COLORADO
Department of Health Care Policy & Financing

MINUTES OF THE QUARTERLY OPEN MEETING
Health First Colorado, Colorado's Medicaid Program
Drug Utilization Review Board
Department of Health Care Policy and Financing

November 9, 2021
Open Session
1:00 pm – 5:00 pm

1. Call to Order

Today's meeting was held virtually via Zoom. The meeting was called to order at 1:01 pm by L Claus, Board Chair.

2. Roll Call / Introductions

All board members, HCPF staff, and CO DUR team members who were present introduced themselves. There were sufficient members for a quorum with eight voting members participating. Quorum is five members.

a. **Members Present:** Liza Claus, PharmD (Chair); Allison Shmerling, MD, MPH (Vice Chair); Todd Brubaker, DO; Patricia Lanius, BSPharm, MHA; L Laird, PharmD (Industry Representative); Scott VanEyk, MD; Miroslav Anguelov, PharmD; Brian Jackson, MD, MA; Shilpa Klocke, PharmD
b. **Members Absent:** None
c. **Medicaid Pharmacy Staff:** Jim Leonard, PharmD; Jeffrey Taylor, PharmD
d. **CO-DUR Team**: Robert Page, PharmD, MSPH; Julia Rawlings, PharmD

3. Virtual Meeting Information and General Announcements

J Rawlings shared several announcements:

- This meeting is being recorded for internal use by the Department
- We ask that speakers and other attendees who are not on the Board or facilitating the meeting to remain off-video with microphones muted.
- Nicholas Tieu, University of Colorado DUR pharmacy intern, will be managing the technical aspects of today's Zoom meeting.
- Stakeholders who have signed up in advance to provide testimony will have their microphones unmuted at the appropriate time.
    - Speakers providing testimony, and other meeting guests, are asked to keep video turned off throughout the meeting so that we can more easily see and track Board members votes

Reminders for Board Members:

- Video and microphone for Board members will be turned ON. To facilitate the voting process, keeping your video turned on as much as possible during the meeting is encouraged.
- If you experience technical difficulties or your connection interrupted during the meeting, please leave the meeting and use the same Zoom meeting link to be readmitted, as that usually resolves the issue.

- An updated meeting binder was sent to Board members this morning. A reminder to use the icon on the left that looks like a ribbon to pull up links that will allow you to quickly navigate to specific documents.
- Shaded rows on the market share tables indicate the current preferred products on the PDL.
- An important reminder to all Board members to DELETE the meeting binder immediately following this meeting
- Voting may be conducted by raising your hand and/or by verbal "ayes" and "nays," abstentions, and recusals as determined by the Board Chair or Vice-Chair.

4. Colorado Department of Health Care Policy and Financing Updates

J Taylor provided updates from the Department:

Dr. Pete Walsh, Chief Medical Officer for the Department, passes along his thank you to all DUR Board members for your service and expertise.

Dr. Kamleh Shaban will be filling the role of child psychiatry consultant for the Department. This role has previously been filled by Dr. Charlie Lippolis for the past few years. Thank you to Dr. Lippolis for her service over the years in this capacity and welcome to Dr. Shaban.

Plans are underway to move to a new online form for speakers to sign up for DUR Board meetings. Additional details regarding the new process, when they are available, will be posted on the DUR Board webpage.

The new Physician Administered Drug prior authorization (PAD PAR) program is tentatively scheduled for implementation during 1Q2022. This program will affect medications administered in medical settings under the medical benefit. The Department will make additional announcements as more details become available.

Proposed prior authorization criteria will be reviewed today for these three drug products that fall under both the pharmacy and the medical benefit: PDL Immune Globulins, infliximab products, and Entyvio® (vedolizumab). The criteria will apply when these products are administered in the home or a long term care facility and will also apply to the medical benefit once the PAD PAR program is up and running.

We will be continuing the format adopted to read aloud only proposed additions and changes to DUR criteria currently posted on the PDL and Appendix P. For products and drug classes being newly managed and undergoing review, all proposed criteria will be read aloud during the meeting. For products and drug classes that are currently managed with DUR criteria posted on the PDL and Appendix P, only proposed changes to the currently posted criteria will be read aloud. The current PDL and Appendix P are available on the Department's Pharmacy Resources page at https://hcpf.colorado.gov/pharmacy-resources

It is possible that items included in the mass review section of today's agenda may be moved out of mass review. We will acknowledge any changes to the mass review process once we reach that section.

The next Board meeting is tentatively scheduled to be held virtually on Tuesday, February 8, 2022, from 1:00 pm to 5:00 pm. DUR Board meeting agendas are posted on the DUR Board web page.

5. Final Approval of Minutes from August 10, 2021 Meeting

Board Chair L Claus asked if there were any changes to propose for minutes from the August 10 DUR Board meeting. With no discussion, a motion to approve the minutes as written made by B Jackson and seconded by T Brubaker. The motion passed unanimously.

6. Reading of Rules for Public Testimony and Disclosure of Conflicts of Interest

J Taylor read the following rules for Board members and speakers:

Rules for Speaker Testimony: Presentations shall be restricted to products being reviewed for prior authorization criteria. Presentations shall be limited to a maximum of three minutes per drug product. Only one presentation per product will be permitted for a manufacturer. Persons must sign up no later than 24 hours in advance with the DUR Account Manager in order to speak at the DUR Board Meeting. Persons will be called in the order in which they signed in for each set of prior authorization criteria. Presentations must be limited to verbal comments. No visual aids, other than designated handouts are permitted. Persons giving oral presentations must verbally disclose all relationships to pharmaceutical manufacturers at the time they are speaking.

DUR Board Conflicts of Interest: DUR Board Members must verbally disclose any conflicts of interest that would make it difficult to fulfill DUR Board duties in an objective manner. If a conflict of interest exists, members must recuse themselves from the applicable vote or discuss with the Board during the meeting whether the situation rises to the level of an actual conflict. If a Board member recuses, they should not participate in the discussion of the agenda item or any vote regarding that item.

Dr. Laird, Industry Representative, has disclosed his conflicts of interest in the psychiatric, respiratory, neurologic, and sedative/hypnotic therapeutic drug classes.

7. Clinical Updates and General Orders

- **FDA New Product & Safety Updates**

DUR Intern Juliana Gassmann presented a summary of recent FDA drug approvals.

DUR Intern Jenni Mun presented FDA Safety information about JAK inhibitors, along with an FDA safety alert regarding the risk of serious eye injuries due to contact with alcohol-based hand sanitizers.

- **Quarterly Clinical Modules**

R Page presented an update on Quarterly Clinical Modules, complex clinical modules created by the CO-DUR team based on the needs of the Department and to assist with policy development.

  - Hemophilia and Associated Treatment Among Health First Colorado Members
    (final module submitted 9/30/2021)
  - HIV Prevention and Treatment
    (final module to be delivered by 12/31/2021)
  - Analysis of the First Health Colorado DUR Pain Management Consultation Service
    (draft module to be delivered by 12/31/2021)
  - Analysis of Targeted Immune Modulators (TIMs)
    (draft module to be delivered by 3/31/2022)

- **Retrospective DUR Reports**

R Page presented the RDUR summary.

  - There was a drop during 3Q2021 in the number of members <18 years of age who received two or more antipsychotic medications concomitantly for 45 or days or more.

- Data regarding the number of members who had two or more benzodiazepine claims concomitantly for ≥ 90 days remained fairly constant in both the number of providers and members between 3Q2020 and 3Q2021.
- The number of members who received an opioid, a benzodiazepine and a skeletal muscle relaxant concomitantly for 60 or more days (excluding individuals with cancer and with sickle cell disease) decreased overall between 2Q2020 and 3Q2021. The number of prescribers on this report has also decreased during the same time period.
- The number of members with claims for opioids exceeding an average of 200 MME in a 30-day period has declined overall since 1Q2020. However, the number of members and prescribers on this report is showing a slight uptick based on Q32021 data.
- Members with multiple claims for opioid prescriptions that total >150 MME (averaged over 30 days) and no naloxone fill within the 12 months prior to or during the current quarter has moved in a positive direction (358 to 322) from 1Q2021 (when this RDUR intervention was initiated) through 3Q2021.

- **Quarterly Drug Utilization Reports**

  Board members were referred to these reports in the meeting binder. R Page highlighted that the top drugs in 3Q2021 by number of claims were Proair HFA, gabapentin, sertraline, omeprazole, cetirizine, and ibuprofen. Top drugs by cost were Humira®, Trikafta®, Biktarvy®, Novolog®, and Lutuda®.

9. New Business

J Rawlings referred Board members to the proposed DUR criteria section of the Meeting Binder and described the steps of the review process:

- Board members will be asked if they have potential conflicts of interest to disclose prior to reviewing the therapeutic drug classes listed in the meeting agenda.
- For products and drug classes being newly managed and undergoing review, all proposed criteria will be read aloud during the meeting. For products and drug classes that are currently managed with DUR criteria posted on the PDL and Appendix P, only proposed changes to the currently posted criteria will be read aloud.
- Time is permitted for stakeholder comment. All speakers have registered in advance, and each will be given up to 3 minutes of speaking time.
- There will be an opportunity for Board discussion
- Then we will capture for the minutes all motions made by the Board:
  - Name of the member who makes the motion
  - Name of the member who 2nds the motion
  - Abstentions, recusals, and voting results
  - To facilitate recordkeeping for this meeting, a reminder to Board members to please clearly and state your name when making motions and offering seconds

R Page proceeded with the review process of proposed criteria

Proposed Criteria

Red indicates proposed deleted text

Yellow indicates proposed new text

1. Hepatitis C Virus Treatments - Direct Acting Antivirals (DAAs)

Preferred Agents

***PA Required for all agents in this class**

*EPCLUSA[BNR] 200 mg-50 mg (sofosbuvir/velpatasvir)
*HARVONI[BNR] 45 mg-200 mg tablet, pellets (ledipasvir/sofosbuvir)
*Ledipasvir/sofosbuvir 90 mg-400 mg tablet *(Asequa only)*
*MAVYRET (glecaprevir/pibrentasvir)
*Sofosbuvir/velpatasvir 400 mg-100 mg *(Asequa only*)
*VOSEVI [2nd Line] (sofosbuvir/velpatasvir/ voxilaprevir)

Prior authorization requests must be submitted via the Hepatitis C Prior Authorization Request Form linkspecific PAR form which can be accessed on the Pharmacy Resources page at https://www.colorado.gov/hcpf/pharmacy-resources

<table>
<tr><th colspan="2">Preferred Hepatitis C Virus Treatment Regimens</th></tr>
<tr><td>HARVONI
(ledipasvir/sofosbuvir)</td><td>May be approved for members 3 years and older for GT 1, 4-6 who are NC, have CC; or GT 1 in combination with ribavirin in DC; or GT 1,4 in combination with ribavirin for liver transplant recipients who are NC, have CC; AND meet the below applicable criteria</td></tr>
<tr><td>MAVYRET
(glecapravir/pibrentasvir)</td><td>May be approved for members 12 years and older or weighing at least 45 kg GT 1-6 who are NC or have CC (Child-Pugh A) AND meet the below applicable criteria</td></tr>
<tr><td>EPCLUSA
(sofosbuvir/velpatasvir)</td><td>May be approved for members 6 years and older or weighing at least 17 kg for GT 1-6 who are NC, have CC (Child-Pugh A); or in combination with ribavirin in DC; AND meet the below applicable criteria</td></tr>
<tr><td>HARVONI PELLET
(ledipasvir/sofosbuvir)</td><td>May be approved for members 3 years of age or older weighing
less thant 17 kg OR members 3 years of age or older that are unable to take/swallow ledipasvir/sofosbuvir oral tablets AND meeting one of the following:
GT 1, 4-6 who are NC, have CC
GT 1 in combination with ribavirin in DC
GT 1,4 in combination with ribavirin for liver transplant recipients who are NC, have CC
AND meet the below applicable criteria below<table><tr><th>Body Weight</th><th>Dosing</th><th>Maximum Daily Dose</th></tr><tr><td>< 17 kg</td><td>one 33.75mg/150mg packet once daily x 12 weeks</td><td>33.75mg/150mg</td></tr><tr><td>17- 34 kg</td><td>one 45mg/200mg packet once daily x 12 weeks</td><td>45mg/200mg</td></tr><tr><td>≥ 35 kg</td><td>two 45mg/200mg packets once daily x 12 weeks</td><td>90mg/400 mg</td></tr></table></td></tr>
<tr><td>VOSEVI tablet[2nd Line]
(sofosbuvir/velpatasvir/ voxilaprevir)</td><td>May be approved for members 18 years or older with chronic HCV infection who are NC, have CC (Child-Pugh A) AND meet one of the following:</td></tr>
</table>

	• GT 1-6 and has previously failed treatment with a regimen containing an NS5A inhibitor (such as ledipasvir, daclatasvir, or ombitasvir) OR • GT 1a or 3 and has previously failed treatment with a regimen containing sofosbuvir without an NS5A inhibitor AND meet the below applicable criteria for re-treatment.

Initial Treatment (all agents):
Preferred agents may be approved for initial treatment if the following criteria are met:

- Physician attests that one quantitative HCV RNA test result from 12-24 weeks post-treatment will be provided in order to document SVR (sustained virologic response) **AND**
- Member must have received, or be in the process of receiving, full courses of both Hepatitis A and Hepatitis B vaccinations, or have immunity **AND**
- If a non-pan genotypic DAA will be prescribed, then test for HCV genotype and subtype. Members must have genotyping results within 1 year prior to the anticipated therapy start date **AND**
- Agent must be prescribed by an infectious disease specialist, gastroenterologist, or hepatologist **OR** prescribed by any primary care provider in consultation with an infectious disease specialist, gastroenterologist or hepatologist **OR** for treatment naïve members without cirrhosis, prescribed by any primary care who has completed the hepatitis C (HCV) ECHO series (four, 1-hour trainings) **AND**
- Physician attests to the member's readiness for adherence to treatment (prescribers may utilize assessment tools to evaluate readiness of the patient for treatment. Some examples are available at: https://www.thenationalcouncil.org/wp-content/uploads/2020/04/Screening-for-Viral-Hepatitis-within-Behavioral-Health-Organizations-7.9.14.pdf?daf=375ateTbd56 or Psychosocial Readiness Evaluation and Preparation for Hepatitis C Treatment (PREP-C) available at: https://prepc.org/) **AND**
- If member is abusing/misusing alcohol or controlled substances, member must be receiving counseling or will be enrolled in counseling or a substance use treatment program prior to initiation of treatment for HCV infection **AND**
- Member's complete current medication list has been reviewed and screened for significant drug-drug interactions (reference tool available at https://www.hep-druginteractions.org/) **AND**
- Physician attests to meeting one of the following:
    - Member has a diagnosis of chronic HCV infection (presence of HCV RNA viral load for ≥ 6 months) **OR**
    - Member has a diagnosis of acute HCV infection in the setting of solid organ transplant **OR**
    - Prescriber wishes to treat a member with acute HCV infection upon initial diagnosis and acknowledges that the rate of spontaneous resolution of acute infection has been considered as part of assessing the need to initiate antiviral therapy (acute HCV infection may spontaneously clear in 20-50% of patients) **AND**
- For women of childbearing potential, pregnancy test results have been documented within 30 days of expected direct-acting antiviral start date, and counseling has been provided regarding pregnancy and breastfeeding **AND**
- The following laboratory tests and assessments conducted within 6 months of initiating therapy have been provided:
    - Quantitative HCV-RNA
    - Complete Blood Count (CBC)
    - Hepatic Function Panel (i.e. albumin, total and direct bilirubin, alanine aminotransferase (ALT), aspartate aminotransferase (AST), and alkaline phosphatase levels)
    - Calculated glomerular filtration rate (GFR)

- If cirrhosis is present, calculation of the Child-Turcotte-Pugh (CTP) Score
- o Transplant status as applicable (pre-, post-, N/A)

All other non-preferred agents may be approved if the criteria for initial treatment above is are satisfied **AND** documentation is provided indicating an acceptable rationale for not prescribing a preferred treatment regimen (acceptable rationale may include patient specific medical contraindications to a preferred treatment or cases where a member has initiated treatment on a non-preferred drug and needs to complete therapy).

Re-treatment:
All requests for HCV re-treatment for members who have failed therapy with a DAA will be reviewed on a case-by-case basis. Additional information will be requested for retreatment requests including (but not limited to):

- Previous regimen medications and dates treated
- Genotype of previous HCV infection
- Any information regarding adherence to previously trialed regimen(s) and current chronic medications
- Adverse effects experienced from previous treatment regimen
- Concomitant therapies during previous treatment regimen
- VOSEVI regimens will require verification that member has been tested for evidence of active hepatitis B virus (HBV) infection and for evidence of prior HBV infection prior to initiating treatment.

For ribavirin-containing regimens only:

- Member is not a pregnant female or a male with a pregnant female partner **AND**
- Women Members of childbearing potential and their male partners must attest that they will use two forms of effective (non-hormonal) contraception during treatment **AND**
- Member does not meet any of the following ineligibility criteria for use of ribavirin:
  - Members who are Ppregnant women and malesen whose female partners are pregnant
  - Known hypersensitivity to ribavirin
  - Autoimmune hepatitis
  - Hemoglobinopathies
  - Creatinine Clearance < 50mL/min
  - Co-administered with didanosine

Grandfathering: Members currently receiving treatment with a non-preferred agent will receive approval to finish their treatment regimen, provided required documentation is sent via normal PAR process.

Stakeholder input:
Epclusa Summary
Letter, HCV Class, Denver Health

Scheduled testimony presentations:
N Rose, Gilead – Epclusa
L Hill, AbbVie – Mavyret
S Rowan – Denver Health

Discussion

- No Board members reported a conflict of interest for this therapeutic class.
- B Jackson asked about continuing the requirement for newly-trained primary care providers, or providers new to Colorado, who did not have access to the previous ECHO training series to consult with an infectious disease specialist, gastroenterologist, or hepatologist each time they

wanted to prescribe HCV treatment. This may be overly restrictive since HCV treatment is now relatively common.

- B Jackson suggested that either a new HCV training program should be created to allow primary care providers to allow them to become eligible to prescribe these medications or the subspeciality consultation requirement should be removed.
- Dr. Sarah Rowan offered that, although the full HCV ECHO training program may not be offered again in the future, perhaps the training information could be made available for providers to review online.
- L Claus suggested removing the required subspecialty consultation requirement and adding language to the criteria stating, "Primary care providers who are prescribing these therapies are encouraged to review the ECHO series training."
- A Shmerling suggested editing this requirement to, "Agent must be prescribed by an infectious disease specialist, gastroenterologist, or hepatologist OR prescribed by any primary care provider who is comfortable managing this disease process. Primary care providers are encouraged to review the ECHO material."
- B Jackson proposed, "Primary care providers are encouraged to review the ECHO material or similar material." Using training materials available through professional societies would allow for updates and allow for alternative ways to obtain HCV treatment information.
- B Jackson suggested that the bullet point regarding substance abuse be edited to clarify that the reason for assessing substance abuse status is based on concerns about adherence to prescribed dosing regimens for HCV treatment or significant drug-drug interactions, and not based solely on the fact that the member has a substance use disorder.
- A Shmerling proposed removing all language related to substance use and include, "Provider attests that patient is able to adhere to the treatment protocol." B Jackson agreed.
- S Klocke proposed removing the bullet point that begins, "Physician attests to the member's readiness for adherence to treatment…" B Jackson agreed, adding that adherence is difficult to predict and the existing bullet point may introduce biases.
- B Jackson commented that a 2017 interim analysis of the ribavirin pregnancy registry suggested that the safety risk to pregnant women and their male partners due to exposure to ribavirin may be negligible. The current criteria are based on product labeling. Dr. Jackson requests that the Department review the ribavirin criteria section to determine if these drug safety precautions apply females, males, and other-gendered members or only in certain situations. He asks that the Department determine where the risk from ribavirin, if any, is coming from so as not to create an unnecessary barrier to receiving treatment for HCV if the risk is now considered negligible based on the new analysis. Consider removing all or part of this language, if appropriate, particularly for members who are already pregnant and their partners and for same-sex couples.
- Dr. VanEyk emphasized that any changes to the language regarding HCV medication prescribing requirements for primary care providers will apply only to treatment-naïve members without cirrhosis unless the Board wants to broaden that patient population.
- A Shmerling moved to approve the proposed criteria, with these amendments:
  1. Update Mavyret criteria to include current indicated age range for children
  2. Explore ribavirin data regarding pregnancy outcomes
  3. Remove entire bullet point that begins, "Physician attests to the member's readiness for adherence to treatment…", and
  4. Remove entire bullet point regarding alcohol and substance misuse/abuse
  5. Modify current language requiring primary care providers to consult with subspecialists prior to prescribing treatment for HCV and replacing it with qualifications to prescribe, "Either through consultation with an expert in hepatitis C treatment or the primary care provider attests to having received sufficient education to safely prescribe the listed hepatitis C medications (such as through viewing the ECHO modules or similar educational materials)"

Motion seconded by B Jackson. T Brubaker opposed. P Lanius abstained. Motion passed with six aye votes.

2. Human Immunodeficiency Virus (HIV) Agents, Oral

Preferred Agents
All products are preferred
Branded multisource agents will not require prior authorization

Stakeholder input:
Letter, Vivent Health
Biktarvy overview for P&T
Descovy for PrEP summary
Letter, HIV Class, Denver Health
Letter, 5280 Fast Track Cities
Prescribing information, Janssen - Symtuza

Scheduled testimony presentations:
M Pagnotti – Vivent Health
N Rose, Gilead – Biktarvy
N Rose, Gilead - Descovy
S Rowan – Denver Health
B Cardell - 5280 Fast Track Cities
B Bongiovanni – Colorado Organizations and Individuals Responding to HIV AIDS

Discussion
- J Taylor introduced this new class that will be added to the PDL on 1/1/2022. Following the usual process, this class has undergone P&T review and the final decision was to make all products in this class preferred products. The Department is proposing that there be no prior authorization criteria for any products in this class. The DUR Board's role is to review and proposal that no prior authorization criteria or coverage limitations be applied to medications in this class.
- J Taylor clarified that branded multisource agents will not require prior authorization with inclusion of a Dispense as Written or DAW1 designation, with no coverage restrictions. This is related to the generic mandate policy exception for HIV medications.
- No Board members reported a conflict of interest for this therapeutic class.
- A Shmerling moved to accept the DUR management of this therapeutic class as proposed by the Department. Seconded by T Brubaker. Motion passed unanimously.

3.a. Pulmonary Arterial Hypertension (PAH), Phosphodiesterase Inhibitors

Preferred Agents
***Must meet eligibility criteria**
*REVATIO^{BNR} (sildenafil) oral suspension
*Sildenafil (generic REVATIO) 20 mg tablet
*Tadalafil (generic ADCIRCA) 20 mg tablet

***Eligibility Criteria for all agents in the class**

Approval for **Sildenafil or tadalafil tablets** will be granted may be approved for a diagnosis of pulmonary hypertension or right-sided heart failure.

REVATIO (sildenafil) suspension may be approved for:
- Members with a diagnosis of pulmonary hypertension **AND**
- Members who are < 5 years of age OR members ≥ 5 years who are unable to take/swallow tablets

Non-preferred products may be approved for members who have failed treatment with preferred sildenafil AND preferred tadalafil. Failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects, or significant drug-drug interaction.

REVATIO (sildenafil) suspension will approved for members who are unable to take/swallow tablets

Grandfathering: Members who have been previously stabilized on a non-preferred product canmay receive approval to continue on the medication

Discussion
- No Board members reported a conflict of interest for this therapeutic sub-class.
- T Brubaker moved to accept these criteria as written. Seconded by S Klocke. Motion passed unanimously.

3.b. Pulmonary Arterial Hypertension, Endothelin Antagonists

Preferred Agents
***Must meet eligibility criteria**
*Ambrisentan tablet (generic LETAIRIS)
*LETAIRIS[BNR] (ambrisentan) tablet
*TRACLEER[BNR] (bosentan) 62.5 mg, 125 mg tablet

***Eligibility Criteria for all agents in the class**
Approval willmay be granted for a diagnosis of pulmonary hypertension. Member and prescriber should be enrolled in applicable REMS program for prescribed medication.

Non-preferred agents willmay be approved for members who have trialed and failed two preferred agents. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.

Grandfathering: Members who have been previously stabilized on a non-preferred product canmay receive approval to continue on the medication.

Stakeholder input:
Clinical summary, Janssen Scientific Affairs, LLC - Opsumit

Discussion
- No Board members reported a conflict of interest for this therapeutic sub-class.
- P Lanius moved to accept these criteria as written. Seconded by B Jackson. Motion passed unanimously.

3.c. Pulmonary Arterial Hypertension, Prostanoids

Preferred Agents
***Must meet eligibility criteria**
*Epoprostenol (generic FLOLAN) vial
*ORENITRAM (treprostinil) ER tablet
*VENTAVIS (iloprost) inhalation solution

***Eligibility Criteria for all agents in the class**
Approval will be granted for a diagnosis of pulmonary hypertension.

Non-preferred products willmay be approved for members who have failed treatment with a Preferred Product. (Failure is defined as: lack of efficacy, allergy, intolerable side effects, contraindication to IV therapy or significant drug-drug interaction).

Grandfathering: Members who have been previously stabilized on a non-preferred product can receive approval to continue on the medication.

Scheduled testimony presentations:
K Schreur, United Therapeutics

Discussion
- No Board members reported a conflict of interest for this therapeutic sub-class.
- B Jackson moved to accept these criteria as written. Seconded by S Klocke. Motion passed unanimously.

3.d. Pulmonary Arterial Hypertension, Guanylate Cyclase Stimulator (sGC)

Preferred Agents
NONE

ADEMPAS (riociguat) willmay be approved for patientsmembers who meet the following criteria:
- PatientMember is not a pregnant female and is able to receive monthly pregnancy tests while taking ADEMPAS and one month after stopping therapy **AND**
- WomenMembers of childbearing potential and their male partners must use one of the following contraceptive methods during treatment and for one month after stopping treatment (e.g. IUD, contraceptive implants, tubal sterilization, a hormone method with a barrier method, two barrier methods, vasectomy with a hormone method, or vasectomy with a barrier method) **AND**
- PatientMember is does have or has severe renal failure (e.g. a CrCl < ≥ 15 mL/min) and is not on dialysis **AND**
- PatientMember does not have severe liver impairment (e.g. Child Pugh C) **AND**
- Prescriber must be enrolled with the ADEMPAS REMS Program **AND**
- Female patients, regardless of reproductive potential, Members must be enrolled in the ADEMPAS REMS program prior to starting therapy, if required, **AND**
- PatientMember has a diagnosis of persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH) (WHO Group 4) after surgical treatment or has inoperable CTEPH **OR**
- PatientMember has a diagnosis of pulmonary hypertension and has failed treatment with a preferred product for pulmonary hypertension. (Failure is defined as a lack of efficacy, allergy, intolerable side effects, or significant drug-drug interactions).

Discussion
- No Board members reported a conflict of interest for this therapeutic sub-class.
- P Lanius asked if the statement, "Members must be enrolled in the ADEMPAS REMS program prior to starting therapy, if required" can be evaluated to determine if all members are required to be enrolled in the Adempas REMS program or if this applies only to specific subsets of patients.
- P Lanius moved to accept these criteria as written. Seconded by A Shmerling. Motion passed unanimously.

4. Newer Generation Antidepressants

Preferred Agents
- Bupropion IR, SR, XL
- Citalopram tablet, solution
- Desvenlafaxine succinate ER tablet
- Duloxetine (generic CYMBALTA) capsule
- Escitalopram tablet
- Fluoxetine capsule, solution
- Fluvoxamine tablet
- Mirtazapine tablet, ODT
- Paroxetine IR tablet
- Sertraline tablet, solution
- Trazodone tablet
- Venlafaxine IR tablet
- Venlafaxine ER capsule

Non-preferred brand name medications do not require a prior authorization when the equivalent generic is preferred and "dispense as written" is indicated on the prescription.

Prior authorization for FETZIMA, TRINTELLIX, or VIIBRYD willmay be approved for members who have failed an adequate trial with four preferred newer generation anti-depressant products. (Failure is defined as lack of efficacy with 6-week trial, allergy, intolerable side effects, or significant drug-drug interaction).

All non-preferred products not listed above willmay be approved for members who have failed adequate trial with three preferred newer generation anti-depressant products. If three preferred newer generation anti-depressant products are not available for indication being treated, approval of prior authorization for non-preferred products will require adequate trial of all preferred products FDA approved for that indication. (Failure is defined as lack of efficacy with 6-week trial, allergy, intolerable side effects, or significant drug-drug interaction).

Citalopram doses higher than 40mg/day for ≤ 60 years of age and 20mg/day for >60 years of age will require prior authorization. Please see the FDA guidance at: https://www.fda.gov/drugs/drugsafety/ucm297391.htm for important safety information.

Grandfathering: Members currently stabilized on a non-preferred newer generation antidepressant canmay receive approval to continue on that agent for one year if medically necessary. **Verification may be provided from the prescriber or the pharmacy.**

Discussion
- Dr. Laird verbalized a conflict of interest regarding review of this therapeutic class.
- A Shmerling moved to accept these criteria as written. Seconded by T Brubaker. Motion passed unanimously.

5.a. Antiemetics, Oral

Preferred Agents

Doxylamine/pyridoxine tablet (generic DICLEGIS) *(Analog Pharma only)*
DICLEGIS[BNR] (doxylamine/pyridoxine) tablet
Meclizine (RX) tablet
Metoclopramide solution, tablet
Ondansetron ODT, tablet
Ondansetron oral suspension/ solution (for members <5 years of age)
Prochlorperazine tablet
Promethazine syrup, tablet
Trimethobenzamide capsule

Ondansetron solution may be approved for members < 5 years and those members > 5 years of age with a feeding tube.

EMEND (aprepitant) TriPack or **EMEND (aprepitant) powder kit** may be approved following trial and failure of two preferred products AND Emend (aprepitant) capsule. Failure is defined as lack of efficacy with 14-day trial, allergy, intolerable side effects, or significant drug-drug interaction.

DICLEGIS DR (dDoxylamine/pyridoxine) tablet (brand) and **BONJESTA (doxylamine/pyridoxine)** may be approved for 9 months if meeting the following criteria:

- Member has nausea and vomiting associated with pregnancy **AND**
- Member has trialed and failed generic doxylamine/pyridoxine DICLEGIS DR tablet (generic DICLEGIS) **AND** one of the following (failure is defined as lack of efficacy with a 7-day trial, allergy, intolerable side effects, or significant drug-drug interaction):
    - Antihistamine (such as diphenhydramine, dimenhydrinate, meclizine) **OR**
    - Dopamine antagonist (such as metoclopramide, prochlorperazine, promethazine) **OR**
    - Serotonin antagonist (ondansetron, granisetron)

All other non-preferred products may be approved for members who have trialed and failed treatment with two preferred products. Failure is defined as lack of efficacy with 14-day trial, allergy, intolerable side effects, or significant drug-drug interaction.

Dronabinol prior authorization may be approved for members meeting above non-preferred criteria OR via AutoPA for members with documented HIV diagnosis.

Discussion

- No board members reported a conflict of interest for this therapeutic class.
- L Claus moved to accept these criteria as written. Seconded by B Jackson. Motion passed unanimously.

5.b. Antiemetics, Non-oral

Preferred Agents

PHENADOZ (promethazine) 12.5mg, 25 mg suppository
Prochlorperazine suppository
Promethazine 12.5 mg, 25 mg suppository
Scopolamine patch

All other non-preferred products may be approved for members who have trialed and failed treatment with two preferred products. Failure is defined as lack of efficacy with 14-day trial, allergy, intolerable side effects, or significant drug-drug interaction.

Discussion
- No board members reported a conflict of interest for this therapeutic class.
- P Lanius moved to accept these criteria as written. Seconded by S Klocke. Motion passed unanimously.

6. *H. Pylori* Treatments

Preferred Agents
PYLERA (bismuth subcitrate/ metronidazole/tetracycline) tablet

Non-preferred *H. pylori* treatments should be used as individual product ingredients unless one of the individual products is not commercially available, then a PA for the combination product may be given.

Discussion
- No board members reported a conflict of interest for this therapeutic class.
- B Jackson moved to accept these criteria as written. Seconded by S Klocke. Motion passed unanimously.

7. Targeted Immune Modulators (TIMs)

Stakeholder input:
Letter, Children's Hospital Colorado - Dept of Gastroenterology
Letter, Children's Hospital Colorado - Dept of Rheumatology
Clinical summary, Novartis - Ilaris

Scheduled testimony presentations:
K Schlageter, Bristol Myers Squibb – Orencia
C Johnson, Amgen - Otezla
B Bentz, Lilly - Taltz
L Hill, AbbVie – Humira, Rinvoq, Skyrizi *(yielded speaking time)*
P Wettestad, Novartis - Ilaris

7.a. Targeted Immune Modulators (TIMs) - Rheumatoid Arthritis, Polyarticular Course Juvenile Idiopathic Arthritis (pJIA), Systemic Juvenile Idiopathic Arthritis (sJIA), and Ankylosing Spondylitis

Preferred Agents
No PA Required (if diagnosis met)
***Must meet eligibility criteria**
*ENBREL (etanercept)
*HUMIRA (adalimumab)
*KEVZARA (sarilumab)
*TALTZ (ixekizumab) autoinjector, syringe
*XELJANZ IR (tofacitinib) tablet

First line preferred agents (HUMIRA, ENBREL, and XELJANZ IR) may receive approval for use for FDA-labeled indications.

Quantity Limit: XELJANZ IR is limited to 2 tablets per day or 60 tablets for a 30-day supply

***TALTZ (ixekizumab)** may receive approval for use for FDA-labeled indications following trial and failure‡ of HUMIRA or ENBREL.

***KEVZARA (sarilumab)** may receive approval for use for FDA-labeled indications following trial and failure‡ of HUMIRA or ENBREL **AND** XELJANZ IR.

KINERET (anakinra) may receive approval for use for:

- FDA-labeled indications following trial and failure‡ of HUMIRA or ENBREL **AND** XELJANZ IR **OR**
- Treatment of systemic juvenile idiopathic arthritis (sJIA)

ILARIS (canakinumab) may receive approval if meeting the following:

- Medication is being prescribed for systemic juvenile idiopathic arthritis (sJIA) or Adult Onset Still's Disease (AOSD), **AND**
- Member has trialed and failed‡ KINERET (anakinra) **AND** ACTEMRA (tocilizumab)

XELJANZ (tofacitinib) XR approval will require verification of the clinically relevant reason for use of the XELJANZ XR formulation versus the XELJANZ IR formulation, in addition to meeting non-preferred criteria listed below above.

All other non-preferred agents may receive approval for FDA-labeled indications following trial and failure‡ of ALL indicated first line preferred agents. (HUMIRA, ENBREL, and XELJANZ IR).

Agents listed below must meet the following additional criteria for approval of that agent:

‡Failure is defined as lack of efficacy with a three-month trial, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction.

Grandfathering: Members with current prior authorization approval on file for Members currently taking COSENTYX (secukinumab) may receive approval to continue on that agent.

The Department would like to remind providers that many products are associated with patient-centered programs that are available to assist with drug administration, education, and emotional support related to our members' various disease states.

Discussion

- No Board members reported a conflict of interest for this therapeutic sub-class.
- L Claus moved to accept criteria for this class as written. Seconded by S Klocke. Motion passed unanimously.

7.b. Targeted Immune Modulators (TIMs) - Psoriatic Arthritis

Preferred Agents
No PA Required (if diagnosis met)
***Must meet eligibility criteria**
*ENBREL (etanercept)
*HUMIRA (adalimumab)
*OTEZLA (apremilast) tablet
*TALTZ (ixekizumab)
*XELJANZ IR (tofacitinib) tablet

First line preferred agents (HUMIRA, ENBREL, XELJANZ IR) may receive approval for psoriatic arthritis indication.

Quantity Limit: XELJANZ IR is limited to 2 tablets per day or 60 tablets for a 30-day supply

***OTEZLA (apremilast)** may receive approval for psoriatic arthritis indication following trial and failure‡ of HUMIRA or ENBREL **AND** XELJANZ IR or TALTZ.

***TALTZ (ixekizumab)** may receive approval for psoriatic arthritis indication following trial and failure‡ of HUMIRA or ENBREL **AND** XELJANZ IR or OTEZLA.

STELARA (ustekinumab) syringe for subcutaneous use may receive approval if meeting the following:

- Member has trial and failure‡ of HUMIRA or ENBREL **AND** XELJANZ IR **AND** TALTZ or OTEZLA **AND**
- Prescriber acknowledges that loading dose administration prior to approval of STELARA for maintenance therapy using the above criteria should be avoided and will not result in an automatic approval of STELARA for maintenance therapy **AND**
- Prior authorization approval may be given for an initial 16 week supply and authorization approval for continuation may be provided based on clinical response.
- STELARA IV vial formulation may receive approval under the pharmacy benefit if meeting non-preferred criteria listed above **AND** if being administered in a long-term care facility or the member's home by a home health provider (initial 16-week authorization may be placed for both IV and subcutaneous formulations at time of STELARA IV vial approval).

XELJANZ (tofacitinib) XR approval will require verification of the clinically relevant reason for use of the XELJANZ XR formulation versus the XELJANZ IR formulation, in addition to meeting non-preferred criteria listed below above.

All other non-preferred agents may receive approval for psoriatic arthritis following trial and failure‡ of HUMIRA or ENBREL **AND** XELJANZ IR **AND** TALTZ or OTEZLA. Agents listed below must meet the following additional criteria for approval of that agent:

‡Failure is defined as lack of efficacy with a three-month trial, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction.
Grandfathering: Members with current prior authorization approval on file for

Members currently taking COSENTYX (secukinumab) may receive approval to continue on that agent.

The Department would like to remind providers that many products are associated with patient-centered programs that are available to assist with drug administration, education, and emotional support related to our members' various disease states.

Discussion

- No Board members reported a conflict of interest for this therapeutic sub-class.
- L Claus moved to accept criteria for this class as written. Seconded by S Klocke. Motion passed unanimously.

7.c. Targeted Immune Modulators (TIMs) - Plaque Psoriasis

Preferred Agents
No PA Required (if diagnosis met)
***Must meet eligibility criteria**
*ENBREL (etanercept)
*HUMIRA (adalimumab)
*OTEZLA (apremilast) tablet
*TALTZ (ixekizumab)

First line preferred agents (HUMIRA, ENBREL) may receive approval for plaque psoriasis indication.

*Second line preferred agents (TALTZ, OTEZLA) may receive approval for plaque psoriasis indication following trial and failure‡ of HUMIRA OR ENBREL.

STELARA (ustekinumab) syringe for subcutaneous use may receive approval if meeting the following:

- Member has trial and failure‡ of one indicated first line agent (HUMIRA, ENBREL) **AND** two indicated second line agents (TALTZ, OTEZLA), **AND**
- Prescriber acknowledges that loading dose administration prior to approval of STELARA for maintenance therapy using the above criteria should be avoided and will not result in an automatic approval of STELARA for maintenance therapy **AND**
- Prior authorization approval may be given for an initial 16 week supply and authorization approval for continuation may be provided based on clinical response.
- STELARA IV vial formulation may receive approval under the pharmacy benefit if meeting non-preferred criteria listed above **AND** if being administered in a long-term care facility or the member's home by a home health provider (initial 16-week authorization may be placed for both IV and subcutaneous formulations at time of STELARA IV vial approval).

All other non-preferred agents may receive approval for plaque psoriasis indication following trial and failure‡ of one indicated first line agent (HUMIRA, ENBREL) AND two second line agents (TALTZ, OTEZLA). Agents listed below must meet the following additional criteria for approval of that agent:

‡Failure is defined as lack of efficacy with a three-month trial, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction.

Grandfathering: Members with current prior authorization approval on file for Members currently taking COSENTYX (secukinumab) may receive approval to continue on that agent.

The Department would like to remind providers that many products are associated with patient-centered programs that are available to assist with drug administration, education, and emotional support related to our members' various disease states.

Discussion

- No Board members reported a conflict of interest for this therapeutic sub-class.
- S Klocke moved to accept criteria for this class as written. Seconded by L Claus. Motion passed unanimously.

7.d. Targeted Immune Modulators (TIMs) - Crohn's Disease and Ulcerative Colitis

Preferred Agents
No PA Required (if diagnosis met)
***Must meet eligibility criteria**
HUMIRA (adalimumab)
*XELJANZ IR (tofacitinib) tablet

First line preferred agents (HUMIRA) may receive approval for Crohn's disease and ulcerative colitis indications.

*XELJANZ IR may receive approval for ulcerative colitis indication following trial and failure‡ of HUMIRA.

Quantity Limit: XELJANZ IR is limited to 2 tablets per day or 60 tablets for a 30 day supply

STELARA (ustekinumab) syringe for subcutaneous use may receive approval if meeting the following:

- For treatment of moderately-to-severely active Crohn's disease, member has trial and failure† of all indicated preferred agents (HUMIRA) AND CIMZIA **OR** for treatment of moderately-to-severely active ulcerative colitis, member has trial and failure† of all indicated preferred agents (HUMIRA and XELJANZ IR) **AND**
- Prescriber acknowledges that loading dose administration prior to approval of STELARA for maintenance therapy using the above criteria should be avoided and will not result in an automatic approval of STELARA for maintenance therapy **AND**
- Prior authorization approval may be given for an initial 16 week supply and authorization approval for continuation may be provided based on clinical response.
- STELARA IV vial formulation may receive approval under the pharmacy benefit if meeting non-preferred criteria listed above **AND** if being administered in a long-term care facility or the member's home by a home health provider (initial 16-week authorization may be placed for both IV and subcutaneous formulations at time of STELARA IV vial approval).

XELJANZ (tofacitinib) XR approval will require verification of the clinically relevant reason for use of the XELJANZ XR formulation versus the XELJANZ IR formulation, in addition to meeting non-preferred criteria listed below above.

All other non-preferred agents may receive approval for FDA-labeled indications following trial and failure† of all indicated preferred agents.

Grandfathering: Members with current prior authorization approval on file forMembers currently taking COSENTYX (secukinumab) may receive approval to continue on that agent.

†Failure is defined as lack of efficacy with a three-month trial, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction. Note that trial and failure of Xeljanz IR will not be required when prescribed for ulcerative colitis for members ≥ 50 years of age that have an additional CV risk factor.

The Department would like to remind providers that many products are associated with patient-centered programs that are available to assist with drug administration, education, and emotional support related to our members' various disease states.

Discussion

- No Board members reported a conflict of interest for this therapeutic sub-class.
- P Lanius moved to accept criteria for this class as written. Seconded by B Jackson. Motion passed unanimously.

7.e. Targeted Immune Modulators (TIMs) – Other Indications

Preferred Agents
Must meet eligibility criteria*
ENBREL (etanercept)
HUMIRA (adalimumab)
*OTEZLA (apremilast) tablet
*TALTZ (ixekizumab) autoinjector, syringe
XELJANZ IR (tofacitinib) tablet

First line preferred agents (HUMIRA, ENBREL, and XELJANZ IR) may receive approval for use for FDA-labeled indications.

Quantity Limit: XELJANZ IR is limited to 2 tablets per day or 60 tablets for a 30-day supply

Second-line preferred agents may receive approval for FDA-labeled indications following trial and failure‡ of all indicated first-line preferred agents (ENBREL, HUMIRA, XELJANZ IR).

ARCALYST (rilonacept) may receive approval if meeting the following:

- Medication is being prescribed for one of the following autoinflammatory periodic fever syndromes (approval for all other indications is subject to meeting nonpreferred criteria listed below above):
  - Adult-Onset Still's Disease (AOSD)
  - Cryopyrin-associated Autoinflammatory Syndrome (CAPS), including:
    - Familial Cold Autoinflammatory Syndrome (FCAS)
    - Muckle-Wells Syndrome (MWS)
  - Maintenance of remission of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) in adults and pediatric patients weighing at least 10 kg
  - Treatment of recurrent pericarditis and reduction in risk of recurrence in adults and children ≥ 12 years of age

  AND
- Member has trialed and failed‡ colchicine **AND**
- Initial approval will be given for 12 weeks and authorization approval for continuation will be provided based on clinical response.

ILARIS (canakinumab) may receive approval if meeting the following:

- Medication is being prescribed for one of the following autoinflammatory periodic fever syndromes (approval for all other indications is subject to meeting nonpreferred criteria listed below above):
  - Adult onset Still's Disease (AOSD)
  - Familial Mediterranean Fever (FMF)
  - Hyperimmunoglobulinemia D syndrome (HIDS)
  - Mevalonate Kinase Deficiency (MKD)
  - Neonatal onset multisystem inflammatory disease (NOMID)
  - Systemic Juvenile Idiopathic Arthritis (sJIA)
  - TNF Receptor Associated Periodic Syndrome (TRAPS)
  - Cryopyrin-associated Autoinflammatory Syndrome (including Familial Cold Autoinflammatory Syndrome and Muckle-Wells Syndrome)

AND

- Member has trialed and failed‡ colchicine.

KINERET (anakinra) may receive approval if meeting the following:

- Medication is being prescribed for one of the following indications (approval for all other indications is subject to meeting non-preferred criteria listed below above):
  - Neonatal onset multisystem inflammatory disease (NOMID)
  - Familial Mediterranean Fever (FMF)

AND

- Member has trialed and failed‡ colchicine.

All other non-preferred agents may receive approval for FDA-labeled indications following trial and failure‡ of all indicated preferred agents (ENBREL, HUMIRA, XELJANZ IR, TALTZ, OTEZLA). Agents listed below must meet the following additional criteria for approval of that agent:

‡Failure is defined as lack of efficacy with a three-month trial, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction.

Grandfathering: Members with current prior authorization approval on file forMembers currently taking COSENTYX (secukinumab) may receive approval to continue on that agent.

The Department would like to remind providers that many products are associated with patient-centered programs that are available to assist with drug administration, education, and emotional support related to our members' various disease states.

Discussion

- No Board members reported a conflict of interest for this therapeutic sub-class.
- S Klocke moved to accept criteria for this class as written. Seconded by M Anguelov. Motion passed unanimously.

8. Respiratory Agents, Inhaled Anticholinergics (single agent)

Preferred Agents
No PA Required (unless indicated*)

Solutions
Ipratropium (generic ATROVENT) solution

Short-Acting Inhalersation Devices
ATROVENT HFA (ipratropium)

Long-Acting Inhalersation Devices
SPIRIVA Handihaler (tiotropium)
*SPIRIVA RESPIMAT (tiotropium)

***SPIRIVA RESPIMAT (tiotropium) 1.25 mcg** may be approved for members ≥ 6 years of age with a diagnosis of asthma (qualifying diagnosis verified by AutoPA). SPIRIVA RESPIMAT is intended to be used by members whose asthma is not controlled with regular use of a combination medium-dose inhaled corticosteroid and long-acting beta agonist (LABA).

***SPIRIVA RESPIMAT (tiotropium) 2.5 mcg** may be approved for members with a diagnosis of COPD who meet non-preferred criteria for single agent inhaled anticholinergics listed below. who have trialed and failed SPIRIVA HANDIHALER. Failure is defined as intolerable side effects or inability to use dry powder inhaler (DPI) formulation.

LONHALA MAGNAIR (glycopyrrolate) may be approved for members ≥ 18 years of age with a diagnosis of COPD including chronic bronchitis and emphysema who have trialed and failed‡ treatment with two preferred anticholinergic agents.

Non-preferred single agent anticholinergic agents may be approved for members with a diagnosis of COPD including chronic bronchitis and/or emphysema who have trialed and failed‡ treatment with two preferred agents, one of which must be SPIRIVA HANDIHALER.

‡Failure is defined as lack of efficacy with 6-week trial, allergy, intolerable side effects, or significant drug-drug interaction

Discussion
- Dr. Laird verbalized a conflict of interest for this therapeutic class.
- L Claus moved to accept these criteria as written. Seconded by T Brubaker. Motion passed unanimously.

9. Respiratory Agents, Inhaled Anticholinergics (combination products)

Preferred Agents

Solutions
Albuterol/ipratropium solution for nebulizer

Short-Acting Inhalersation Devices
COMBIVENT RESPIMAT (albuterol/ipratropium)

Long-Acting Inhalersation Devices
ANORO ELLIPTA (umeclidinium/vilanterol)

BREZTRI AEROSPHERE (budesonide/glycopyrrolate/formoterol) may be approved for members ≥ 18 years of age with a diagnosis of COPD who have trialed and failed‡ treatment with two preferred anticholinergic-containing agents.

DUAKLIR PRESSAIR (aclidinium/formoterol) may be approved for members ≥ 18 years of age with a diagnosis of COPD who have trialed and failed‡ treatment with two preferred anticholinergic-containing agents.

All other non-preferred inhaled anticholinergic combination agents may be approved for members with a diagnosis of COPD including chronic bronchitis and/or emphysema who have trialed and failed‡ treatment with two preferred inhaled anticholinergic combination agents OR three preferred inhaled anticholinergic-containing agents (single ingredient or combination).

Members who are currently stabilized on BEVESPI AEROSPHERE may receive approval to continue therapy with that product.

‡Failure is defined as lack of efficacy with 6-week trial, allergy, intolerable side effects, or significant drug-drug interaction.
Discussion

- Dr. Laird verbalized a conflict of interest for this therapeutic class.
- B Jackson moved to accept these criteria as written. Seconded by L Claus. Motion passed unanimously.

10. Respiratory Agents, Inhaled Beta$_2$ Agonists, Short-acting (SABA)

Preferred Agents

Solutions
Albuterol (generic) solution, for nebulizer

Short-Acting Inhalersation Devices
PROAIR[BNR] HFA (albuterol)
VENTOLIN[BNR] HFA (albuterol)

Non-preferred, short acting beta2 agonists may be approved for members who have failed Treatment with one preferred agent. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.

MDI formulation quantity limits: 2 inhalers / 30 days

Discussion
- Dr. Laird verbalized a conflict of interest for this therapeutic class.
- S Klocke moved to accept these criteria as written. Seconded by P Lanius. Motion passed unanimously.

11. Respiratory Agents, Inhaled Beta$_2$ Agonists, Long-acting (LABA)

Preferred Agents
***Must meet eligibility criteria**

Solutions
NONE

Long-Acting Inhalersation Devices
*SEREVENT DISKUS (salmeterol) inhaler

***SEREVENT (salmeterol)** may be approved for members with moderate to very severe COPD. Serevent will not be approved for treatment of asthma in members needing add-on therapy due to safety risks associated with monotherapy.

Non-preferred agents may be approved for members with moderate to severe COPD, AND members must have failed a trial of Serevent. Failure is defined as lack of efficacy with a 6-week trial, allergy, intolerable side effects, or significant drug-drug interaction.

For treatment of members with diagnosis of asthma needing add-on therapy, please refer to preferred agents in combination Long-Acting Beta Agonist/Inhaled Corticosteroid therapeutic class.

Discussion
- Dr. Laird verbalized a conflict of interest for this therapeutic class.
- L Claus moved to accept these criteria as written. Seconded by S VanEyk. Motion passed unanimously.

12. Respiratory Agents, Inhaled Corticosteroids (single agent)

Preferred Agents

Solutions
Budesonide nebules

Inhalersation Devices
ASMANEX Twisthaler (mometasone)
FLOVENT DISKUS (fluticasone)
FLOVENT HFA (fluticasone)
PULMICORT FLEXHALER (budesonide)

Non-preferred inhaled corticosteroids may be approved in members with asthma who have failed an adequate trial of two preferred agents. An adequate trial is defined as at least 6 weeks. (Failure is defined as: lack of efficacy with a 6-week trial, allergy, contraindication to, intolerable side effects, or significant drug-drug interactions.)

Maximum Dose:
Pulmicort (budesonide) nebulizer suspension: 2mg/day

Discussion
- Dr. Laird verbalized a conflict of interest for this therapeutic class.
- B Jackson moved to accept these criteria as written. Seconded by L Claus. Motion passed unanimously.

12. Respiratory Agents, Inhaled Corticosteroid Combinations

Preferred Agents
ADVAIR DISKUS[BNR] (fluticasone/salmeterol)
ADVAIR HFA (fluticasone/salmeterol)
DULERA (mometasone/ formoterol)
SYMBICORT[BNR] (budesonide/formoterol) inhaler

Non-preferred inhaled corticosteroid combinations may be approved for members meeting both of the following criteria:
- Member has a qualifying diagnosis of asthma or severe COPD; AND
- Member has failed two preferred agents (Failure is defined as lack of efficacy with a 6-week trial, allergy, intolerable side effects, significant drug-drug interactions, or dexterity/coordination limitations (per provider notes) that significantly impact appropriate use of a specific dosage form.)

TRELEGY ELLIPTA (fluticasone furoate/umeclidinium/vilanterol) may be approved if the member has trialed/failed three preferred inhaled corticosteroid combination products AND Spiriva. Failure is defined as lack of efficacy with a 6-week trial, allergy, intolerable side effects, significant drug-drug interactions, or dexterity/coordination limitations (per provider notes) that significantly impact appropriate use of a specific dosage form.

Discussion
- Dr. Laird verbalized a conflict of interest for this therapeutic class.
- P Lanius moved to accept these criteria as written. Seconded by S Klocke. Motion passed unanimously.

Three classes with proposed changes in criteria were pulled out of mass review section for a full review. These classes were **Oral Ulcerative Colitis Agents** (section 31.a), **Immune Globulins** (section 32), and **Methotrexate Products** (section 37).

31.a Non-Biologic Ulcerative Colitis Agents, Oral

Preferred Agents
APRISO ER[BNR] (mesalamine ER) capsule
LIALDA[BNR] (mesalamine DR) tablet
PENTASA (mesalamine) capsule
Sulfasalazine IR and DR tablet

Prior authorization for non-preferred oral formulations will require trial and failure of two preferred oral products with different active ingredients AND a one preferred rectal product. If inflammation is not within reach of topical therapy, trial of preferred rectal product is not required. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.

UCERIS (budesonide ER) tablet: If the above criteria is met, Prior authorization may be approved following trial and failure of one preferred oral product AND one preferred rectal product. If inflammation is not within reach of topical therapy, trial of preferred rectal product is not required. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. Approval will be placed for 8 weeks. Further prior authorization may be approved if 7 days of steroid-free time has elapsed and member continues to meet the above criteria.

Discussion

- No Board members reported a conflict of interest for this therapeutic class.
- B Jackson moved to accept criteria for this class as written. Seconded by L Claus. Motion passed unanimously.

32. Immune Globulins

Preferred Agents
CUVITRU 20% SQ liquid
GAMMAGARD 10% IV/SQ liquid
GAMMAKED 10% IV/SQ liquid
GAMMAPLEX 5%, 10% IV liquid
GAMUNEX-C 10% IV/SQ liquid
HIZENTRA 20% SQ liquid
PRIVIGEN 10% IV liquid

If immune globulin is being administered in a long-term care facility or in a member's home by a home healthcare provider, it should be billed as a pharmacy claim. All other claims must be submitted through the medical benefit.
Preferred agents may be approved for members meeting at least one of the approved conditions listed below for prescribed doses not exceeding maximum (Table 1).

Non-preferred agents may be approved for members meeting the following:
- Member meets at least one of the approved conditions listed below **AND**
- Member has history of trial and failure of two preferred agents (failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions)

AND

- Prescribed dose does not exceed listed maximum (Table 1)

Approved Conditions for Immune Globulin Use:

- Primary Humoral Immunodeficiency disorders including:
  - Common Variable Immunodeficiency (CVID)
  - Severe Combined Immunodeficiency (SCID)
  - X-Linked Agammaglobulinemia
  - X-Linked with Hyperimmunoglobulin M (IgM) Immunodeficiency
  - Wiskott-Aldrich Syndrome
  - Members < 13 years of age with pediatric Human Immunodeficiency Virus (HIV) and CD-4 count > 200/mm^3
- Neurological disorders including:
  - Guillain-Barré Syndrome
  - Relapsing-Remitting Multiple Sclerosis
  - Chronic Inflammatory Demyelinating Polyneuropathy
  - Myasthenia Gravis
  - Polymyositis and Dermatomyositis
  - Multifocal Motor Neuropathy
- Kawasaki Syndrome
- Chronic Lymphocytic Leukemia (CLL)
- Autoimmune Neutropenia (AN) with absolute neutrophil count < 800 mm and history of recurrent bacterial infections
- Autoimmune Hemolytic Anemia (AHA)
- Liver or Intestinal Transplant
- Immune Thrombocytopenia Purpura (ITP) including:
  - Requiring pre-operative therapy for undergoing elective splenectomy with platelet count < 20,000
  - Members with active bleeding & platelet count <30,000
  - Pregnant members with platelet counts <10,000 in the third trimester
  - Pregnant members with platelet count 10,000 to 30,000 who are bleeding

Table 1: FDA-Approved Maximum Immune Globulin Dosing	
Asceniv – IV admin	800 mg/kg every 3 to 4 weeks
Bivigam – IV admin	800 mg/kg every 3 to 4 weeks
Cuvitru – SQ admin	12.6 grams every 2 weeks
Flebogamma DIF – IV admin	600 mg/kg every 3 weeks
Gammaplex 5% -- IV Infusion	800mg/kg every 3 weeks
Gammagard liquid – SQ or IV admin	2.4 grams/kg/month
Gammaked – SQ or IV admin	600 mg/kg every 3 weeks
Gamunex-C – SQ or IV admin	600 mg/kg every 3 weeks
Hizentra – SQ admin	0.4g/kg per week
Octagam – IV admin	600 mg/kg every 3 to 4 weeks
Panzyga – IV admin	2 g/kg every 3 weeks
Privigen – IV admin	800mg/kg every 3 weeks

Grandfathering: Members currently receiving a preferred or non-preferred immunoglobulin product may receive approval to continue therapy with that product at prescribed doses not exceeding maximum (Table 1).

Discussion

- No Board members reported a conflict of interest for this therapeutic class.
- B Jackson asked about adding protein-losing enteropathy and Multisystem Inflammatory Syndrome in Children (MIS-C) to the list of approvable diagnoses in this immune globulins class. After some discussion by the Board, it was determined that IVIG for protein-losing enteropathy is less evidence-based than immune globulin use for MIS-C. S Klocke suggested that other off-label indications be considered for addition, as well. B Jackson asked whether specific diagnoses should be included for the immune globulins or should decisions regarding off-label use be left to clinicians' judgment.
- J Taylor commented that indications listed need to have substantial and robust evidence available to support the safety and efficacy of immune globulins used to treat those conditions. There is an exception process in place so that providers can request additional prior authorization review for indications that are not specifically listed.
- J Leonard commented that the Department is required to follow what is in the product labeling. If there is reliable information in compendia or widely-recognized supportive evidence, other indications may be added to the approvable diagnoses list. However, the Department does not approve medications for off-label use if not supported by evidence and medical necessity
- B Jackson suggest that a literature review be conducted to determine if there are other evidence-based indications that should be added to the list of approvable indications in this therapeutic class.
- B Jackson moved to add Multisystem Inflammatory Syndrome in Children (MIS-C) to the list of approved indications. Seconded by T Brubaker. Motion passed unanimously.
- S Klocke move to approve all other criteria in this section as written. Seconded by T Brubaker. Motion passed unanimously.

37. Methotrexate Products

Preferred Agents
Methotrexate tablet, vial, PF vial

OTREXUP or **RASUVO** may be approved if meeting the following criteria:
- Member has diagnosis of severe, active rheumatoid arthritis OR active polyarticular juvenile idiopathic arthritis (pJIA) OR inflammatory bowel disease (IBD) **AND**
- Member has trialed and failed preferred methotrexate tablet formulation (failure is defined as lack of efficacy, allergy, intolerable side effects, or inability to take oral product formulation) **AND**
- Member is unable to administer preferred methotrexate vial formulation due to limited functional ability (such as vision impairment, limited manual dexterity, and/or limited hand strength).

TREXALL may be approved if meeting the following criteria:
- Member has trialed and failed preferred methotrexate tablet formulation. Failure is defined as allergy or intolerable side effects.

XATMEP may be approved for members who meet the following criteria:
- Member is < 18 years of age
- Member has a diagnosis of acute lymphoblastic leukemia AND OR
- Member has a diagnosis of active polyarticular course juvenile idiopathic arthritis (pcJIA) and has had an insufficient therapeutic response to, or is intolerant to, an adequate trial of first-line therapy including full dose non-steroidal anti-inflammatory agents (NSAIDs) **AND**

- Member has a documented swallowing difficulty due to young age and/or a medical condition and is unable to use the preferred methotrexate tablet formulation. **AND**
- If prescribed for a male member with reproductive potential, the member has been counseled regarding the use of contraception during therapy and for at least 3 months after the final dose **OR**
- If prescribed for a female member of reproductive age:
  - Member has been counseled regarding use of contraception during therapy and for at least 6 months after the final dose **AND**
  - If prescribed for a non-malignant disease indication, the member has a documented negative pregnancy test prior to initiating therapy

Methotrexate can cause serious embryo-fetal harm when administered during pregnancy and it is contraindicated for use during pregnancy for the treatment of non-malignant diseases. Advise members of reproductive potential to use effective contraception during and after treatment with methotrexate, according to FDA product labeling.

Grandfathering: Members currently stabilized on a non-preferred methotrexate product may receive approval to continue on that agent.

Discussion

- S Klocke move to approve the criteria in this section as written. Seconded by L Claus. Motion passed unanimously.

Mass review drug classes*

**Proposed criteria for drug classes designated for mass review will not be read aloud at the time of DUR Board review, as there are no proposed changes to criteria currently implemented for these designated classes. The DUR Board may determine if designated mass review drug classes will undergo full review based on board vote.*

14. Non-Steroidal Anti-Inflammatories (NSAIDs), oral

Preferred Agents
Celecoxib capsule
Diclofenac potassium tablet
Diclofenac sodium EC/DR tablet
Ibuprofen suspension, tablet (RX)
Indomethacin capsule, ER capsule
Ketorolac tablet**
Meloxicam tablet
Nabumetone tablet
Naproxen EC, DR/ER, suspension, tablet (RX)
Sulindac tablet

DUEXIS (ibuprofen/famotidine) or **VIMOVO (naproxen/esomeprazole)** may be approved if the member meets the following criteria:
- Trial and failure‡ of all preferred NSAIDs at maximally tolerated doses **AND**
- Trial and failure‡ of three preferred proton pump inhibitors in combination with NSAID within the last 6 months **AND**
- Hasve a documented history of gastrointestinal bleeding

All other non-preferred oral agents may be approved following trial and failure‡ of four preferred agents.

‡Failure is defined as lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interactions.

**Ketorolac tablet quantity limitations: 5-day supply per 30 days and 20 tablets per 30 days

15. Non-Steroidal Anti-Inflammatories (NSAIDs), non-oral

Preferred Agents
Diclofenac 1.5% topical solution
VOLTAREN (diclofenac) 1% gel (RX)
Diclofenac sodium 1% (generic VOLTAREN) gel (RX)

SPRIX (ketorolac) may be approved if meeting the following criteria:
- Member is unable to tolerate, swallow or absorb oral NSAID formulations **OR**
- Member has trialed and failed three preferred oral or topical NSAID agents (failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions)
- Quantity limit: 5-single day nasal spray bottles per 30 days

All other non-preferred topical agents may be approved for members who have trialed and failed one preferred agent. Failure is defined as lack of efficacy with 14-day trial, allergy, intolerable side effects, or significant drug-drug interaction.

FLECTOR (diclofenac) patch quantity limit: 2 patches per day

Diclofenac 3% gel (generic SOLARAZE) prior authorization criteria can be found in the Antineoplastic agents, topical, section of the PDL.

16. Antibiotics, Inhaled

Preferred Agents
***Must meet eligibility criteria**
Tobramycin inhalation solution (generic TOBI)
*CAYSTON (aztreonam) inhalation solution

***CAYSTON (aztreonam)** inhalation solution may be approved if the following criteria are met:
- Member has a history of trial and failure of preferred tobramycin solution for inhalation (failure is defined as lack of efficacy with a 4-week trial, intolerable side effects, or significant drug-drug interactions) **OR** provider attests that member cannot use preferred tobramycin solution for inhalation due to documented allergy or contraindication to therapy **AND**
- The member has known colonization of *Pseudomonas aeruginosa* in the lungs **AND**
- The member has been prescribed an inhaled beta agonist to use prior to nebulization of CAYSTON (aztreonam).

ARIKAYCE (amikacin) may be approved if the following criteria are met:
- Member has refractory mycobacterium avium complex (MAC) lung disease with limited or no alternative treatment options available **AND**
- Member has trialed and failed 6 months of therapy with a 3-drug regimen that includes a macrolide (failure is defined as lack of efficacy, contraindication to therapy, allergy,

intolerable side effects, or significant drug-drug interactions).

All other non-preferred inhaled antibiotic agents may be approved if the following criteria are met:
- The member has a diagnosis of cystic fibrosis with known colonization of *Pseudomonas aeruginosa* in the lungs **AND**
- Member has history of trial and failure of preferred tobramycin solution for inhalation (failure is defined as lack of efficacy with a 4-week trial, contraindication to therapy, allergy, intolerable side effects or significant drug-drug interactions).

Table 1: Minimum Age, Maximum Dose and Quantity Limitations			
	Minimum Age	**Maximum Dose**	**Quantity Limit (based on day supply limitation for pack size dispensed)**
ARIKAYCE (amikacin)	≥ 18 years	590 mg daily	Not applicable
BETHKIS (tobramycin)	≥ 6 years	300 mg twice daily	28-day supply per 56-day period
CAYSTON (aztreonam)	≥ 7 years	225 mg daily	28-day supply per 56-day period
KITABIS PAK (tobramycin)	≥ 6 years	300 mg twice daily	28-day supply per 56-day period
TOBI† (tobramycin)	≥ 6 years	300 mg twice daily	28-day supply per 56-day period
TOBI PODHALER (tobramycin)	≥ 6 years	112 mg twice daily	28-day supply per 56-day period
† *Limitations apply to brand product formulation only*			

Grandfathering: Members currently stabilized on any inhaled antibiotic agent in this class may receive approval to continue on that agent.

17. Antiherpetic Agents, Oral

Preferred Agents
Acyclovir tablet, capsule
Acyclovir suspension *(members under 5 years or with a feeding tube)*
Famciclovir tablet
Valacyclovir tablet

Non-preferred products may be approved for members who have failed an adequate trial with two preferred products with different active ingredients. Failure is defined as lack of efficacy with 14-day trial, allergy, intolerable side effects, or significant drug-drug interaction.

SITAVIG (acyclovir) buccal tablet may be approved for diagnosis of recurrent herpes labialis (cold sores) if member meets non-preferred criteria listed above AND has failed trial with oral acyclovir suspension. Failure is defined as lack of efficacy with 14-day trial, allergy, intolerable side effects, or significant drug-drug interaction.

For members with a diagnosis of Bell's palsy, valacyclovir 1,000 mg three times daily willmay be approved for 7 days if member presents with severe facial palsy.
Acyclovir suspension may be approved for:
- Members under 5 years of age OR

- Members with a feeding tube OR
- Members meeting non-preferred criteria listed above

Maximum Dose Table		
	Adult	**Pediatric**
Acyclovir	4,000 mg daily	3,200 mg daily
Valacyclovir	4,000 mg daily	Age 2-11 years: 3,000 mg daily Age ≥ 12 years: 4,000 mg daily

18. Antiherpetic Agents, Topical

Preferred Agents

Acyclovir ointment
DENAVIR (penciclovir) cream
ZOVIRAX[BNR] (acyclovir) cream

Non-Preferred Zovirax and acyclovir ointment/cream formulations may be approved for members who have failed an adequate trial with the preferred topical acyclovir ointment/cream product (diagnosis, dose and duration) as deemed by approved compendium. (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction)

XERESE (acyclovir/hydrocortisone) prior authorization willmay be approved for members that meet the following criteria:

- Documented diagnosis of recurrent herpes labialis AND
- Member is immunocompetent AND
- Member has failed treatment of at least 10 days with acyclovir (Failure will beis defined as significant drug-drug interaction, lack of efficacy, contraindication to or intolerable side effects) AND
- Member has failed treatment of at least one day with famciclovir 1,500 mg OR valacyclovir 2 grams GM twice daily (Failure is defined as significant drug-drug interaction, lack of efficacy, contraindication to or intolerable side effects)

19. Fluoroquinolones, Oral

Preferred Agents

*CIPRO (ciprofloxacin) oral suspension (< 5 years of age)
*Ciprofloxacin oral suspension (<5 years of age)
Ciprofloxacin tablet
Levofloxacin tablet

***CIPRO (ciprofloxacin) suspension** may be approved for members < 5 years of age without prior authorization. For members ≥ 5 years of age, CIPRO (ciprofloxacin) suspension may be approved for members who cannot swallow a whole or crushed tablet.

Non-preferred products may be approved for members who have failed an adequate trial (7 days) with at least one preferred product. (Failure is defined as lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction).

Levofloxacin solution may be approved for members < 5 years of age with prescriber attestation that member is unable to take CIPRO (ciprofloxacin) crushed tablet or suspension OR for members < 5 years of age for treatment of pneumonia.

For members ≥ 5 years of age, levofloxacin solution may be approved for members who require administration via feeding tube OR who have failed an adequate trial (7 days) of ciprofloxacin suspension. Failure is defined as lack of efficacy, allergy, intolerable side effects, significant drug-drug interaction, or contraindication to therapy.

20. Hepatitis C Virus Treatments - Ribavirin Products

Preferred Agents
Ribavirin capsule
Ribavirin tablet

Non-preferred ribavirin products require prior authorizations which will be evaluated on a case-by-case basis.

Members currently receiving non-preferred ribavirin product will receive approval to continue that product for the duration of their HCV treatment regimen.

21. Monoamine Oxidase Inhibitors (MAOIs)

Preferred Agents
NONE

Non-preferred products willmay be approved for members who have failed adequate trial (8 weeks) with three preferred antidepressant products. If three preferred antidepressant products are not available for indication being treated, approval of prior authorization for non-preferred products will require adequate trial of all preferred antidepressant products FDA approved for that indication. (Failure is defined as: lack of efficacy after 8-week trial, allergy, intolerable side effects, or significant drug-drug interaction).

Grandfathering: Members currently stabilized on a non-preferred MAOi antidepressant can may receive approval to continue on that agent for one year if medically necessary. **Verification may be provided from the prescriber or the pharmacy.**

22. Tricyclic Antidepressants (TCAs)

Preferred Agents
Amitriptyline tablet
Doxepin 10mg, 25mg, 50mg, 75mg, 100mg, 150mg capsule
Doxepin solution
Imipramine HCl tablet
Nortriptyline capsule, solution

Non-preferred brand name medications do not require a prior authorization when the equivalent generic is preferred and "dispense as written" is indicated on the prescription.

Non-preferred products will be approved for members who have failed adequate trial (8 weeks) with three preferred tricyclic products. If three preferred products are not available for indication being treated, approval of prior authorization for non-preferred products will require adequate trial of all tricyclic preferred products FDA approved for that indication. (Failure is

defined as: lack of efficacy after 8-week trial, allergy, intolerable side effects, or significant drug-drug interaction)

Grandfathering: Members currently stabilized on a Non-preferred TCA antidepressant can receive approval to continue on that agent for one year if medically necessary. **Verification may be provided from the prescriber or the pharmacy.**

SILENOR (doxepin 3mg, 6mg) approval criteria can be found on the Appendix P.

23. Triptans and Other Migraine Agents, Oral

Preferred Agents
(quantity limits may apply)
Eletriptan tablet (generic RELPAX)
Naratriptan tablet (generic AMERGE)
Rizatriptan tablet, ODT (generic MAXALT)
Sumatriptan tablet (generic IMITREX)

Non-preferred oral triptan products may be approved for members who have trialed and failed three preferred oral products. Failure is defined as lack of efficacy with 4 week trial, allergy, intolerable side effects or significant drug-drug interaction.

Quantity Limits:

Amerge (naratriptan), Frova (frovatriptan), Imitrex (sumatriptan), Zomig (zolmitriptan)	Max 9 tabs/30 days
Treximet (sumatriptan/naproxen)	Max 9 tabs/30 days
Axert (almotriptan) and Relpax (eletriptan)	Max 6 tabs/30 days
Maxalt (rizatriptan)	Max 12 tabs/30 days
Reyvow (lasmiditan)	Max 8 tabs/30 days

24. Triptans and Other Migraine Agents, Non-Oral

Preferred Agents
(quantity limits may apply)
IMITREX[BNR] (sumatriptan) nasal spray
Sumatriptan vial
Zolmitriptan nasal spray *(Amneal only)*

ZEMBRACE Symtouch injection, **TOSYMRA nasal spray**, or **ONZETRA Xsail nasal powder** may be approved for members who have trialed and failed one preferred non-oral triptan products AND two oral triptan agents with different active ingredients. Failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects, significant drug-drug interaction, or documented inability to take alternative dosage form.

All other non-preferred products may be approved for members who have trailed and failed one preferred non-oral triptan product AND one preferred oral triptan product. Failure is defined as lack of efficacy with 4 week trial, allergy, intolerable side effects or significant drug-drug interactions, documented inability to tolerate dosage form.

Quantity Limits:

Imitrex (sumatriptan) injection	Max 4 injectors / 30 days
Imitrex (sumatriptan) nasal spray	Max 6 inhalers / 30 days
Onzetra Xsail (sumatriptan) nasal powder	Max 16 nosepieces / 30 days
Tosymra (sumatriptan) nasal spray	Max 12 nasal spray devices / 30 days
Zembrace Symtouch (sumatriptan) injection	Max 36 mg / 30 days
Zomig (zolmitriptan) nasal spray	Max 6 inhalers / 30 days

Grandfathering: Members currently stabilized on ZOMIG (zolmitriptan) nasal spray may receive approval to continue therapy with that product at the prescribed dose, not exceeding 6 inhalers per 30 days

25. Antipsoriatics, Oral

Preferred Agents

Acitretin capsule

Prior authorization for non-preferred oral agents will be approved with failure of two preferred anti-psoriatic agents, one of which must be a preferred oral agent. Failure is defined as lack of efficacy of a 4-week trial, allergy, intolerable side effects or significant drug-drug interaction.

26. Antipsoriatics, Topical

Preferred Agents

Calcipotriene solution
DOVONEX[BNR] (calcipotriene) cream
TACLONEX SCALP[BNR] (calcipotriene/betamethasone) suspension
TACLONEX OINTMENT[BNR] (calcipotriene/betamethasone)

Prior authorization for non-preferred topical agents will be approved with failure of two preferred topical agents. If non-preferred topical agent being requesting is a combination product, trial of two preferred agents must include a preferred combination agent. Failure is defined as lack of efficacy of a 4-week trial, allergy, intolerable side effects or significant drug-drug interaction.

Preferred and non-preferred products that contain a corticosteroid ingredient (such as betamethasone) will be limited to 4 weeks of therapy. Continued use will require one week of steroid-free time in between treatment periods.

Members with >30% of their body surface area affected may not use ENSTILAR (calcipotriene/betamethasone DP) foam or TACLONEX (calcipotriene/betamethasone DP) ointment products as safety and efficacy have not been established.

27. Immunomodulators, Topical

Preferred Agents

ELIDEL[BNR] (pimecrolimus)
PROTOPIC[BNR] (tacrolimus)

Non-preferred topical immunomodulator products may be approved for atopic dermatitis following adequate trial and failure‡ of one prescription topical corticosteroid AND two preferred agents. ‡Failure is defined as a lack of efficacy with one month trial, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions.

For members under 18 years of age, must be prescribed by or in consultation with a dermatologist or allergist/immunologist.

28. Topical Steroids

Low potency
Preferred Agents
Hydrocortisone (RX) cream, ointment, lotion
DERMA-SMOOTHE-FS[BNR] (fluocinolone) 0.01% oil
Desonide 0.05% cream, ointment
Fluocinolone 0.01% cream

Non-preferred Low Potency topical corticosteroids may be approved following adequate trial and failure of two preferred agents in the Low Potency class. (Failure is defined as lack of efficacy with 4 week trial, allergy, intolerable side effects or significant drug-drug interactions).

Medium potency
Preferred Agents
Betamethasone dipropionate 0.05% lotion
Betamethasone valerate 0.1% cream, 0.1% ointment
Fluocinolone acetonide 0.025% cream
Fluticasone propionate 0.05% cream, 0.005% ointment
Mometasone 0.1% cream, 0.1% ointment, 0.1% solution
Triamcinolone acetonide 0.025% cream, 0.1% cream, 0.025% ointment, 0.05% ointment, 0.1% ointment, 0.025% lotion, 0.1% lotion

Non-preferred Medium Potency topical corticosteroids may be approved following adequate trial and failure of two preferred agents in the Medium Potency class. (Failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions).

High potency
Preferred Agents
No PA Required (unless exceeds duration of therapy*)
*Betamethasone dipropionate propylene glycol (aug) 0.05% cream
*Fluocinonide 0.05% cream, 0.05% gel, 0.05% solution, 0.05% ointment
*Triamcinolone acetonide 0.5% cream, 0.5% ointment

Non-preferred High Potency topical corticosteroids may be approved following adequate trial and failure of two preferred agents in the High Potency class. (Failure is defined as lack of efficacy with 4 week trial, allergy, intolerable side effects or significant drug-drug interactions).
*All High Potency topical corticosteroids will require prior authorization beyond 4 weeks of therapy. The provider will be encouraged to transition to a medium or low potency topical steroid after this time has elapsed.

Very high potency

Preferred Agents

(No PA Required unless exceeds duration of therapy*)

*Betamethasone dipropionate propylene glycol (aug) 0.05% ointment
*Clobetasol 0.05% cream, 0.05% gel, 0.05% ointment, 0.05% solution
*Fluocinonide 0.1% cream

Non-preferred Very High Potency topical corticosteroids may be approved following adequate trial and failure of clobetasol propionate in the same formulation as the product being requested (if the formulation of the requested non-preferred product is not available in preferred clobetasol product options, then trial and failure of any preferred clobetasol product formulation will be required). Failure is defined as lack of efficacy with 2-week trial, allergy, intolerable side effects or significant drug-drug interactions.

*All Very High Potency topical corticosteroids will require prior authorization beyond 2 weeks of therapy. If clobetasol propionate shampoo is being used to treat plaque psoriasis, then prior authorization will be required beyond 4 weeks of therapy. The provider will be encouraged to transition to a medium or low potency topical steroid after this time has elapsed.

29. Pancreatic Enzymes

Preferred Agents
CREON (pancrelipase) capsule
PANCREAZE DR (pancrelipase) capsule
ZENPEP (pancrelipase) capsule

Non-preferred products willmay be approved for members who have failed an adequate trial (4 weeks) with at least two preferred products. (Failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interaction.)

Grandfathering: Members currently stabilized on a non-preferred pancreatic enzyme canmay receive approval to continue on that agent for one year if medically necessary.

30. Proton Pump Inhibitors (PPIs)

Preferred Agents
Esomeprazole DR capsule (RX)
Lansoprazole DR capsule (RX)
Lansoprazole DR ODT (RX) (for members < 2 years)
NEXIUM[BNR] (esomeprazole) packet
Omeprazole DR capsule (RX)
Pantoprazole tablet
PREVACID Solutab[BNR] (lansoprazole) (members < 2)

For members treating GERD symptoms that are controlled on PPI therapy, it is recommended that the dose of the PPI be re-evaluated or step-down with an H2 blocker (such as famotidine or ranitidine) be trialed in order to reduce long-term PPI use.

Prior authorization for non-preferred proton pump inhibitors may be approved if all of the following criteria are met:

- Member has a qualifying diagnosis (below) **AND**
- Member has trailed and failed therapy with three preferred agents within the last 24 months. (Failure is defined as lack of efficacy following 4 week trial, allergy, intolerable side effects, or

significant drug-drug interaction) **AND**

- Member has been diagnosed using one of the following diagnostic methods:
  - Diagnosis made by GI specialist
  - Endoscopy
  - X-ray
  - Biopsy
  - Blood test
  - Breath Test

Qualifying Diagnoses:
Barrett's esophagus, duodenal ulcer, erosive esophagitis, gastric ulcer, GERD, GI Bleed, *H. pylori* infection, hypersecretory conditions (Zollinger-Ellison), NSAID-induced ulcer, pediatric esophagitis, requiring mechanical ventilation, requiring a feeding tube.

Quantity Limits:
All agents will be limited to once daily dosing except when used for the following diagnoses: Barrett's esophagus, GI Bleed, *H. pylori*, hypersecretory conditions (Zollinger-Ellison), or members who have Sspinal Ccord Injury patients with associated acid reflux.

Adult members with GERD on once daily, high-dose PPI therapy who continue to experience symptoms may receive initial prior authorization approval for a 4-week trial of twice daily, high-dose PPI therapy. Continuation of the twice daily dosing regimen for GERD beyond 4 weeks will require additional prior authorization approval verifying adequate member response to the dosing regimen and approval may be placed for one year. If a member with symptomatic GERD does not respond to twice daily, high-dose PPI therapy, this should be considered a treatment failure.

Pediatric members (< 18 years of age) on once daily dosing of a PPI who continue to experience symptoms may receive one-year prior authorization approval for twice daily PPI therapy.

Age Limits:
NEXIUM 24H and **ZEGERID** will not be approved for members less than 18 years of age.

PREVACID Solutab willmay be approved for members < 2 years of age OR for members ≥ 2 years of age with a feeding tube.

31. Non-Biologic Ulcerative Colitis Agents

31.b Non-Biologic Ulcerative Colitis Agents, Rectal

Preferred Agents
Mesalamine (generic CANASA) suppository
Mesalamine 4gm/60 mL sulfite-free enema (generic SF ROWASA)

Prior authorization for non-preferred rectal formulations will require trial and failure of one preferred rectal formulation and one preferred oral formulation (Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction).

UCERIS (budesonide) foam: If the above criteria isare met, UCERIS (budesonide) foam prior authorization willmay be approved for 6 weeks. Further prior authorization may be approved if 7 days of steroid-free time has elapsed and member continues to meet the above criteria.

33. Newer Generation Antihistamines, Single Agent

Preferred Agents
Cetirizine (generic OTC ZYRTEC) tablet, syrup/solution
Cetirizine (RX) syrup
Desloratadine tablet

Levocetirizine tablet (RX/OTC)
Loratadine (generic OTC CLARITIN) 10mg tablet, syrup

Non-preferred single agent antihistamine products may be approved for members who have failed treatment with two preferred products in the last 6 months. For members with respiratory allergies, an additional trial of an intranasal corticosteroid will be required in the last 6 months.

Failure is defined as lack of efficacy with a 14 day trial, allergy, intolerable side effects, or significant drug-drug interaction.

34. Antihistamine/Decongestant Combinations

Preferred Agents
Loratadine-D (loratadine/pseudoephedrine) tablet (OTC)

Non-preferred antihistamine/decongestant combinations may be approved for members who have failed treatment with two preferred products in the last 6 months. For members with respiratory allergies, an additional trial of an intranasal corticosteroid will be required in the last 6 months.

Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.

35. Intranasal Rhinitis Agents

Preferred Agents
Azelastine 0.15%, 137 mcg
Budesonide 32 mcg (OTC)
Fluticasone 50 mcg (RX)
Ipratropium
Triamcinolone acetonide (generic NASACORT) (OTC)

Non-preferred products may be approved following trial and failure of treatment with three preferred products (failure is defined as lack of efficacy with a 2-week trial, allergy, intolerable side effects or significant drug-drug interactions).

Non-preferred combination agents may be approved following trial of individual products with same active ingredients AND trial and failure of one additional preferred agent (failure is defined as lack of efficacy with 2-week trial, allergy, intolerable side effects or significant drug-drug interactions)

36. Leukotriene Modifiers

Preferred Agents
Montelukast tablet, chewable tablet

Non-preferred products may be approved if meeting the following criteria:

- Member has trialed and failed treatment with one preferred product (failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions) **AND**
- Member has a diagnosis of asthma.

Montelukast granules may be approved if a member has tried and failed montelukast chewable tablets AND has difficulty swallowing.

38. Epinephrine Products, Self-Administered

Preferred Agents
Epinephrine 0.15mg/0.3ml, 0.3mg/0.3ml auto-injector (generic EPIPEN) - *Mylan only*
EPIPEN[BNR] 0.15mg/0.3mL
EPIPEN[BNR] JR 0.3mg/0.3mL auto-injector

Non-preferred products willmay be approved if the member has failed treatment with one of the preferred products. Failure is defined as allergy to ingredients in product or intolerable side effects.

Quantity limit: 4 auto injectors per year unless used/damaged/lost

39. Newer Hereditary Angioedema (HAE) Agents

Preferred Agents
PA Required for all agents in this class

Prophylaxis:
HAEGARDA (C1 esterase inhibitor) vial

Treatment:
BERINERT (C1 esterase inhibitor) kit
Icatibant syringe (generic FIRAZYR)

Medications Indicated for Routine Prophylaxis:
Members are restricted to coverage of one medication for routine prophylaxis at one time.

Prior authorization approval will be for one year.

HAEGARDA (C1 esterase inhibitor (human)) may be approved for members meeting the following criteria:

- Member has a diagnosis of HAE confirmed by laboratory tests obtained on two separate instances at least one month apart (C4 level, C1-INH level) **AND**
- Member has a documented history of at least one symptom of a moderate to severe HAE attack (moderate to severe abdominal pain, facial swelling, airway swelling) in the absence of hives or a medication known to cause angioedema **AND**
- Member meets at least one of the following:
  - HAEGARDA® is being used for short-term prophylaxis to undergo a surgical procedure or major dental work OR
  - HAEGARDA® is being used for long-term prophylaxis and member meets one of the following:
    - History of ≥1 attack per month resulting in documented ED admission or hospitalization **OR**
    - History of laryngeal attacks **OR**
    - History of ≥2 attacks per month involving the face, throat, or abdomen **AND**
- Member is not taking medications that may exacerbate HAE including ACE inhibitors and estrogen-containing medications **AND**
- Member has received hepatitis A and hepatitis B vaccination **AND**
- Provider attests to performing annual testing or screening (as appropriate) for HBV, HCV, and HIV

Maximum Dose: 60 IU/kg
Minimum Age: 10 years

CINRYZE (C1 esterase inhibitor (human)) may be approved for members meeting the following criteria:

- Member has history of trial and failure of HAEGARDA®. Failure is defined as lack of efficacy allergy, intolerable side effects, or a significant drug-drug interaction **AND**
- Member has a diagnosis of HAE confirmed by laboratory tests obtained on two separate instances at least one month apart (C4 level, C1-INH level) **AND**
- Member has a documented history of at least one symptom of a moderate to severe HAE attack (moderate to severe abdominal pain, facial swelling, airway swelling) in the absence of hives or a medication known to cause angioedema **AND**
- Member meets at least one of the following:
  - CINRYZE® is being used for short-term prophylaxis to undergo a surgical procedure or major dental work **OR**
  - CINRYZE® is being used for long-term prophylaxis and member meets one of the following:
    - History of ≥1 attack per month resulting in documented ED admission or hospitalization **OR**
    - History of laryngeal attacks **OR**
    - History of ≥2 attacks per month involving the face, throat, or abdomen **AND**
- Member is not taking medications that may exacerbate HAE including ACE inhibitors and estrogen-containing medications **AND**
- Member has received hepatitis A and hepatitis B vaccination **AND**
- Provider attests to performing annual testing or screening (as appropriate) for HBV, HCV, and HIV.

Minimum age: 6 years
Maximum dose: 100 Units/kg

ORLADEYO (berotralstat) may be approved for members meeting the following criteria:

- Member has history of trial and failure of HAEGARDA. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction **AND**
- Member has a diagnosis of HAE confirmed by laboratory tests obtained on two separate instances at least one month apart (C4 level, C1-INH level) **AND**
- Member has a documented history of at least one symptom of a moderate to severe HAE attack (moderate to severe abdominal pain, facial swelling, airway swelling) in the absence of hives or a medication known to cause angioedema **AND**
- ORLADEYO is prescribed by or in consultation with an allergist or immunologist **AND**
- Appropriate drug interaction interventions will be made for members using concomitant medications that may require dose adjustments (such as cyclosporine, fentanyl, pimozide, digoxin) **AND**
- Member meets at least one of the following:
  - ORLADEYO is being used for short-term prophylaxis to undergo a surgical procedure or major dental work
  - ORLADEYO is being used for long-term prophylaxis and member meets one of the following:
    - History of ≥ 1 attack per month resulting in documented ED admission or hospitalization **OR**
    - History of laryngeal attacks **OR**
    - History of ≥ 2 attacks per month involving the face, throat, or abdomen **AND**
- Member is not taking medications that may exacerbate HAE, including ACE inhibitors and estrogen-containing medications

Minimum age: 12 years
Maximum dose: 150 mg once daily

TAKHZYRO (lanadelumab-flyo) may be approved for members meeting the following criteria:
- Member has history of trial and failure of Haegarda. Failure is defined as: lack of efficacy, allergy, intolerable side effects, or a significant drug-drug interaction **AND**
- Member has a diagnosis of HAE confirmed by laboratory tests obtained on two separate instances at least one month apart (C4 level, C1-INH level) **AND**
- Member has a documented history of at least one symptom of a moderate to severe HAE attack (moderate to severe abdominal pain, facial swelling, airway swelling) in the absence of hives or a medication known to cause angioedema **AND**
- Member is not taking medications that may exacerbate HAE including ACE inhibitors and estrogen-containing medications **AND**
- Member has received hepatitis A and hepatitis B vaccination

Minimum age: 12 years

Maximum dose: The recommended starting dose is 300mg every 2 weeks. A dosing interval of 300 mg every 4 weeks is also effective and may be considered if the patient is well controlled (attack free) for more than 6 months

Medications Indicated for Treatment of Acute Attacks:
Members are restricted to coverage of one medication for treatment of acute attacks at one time. Prior authorization approval will be for one year.

FIRAZYR (icatibant acetate) may be approved for members meeting the following criteria:
- Member has a diagnosis of HAE confirmed by laboratory tests obtained on two separate instances at least one month apart (C4 level, C1-INH level) **AND**
- Member has a documented history of at least one symptom of a moderate to severe HAE attack (moderate to severe abdominal pain, facial swelling, airway swelling) in the absence of hives or a medication known to cause angioedema **AND**
- Member is not taking medications that may exacerbate HAE including ACE inhibitors and estrogen-containing medications

Minimum age: 18 years
Maximum dose: 30mg

BERINERT (C1 esterase inhibitor (human)) may be approved for members meeting the following criteria:
- Member has a diagnosis of HAE confirmed by laboratory tests obtained on two separate instances at least one month apart (C4 level, C1-INH level) **AND**
- Member has a documented history of at least one symptom of a moderate to severe HAE attack (moderate to severe abdominal pain, facial swelling, airway swelling) in the absence of hives or a medication known to cause angioedema **AND**
- Member is not taking medications that may exacerbate HAE including ACE inhibitors and estrogen-containing medications **AND**
- Member has received hepatitis A and hepatitis B vaccination **AND**
- Provider attests to performing annual testing or screening (as appropriate) for HBV, HCV, and HIV

Minimum age: 6 years
Maximum dose: 20 IU/kg

RUCONEST (C1 esterase inhibitor (recombinant)) may be approved for members meeting the following criteria:

- Member has a history of trial and failure of FIRAZYR® OR BERINERT®. Failure is defined as lack of efficacy, allergy, intolerable side effects, or a significant drug-drug interaction **AND**
- Member has a diagnosis of HAE confirmed by laboratory tests obtained on two separate instances at least one month apart (C4 level, C1-INH level) **AND**
- Member has a documented history of at least one symptom of a moderate to severe HAE attack (moderate to severe abdominal pain, facial swelling, airway swelling) in the absence of hives or a medication known to cause angioedema **AND**
- Member is not taking medications that may exacerbate HAE including ACE inhibitors and estrogen-containing medications **AND**
- Member has received hepatitis A and hepatitis B vaccination **AND**
- Provider attests to performing annual testing or screening (as appropriate) for HBV, HCV, and HIV

Minimum age: 13 years

Maximum dose: 4200 Units/dose

All other non-preferred agents may be approved if the member has trialed and failed at least two preferred agents with the same indicated role in therapy as the prescribed medication (prophylaxis or treatment). Failure is defined as lack of efficacy, allergy, intolerable side effects, or a significant drug-drug interaction.

40. Antihyperuricemics

Preferred Agents
- Allopurinol tablet
- MITIGARE[BNR] (colchicine) capsule
- COLCRYS[BNR] (colchicine) tablet
- Probenecid tablet
- Probenecid/Colchicine tablet

Non-preferred xanthine oxidase inhibitor products (allopurinol or febuxostat formulations) may be approved following trial and failure of preferred allopurinol. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. If member has tested positive for the HLA-B*58:01 allele, it is not recommended that they trial allopurinol. A positive result on this genetic test will count as a failure of allopurinol.

Prior authorization for all other non-preferred agents (non-xanthine oxidase inhibitors) may be approved after trial and failure of two preferred products. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.

GLOPERBA (colchicine) oral solution may be approved for members who require individual doses <0.6 mg OR for members who have documented swallowing difficulty due to young age and/or a medical condition (preventing use of solid oral dosage form).

Prior authorization for colchicine tablets may be approved for members requiring treatment of gout flares.

Colchicine tablet quantity limits:
- Chronic hyperuricemia/gout prophylaxis: 60 tablets per 30 days
- Familial Mediterranean Fever: 120 tablets per 30 days

41. Respiratory Agents, Phosphodiesterase Inhibitors (PDEIs)

Preferred Agents
NONE

DALIRESP (roflumilast) may be approved for members when the following criteria are met:

- Member has severe COPD associated with chronic bronchitis and a history of COPD exacerbations (2 or more per year) AND
- Member must be ≥ 18 years of age AND
- Member must have failed a trial of TWO of the following (Failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interaction):
  - A long-acting beta$_2$ agonist
  - A preferred inhaled anticholinergic or anticholinergic combination product

  AND
- Member does not have moderate to severe liver disease (Child Pugh B or C)

Discussion

- No Board members reported a conflict of interest for the therapeutic classes included in today's mass review section.
- C Claus moved to edit the failure definition for Triptans and Other Migraine Agents, Oral in the non-preferred product criteria section. New proposed text is, "Non-preferred oral triptan products may be approved for members who have trialed and failed three preferred oral products. Failure is defined as lack of efficacy with 4 week trial, allergy, intolerable side effects or significant drug-drug interaction or contraindication to therapy." Seconded by S Klocke. Motion passed unanimously.
- A Shmerling moved to include the same criteria language included for ribavirin above (in Section 1) to the ribavirin criteria included in mass review (Ribavirin-containing products, Section 20). Seconded by B Jackson. Motion passed unanimously.
- L Claus moved to accept the remainder of mass review criteria as written. Seconded by T Brubaker. Motion passed unanimously.

Proposed ProDUR and Prior Authorization Criteria for Other Selected Products

1. Intravenous (IV) Targeted Immune Modulators

1.a Infliximab (Remicade and biosimilar products) for IV Infusion

Infliximab (Remicade and biosimilar products) may be approved if meeting the following criteria:

1. If billing under the pharmacy benefit, the medication is being administered in the member's home or in a long-term care facility **AND**
2. Member has one of the following diagnoses:
   - Crohn's disease (and ≥ 6 years of age)
   - Ulcerative colitis (and ≥ 6 years of age)
   - Rheumatoid arthritis (and ≥ 4 years of age)
   - Psoriatic arthritis (and ≥ 18 years of age)
   - Ankylosing spondylitis (and ≥ 18 years of age)
   - Juvenile idiopathic arthritis (and ≥ 4 years of age)
   - Plaque psoriasis (and ≥ 18 years of age)
   - Hydradenitis suppurativa (HS)

AND

3. If the prescribed infliximab agent is Remicade or a biosimilar product formulation other than RENFLEXIS (infliximab-adba), then the member has trialed and failed† RENFLEXIS (infliximab-adba) **AND**
4. Member meets one of the following, based on prescribed indication:
    a. For continuation of infliximab therapy that was initiated in the hospital setting for treating severe ulcerative colitis, no additional medication trial is required **OR**
    b. For treatment of moderate to severe hidradenitis suppurativa, no additional medication trial is required **OR**
    c. For all other prescribed indications, the member has trialed and failed†* all preferred agents in the Targeted Immune Modulators PDL drug class that are FDA labeled for use for the prescribed indication (with only one preferred TNF inhibitor trial required).

†Failure is defined as: lack of efficacy, allergy, contraindication to therapy, intolerable side effects, or significant drug-drug interaction.

*Members ≥ 50 years of age with an additional CV risk factor will not need a trial and failure of Xeljanz IR.

Maximum Dose: 10 mg/kg

Discussion

- No Board members reported a conflict of interest for this product.
- B Jackson moved to accept criteria for this class as written. Seconded by M Anguelov. Motion passed unanimously.

1.b ENTYVIO (vedolizumab) for IV infusion

ENTYVIO (vedolizumab) may be approved for members who are receiving infusion in their home or in a long-term care facility and who meet the following criteria:

1. Medication is being used in a member ≥ 18 years of age with moderately-to-severely active ulcerative colitis OR moderately-to-severely active Crohn's disease **AND**
2. Member has had an inadequate response with, intolerance to, or demonstrated a dependence on corticosteroids, **AND**

- Member is not receiving ENTYVIO in combination with Cimzia, Enbrel, Humira, infliximab, Simponi or Tysabri **AND**

For members with Crohn's Disease:

- Medication is initiated and titrated per FDA-labeled dosing for Crohn's Disease **AND**
- Member has trialed and failed† therapy with HUMIRA (adalimumab) **OR** an infliximab-containing product **OR** the member is ≥ 65 years of age with increased risk of serious infection.

For members with Ulcerative Colitis:

- Medication is initiated and titrated per FDA-labeled dosing for Ulcerative Colitis **AND**
- Member has trialed and failed† therapy with HUMIRA **OR** an infliximab-containing product **OR** SIMPONI (golimumab) **OR** the member is ≥ 65 years of age with increased risk of serious infection.

†Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction

Maximum Dose: 300 mg IV infusion every 8 weeks

Discussion

- No Board members reported a conflict of interest for this product.
- L Claus moved to accept criteria for this class as written. Seconded by B Jackson. Motion passed unanimously.

1.c STELARA (usetekinumab) IV injection

STELARA (ustekinumab) for IV infusion may be approved if meeting the following criteria:

- STELARA IV injection is being administered in a healthcare facility by a healthcare provider **AND**
- Member is ≥ 18 years of age **AND**
- Member has a diagnosis of moderate-to-severely active Crohn's disease or moderate-to-severely active ulcerative colitis, **AND**
- Member has trialed and failed† ENTYVIO (vedolizumab) OR RENFLEXIS (infliximab-abda)

Initial prior authorization approval may be given for 16 weeks. Prior authorization for one year may be approved for continuation of therapy based on clinical response.

†Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.

Maximum Dose: 520 mg initial IV dose for members weighing > 85 Kg (187 pounds)

Quantity Limit: For initial IV infusion, four 130 mg/26 mL single-dose vials

Discussion

- No Board members reported a conflict of interest for this product.
- M Anguelov moved to accept criteria for this class as written. Seconded by T Brubaker. Motion passed unanimously.

1.d ACTEMRA (tocilizumab) injection for IV infusion

ACTEMRA (tocilizumab) IV injection may be approved if the following criteria are met:

- Actemra IV injection is being administered by a healthcare professional in the member's home or in a long-term care facility **AND**
- Actemra is being prescribed for an FDA-labeled indication and within an FDA-approved age range (per product package labeling) **AND**
- Member is not concomitantly receiving any other biological DMARDs **AND**
- Member has trialed and failed† all preferred agents in the Targeted Immune Modulators PDL drug class that are FDA labeled for use for the prescribed indication (with only one preferred TNF inhibitor trial required).

†Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.

Maximum Dose: 800 mg per infusion for cytokine release syndrome (CRS) and rheumatoid arthritis (RA).

162 mg once a week for other indications

Discussion

- No Board members reported a conflict of interest for this product.
- L Claus moved to accept criteria for this class as written. Seconded by S VanEyk. Motion passed unanimously.

2. CRYSVITA (burosumab) subcutaneous injection

CRYSVITA (burosumab) may be approved if the following criteria are met:

1. CRYSVITA (burosumab) is being administered by a healthcare professional in the member's home or in a long-term care facility **AND**
2. Member is ≥ 6 months of age and has a diagnosis of X-linked hypophosphatemia (XLH) **OR**
3. Member is ≥ 2 years of age and has a diagnosis of FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumors that cannot be curatively resected or localized **AND**
4. Member has an estimated GFR of ≥ 30 mL/min **AND**
5. Member is not taking an oral phosphate product and/or an active vitamin D analog (such as calcitriol, paricalcitol, doxercalciferol or calcifediol).

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Maximum Dose: 180 mg every two weeks

Quantity Limit: Six 30 mg/mL single dose vials per 14 days

Discussion

- No Board members reported a conflict of interest for this product.
- T Brubaker moved to accept criteria for this class as written. Seconded by S Klocke. Motion passed unanimously.

3. BREXAFEMME (ibrexafungerp) oral tablet

BREXAFEMME (ibrexafungerp) may be approved if the following criteria are met:

1. Member is post-menarchal and ≥ age 17 years, **AND**
2. BREXAFEMME (ibrexafungerp) is being prescribed to treat vulvovaginal candidiasis **AND**
3. Member has trialed and failed† two azole antifungal products (oral and/or topical) **AND**
4. Member is not pregnant or breastfeeding

Maximum Dose: 600 mg/day

Quantity Limit: 120 tablets/30 days

†Failure is defined as: lack of efficacy, allergy, intolerable side effects, contraindication, or significant drug-drug interaction.

Discussion

- No Board members reported a conflict of interest for this product.
- L Claus moved to accept criteria for this class as written. Seconded by B Jackson. Motion passed unanimously.

4. AFINITOR DISPERZ (everolimus) tablet for oral suspension formulation

AFINITOR DISPERZ (everolimus) may be approved if the following criteria are met:

1. Member is ≥ 1 year of age and AFINITOR DISPERZ is being prescribed for Tuberous Sclerosis Complex (TSC) for treatment of Subependymal Giant Cell Astrocytoma (SEGA) that requires therapeutic intervention but cannot be curatively resected, **OR**
2. Member is ≥ 2 year of age and AFINITOR DISPERZ is being prescribed for adjunctive treatment of TSC-associated partial-onset seizures

Discussion

- No Board members reported a conflict of interest for this product.
- S Klocke moved to accept criteria for this class as written. Seconded by L Claus. Motion passed unanimously.

5. CYSTADROPS (cysteamine hydrochloride) ophthalmic solution

CYSTADROPS (cysteamine hydrochloride) may be approved if the following criteria are met:

1. Member has a diagnosis of corneal cystine crystal deposits associated with cystinosis, **AND**
2. CYSTADROPS are being prescribed by a physician experienced in the management of cystinosis **AND**
3. Member has been counseled to store unopened bottles in the refrigerator in the original carton (avoid freezing) **AND**
4. Member has been counseled to store the bottle of CYSTADROPS currently in use in the original carton, tightly closed and at room temperature **AND**
5. Member has been counseled that each bottle of CYSTADROPS should be discarded 7 days after first opening, even if there is medication left in the bottle **AND**
6. Member has been counseled to remove soft contact lenses prior to use of CYSTADROPS and wait at least 15 minutes to reinsert lenses after use

Maximum Dose: 1 drop in each eye 4 times a day (8 drops total/day)

Quantity Limit: Four 5 mL bottles per 28 days

Scheduled testimony presentations:
A Vorobeva, Recordati Rare Diseases, Inc.

Discussion

- No Board members reported a conflict of interest for this product.
- L Claus moved to accept criteria for this class as written. Seconded by M Anguelov. Motion passed unanimously.

6. AEMCOLO (rifamycin) delayed-release tablet

AEMCOLO (rifamycin) may be approved if the following criteria are met:

1. Member is ≥ 18 years of age **AND**
2. Member has a diagnosis of travelers' diarrhea caused by a non-invasive strain of *E. Coli*, without fever and without bloody stool, **AND**
3. Member has trialed and failed† treatment with oral azithromycin **AND**
4. Member is not allergic to the rifamycin drug class (such as rifamycin, rifaximin, rifampin)

Maximum Dose: 4 tablets/day

Quantity Limit: 12 tablets (3 day supply)

Length of authorization approval: 6 months

Discussion

- No Board members reported a conflict of interest for this product.
- S Klocke moved to accept criteria for this class as written. Seconded by B Jackson. Motion passed unanimously.

10. Adjournment

L Claus reminded the Board that the next meeting is scheduled for Tuesday, February 8, from 1:00 to 5:00 pm on Zoom. Dr. Claus also reminded all Board members to delete the meeting binder immediately after today's meeting.

T Brubaker moved to adjourn the meeting, seconded by B Jackson. Motion passed unanimously. The meeting was adjourned at 5:06 pm.

Minutes respectfully submitted by Julia Rawlings, PharmD