.5	6.0	1.5
	1st HF Hospitalization	NR	NR	1.6
DAPA-HF (Farxiga vs. placebo)	Primary composite endpoint[1]	15.6	11.6	4.0
	CV death[2]	7.9	6.5	1.4
	1st HF Hospitalization	9.8	6.9	2.9
EMPEROR-Reduced (Jardiance vs. placebo)	Primary composite endpoint[1]	21.0	15.8	5.2
	CV death[2]	8.1	7.6	0.5
	1st HF Hospitalization	15.5	10.7	4.8
VICTORIA (vericiguat vs. placebo)	Primary composite endpoint[1]	37.8	33.6	4.2
	CV death[2]	13.9	12.9	1.0
	1st HF Hospitalization	28.2	25.5	2.7

[1]Composite endpoint of CV death OR 1st HF hospitalization OR 1st urgent care visit for HF (Farxiga only)
[2]with or without preceding hospitalization for HF

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Vericiguat: safety

- Similar discontinuation rate between vericiguat (24.1%) and placebo (22.4%) groups.
  - Reason for discontinuation were adverse events (28.6%), discontinued by physician (27.8%), discontinued for other reasons (43.6%) with no large difference between groups
- Similar rates of serious adverse events between vericiguat (32.8%) and placebo (34.8%) groups
- Adverse events of clinical interest:

Key AE	vericiguat (N = 2519)	Placebo (N = 2512)	P-value
Symptomatic hypotension	9.1% (229)	7.9% (198)	NS
Syncope	4.0% (101)	3.5% (87)	NS

- Most common adverse events:

Adverse event (%)	vericiguat (N =2519)	Placebo (N = 2515)
Hypotension	15.4	14.1
Anemia	7.6	5.7
Diarrhea	5.3	4.9
Nausea	3.8	2.7
Headache	3.4	2.4
Dyspepsia	2.7	1.1

**Adverse events that occurred in ≥2% of patients and at a ≥1% than placebo*

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Cost considerations

Drug	Dosing	Cost/unit	Cost per 30 days (Target/Max dose)
vericiguat 2.5 mg, 5 mg and 10 mg tablets	Initial: 2.5 mg daily Target: 10 mg daily	Under review by FDA for HFrEF	
Farxiga (dapagliflozin) 5 and 10 mg tablets	10 mg once daily	AWP = $20.69/tab	$621
Entresto (sacubitril/valsartan) 24/26, 49/51, and 97/103 mg tablets	Initial: 49/51 or 24/26 mg BID Target: 97/103 mg BID	AWP= $10.90/tab	$654
Corlanor (ivabradine) 5 and 7.5 mg tablets 5 mg/5 mL oral solution	Initial: 5 mg BID Max: 7.5 mg BID (target is 50-60 bpm)	AWP= $9.28/tab $1.86/mL	$557 (tablets) $837 (oral solution)
digoxin 125 and 250 mcg tablets 50 mcg/mL oral solution	Ranges from 125 mcg to 250 mcg every other day to once daily	MAC= $0.34/125mcg tab $0.44/250 mcg tab AWP= $2.80/mL oral solution	$5-$13 $105-$420
Inspra (eplerenone) 25 and 50 mg tablets	Initial: 25 mg once daily Target: 50 mg once daily	MAC= $0.99/25 mg tab $1.29/50 mg tab	$39

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BID = twice daily; HFrEF = heart failure with reduced ejection fraction; IR = immediate release; TID = three times daily

Cost considerations continued

Drug	Dosing	Cost/unit	Cost per 30 days (Target/Max dose)
Aldactone (spironolactone) 25, 50, and 100 mg tablets	Initial: 12.5-25 mg daily Target: 25 mg once or twice daily	MAC= $0.11/25 mg tab $0.23/50 mg tab $0.33/100 mg tab	$3-$7
Carospir (spironolactone) 5 mg/mL oral suspension	Initial: 20 mg once daily Target: 37.5 mg once daily	AWP= $2.93-$3.26/mL	$659-$734
BiDil (hydralazine/ isosorbide dinitrate) 37.5/20 mg tablets	Initial: 37.5/20 mg TID Target: 75/40 mg TID	AWP= $4.47/tab	$805
Hydralazine 10, 25, 50, and 100 mg tablets	Initial: 25-50 mg three or four times daily Target: 100 mg three times daily	MAC= $0.08/10 mg tab $0.06-$0.08/25 mg tab $0.07/50 mg tab $0.09-$0.12/100 mg tab	$8-$11
Isosorbide dinitrate 5, 10, 20, 30, and 40 mg IR tablets	Initial: 20 to 30 mg three or four times daily Target: 40 mg three times daily	MAC= $0.55/5 mg tab $0.48/10 mg tab $0.38/20 mg tab $0.82/30 mg tab $15.99/40 mg tab	$68 (using 20 mg tabs) $1,439 (using 40 mg tabs)

External review: vericiguat

Typical treatment approach for HFrEF	…initially with an ACEi/ARB, a beta blocker and an aldosterone antagonist. However, not all patients will be on triple therapy because of side effects.	[External Reviewer #2]…mainstay of therapy for HFrEF is vasodilators including ACEi, angiotensin receptor blockers, neprilysin inhibitors, and beta blockers, and then aldosterone inhibitors, and of course diuretics for symptomatic relief. [External Reviewer #3]…de novo in our clinic, and this is sort of against the guidelines, we will initiate sacubitril/valsartan…add in the next step, which is a beta blocker…then in the midst of that [up-titration of BB and ACEi/ARB/ARNI] start a mineralocorticoid receptor antagonist.
	The next step in treatment tends to be more individualized based on the patient's clinical situation, the trend in EF over time, and the patient's ability to tolerate additional therapy.	
	I do not see any of the three newer treatment options [Entresto, Farxiga, and vericiguat] being superior to the others.	
	We don't have strong data to support using more than one of these [newer] agents at a time.	
Place in therapy	I suspect that vericiguat will initially be used for this type of patient [recently decompensated HF] who is not stable despite triple therapy.	
Utilization management	It would be appropriate to have step therapy that mirrors the VICTORIA…an ACEi/ARB/ARNI, a beta-blocker and an aldosterone antagonist (unless contraindicated).	
	Yes that would be appropriate [concurrent edit of no long-acting nitrate and PDE-5 inhibitors] to avoid the risk of hypotension or syncope	

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vericiguat summary

- If approved, vericiguat will be the first soluble guanylate cyclase (sGC) stimulator for use in HFrEF
- Initial use will likely be limited to patients with a recent decompensating HF event

Efficacy:

- Vericiguat met the primary endpoint of composite CV death or 1st hospitalization for HF
  - Trial result was relatively small compared to recently approved HFrEF agents, but comparison is difficult due to shorter trial duration and sicker cohort inclusion.
  - vericiguat's difference in annualized event rate vs. placebo was comparable to that of Farxiga and Jardiance.
- Vericiguat's benefit is largely in reducing HF hospitalization events.

Safety:

- Well tolerated agent by HFrEF patients on conventional therapy (ACEi/ARB/ARNI + BB ± aldosterone antagonist)
- Symptomatic hypotension and syncope rates were not significantly different between vericiguat and placebo groups

Utilization management:

- Newer HFrEF agents (e.g. Entresto, Farxiga) are currently managed with QL ± ST
- Newer agents had PA P&T approved prior to drug launch to allow flexibility in UM strategy

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QUESTIONS?

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P&T: Prospective Drug Review

Rolontis (eflapegrastim)

OCTOBER 16, 2020

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Rolontis (eflapegrastim)

PDUFA	Manufacturer	MOA	Proposed Indication	Studied Dosing
10/24/20 BLA	Spectrum Pharmaceuticals	Long-acting granulocyte-colony stimulating factor (G-CSF)	Chemotherapy-induced febrile neutropenia	13.2 mg/0.6mL subcutaneous injection

Originally BLA was submitted in 2018, but withdrew in March 2019; the updated filing 10/2019 included additional information for Chemistry, Manufacturing, and Controls (CMC) section

- **Rolontis:** comprised of two protein components; an analog of G-CSF and an Fc antibody fragment
  - Fc fragment proposed to interact in the endothelial cells and bone marrow to prolong retention in these areas
- **Specific Indication (proposed):** decrease incidence of infection, as manifested by FN in patients with non-myeloid malignancies receiving **myelosuppressive anti-cancer drugs** associated with a clinically significant incidence of febrile neutropenia

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Myelosuppression/Neutropenia

- Myelosuppression, particularly neutropenia, presents challenges for oncology treatments
  - 1st cytotoxic chemotherapy introduced in 1950s
  - 1st recombinant human granulocyte-colony stimulating factor (G-CSF) in 1990s (filgrastim)
    - Safe/effective to reduce burden of infection-related morbidity and mortality associated with chemotherapy-induced neutropenia (CIN)
  - **1st long-acting G-CSF in 2000s: pegfilgrastim**
    - Simplifies care for CIN by using once-per-chemo cycle option
  - Rapid development of innovative, effective cancer treatments but have been limited by development of CIN, which may impede patient's completion of chemo regimen
- **Rolontis (eflapegrastim):** non-biosimilar, long-acting G-CSF
  - Consists of recombinant human G-CSF analog plus a recombinant human IgG Fc fragment
    - The IgG Fc fragment is a strategy to extend the drug's half-life (has been used before in other agents such as etanercept, aflibercept, dulaglutide)
    - Has demonstrated increased uptake to the bone marrow, presumably due to the action of the Fc fragment with Fc receptors on the vascular endothelial surface
    - Phase 1 and 2 trials demonstrate potential to have improved therapeutic index vs pegfilgrastim
    - 13.2 mg eflapegrastim (3.6 mg G-CSF) is equivalent to 6 mg G-CSF in pegfilgrastim; dose was chosen based on results of phase 2 dose-ranging study showing non-inferiority to pegfilgrastim

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Neulasta Product Comparison

Indication	Reference Product	Biosimilars			
	Neulasta (pegfilgrastim) Approved 2002	**Fulphila** (pegfilgrastim-jmdb) Approved 2018	**Udenyca** (pegfilgrastim-cbqv) Approved 2018	**Ziextenzo** (pegfilgrastim-bmez) Approved 2019	**Nyvepria** (pegfilgrastim-apgf) Approved 2020
Decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving **myelosuppressive anti-cancer drugs** associated with a clinically significant incidence of febrile neutropenia	✔	✔	✔	✔	✔
Increase survival in patients acutely exposed to **myelosuppressive doses of radiation** (Hematopoietic Subsyndrome of Acute Radiation Syndrome)	✔				

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ROLONTIS (EFLAPEGRASTIM): CHEMO-INDUCED NEUTROPENIA

ADVANCE & RECOVER

Design	Two identical P3, Active-Controlled, Multicenter, Open label	
Patients	Early-stage breast cancer (I-IIIA) on docetaxel/cyclophosphamide q 21 days	
Methods	1:1 Rolontis 13.2 mg or Pegfilgrastim 6 mg subcut x1 dose on day 2 of each cycle; 4 cycles total	
Endpoints	**Primary endpoint:** Duration of severe neutropenia (DSN) (ANC<0.5x109/L) in cycle 1	**Secondary endpoints:** DSN for cycles 2, 3, and 4, time to ANC recovery, depth of ANC nadir, incidence of FN
Results	Primary endpoint both trials overall: Mean DSN±SD (days) **Rolontis: 0.24±0.581, Pegfilg: 0.36±0.789** p<0.0001 for NI	Secondary endpoint both trials overall: DSN across all 4 cycles P<0.0001 for NI
	ADVANCE n=406 Median age 61, Weight: 78.6 kg DSN cycle 1 (days): **Rolontis 0.19 vs Pegfilg 0.34** Rolontis: actually met statistical threshold for superiority as well in the primary endpoint of cycle 1 DSN, with a 42% decrease vs Pegfilg (p = .013).	Not prespecified, but subgroup analyses of cycle 1 DSN showed statistical superiority for Rolontis versus Pegfilg in age ≥65 years and increased bodyweight (>75 kg) subgroups
	RECOVER n=237 Median age: 58-59, Weight: 76.5 kg Mean DSN cycle 1 (days): **Rolontis 0.31 vs Pegfilg 0.39**	--
Safety	Occurrence of severe neutropenia (SN) (Grade 4, <0.5 x 10^9/L) Rolontis: 17.5%, Pegfilgrastim: 24% ARR: 6.5% (NNT 15) Other safety items comparable to Pegfilgrastim overall	

DSN: duration of severe neutropenia (ANC<0.5x10^9/L); **ANC:** absolute neutrophil count; FN: febrile neutropenia; **NI:** non-inferiority; **ARR:** absolute risk reduction defined as difference in % of patients who experienced severe neutropenia

Efficacy: ADVANCE & RECOVER

Duration of severe neutropenia (ANC <0.5 x 10^9/L) for fixed dose 13.2 mg Rolontis and Pegfilgrastim in cycles 1-4

Mean DSN, days	ADVANCE			RECOVER		
	Rolontis n=196	**Pegfilg** n=210	Difference	**Rolontis** n=118	**Pegfilg** n=119	Difference
Cycle 1 (primary)	**0.20**	**0.35**	**-1.48 p<0.0001**	**0.31**	**0.39**	**-0.074 p<0.0001**
Cycle 2 (secondary)	0.13	0.09	0.042 p<0.0001	0.08	0.09	-0.016 p<0.0001
Cycle 3 (secondary)	0.11	0.08	0.026 p<0.0001	0.07	0.07	0.000 p<0.0001
Cycle 4 (secondary)	0.11	0.09	0.027 p<0.0001	0.07	0.08	-0.008 p<0.0001

Secondary Endpoints	ADVANCE								RECOVER							
	Cycle 1		Cycle 2		Cycle 3		Cycle 4		Cycle 1		Cycle 2		Cycle 3		Cycle 4	
Mean days to ANC recovery	R 3.2	P 3.5	R 2.3	P 2.1	R 2.7	P 1.9	R 2.8	P 2.5	R 3.5	P 3.4	R 2.2	P 2.0	R 2.0	P 2.1	R 1.9	P 1.7
	p=0.69		*p=0.80*		*p=0.30*		*p=0.71*		*p=0.87*		*p=0.81*		*p=0.89*		*p=0.77*	
Median depth ANC nadir (x10^9/L)	R 1.6	P 1.3	R 2.5	P 3.3	R 2.3	P 3.7	R 2.0	P 2.8	R 1.6	P 1.6	R 4.0	P 2.8	R 3.5	P 3.1	R 3.7	P 2.9
	p=0.16		*p=0.10*		*p=0.01*		*p=0.11*		*p=0.36*		*p=0.14*		*p=0.42*		*p=0.52*	
Incidence of FN, %	R 2	P 1	R 0.5	P 0.5	R 2	P 0.5	R 1	P 0	R 0.8	P 3.4	R 0	P 1.7	R 0	P 0	R 0	P 0
	p=0.45		*n/a*		*p=0.20*		*p=0.23*		*p=0.37*		*p=0.50*		*n/a*		*n/a*	
Incidence of neutropenic complications, %	R 4.1	P 3.8	R 2	P 1.9	R 2.6	P 1.4	R 1.5	P 1	R 0.8	P 4.2	R 0.8	P 0.8	R 0	P 0.8	R 0.8	P 0
	n/a		*n/a*		*p=0.68*		*p=0.55*		*p=0.21*		*n/a*		*n/a*		*p=0.5*	

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Cycle 1: Severe Neutropenia Duration

ADVANCE

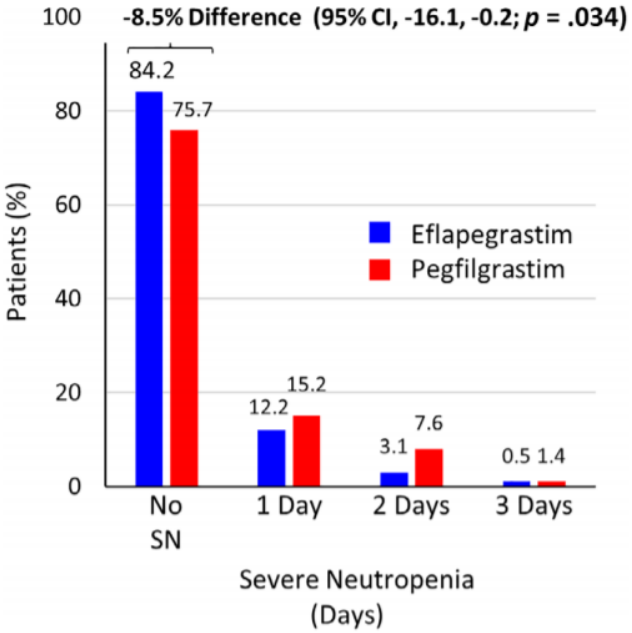

Figure 2. Duration of severe neutropenia (absolute neutrophil count <0.5 × 10^9 per L; grade 4 per National Cancer Institute CTCAE, Version 4.03) in cycle 1 in patients treated with a fixed-dose 13.2 mg eflapegrastim (3.6 mg granulocyte-colony stimulating factor [G-CSF]) or pegfilgrastim (6.0 mg G-CSF).
Abbreviations: CI, confidence interval; SN, severe neutropenia.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7418343/pdf/ONCO-25-e1233.pdf

RECOVER

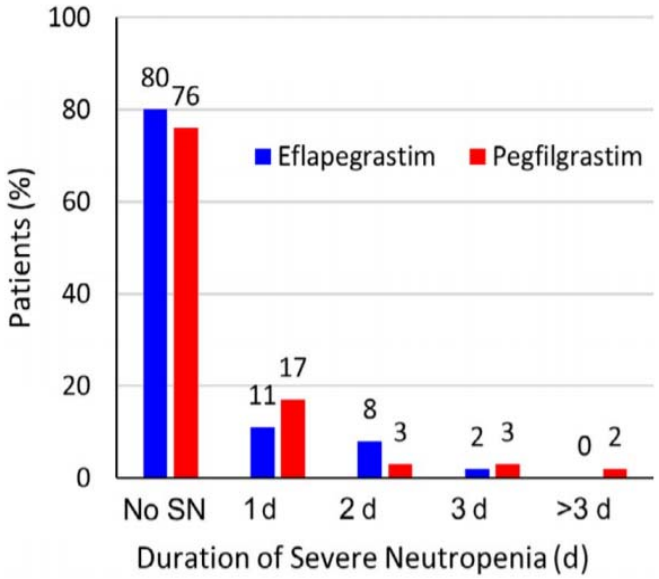

FIGURE 2 Duration of severe neutropenia (SN) in Cycle 1 (ANC <0.5 × 10^9/L; Grade 4 per NCI CTCAE, V 4.03) for fixed dose 13.2 mg eflapegrastim (3.6 mg G-CSF) and pegfilgrastim (6.0 mg G-CSF)

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7476820/pdf/CAM4-9-6234.pdf

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RECOVER: Safety

	Rolontis		Pegfilgrastim	
ADE n%, any grade	**RECOVER** n=117	**ADVANCE** n=197	**RECOVER** n=118	**ADVANCE** n=208
Any event	63	83	61	70
Bone pain	34	32	38	32
Myalgia	15	15	9	9
Diarrhea	10	8	0	5
Back pain	9	16	4	12
Pyrexia	9	7	8	8
Arthralgia	8	19	6	13
Nausea	8	8	3	5
WBC increased	8	13	3	7
Headache	7	12	6	9
Fatigue	6	9	8	11
Pain in extremity	6	6	3	6
Lymphocyte count decreased/ lymphopenia	2	6	5	3
Pain	--	11	--	11
Hypersensitivity	--	7	--	7
Dizziness	--	5	--	2

Discontinuation due to AE <5%

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Rolontis (eflapegrastim): Key Takeaways

PDUFA	Manufacturer	MOA	Proposed Indication	Studied Dosing
10/24/20 BLA	Spectrum Pharmaceuticals	Long-acting granulocyte-colony stimulating factor (G-CSF)	Chemotherapy-induced febrile neutropenia	13.2 mg/0.6mL subcutaneous injection

- **Place in therapy:**
  - **Rolontis is another G-CSF that will compete with Neulasta and its biosimilars**
    - First novel G-CSF in over 15 years
  - Would be the sixth long-acting G-CSF approved (Neulasta plus biosimilars), which will be steep competition for Rolontis
- **Efficacy:** non-inferior to pegfilgrastim in reduction of duration of severe neutropenia
- **Safety:** similar ADE as pegfilgrastim (e.g., FN and neutropenic complications)
  - Absolute risk reduction (ARR) occurrence of severe neutropenia 6.5% vs pegfilgrastim
- Future studies, if completed, may help determine if severe neutropenia occurrence/duration differences are meaningful/superior; could help potentially stand Rolontis apart from the pack
- Different MOA does not appear to make clinically relevant differences in safety/efficacy overall at this time
- Proposed similar management (PA) as existing long-acting G-CSF

ANC: absolute neutrophil count; FN: febrile neutropenia; **ARR:** absolute risk reduction defined as difference in % of patients who experienced severe neutropenia

P&T: Prospective Drug Review

inclisiran

OCTOBER 16, 2020

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PDUFA	Manufacturer	MOA	Proposed Indication	Studied Dosing
12/2020	Novartis	Long-acting synthetic small-interfering RNA (siRNA) targeting PCSK9	1) dyslipidemia 2) hypercholesterolemia including heterozygous familial hypercholesterolemia (HeFH) 3) atherosclerotic cardiovascular disease (ASCVD) *with max tolerated statin (?)	300 mg subcutaneous given by HCP every 6 months after dose at day 0 and day 90

- **Mechanism:** long-acting synthetic small-interfering RNA (siRNA) targeting PCSK9 → PCSK9 inhibition → LDL-C lowering
  - Inclisiran works differently than current PCSK9 agents as a first-in-class cholesterol-lowering agent utilizing a siRNA
    - mAb PCSK9 Repatha/Praluent: binds selectively to PCSK9 after it is produced and prevents it from binding to the LDL receptor on liver cell surface, preventing LDL receptor degradation
    - Inclisiran: blocks the expression of a gene that leads to manufacturing of PCSK9
    - Inhibition of PCSK9 leads to prevention of LDL receptor degradation, which allows for blood LDL-C uptake and blood levels to decrease
  - siRNA: binds intracellularly to the RISC and cleaves mRNA molecules specifically encoding PCSK9
    - Works predominantly in the liver, main site of PCSK9 production
    - Peak ~4 hours, excreted through kidney, not detectable in plasma within 24-48 hours
    - Without further injections, LDL-C reduction of 2% per month (effects persist up to 2 years)
- **Proposed dosing:** 300 mg subcutaneous given by HCP every 6 months after dose at day 0 and day 90
  - Twice per year dosing (regardless of renal/hepatic) encourages routine clinic visits and medication adherence
  - Existing PCSK9: Praluent and Repatha are mAbs given either every two weeks or once per month

HCP: health care professional; **siRNA:** small interfering RNA; **mAbs:** monoclonal antibody; **PCSK9:** proprotein convertase subtilisin kexin type 9; **ASCVD:** atherosclerotic cardiovascular disease; **hoFH**: homozygous familial hypercholesterolemia; **heFH**: heterozygous familial hypercholesterolemia

Dyslipidemia, Hypercholesterolemia, Hyperlipidemia

- **Prevalence:** based on CDC data from 2015-2016, adults in US age ≥20
  - >12% had total cholesterol >240 mg/dL; 95 million have TC levels >200 mg/dL
  - >18% had HDL-L <40 mg/dL
- **Causes of high lipids:** normal LDL-C is 130 mg/dL or less
  - Dietary consumption (saturated fats, trans fats)
  - Medical conditions (diabetes (DM), hypothyroidism, metabolic syndrome, Cushing's syndrome, polycystic ovary syndrome, kidney disease)
  - Other causes: lack of exercise, smoking, some medications
  - Genetic conditions: underdiagnosed, 20x increase in risk of premature CV death
    - **HeFH**: heterozygous familial hypercholesterolemia; 1 in 250-500 worldwide, LDL-C ≥190
    - **HoFH**: homozygous familial hypercholesterolemia; 1 in 1 million worldwide, LDL-C 700-1,000
      - *Treatment: LDL apheresis, Juxtapid (lomitapide) in addition to conventional items*
- **Symptoms:** often asymptomatic, but patients may experience symptoms after the cholesterol has caused significant damage (angina, nausea, fatigue, MI, stroke, etc.)
- **Well-established association between lipid concentrations and risk of cardiovascular disease (CVD), the leading cause of death in US**
- **ASCVD:** caused by plaque buildup in arterial walls
  - Risk factors: dyslipidemia, smoking, hypertension, diabetes, chronic kidney disease (CKD), aging, male sex, history of coronary artery disease (CAD), non-cardiogenic cerebral infarction, peripheral artery disease (PAD), etc.
  - Treatment: antihypertensive therapy (e.g., ACE/ARB), statin, low-dose aspirin
- **Goal of management:**
  - Initiation of therapy to lower the LDL cholesterol level as soon as possible after diagnosis
  - More intensive lipid-lowering therapy in patients with established atherosclerosis

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2017 AACE Guideline on the Management of Dyslipidemia and Prevention of Cardiovascular Disease: Target-based approach

ASCVD Risk Categories and LDL-C Treatment Goals

10-YEAR RISK (%)	Risk Category	Risk factors/10-year risk	Treatment Goals (mg/dL)		
			LDL-C	Non-HDL-C	Apo B
>30	Extreme risk	• Progressive ASCVD including unstable angina in individuals after achieving an LDL-C <70 mg/dL • Established clinical cardiovascular disease in individuals with DM, stage 3 or 4 CKD, or HeFH • History of premature ASCVD (<55 male, <65 female)	<55	<80	<70
>20	Very high risk	• Established or recent hospitalization for ACS, coronary, carotid or peripheral vascular disease, 10-year risk >20% • DM or stage 3 or 4 CKD with 1 or more risk factor(s) • HeFH	<70	<100	<80
10 – 20	High risk	• ≥2 risk factors and 10-year risk 10%-20% • DM or stage 3 or 4 CKD with no other risk factors	<100	<130	<90
<10	Moderate risk	• ≤2 risk factors and 10-year risk <10%	<100	<130	<90
<10	Low risk	• 0 risk factors	<130	<160	NR

Medication recommendations to treat to goal:

- Typically moderate to high intensity statin, with general recommendations to add ezetimibe or PCSK9 inhibitor, depending on how much LDL-C lowering is required; the guidelines do make call-outs for other pharmacological treatment options, but for specific patient situations
- Extremely low LDL-C (<20 mg/dL) was previously unheard of but had been shown to be safe and potentially beneficial, leading to this “extreme” risk category recommendation

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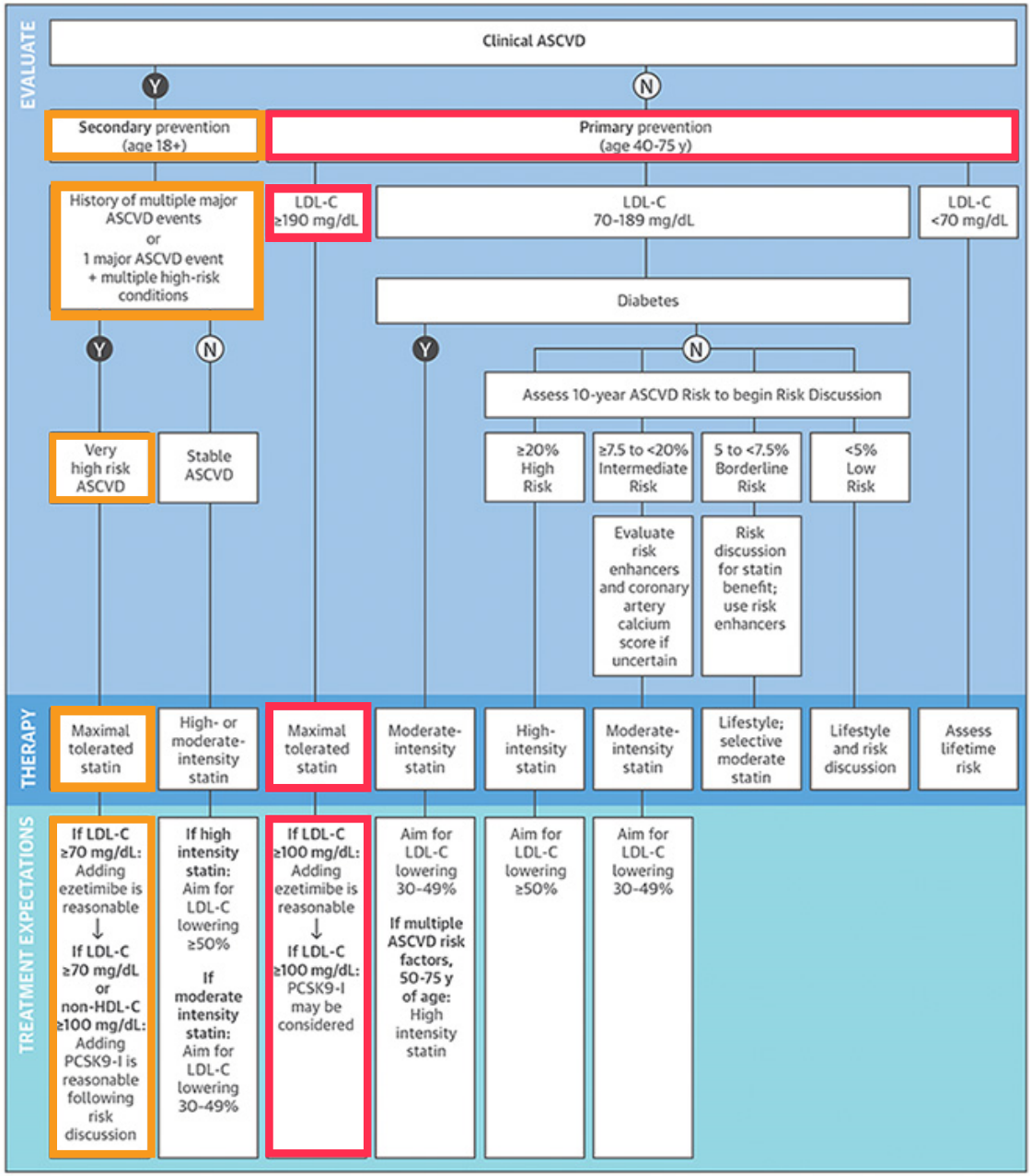
https://www.aace.com/sites/default/files/2019-04/aace_lipid_guidelines_visual_guide.pdf

2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA **Guideline on the Management of Blood Cholesterol: Risk-based approach**

- Clinical ASCVD: stroke, transient ischemic attack (TIA), documented coronary artery disease (CAD) with stable angina, acute coronary syndromes (ACS), coronary or other arterial revascularization, peripheral vascular disease with or without claudication, and aortic aneurysm.
- Most treated with statins alone; goal ~50% LDL ↓
- % LDL-C reduction and LDL-C numeric threshold in certain populations
- Addition of non-statins to max tolerated statins:
  - LDL-C >70 mg/dL in ASCVD, very high risk (h/o multiple major ASCVD events or 1 major event and multiple high risk conditions) ***Secondary Prevention, adults***
    - Ezetimibe first, then add PCSK9 inhibitor (though long-term safety >3 years uncertain and cost effectiveness low)
  - LDL-C >100 mg/dL in primary severe hyperlipidemia ***Primary Prevention, age 40-75;*** very high risk ASCVD, use LDL-C >70 mg/dL threshold
    - Ezetimibe first, then add PCSK9 inhibitor (though long-term safety >3 years uncertain and economic value is uncertain)



Grundy, S.M., et al. J Am Coll Cardiol. 10.1016/j.jacc.2018.11.003.

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2019 ACC/AHA Guideline on Primary Prevention of Cardiovascular Disease: many reiterations from the 2018 multidisciplinary guidelines

- Adults 40-75 should undergo 10-year ASCVD risk estimation with discussion before starting medication
- Aspirin should be used infrequently in routine primary prevention of ASCVD (lack of net benefit)
- Statin therapy is first-line for primary prevention of ASCVD for patients with:
  - Elevated LDL-C (≥190 mg/dL) (high-intensity statin, LDL-C ↓ ≥50%)
    - Refer to 2018 cholesterol guideline for use of non-statin therapies
  - Diabetes (also first line is metformin, then SGLT2 or GLP1)
  - Age 40-75 years old (moderate-intensity statin, LDL-C ↓ 25%) *(Strong, high quality)*
  - Those determined to be at sufficient ASCVD risk after clinician-patient risk discussion
  - Adults at intermediate risk (≥7.5% to <20% 10-year ASCVD risk), moderate-intensity statin with goal of LDL-C reduction by 30% or more *(Strong, high quality)*
  - Adults at high risk (ASCVD risk ≥20%) reduction of 50% or more recommended, high-intensity statin *(Strong, high quality)*

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INCLISIRAN: HYPERLIPIDEMIA

LDL Lowering Options (in addition to diet)

Class	Drug(s)	LDL-C ↓ Potential	ASCVD label	Primary HLP	Mixed HLP	HeFH	HoFH
siRNA PCSK9 inhibitor	inclisiran	49-54%†	*Under review*	*Under review*	--	*Under review*	*Under review*
Cholesterol absorption inhib.	**Zetia** (ezetimibe)	18-25%†	--	Yes	Yes, w/ fenofibrate	--	Yes, with atorv or simvast
PCSK9 inhibitor	**Repatha** (evolocumab)	45-70%†	Yes*	Yes	--	Yes	Yes, with other LDL ↓ items
	Praluent (alirocumab)		Yes^				--
Statins	**Lipitor** (atorvastatin) **Crestor, Ezallor** (rosuvastatin) **Zocor** (simvastatin) **Altoprev** (lovastatin) **Pravachol** (pravastatin) **Livalo**, **Zypitamag** (pitavastatin) **Lescol** (fluvastatin)	20-60%	Yes-	Yes	Yes	Yes	Yes
ATP citrate lyase inhibitor	***Nexletol, Nexlizet*** *(bempedoic acid, with ezetimibe)*	*17†, 36%†*	*Yes+, w/ max tol statin*	--	--	*Yes, with max tol statin*	--
Bile acid sequestrants	***Welchol*** *(colesevelam)* ***Prevalite***, ***Questran*** *(cholestyramine)* ***Colestid*** *(colestipol)*	*10-28%†*	--	*Yes*	--	--	--
Fibrates	***Triglide, Lipofen, Fenoglide, Tricor*** *(fenofibrate)*	*15-48%†*	--	*Yes*	*Yes*	--	--

*: ↓ risk of MI, stroke, and unstable angina requiring hospitalization in adults with established CVD; **%**MI, stroke, revascularization, hospitalization for unstable angina with elevated TG and established CVD, DM2 and two+ risk factors for CVD; **^**: ↓ risk of MI, stroke, and coronary revascularization in adults with established CVD; **-**: variety including: ↓ risk of MI, stroke, revascularization, and angina in adults without CVHD, but multiple risk factors; ↓ MI, stroke in adults with DM2 without coronary heart disease (CHD), but multiple risk factors; ↓ risk of non-fatal MI, fatal and non-fatal stroke, revascularization procedures, hospitalization for CHF in adults with CHD
+: established atherosclerotic cardiovascular disease (ASCVD); effect on cardiovascular morbidity/mortality not determined
HLP: Hyperlipidemia; **HCL**: Hypercholesterolemia; **hoFH**: homozygous familial hypercholesterolemia; **heFH**: heterozygous familial hypercholesterolemia;
† with statin; information provided from package insert where available or 2017 ACC guidelines; difference from placebo

INCLISIRAN: HYPERLIPIDEMIA

LDL Lowering Options (in addition to diet)

Class	Drug(s)	LDL-C ↓ Potential	ASCVD label	Primary HLP	Mixed HLP	HeFH	HoFH
siRNA PCSK9 inhibitor	inclisiran	49-54%†	*Under review*	*Under review*	--	*Under review*	*Under review*
Cholesterol absorption inhib.	**Zetia** (ezetimibe)	18-25%†	--	Yes	Yes, w/ fenofibrate	--	Yes, with atorv or simvast
PCSK9 inhibitor	**Repatha** (evolocumab)	45-70%†	Yes*	Yes	--	Yes	Yes, with other LDL ↓ items
	Praluent (alirocumab)		Yes^				--
Statins	**Lipitor** (atorvastatin) **Crestor, Ezallor** (rosuvastatin) **Zocor** (simvastatin) **Altoprev** (lovastatin) **Pravachol** (pravastatin) **Livalo**, **Zypitamag** (pitavastatin) **Lescol** (fluvastatin)	20-60%	Yes-	Yes	Yes	Yes	Yes
ATP citrate lyase inhibitor	***Nexletol, Nexlizet*** *(bempedoic acid, with ezetimibe)*	*17†, 36%†*	*Yes+, w/ max tol statin*	--	--	*Yes, with max tol statin*	--
Bile acid sequestrants	***Welchol*** *(colesevelam)* ***Prevalite***, ***Questran*** *(cholestyramine)* ***Colestid*** *(colestipol)*	*10-28%†*	--	*Yes*	--	--	--
Fibrates	***Triglide, Lipofen, Fenoglide, Tricor*** *(fenofibrate)*	*15-48%†*	--	*Yes*	*Yes*	--	--

*: ↓ risk of MI, stroke, and unstable angina requiring hospitalization in adults with established CVD; **%**MI, stroke, revascularization, hospitalization for unstable angina with elevated TG and established CVD, DM2 and two+ risk factors for CVD; **^**: ↓ risk of MI, stroke, and coronary revascularization in adults with established CVD; **-**: variety including: ↓ risk of MI, stroke, revascularization, and angina in adults without CVHD, but multiple risk factors; ↓ MI, stroke in adults with DM2 without coronary heart disease (CHD), but multiple risk factors; ↓ risk of non-fatal MI, fatal and non-fatal stroke, revascularization procedures, hospitalization for CHF in adults with CHD
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INCLISIRAN: HYPERLIPIDEMIA

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Cholesterol absorption inhib.	**Zetia** (ezetimibe)	18-25%†	--	Yes	Yes, w/ fenofibrate	--	Yes, with atorv or simvast
PCSK9 inhibitor	**Repatha** (evolocumab)	45-70%†	Yes*	Yes	--	Yes	Yes, with other LDL ↓ items
	Praluent (alirocumab)		Yes^				--
Statins	**Lipitor** (atorvastatin) **Crestor, Ezallor** (rosuvastatin) **Zocor** (simvastatin) **Altoprev** (lovastatin) **Pravachol** (pravastatin) **Livalo**, **Zypitamag** (pitavastatin) **Lescol** (fluvastatin)	20-60%	Yes-	Yes	Yes	Yes	Yes
ATP citrate lyase inhibitor	***Nexletol, Nexlizet*** *(bempedoic acid, with ezetimibe)*	*17†, 36%†*	*Yes+, w/ max tol statin*	--	--	*Yes, with max tol statin*	--
Bile acid sequestrants	***Welchol*** *(colesevelam)* ***Prevalite***, ***Questran*** *(cholestyramine)* ***Colestid*** *(colestipol)*	*10-28%†*	--	*Yes*	--	--	--
Fibrates	***Triglide, Lipofen, Fenoglide, Tricor*** *(fenofibrate)*	*15-48%†*	--	*Yes*	*Yes*	--	--

*: ↓ risk of MI, stroke, and unstable angina requiring hospitalization in adults with established CVD; **%**MI, stroke, revascularization, hospitalization for unstable angina with elevated TG and established CVD, DM2 and two+ risk factors for CVD; **^**: ↓ risk of MI, stroke, and coronary revascularization in adults with established CVD; **-**: variety including: ↓ risk of MI, stroke, revascularization, and angina in adults without CVHD, but multiple risk factors; ↓ MI, stroke in adults with DM2 without coronary heart disease (CHD), but multiple risk factors; ↓ risk of non-fatal MI, fatal and non-fatal stroke, revascularization procedures, hospitalization for CHF in adults with CHD
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† with statin; information provided from package insert where available or 2017 ACC guidelines; difference from placebo

Inclisiran Clinical Trial Program: ORION

ORION	Trial Design	Methods	Results
1	P2 DB N=~500	100-500 mg d1 vs d1 & d90	≥50% to up to 88% LDL-C lowering, occurs within 1st 30 days and sustained 6 months
3	P2 OLE N=~300	300 mg q6 months	
2	P2 N=4	Pts w/H**o**FH on statins/ezetimibe, 300 mg d1	Up to 40% LDL-c lowering, sustained 6 months; no need for higher dosing
4	P3 CV N=15,000	5 years, pts with ASCVD or risk equivalents (h/o MI/stroke/etc.)	↓ risk of MI/stroke? ~2024 for data
5	P3 N=45	Pts w/H**o**FH, establishing frequency	--
6	PK trial	Renal/Hepatic impaired patients	--
7	PK trial		--
8	P3 OLE N=~3,700	Patients who completed P3 ORION trials on current lipid lowering items with no planned changes to regimen/dose	Recruiting, completion 12/2023; % of patients achieving LDL-C <70 mg/dL and <100 mg/dL
9 published NEJM	P3 DB PC N=~500	Pts w/H**e**FH	Superior vs placebo to reduce LDL-C; ~40% vs 8% (-70.6 mg/dL)
10 published NEJM	P3 DB PC	Pts w/ASCVD (or ASCVD equivalents in Orion 11) and on max tol statins; ezetimibe allowed	Superior vs placebo to reduce LDL-C ~17 months, LDL-C ↓ by ≥50% (BL LDL-C ~112; ~92% on statin, 74% on high intensity)
11 published NEJM	P3 DB PC N=1,617		

HoFH: homozygous familial hypercholesterolemia; **HeFH**: heterozygous familial hypercholesterolemia; **OLE**: open label extension; **ORION 13** HoFH peds, **ORION 16** HeFH peds

ORION-9 HeFH

- **Trial:** Phase 3, R, DB, PC
- **Inclusion:** patients with HeFH
  - Adults with HeFH on statins at max tolerated dosing or documented evidence of intolerance to all doses of at least 2 different statins
- **Exclusion:**
  - NYHA class IV HF, uncontrolled cardiac arrhythmia/severe hypertension, liver disease
- **Methods:** Subcutaneous inclisiran 300 mg (or placebo) day 1, 90, 270, and 450
- **Co-primary endpoints:**
  - % change from baseline in the LDL cholesterol level on day 510
  - Time-adjusted % change from baseline in the LDL cholesterol level between day 90 and day 540
- **Results:** n=482, median age 56
  - Mean baseline LDL-C 153 mg/dL
  - 90% on statin, 71-76% high intensity, 50-55% ezetimibe
  - **Primary:** Inclisiran vs placebo LDL-C ↓ 48% (71 mg/dL, p<0.0001)
    - ↓ 39.7% in inclisiran, ↑ 8.2% in placebo
  - **Primary:** Time-averaged placebo-adjusted LDL-C ↓ of 44% (63 mg/dL, p<0.0001)
    - ↓ 38.1% in inclisiran, ↑ 6.2% in placebo
  - Inclisiran also associated with ↓ total cholesterol, non–HDL cholesterol, apolipoprotein B, and triglycerides vs placebo, along with higher HDL-C
- **Safety**: similar between inclisiran/placebo
  - Injection site reaction (9% vs 0%)
  - 1 death each group not considered to be related to trial

HoFH: homozygous familial hypercholesterolemia; **HeFH**: heterozygous familial hypercholesterolemia

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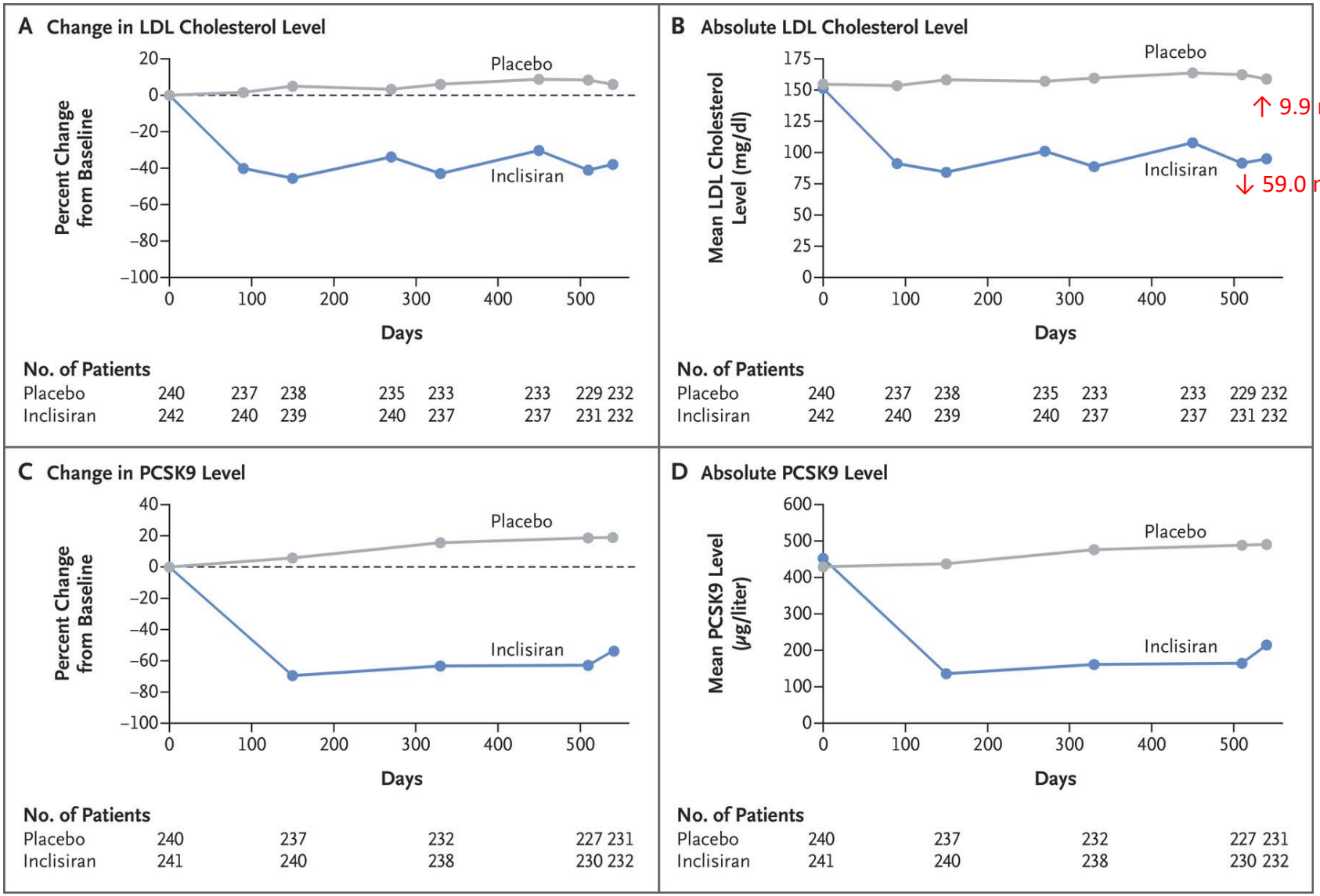
ORION-9 HeFH



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https://www.nejm.org/doi/full/10.1056/NEJMoa1913805?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%3dpubmed

ORION-10 & 11 ASCVD and ↑ LDL-C

- **Trial:** Phase 3, R, DB, PC, multicenter
- **Inclusion:** Adults with elevated LDL-C
  - ORION 10 (U.S.): ASCVD and LDL ≥70 mg/dL
  - ORION 11 (Europe/South Africa): ASCVD or ASCVD risk equivalent and LDL-C ≥100 mg/dL
    - Risk equivalent: DM2, HeFH, 10-year risk of CV event of ≥20% per Framingham risk score or equivalent
  - If on statin, taking max tolerated dose; if not on statin, documented evidence of intolerance to all doses of at least 2 different statins
- **Exclusion:**
  - NYHA class IV HF, uncontrolled cardiac arrhythmia/severe hypertension, liver disease, PCSK9 w/in 90 days
- **Methods:** Subcutaneous inclisiran 284 mg (or placebo) day 1, 90, 270, 450 (every 6 months)
- **Primary endpoints:**
  - % change from baseline in the LDL cholesterol level on day 510 (18 months)
  - Time-adjusted % change from baseline in the LDL cholesterol level between day 90 and day 540
- **Results:** ORION 10: n=1,561, ORION 11: n=1,617; median age 66, 70% male, 1-2% HeFH
  - Mean baseline LDL-C 105 mg/dL, in ORION 11 12.5% were of ASCVD risk equivalent
  - 90-95% on statin, 68-80% high intensity, 7-10% ezetimibe, 40-50% DM, 15-20% smoker
  - Inclisiran vs placebo LDL-C ($p<0.0001$)
    - ORION 10: ↓ 51.3% in inclisiran, ↑ 1% in placebo, difference -52.3%
    - ORION 11: ↓ 45.8% in inclisiran, ↑ 4% in placebo, difference -49.9%
  - Time-averaged placebo-adjusted LDL-C ($p<0.0001$)
    - ORION 10: ↓ 51.8% in inclisiran, ↑ 2.5% in placebo, difference 53.8%
    - ORION 11: ↓ 45.8% in inclisiran, ↑ 3.4% in placebo, difference -49.2%
  - Inclisiran also associated with ↓ total cholesterol, non–HDL cholesterol, apolipoprotein B, and triglycerides vs placebo, along with higher HDL-C
- **Safety:** similar between inclisiran/placebo (any ADE 73.5% inclisiran, 75% placebo)
  - Injection site reaction (2.6-4.7% vs 0.5-0.9%), generally mild with none severe/persistent

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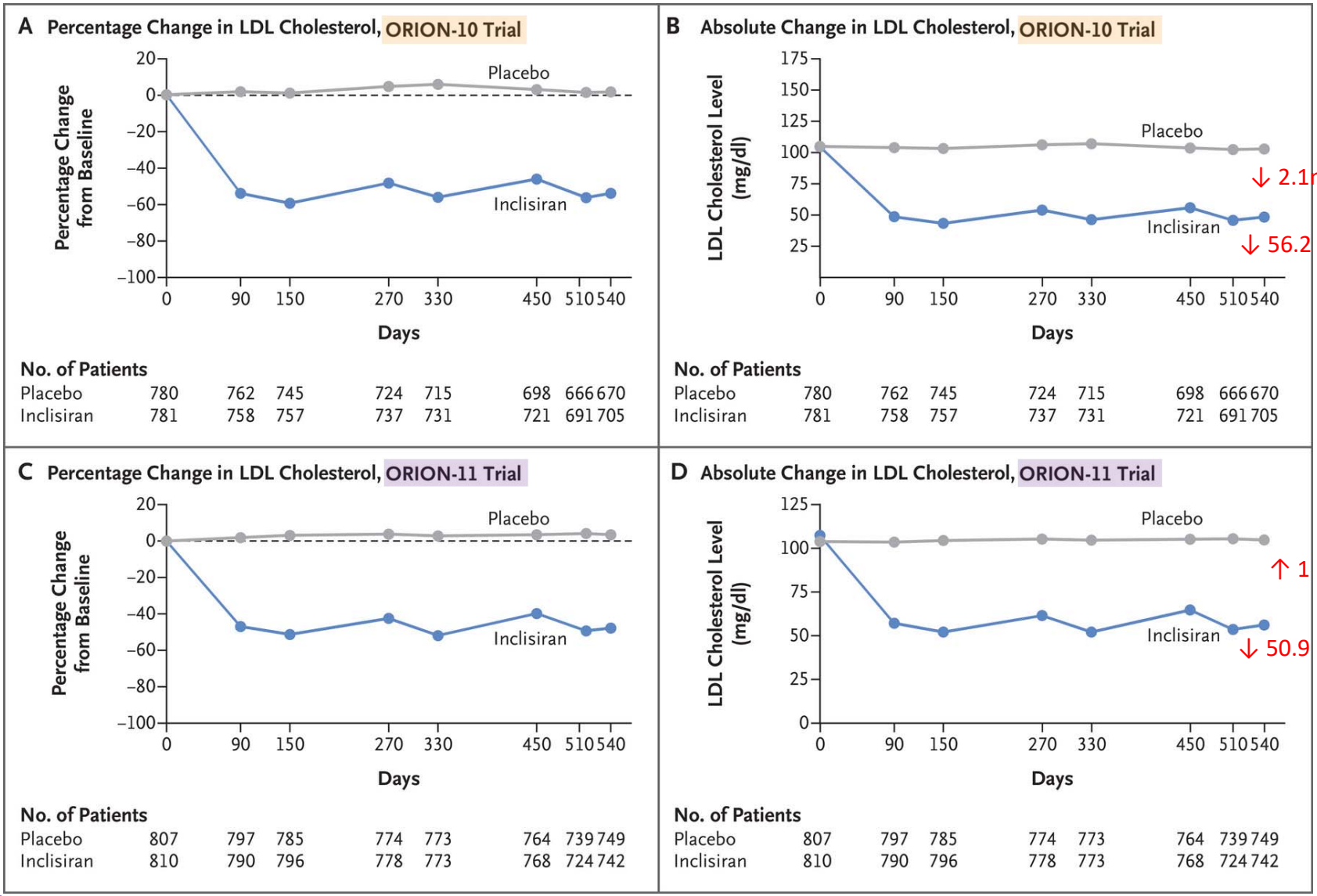
ORION-10 & 11 ASCVD and ↑ LDL-C



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https://www.nejm.org/doi/full/10.1056/NEJMoa1912387?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%3dpubmed

Institute for Clinical and Economic Review (ICER)

ICER Recommendation	MedImpact Action
2015 Original: PCSK9 value-based price $5,300-$7,600 (when cost was ~$15,000/year) • **Recommended PA and step** to enhance health system value to limit treatment to patients for whom extended trials of high-dose statins with ezetimibe have been unsuccessful • PA may need to **include re-trial with statins** for patients who feel they are statin intolerant (lack of widely accepted definition) • Require **specialists in lipid management** **If price were to fall 50-85%, payers likely to consider lifting many elements of PA**	☑ PA for PCSK9 ☑ PA included statin step ☑ PA included provider edit ⃠ PA did not require statin re-trial ☑ **When prices fell, MI lifted PA**
2017 Update: revised value-based price for Repatha to $1,725 – $2,242/year FOURIER: Repatha for ASCVD where LDL-C had not met target of ≤70 mg/dL with statin alone. Overall more stable patients than ODYSSEY; very few on Zetia. Repatha: significantly ↓ composite CV death, MI, stroke or hospitalization for unstable angina or coronary revascularization (9.8% vs 11.3% placebo), RRR of 15% over 2.2 years and ARR of 1.5% (NNT~67). No significant differences in all-cause mortality.	N/A
2019 Update: revised value-based price for Praluent to $2,300-$3,500/year if used to treat all patients who meet ODYSSEY trial eligibility criteria, and $2,700-$4,000 per year for higher-risk patients with LDL cholesterol (LDL-C) ≥ 100 mg/dL despite intensive statin therapy ODYSSEY: when added to max tol statin with a recent acute coronary event and LDL-C ≥70, Praluent ↓ CV events and all-cause mortality by about 15% respectively (NNT ~63); very few on Zetia • Dose titrated to keep the LDL-C between 25 - 50 mg/dL but > 15 mg/dL. • $100,000 -$150,000 per Quality-Adjusted Life Year (QALY) gained. US price of Praluent decreased to $5,850, down from $14,600 when first launched in 2015.	N/A

ICER Upcoming Review 2/2021: inclisiran, bempedoic acid, bempedoic acid/ezetimibe

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Value-based price: range where cost would align with benefit to patients

Inclisiran: Key Takeaways

PDUFA	Manufacturer	MOA	Proposed Indication	Studied Dosing
12/2020	Novartis	Long-acting synthetic small-interfering RNA (siRNA) targeting PCSK9	1) dyslipidemia 2) hypercholesterolemia including heterozygous familial hypercholesterolemia (HeFH) 3) atherosclerotic cardiovascular disease (ASCVD) *with max tolerated statin (?)	300 mg subcutaneous given by HCP every 6 months after dose at day 0 and day 90

Place in therapy:

- Would be 3rd siRNA approved (1st :Onpattro, hereditary TTR amyloidosis, 2nd :Givlaari, acute hepatic porphyria)
- **Efficacy:** Another option for treating hyperlipidemia with substantial LDL-C lowering ability (~50%), specifically targeting PCSK9, but is given only twice per year as opposed to multiple times like the mABs PCSK9 inhibitors
  - Increased adherence, convenience, decreased medication burden
- **Safety:** ADE similar to placebo, no imbalance in death or malignancy; injection site reactions (mild/transient); 94% completed ORION 9, 10, and 11 (reassuring for an agent with such long lasting effects)
- Unlike Praluent and Repatha, which already has cardiovascular trial data and subsequent FDA labels; inclisiran won't have that data available until 2024 (Orion-4)
  - *In Orion 9, 10 and 11, lower prespecified CV endpoints with inclisiran vs placebo (~7.5% vs 10%), but CV events too small for conclusions for benefits on CV outcomes*
- Proposed UM (PA) will be extensive due to potential cost implications based on other siRNA; PA will be mirror of what was PCSK9 criteria

HCP: health care professional; **siRNA:** small interfering RNA; **mAbs:** monoclonal antibody; **PCSK9:** proprotein convertase subtilisin kexin type 9; **ASCVD:** atherosclerotic cardiovascular disease; **hoFH**: homozygous familial hypercholesterolemia; **heFH**: heterozygous familial hypercholesterolemia

4Q20: Quarterly Review

Ophthalmic NSAIDs

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Situation & Background

Situation

- Client requests to evaluate possible UM on ophthalmic non-steroidal anti-inflammatory drugs (NSAIDs)

Background

Ophthalmic NSAIDs:

Bromfenac	Diclofenac	Flurbiprofen	Ketorolac	Nepafenac

Cataract in the Adult Eye Preferred Practice Pattern (American Academy of Ophthalmology 2016):

- Postoperative regimens of topically applied antibiotics, corticosteroids, NSAIDs, and oral analgesic agents vary among practitioners
- No controlled investigations that establish optimal regimens for the use of topical agents
- Therefore, it is the decision of the physician to use any or all of these products singly or in combination

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INDICATIONS

Ophthalmic NSAIDs

Drug[a]	Pain and/or inflammation who have undergone cataract extraction or surgery	Pain and/or photophobia and/or burning/stinging following corneal refractive surgery	Seasonal allergic conjunctivitis	Inhibition of intraoperative miosis
Bromsite (bromfenac) 0.075% solution	✓			
Prolensa (bromfenac) 0.07% solution	✓			
bromfenac 0.09% solution	✓			
diclofenac sodium 0.1% solution	✓	✓		
ketorolac tromethamine 0.4% solution		✓		
ketorolac tromethamine 0.5% solution	✓		✓	
Acuvail (ketorolac tromethamine) 0.45% solution	✓			
flurbiprofen sodium 0.1% solution				✓
Ilevro (nepafenac) 0.3% suspension	✓			
Nevanac (nepafenac) 0.1% suspension	✓			

[a]Brand listed if single-source brand

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4Q20 P&T: New Derivatives, Formulations and Combinations

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Agenda

New derivatives/formulations/combinations:

1. Ortikos (budesonide extended-release) capsules – Crohn's disease
2. Xywav (calcium, magnesium, potassium, and sodium oxybates) – Narcolepsy
3. Gimoti (metoclopramide) nasal spray – Diabetic gastroparesis
4. Conjupri (levamlodipine) – Hypertension
5. Bafiertam (monomethyl fumarate) – Multiple sclerosis
6. Breztri Aerosphere (budesonide, glycopyrrolate, formoterol fumarate) – COPD
7. Trelegy Ellipta (fluticasone furoate, umeclidinium, and vilanterol) powder for oral inhalation – COPD and Asthma

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Ortikos (budesonide) Extended-Release Capsules

- **Initial FDA approval:** 1997
  - Indicated for:
    - Treatment of mild to moderate active Crohn's disease involving the ileum and/or the ascending colon, in patients 8 years and older
    - Maintenance of clinical remission of mild to moderate Crohn's disease involving the ileum and/or the ascending colon for up to 3 months in adults
- **Drug class:** Corticosteroid
- **How supplied:** 6 mg and 9 mg extended-release (ER) capsules
- **Dosing and administration:**
  - Mild to moderate active Crohn's disease:
    - Adults: 9 mg once daily for up to 8 weeks; repeat 8-week treatment courses recurring episodes of active disease
    - Pediatric ages 8-17 years who weigh more than 25kg: 9 mg once daily for up to 8 weeks, followed by 6 mg once daily in the morning for 2 weeks
  - Maintenance of clinical remission of mild to moderate Crohn's disease:
    - Adults: 6 mg once daily for up to 3 months; taper to complete cessation after 3 months
- **Place in therapy:**
  - Budesonide EC is currently available as a 3 mg capsule (generic for Entocort EC) that is approved for the same indication and dosing as Ortikos.
  - Uceris, a budesonide 9 mg ER tablet, is only FDA approved for the induction of remission in patients with active, mild to moderate ulcerative colitis due to the tablet enteric coating delaying budesonide release until exposure to a pH ≥7 in the small intestine.
  - Ortikos was approved by the FDA as a 505(b)(2) in June 2019 with no new notable safety or efficacy clinical data. This dose consolidation may be helpful for certain patients unable to tolerate multiple pills.

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Xywav (calcium, magnesium, potassium, and sodium oxybates) oral solution

- **Initial FDA approval:** July 21, 2020
  - Indicated for treatment of cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy
- **Drug class:** CNS depressant
- **How supplied**: 500 mg/mL oral solution (equivalent to 0.413 g/mL of oxybate)
- **Dosing and administration:** 6-9 g/night in 2 divided doses
  - Take 1st dose at bedtime and 2nd dose 2.5 - 4 hours later
- **Place in therapy:**
  - Xywav is essentially designed to evergreen the patent on Xyrem
  - Xywav and Xyrem both have same active ingredient, sodium oxybate, but Xywav has 92% less sodium per nightly dose vs. Xyrem due to the addition of the counter ions in order to lessen the sodium-related adverse effects

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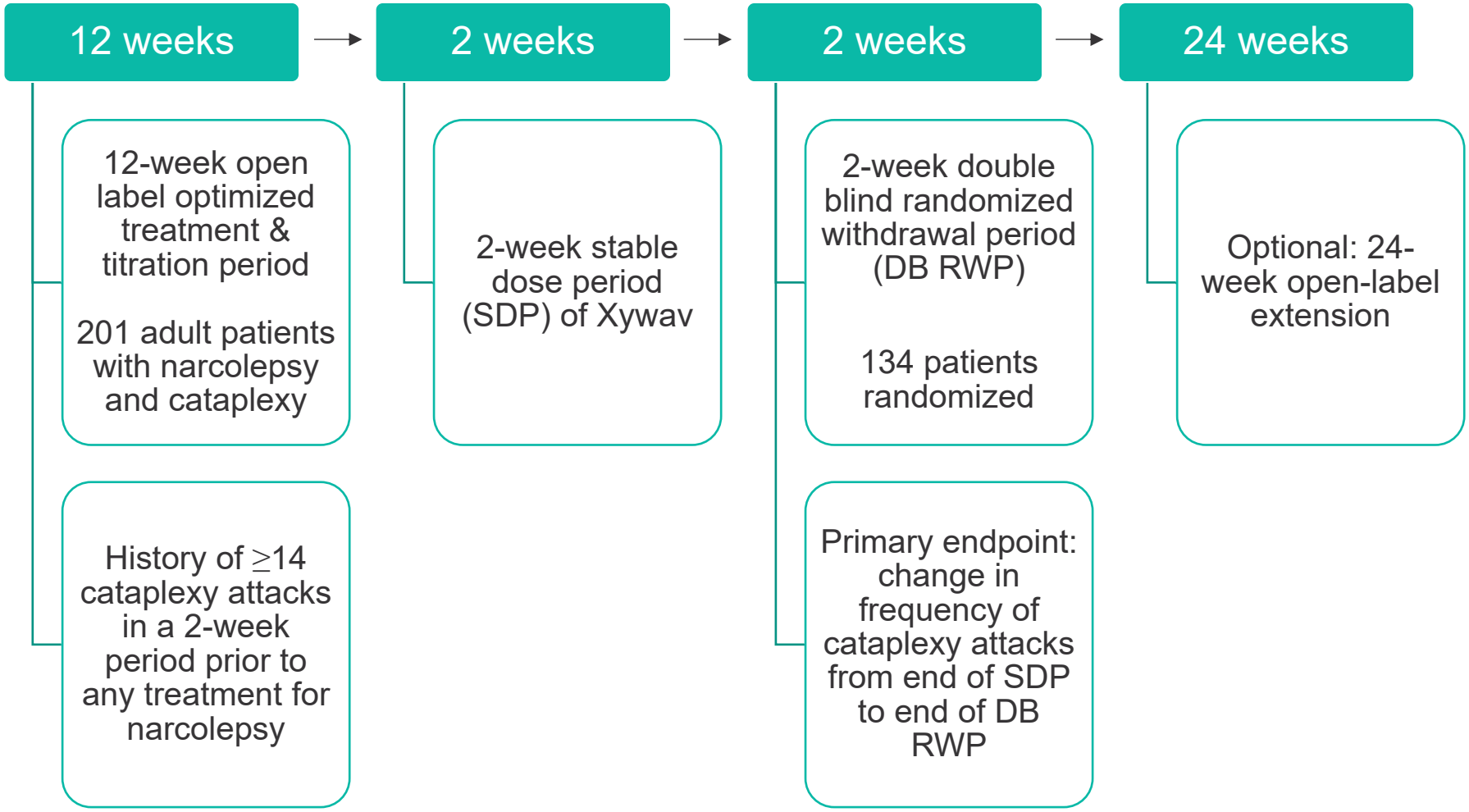
XYWAV ORAL SOLUTION

Approval information

- Approved as a 505(b) with 1 new trial in adults in the label
- Label also included 1 previous Xyrem study in pediatric patients aged 7-17 years old



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Approval information

FDA-Approval Study 1 (NCT 03030599): Double-blind, placebo-controlled, randomized withdrawal study

Study Design: 12-week open label optimized treatment & titration period

1. Xyrem only → **Xywav initiated at gram for gram dose;** minimum of 2 weeks; titrated to a stable, tolerable, and effective dose over 8 weeks
2. Xyrem + another anti-cataplectic drug → **Xywav initiated at gram for gram dose and non-Xyrem anticataplectic tapered off over 2-8 weeks**
3. Non-Xyrem anti-cataplectic drug → **initiate at 4.5 g/night Xywav and non-Xyrem anticataplectic tapered off over 2-8 weeks**
4. Cataplexy-treatment naïve → **initiate at 4.5 g/night Xywav:** titrated at 1-1.5g/night/week to tolerable dose

Results: 2-week SDP vs. 2-week DB RWP

- When Xywav was discontinued, patients got significantly worse.
  - Primary Endpoint: Mean average weekly number of cataplexy attacks significantly increased – placebo: 11.5 vs Xywav: 0.1 ($P < 0.0001$)
  - Secondary Endpoint: Epworth Sleepiness Scale (ESS) score significantly increased ($P < 0.0001$)

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Gimoti (metoclopramide) nasal spray

- **Initial FDA approval:** 1979
  - Indicated for the relief of symptoms in adults with acute and recurrent diabetic gastroparesis
- **Drug class:** Dopamine-2 (D_2) antagonist
- **How supplied**: 15 mg per actuation nasal spray
- **Dosing and administration:** 1 spray (15 mg) in one nostril, 30 minutes before each meal and at bedtime for 2-8 weeks
- **Place in therapy:**
  - Gimoti is now the 5th formulation of metoclopramide indicated for diabetic gastroparesis following an orally disintegrating tablet (ODT), oral solution, tablet and injection
  - Likely most useful in patients who cannot tolerate oral solids/liquids, similar to ODT form
  - Gimoti was approved based on the efficacy established in previous studies of oral metoclopramide with no new trials in the label

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Conjupri (levamlodipine maleate) tablets

- **Initial FDA approval:** 1992
  - Indicated for use alone or in combination with other antihypertensive agents for the treatment of hypertension in adults and pediatric patients 6 years and older
- **Drug class:** dihydropyridine calcium channel blocker (CCB)
- **How supplied:** 1.25, 2.5 and 5 mg tablets
- **Dosing and administration:**
  - **Adults:** 2.5-5 mg orally once daily
  - **Pediatric:** 1.25-2.5 mg orally once daily
- **Place in therapy:**
  - Racemically purified active version of amlodipine
  - Approved via the 505(b)(2) pathway with the safety/efficacy data from amlodipine included in the labeling
  - PK studies indicate Conjupri 5mg is similar to amlodipine 10mg
  - Like other CCBs, Conjupri will be considered a first-line pharmacologic choice for hypertension according to JNC8 along with thiazides, angiotension-converting enzyme (ACE) inhibitors or angiotension II receptor blockers (ARBs)

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Bafiertam (monomethyl fumarate) delayed-release (DR) capsules

- **Initial FDA approval:** 2013
  - Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults
- **Drug class:** Fumaric acid derivative; MS platform therapies
- **How supplied:** 95 mg capsules
- **Dosing and administration:** 95 mg orally twice daily with or without food for 7 days, then increase to maintenance dosage of 190 mg twice daily
- **Place in therapy:**
  - While the two existing monomethyl fumarate (MMF) drugs, Tecfidera (dimethyl fumarate) and Vumerity (diroximel fumarate) utilize prodrug formulations to delay release of MMF into the small intestine, Bafiertam utilizes a DR capsule
  - Bafiertam joins the existing drugs in the MS treatment space known as “platform therapies”
  - 505(b)(2) approval on the basis of bioavailability equivalence to the monomethyl fumarate levels attained post-Tecfidera administration
  - No new efficacy/safety data (Tecfidera’s pivotal data used)

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Breztri Aerosphere (budesonide, glycopyrrolate, formoterol fumarate) inhaler

- **Initial FDA approval:** July 24, 2020
  - Indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD)
- **Drug class:** Combination of inhaled corticosteroid (ICS), long-acting muscarinic antagonist (LAMA) and a long-acting beta2-adrenergic agonist (LABA)
- **How supplied:** budesonide 160 mcg, glycopyrrolate 9 mcg, and formoterol fumarate 4.8 mcg per inhalation metered dose inhaler (MDI)
- **Dosing and administration:** 2 oral inhalations twice daily
- **Place in therapy:**
  - Like Trelegy Ellipta (fluticasone furoate, umeclidinium and vilanterol inhalation powder) before it, Breztri Aerosphere is intended to be used in patients who continue to have symptoms and/or exacerbations while receiving dual therapy with LAMA+LABA or LABA+ICS
  - Unlike Trelegy Ellipta, which is a breath-powered inhaler, Breztri Aerosphere is a pressurized MDI, which could be easier to use in severe COPD, but no current head-to-head trials exist

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Approval information

- Approved as a 505(b)(2) with 2 pivotal trials in labeling
- The safety and efficacy of Breztri were evaluated in 2 phase 3, randomized, double-blind, multicenter, parallel-group trials in subjects with moderate to very severe COPD who remained symptomatic while receiving 2 or more inhaled maintenance treatments for COPD for at least 6 weeks prior to screening
- Both trials compared Breztri Aerosphere to glycopyrrolate + formoterol fumarate (GFF) MDI and budesonide + formoterol fumarate (BFF) MDI

Trial 1

- 52-week duration in a total of 8,588 patients
- The baseline mean post-bronchodilator percent predicted FEV_1 was 43% (range 16% - 73%)
- Primary endpoint: The mean annual rate of moderate or severe exacerbations was less with Breztri (1.08) compared to GFF (1.42, p-value <0.0001) and BFF (1.24, p-value 0.0027)

Trial 2

- 24-week duration in a total of 1,896 patients
- The baseline mean post-bronchodilator percent predicted FEV_1 was 50% (range 22% - 84%)
- Co-primary endpoint 1: Breztri had an increase in on-treatment FEV_1 AUC_{0-4} compared to BFF (difference of 116 mL 95% CI 80, 152)
- Co-primary endpoint 2: Breztri had an increase in the least square (LS) mean change from baseline in morning pre-dose trough FEV_1 compared to GFF (difference of 13 mL 95% CI -9, 36) though this was not statistically significant

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Trelegy Ellipta (fluticasone furoate, umeclidinium, vilanterol) powder for oral inhalation

- **Initial FDA approval:** 2017
  - Indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD)
  - **NEW:** Indicated for the maintenance treatment of asthma in patients 18 years and older
- **Drug class:** Combination of inhaled corticosteroid (ICS), long-acting muscarinic antagonist (LAMA) and a long-acting beta2-adrenergic agonist (LABA)
- **How supplied:** Plastic inhaler contains 2 foil blister strips of powder: 1 strip contains fluticasone furoate 100 or 200 mcg per blister and the other contains umeclidinium/vilanterol 62.5/25 mcg per blister
- **Dosing and administration:** 1 actuation (2 blisters) once daily
  - COPD: 100/62.5/25 mcg once daily
  - Asthma: 100/62.5/25 or 200/62.5/25 mcg once daily
- **Place in therapy:**
  - First triple therapy inhaler approved for the treatment of asthma
  - Current Global Initiative for Asthma (GINA) guidelines only suggest add-on tiotropium for LAMA therapy

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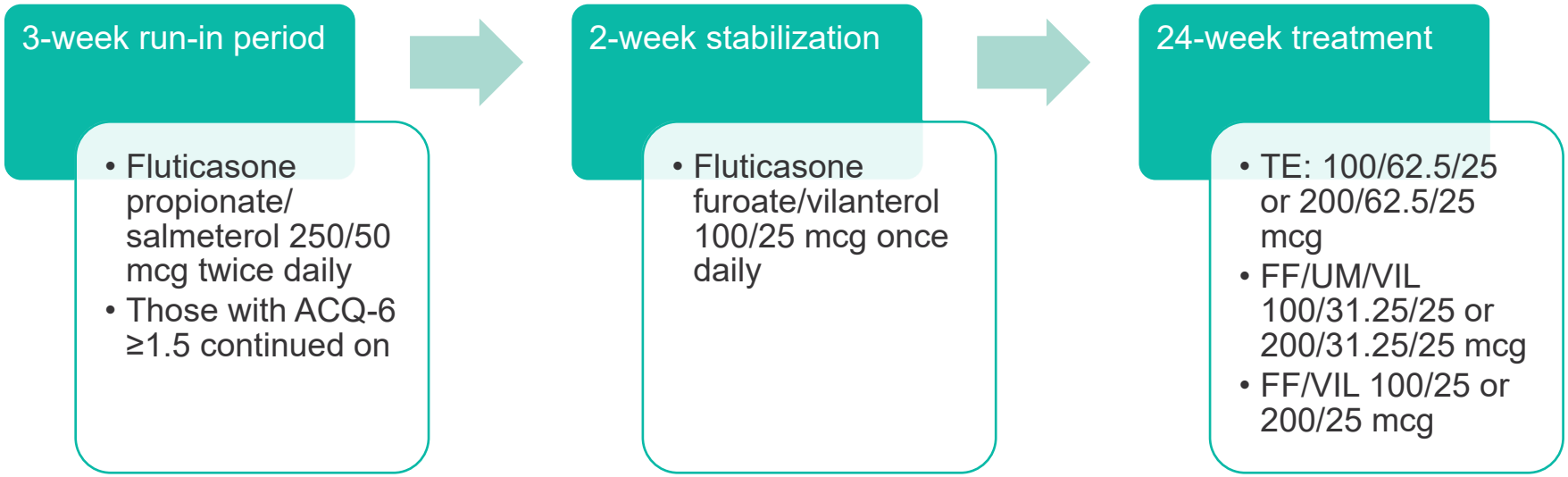
Approval information

- Approved as a 505(b) with 1 new trial added to labeling
- Randomized, double-blind, parallel-group, active-controlled confirmatory trial of 24 to 52 weeks duration



	TE 100	FF/VIL 100	TE 200	FF/VIL 200
Primary endpoint: change from baseline in trough FEV1 at week 24				
LS mean change, mL (SE)	24 (15.7)	134 (15.5)	76 (15.6)	168 (15.5)
Difference in mean change (95% CI)	110 (66, 153)		92 (49, 135)	

TE: Trelegy Ellipta; FF: fluticasone furoate; UM: umeclidinium; VIL: vilanterol; LS: least square

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Santa Clara Family Health Plan™

Pharmacy & Therapeutics Committee

DISCUSSION ITEMS

Pipeline Agents

Santa Clara Family Health Plan™

SANTA CLARA FAMILY HEALTH PLAN

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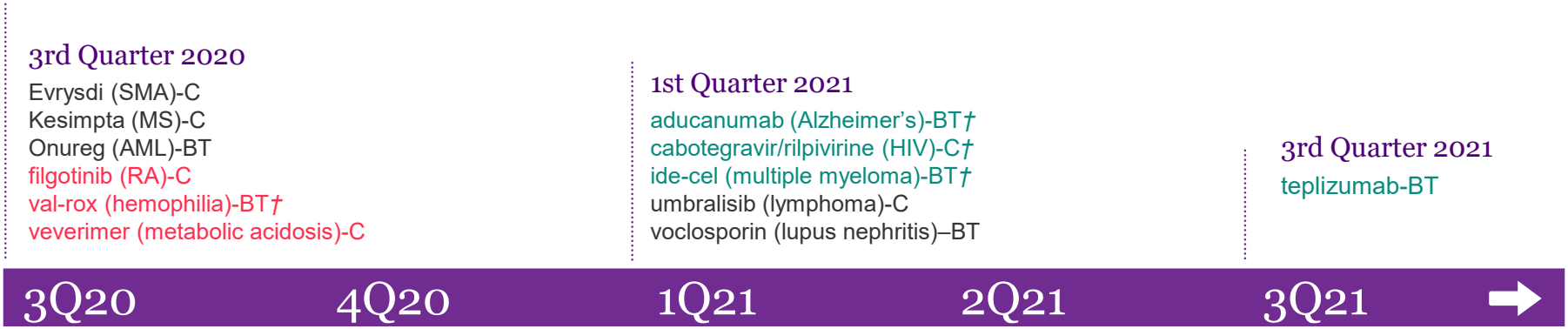
High interest/impact pipeline



Not Yet Filed

efgartigimod-BT

KEY

C = Agent will **compete** with current standard of care
A = Agent will be used in **addition** to current therapy or expands the patient population treated
BT = Agent is a **breakthrough**/novel treatment in an area where no comparable drug therapy previously existed
NI = Previously approved agent with a **new indication** (high impact)
† = Medical Cost
* = Complete Response Letter
# = Emergency Use Authorization

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Generic Pipeline

High impact

4Q2020
Vascepa 1gm*

Vascepa 0.5gm

2020 - 2021
Restasis*

2Q2021
Pomalyst*

4Q 2020
Durezol

Kerydin

2020
Afinitor 10mg*

Zytiga 500mg

Byetta*

Kaletra tablets*

Dec 2020
Absorica

Saphris

Jan 2021
Amitiza

2020 – 2021
Forteo

Thalomid

Feb 2021
Northera

March 2021
Neupro

April 2021
Epaned

May 2021
Zomig Nasal Spray

June 2021
Perforomist*

Medium /Low impact

Bold font = new to slide

Red font = launched

**NO exclusivity*

ǂ Authorized Generic

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