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 14, 2023
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 and Introductions

All board members, HCPF staff, and CO-DUR team members who were present introduced themselves. There were sufficient members for a quorum with seven voting members participating. Quorum is five voting members. Dr. Jackson joined today's meeting at approximately 2:30 pm.

Members Present: Liza Claus, PharmD (Chair); Brian Jackson, MD, MA (Vice Chair); Todd Brubaker, DO; Shilpa Klocke, PharmD; Patricia Lanius, BSPharm, MHA; Ken MacIntyre, DO; Ingrid Pan, PharmD;
Members Absent: None
HCPF Pharmacy Office Staff: Jim Leonard, PharmD; Jeffrey Taylor, PharmD, Veronia Garcia, PharmD, Rachele Poissant, PharmD
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
- Stakeholders who have signed up in advance will be invited to provide testimony at the appropriate time on the meeting agenda.
- If you experience technical difficulties, or if your connection is interrupted during the meeting, please leave the meeting and use the same Zoom link to be readmitted, as that usually resolves the issue.
- Video and microphone for Board members will be turned ON.
- Speakers providing testimony and our other meeting guests are asked to keep video turned off during the meeting so that we can more easily track Board member comments and votes.
- Board members should 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 today by the Chair or Vice Chair
- DUR/Population Health pharmacy interns Renee Sapasap, Diane Lee, Nicole DeLeon, Jordan Hahn and Andy Rukavina will be presenting and/or assisting behind the scenes during our meeting this afternoon.

4. Colorado Department of Health Care Policy and Financing Updates

V Garcia provided updates from the Department:

- Effective 8/30/23, the gender-affirming care policy has been updated to align coverage with the most recent standards of care and allows members easier access to gender-affirming services. Please refer to the Gender-Affirming Care Billing Manual for details.
- In alignment with Senate Bill 21-094, and the State Board of Pharmacy collaborative practice protocols, the PBMS system is being updated to adjudicate claims where an enrolled pharmacist is the prescriber for prescribing of certain therapies including but not limited to HMG-CoA reductase inhibitor therapy (otherwise known as statins). Providers must follow all requirements set forth in the applicable Statewide Protocol to be reimbursed. Refer to the Pharmacist Services Billing Manual for additional information regarding reimbursement for services rendered under Statewide Protocols.
- As part of Governor Polis's Wildly Important Goals (WIGs) for the Department is conducting outreach regarding naloxone coverage and widespread access to opioid antagonist therapies for Health First Colorado members across the state. As part of these efforts, the Department has created a one-page informational handout for the purpose of sharing and dissemination. The handout is available in English and Spanish available on the Pain Management Resources webpage and is located under the "Opioid Overdose Resources" dropdown on the webpage found at: https://hcpf.colorado.gov/pain-management-resources-and-opioid-use.
- Effective 01/01/2024, the Department will be implementing quantity limits to pharmacy claims for long-acting injectable antipsychotic medications, in alignment with FDA-approved dosing outlined in product package labeling.
- For products and drug classes currently managed with prior authorization criteria, only proposed changes to the currently posted criteria will be read aloud during today's meeting.

5. Final Approval of Minutes from the August 8, 2023 Meeting

- Chair L Claus asked the Board to review minutes from the August 8, 2023 meeting.
- K MacIntyre moved to approve the minutes as written. Seconded by T Brubaker. 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.

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.

7. Clinical Updates and General Orders

- **FDA New Product & Safety Updates**
  This quarter's FDA Drug Approvals report, was prepared by Melina Harris and presented by Nicole DeLeon, DUR/Population Health Interns. A Drug Safety Update was not presented this quarter, as no FDA Drug Safety
  Communications have been released since the last DUR Board meeting.

- **Quarterly Clinical Modules**
  R Page presented a summary of last quarter's Quarterly Clinical Module, *Evaluation of Non-oral Antipsychotic Utilization Among Health First Colorado Members* that was delivered to the Department on September 30.

- **Retrospective DUR Report**
  R Page presented the quarterly RDUR summary and also referred Board members to a recently-developed provider educational letter and InfoSheet related to the Governor's goal to reduce opioid overdose deaths in Colorado. This letter was mailed to a subset of Health First Colorado providers in early November.

- **Quarterly Drug Utilization Reports**
  R Page presented highlights from this quarter's drug utilization reports. Ventolin® HFA, gabapentin, cetirizine, sertraline, omeprazole and trazodone were the top drug products by claim count during the 3rd quarter of 2023. Humira®, Trulicity®, Biktarvy®, Trikafta®, Dupixent®, Stelara® and Taltz® were among the top product claims by cost. Board members were referred to utilization reports in the meeting binder for more details.

8. New Business

The New Business section of today's agenda covers the review of proposed criteria for the PDL Drug Classes scheduled for November review, along with several products being reviewed for addition to Appendix P (and/or Appendix Y).

J Rawlings described steps of the review process for this quarter's proposed DUR criteria:

- Board members will be asked if they have potential conflicts of interest to verbally disclose prior to reviewing therapeutic drug classes or individual products listed in the meeting agenda.
- There will be an opportunity for Board discussion.
- Time will be permitted for stakeholder comment. All of today's speakers have registered in advance and each will be given up to 3 minutes to provide testimony

R Page proceeded with the review process of proposed criteria and asked if any Board members had conflicts of interest to report related to the PDL therapeutic classes included on today's agenda up to the Mass Review section.

There was only one potential conflict of interest disclosure for this section. I Pan disclosed that she recently served as an advisory board member for Gamifant® (emapalumab) for the Sobi biopharmaceutical company. Emapalumab is not being reviewed this quarter in the Targeted Immune Modulator class and Dr. Pan does not believe a conflict of interest exists. After a brief discussion among Board members, T Brubaker moved that this situation does not rise to the level of a conflict of interest. Seconded by K MacIntyre. Motion passed with five votes in favor and with Dr. Pan abstaining.

A. Proposed Coverage Criteria for Preferred Drug List (PDL) Drug Classes

Red indicates proposed deleted text

Yellow indicates proposed new text

1. Hepatitis C Virus Treatments

a. Hepatitis C, Direct Acting Antivirals

Preferred Agents

No PA Required for initial treatment

(*must meet eligibility criteria)

EPCLUSA (sofosbuvir/velpatasvir) 200 mg-50 mg, 150 mg-37.5 mg tablet, pellet pack
HARVONI (ledipasvir/sofosbuvir) 45 mg-200 mg tablet, pellet pack
Ledipasvir/Sofosbuvir 90 mg-400 mg tablet (Asequa only)
MAVYRET (glecaprevir/pibrentasvir) tablet, pellet pack
Sofosbuvir/Velpatasvir 400 mg-100 mg *(Asequa only)*
*VOSEVI tablet (sofosbuvir/velpatasvir/voxilaprevir)

Pharmacy claims for preferred products prescribed for initial treatment will be eligible for up to a 90-day supply fill allowing for the appropriate days' duration for completing the initial treatment regimen (with no PA required). Subsequent fills will require prior authorization meeting re-treatment criteria below.

***Second line preferred agents** (Vosevi) may be approved for members 18 years of age or older with chronic HCV infection who are non-cirrhotic or have compensated cirrhosis (Child-Pugh A) AND meet the following criteria:

- 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**
- Request meets the applicable criteria below for re-treatment.

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 may be requested for re-treatment requests including:

- Assessment of member readiness for re-treatment
- 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.

Non-preferred agents may be approved if 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).

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

b. Hepatitis C, 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.

Discussion
- S Klocke moved to accept Hepatitis C criteria as written. Seconded by I Pan. Motion passed unanimously.

2. Human Immunodeficiency Virus (HIV) Treatments, Oral

a. HIV - Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs)

Preferred Agents
- EDURANT (rilpivirine) tablet
- Efavirenz tablet
- Etravirine tablet
- INTELENCE (etravirine) tablet
- Nevirapine IR tablet, ER tablet
- PIFELTRO (doravirine) tablet
- SUSTIVA (efavirenz) capsule, tablet
- VIRAMUNE (nevirapine) suspension
- VIRAMUNE XR (nevirapine ER) tablet

b. HIV - Nucleoside/Nucleotide Reverse Transcriptase Inhibitors (NRTIs)

Preferred Agents
- Abacavir solution, tablet
- Didanosine DR capsule
- Emtricitabine capsule
- EMTRIVA (emtricitabine) capsule, solution
- EPIVIR (lamivudine) solution, tablet
- Lamivudine solution, tablet
- RETROVIR (zidovudine) capsule, syrup
- Stavudine capsule, solution
- Tenofovir (TDF) tablet
- VIREAD (TDF) oral powder, tablet
- ZIAGEN (abacavir) solution, tablet
- Zidovudine capsule, syrup, tablet

**TDF – Tenofovir disoproxil fumarate*

c. HIV - Protease Inhibitors (PIs)

Preferred Agents
- APTIVUS (tipranavir) capsule
- Atazanavir capsule
- CRIXIVAN (indinavir) capsule
- Fosamprenavir tablet
- INVIRASE (saquinavir) tablet
- LEXIVA (fosamprenavir) suspension, tablet
- NORVIR (ritonavir) powder packet, solution, tablet
- PREZISTA (darunavir) suspension, tablet
- REYATAZ (atazanavir) capsule, powder pack
- Ritonavir tablet
- VIRACEPT (nelfinavir) tablet

d. HIV - Other Agents

Preferred Agents

ISENTRESS (raltegravir) chewable, powder pack, tablet
ISENTRESS HD (raltegravir) tablet
Maraviroc tablet
RUKOBIA (fostemsavir tromethamine ER) tablet
SELZENTRY (maraviroc) solution, tablet
SUNLENCA (lenacapavir) tablet
TIVICAY (dolutegravir) tablet
TIVICAY PD (dolutegravir) tablet for suspension
TYBOST (cobicistat) tablet
VOCABRIA (cabotegravir) tablet

e. HIV – Combination Agents

Preferred Agents

No PA Required*

***Dispense as written (DAW) should be indicated on the prescription**

Abacavir/Lamivudine tablet
Abacavir/Lamivudine/Zidovudine tablet
BIKTARVY (bictegravir/emtricitabine/TAF) tablet
CIMDUO (lamivudine/TDF) tablet
COMBIVIR (lamivudine/zidovudine) tablet
COMPLERA (emtricitabine/rilpivirine/TDF) tablet
DELSTRIGO (doravirine/lamivudine/TDF) tablet
DESCOVY (emtricitabine/TAF) tablet
DOVATO (dolutegravir/lamivudine) tablet
Efavirenz/Emtricitabine/TDF tablet
Efavirenz/Lamivudine/TDF tablet
Emtricitabine/TDF tablet
EPZICOM (abacavir/lamivudine) tablet
EVOTAZ (atazanavir/cobicistat) tablet
GENVOYA (elvitegravir/cobicistat/ emtricitabine/TAF) tablet
JULUCA (dolutegravir/rilpivirine) tablet
KALETRA (lopinavir/ritonavir) solution, tablet
Lamivudine/Zidovudine tablet
Lopinavir/Ritonavir solution, tablet
ODEFSEY (emtricitabine/rilpivirine/TAF) tablet
PREZCOBIX (darunavir/cobicistat) tablet
STRIBILD (elvitegravir/cobicistat/ emtricitabine/TDF) tablet
SYMFI/SYMFI LO (efavirenz/lamivudine/TDF) tablet
SYMTUZA (darunavir/cobicistat/ emtricitabine/TAF) tablet
TEMIXYS (lamivudine/TDF) tablet
TRIUMEQ (abacavir/dolutegravir/ lamivudine) tablet
TRIZIVIR (abacavir/lamivudine/zidovudine) tablet
TRUVADA* (emtricitabine/TDF) tablet

TAF – Tenofovir alafenamide
TDF – Tenofovir disoproxil fumarate

All products are preferred and do not require prior authorization.

Discussion

- J Taylor confirmed that the Department currently includes all of the HIV agents on the preferred drug list, with all of the agents listed above as preferred products. There are no prior authorization requirements or limitations on these medications. The Department is proposing today to continue to allow all of these medications to be preferred.
- I Pan recommended adding Triumeq® (abacavir/dolutegravir/ lamivudine) tablet for oral suspension to the list of preferred agents in the HIV Combination Products subclass.
- S Klocke moved to include the additional formulation of Triumeq and to accept the criteria as written. Seconded by T Brubaker. Motion passed unanimously.

3. Targeted Immune Modulators

Preferred agents: ADBRY (tralokinumab-ldrm); DUPIXENT (dupilumab); ENBREL (etanercept); FASENRA (benralizumab) pen; HADLIMA (adalimumab- bwwd); HUMIRA (adalimumab); KEVZARA (sarilumab); OTEZLA (apremilast) tablet; TALTZ (ixekizumab); TEZSPIRE (tezepelumab-ekko) pen; XELJANZ IR (tofacitinib) tablet; XOLAIR (omalizumab) syringe

a. Rheumatoid Arthritis, all other Arthritis (except psoriatic arthritis, see below), and Ankylosing Spondylitis

Preferred Agents
No PA Required (If diagnosis met)
(*Must meet eligibility criteria)
ENBREL (etanercept)
HADLIMA (adalimumab- bwwd) Pushtouch, syringe
HUMIRA (adalimumab)
*KEVZARA (sarilumab) pen, syringe
*TALTZ (ixekizumab)
XELJANZ IR (tofacitinib) tablet

*For information on IV-infused Targeted Immune Modulators please see Appendix P

First line preferred agents (HADLIMA, 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 HADLIMA/HUMIRA or ENBREL.

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

COSENTYX (secukinumab) may receive approval for:

- FDA-labeled indications following trial and failure‡ of all indicated preferred agents OR
- Treatment of enthesitis-related arthritis if meeting the following:
  - Member is ≥ 4 years of age and weighs ≥ 15 kg **AND**
  - Member has had trialed and failed‡ NSAID therapy **AND** ENBREL **AND** HADLIMA/HUMIRA

KINERET (anakinra) may receive approval for:

- FDA-labeled indications following trial and failure‡ of HADLIMA/HUMIRA **OR** ENBREL AND XELJANZ IR **OR**
- Treatment of systemic juvenile idiopathic arthritis (sJIA) or Adult-Onset Still's Disease (AOSD)

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‡ 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.

XELJANZ (tofacitinib) oral solution may be approved for members with a diagnosis of polyarticular course juvenile idiopathic arthritis (pJIA) who require a weight-based dose for <40 kg following trial and failure‡ of HADLIMA/HUMIRA **OR** ENBREL.

All other non-preferred agents may receive approval for FDA-labeled indications following trial and failure‡ of all indicated preferred agents. Non-preferred agents that are being prescribed per FDA-label to treat non-radiographic axial spondyloarthritis (nr-axSpA) will require trial and failure‡ of preferred agents that are FDA-labeled for treating an axial spondyloarthritis condition, including ankylosing spondylitis (AS) or nr-axSpA.

Members currently taking COSENTYX or XELJANZ oral solution 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 preferred TNF inhibitors will not be required when prescribed to treat polyarticular juvenile idiopathic arthritis (pJIA) in members with documented clinical features of lupus.

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.

b. Psoriatic Arthritis

Preferred Agents
No PA Required (If diagnosis met)
(*Must meet eligibility criteria)
ENBREL (etanercept)
HADLIMA (adalimumab-bwwd) Pushtouch, syringe
HUMIRA (adalimumab)
*OTEZLA (apremilast) tablet
*TALTZ (ixekizumab)
XELJANZ IR (tofacitinib) tablet

*For information on IV-infused Targeted Immune Modulators please see Appendix P

First line preferred agents (HADLIMA, 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 HADLIMA/HUMIRA **OR** ENBREL **AND** XELJANZ IR or TALTZ.

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

COSENTYX (secukinumab) may receive approval for psoriatic arthritis indication for members ≥ 2 years of age and weighing ≥ 15 kg following trial and failure‡ of HADLIMA/HUMIRA (adalimumab) **OR** ENBREL AND XELJANZ IR **AND** TALTZ or OTEZLA.

STELARA (ustekinumab) syringe for subcutaneous use may receive approval if meeting the following:
- Member has trial and failure‡ of HADLIMA/HUMIRA or ENBREL AND XELJANZ IR AND TALTZ or OTEZLA **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.

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.

All other non-preferred agents may receive approval for psoriatic arthritis following trial and failure‡ of HADLIMA/HUMIRA **OR** ENBREL AND XELJANZ IR AND TALTZ or OTEZLA.

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

Members currently taking COSENTYX 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.

c. Plaque Psoriasis

Preferred Agents
No PA Required (If diagnosis met) (*Must meet eligibility criteria)
ENBREL (etanercept)
HADLIMA (adalimumab- bwwd) Pushtouch, syringe
HUMIRA (adalimumab)
*OTEZLA (apremilast) tablet
*TALTZ (ixekizumab)
*For information on IV-infused Targeted Immune Modulators please see Appendix-P

First line preferred agents (HADLIMA/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 HADLIMA/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 (HADLIMA/HUMIRA, ENBREL) **AND** two indicated second line agents (TALTZ, OTEZLA), **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.

All other non-preferred agents may receive approval for plaque psoriasis indication following trial and failure‡ of one indicated first line agent (HADLIMA/HUMIRA, ENBREL) AND two second line agents (TALTZ, OTEZLA).

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

Members currently taking COSENTYX 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.

d. Crohn's Disease and Ulcerative Colitis

Preferred Agents
No PA Required (If diagnosis met)
(*Must meet eligibility criteria)
HADLIMA (adalimumab- bwwd) Pushtouch, syringe
HUMIRA (adalimumab)
*XELJANZ IR (tofacitinib) tablet

First line p Preferred agents (HADLIMA, 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 HADLIMA or HUMIRA.

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

SIMPONI (golimumab) may receive approval if meeting the following:
- Member is ≥ 18 years of age **AND**
- Member has a diagnosis of moderately to severely active ulcerative colitis and meets the following:
  - Member has trialed and failure‡ of all preferred agents in the "Targeted Immune Modulators" PDL drug class that are FDA-labeled for use for the prescribed indication **AND**
  - Member has demonstrated corticosteroid dependence or has had an inadequate response to (or failed to tolerate) oral aminosalicylates, oral corticosteroids, azathioprine, or 6-mercaptopurine for inducing and maintaining clinical response, improving endoscopic appearance of the mucosa during induction, inducing clinical remission, or achieving and sustaining clinical remission in induction responders.

SKYRIZI (risankizumab) syringe for subcutaneous use and **on-body injector formulations** may receive approval if meeting the following:
- The requested medication is being prescribed for use for treating moderately-to-severely active Crohn's disease **AND**
- Member is ≥ 18 years of age **AND**
- Member has trial and failure‡ of all indicated preferred agents one preferred adalimumab product AND
- Prescriber acknowledges that administration of IV induction therapy prior to approval of SKYRIZI prefilled syringe or on-body injector formulation using the above criteria should be avoided and will not result in an automatic approval of requests for these formulations.

Dosing Limit: SKYRIZI on-body formulation maintenance dosing is limited to one 360 mg/2.4 mL single-dose prefilled cartridge or one 180 mg/1.2mL prefilled cartridge every 8 weeks.

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 one preferred adalimumab product all indicated preferred agents (HUMIRA) **OR** for treatment of moderately-to-severely active ulcerative colitis, member has trial and failure‡ of all indicated preferred agents one preferred adalimumab product and XELJANZ IR (HUMIRA **AND** XELJANZ IR) **AND**
- The member is ≥ 18 years of age **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.

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.

All other non-preferred agents may receive approval for FDA-labeled indications if meeting the following: trial and failure‡ of all indicated preferred agents.

- The requested medication is being prescribed for treating moderately-to-severely active Crohn's disease or moderately-to-severely active Ulcerative Colitis in alignment with indicated use outlined in FDA-approved product labeling **AND**
- The requested medication meets FDA-labeled indicated age for prescribed use **AND**
- For treatment of moderately-to-severely active Crohn's disease, member has trial and failure‡ of one preferred adalimumab product **OR** for treatment of moderately-to-severely active ulcerative colitis, member has trial and failure‡ of one preferred adalimumab product and XELJANZ IR

Members currently taking COSENTYX 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.

e. Asthma

Preferred Agents
PA Required (*Must meet eligibility criteria)
*DUPIXENT (dupilumab) pen, syringe
*FASENRA (benralizumab) pen
*TEZSPIRE (tezepelumab-ekko) pen
*XOLAIR (omalizumab) syringe

*For information on IV infused or health care professional administered (Fasenra syringe) Targeted Immune Modulators please see Appendix-P

*Preferred products (Fasenra, Dupixent, Tezspire, Xolair) may receive approval if meeting the following:

DUPIXENT (dupilumab): may receive approval if meeting the following:

- Member is 6 years of age or older **AND**
- Member has a diagnosis of an FDA-labeled indicated use for treating one of the following:
  - Moderate to severe asthma (on medium to high dose inhaled corticosteroid and a long-acting beta agonist) with eosinophilic phenotype based on a blood eosinophil level of ≥ 150/mcL **OR**
  - Oral corticosteroid dependent asthma
- **AND**
- Member's asthma has been refractory to recommended evidence-based, guideline-supported pharmacologic therapies. **AND**

- Member has had at least one asthma exacerbation in the past year requiring systemic corticosteroids or emergency department visit or hospitalization OR dependence on daily oral corticosteroid therapy PLUS regular use of high dose inhaled corticosteroid PLUS an additional controller medication **AND**
- Member has trialed and failed‡ both preferred agents (FASENRA and XOLAIR) **AND**
- Medication is being prescribed as add-on therapy to existing asthma regimen. **AND**
- Medication is being prescribed by or in consultation with a rheumatologist, allergist, or pulmonologist **AND**
- For indication of moderate to severe asthma with eosinophilic phenotype:
  - baseline lung function (FEV1) is provided, and baseline eosinophils are greater than 300 cells/mcL **AND**
  - Initial authorization will be for 12 weeks. Continued authorization will require prescriber attestation to improvement in FEV1 of 25% from baseline and will be for 12 months.
- For indication of oral corticosteroid dependent asthma:
  - Dosing of the oral corticosteroid is provided **AND**
  - Initial authorization will be 24 weeks. Continued authorization will require prescriber attestation of a reduction of oral corticosteroid by at least 50% and will be for 12 months.

Quantity Limit: 2 syringes every 28 days after initial 14 days of therapy (first dose is twice the regular scheduled dose)

TEZSPIRE (tezepelumab-ekko):

- Member is ≥ 12 years of age **AND**
- Member has a diagnosis of severe asthma **AND**
- Member's asthma has been refractory to recommended evidence-based, guideline-supported pharmacologic therapies **AND**
- The requested medication is being prescribed as add-on therapy to existing asthma regimen.

Quantity Limit: Four 210 mg unit dose packs every 28 days

XOLAIR (omalizumab) syringe:

- Member is ≥ 6 years of age **AND**
- Member has an FDA-labeled indicated use for treating asthma **AND**
- Member has a positive skin test or in vitro reactivity to a perennial inhaled allergen or has a pre-treatment IgE serum concentration ≥ 30 IU/mL **AND**
- Member's asthma has been refractory to recommended evidence-based, guideline-supported pharmacologic therapies **AND**
- The requested medication is being prescribed as add-on therapy to existing asthma regimen. **AND**
- The requested medication will not be used concomitantly with other biologic products indicated for asthma.

Quantity Limit:
300 mg: Four unit dose packs every 28 days
All other strengths: Two unit dose packs of the same mg strength every 28 days

FASENRA (benralizumab) pen:

- Member is ≥ 12 years of age **AND**
- Member has an FDA-labeled indicated use for treating severe asthma with an eosinophilic phenotype based on a blood eosinophil level of ≥ 150/mcL **AND**
- Member's asthma has been refractory to recommended evidence-based, guideline-supported pharmacologic therapies **AND**
- The requested medication is being prescribed as add-on therapy to existing asthma regimen. **AND**
- The requested medication will not be used concomitantly with other biologic products indicated for asthma.

Quantity Limit: One 30 mg unit dose pack every 28 days for the first 3 doses and then every 8 weeks thereafter

All other n Non-preferred FDA-indicated biologic agents for asthma may receive approval if meeting the following: trial and failure‡ of two preferred agents (FASENRA and XOLAIR)

- The requested medication is being prescribed for treating asthma in alignment with indicated use outlined in FDA-approved product labeling (including asthma type and severity) **AND**
- If prescribed for use for asthma with eosinophilic phenotype, member has a blood eosinophil count ≥ 150 cells/mcL **AND**
- The requested medication meets FDA-labeled indicated age for prescribed use **AND**
- Member's asthma has been refractory to recommended evidence-based, guideline-supported pharmacologic therapies **AND**
- The requested medication is being prescribed as add-on therapy to existing asthma regimen **AND**
- Member has trialed and failed‡ two preferred agents.

Quantity Limits: Non-preferred medications will be subject to quantity limitations in alignment with FDA-approved dosing per product package labeling.

NUCALA (mepolizumab) may receive approval if meeting the following:

- For billing under the pharmacy benefit, the request meets one of the following:
  - The medication is being administered by a healthcare professional in the member's home or in a long-term care facility **OR**
  - The prescriber verifies that the member has been properly trained in subcutaneous injection technique and on the preparation and administration of Nucala (mepolizumab) per information contained in product package labeling

  AND
- Member is 6 years of age or older AND
- Member has diagnosis of severe asthma with an eosinophilic phenotype **AND**
- Member has a blood eosinophil count of greater than or equal to 150 cells/mcL within 6 weeks of dosing or greater than or equal to 300 cells/mcL in the previous 12 months **AND**
- Member has had 2 or more asthma exacerbations requiring use of oral or systemic corticosteroids and/or hospitalizations and/or ER visits OR member requires daily use of oral corticosteroids **AND**
- Baseline FEV1 and frequency of asthma exacerbations per month are provided **AND**
- Member has trialed and failed‡ two preferred agents (FASENRA and XOLAIR).

Initial approval: 1 year

Reauthorization:

- May be approved if member has shown clinical improvement as documented by one of the following:
  - Improvement in lung function, measured in FEV1 **OR**
  - Reduction in the number of asthma exacerbations, defined as a decrease in use of oral or systemic corticosteroids and/or reduced asthma related hospitalizations and/or ER visits.

Dosing Limits: 100mg every 4 weeks (members ≥ 12 years of age); 40mg every 4 weeks (members 6-11 years of age)

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

Members currently taking a preferred agent may receive approval to continue therapy with that agent.

Members with current prior authorization approval on file for a non-preferred agent:
- Will be subject to meeting reauthorization criteria listed above for the prescribed agent **OR**
- If reauthorization criteria are not listed above, may receive approval for continuation of therapy with the prescribed agent.

f. Atopic Dermatitis

Preferred Agents
PA Required (*Must meet eligibility criteria)
*ADBRY (tralokinumab-ldrm) SC syringe
*DUPIXENT (dupilumab) SC pen, syringe

*For information on IV infused Targeted Immune Modulators please see Appendix-P

*Preferred products (Adbry and Dupixent) may receive approval if meeting the following:

ADBRY (tralokinumab-ldrm): may be approved if the following criteria are met:
- Member is ≥ 18 years of age **AND**
- The requested drug is being prescribed for moderate-to-severe atopic dermatitis **AND**
- Member has baseline Investigator Global Assessment (IGA) score for atopic dermatitis severity of at least 3 (Scored 0-4, 4 being most severe) OR moderate erythema and moderate papulation/infiltration **AND**
- Member has been educated by provider regarding the elimination of exacerbating factors including aeroallergens, food allergens, and contact allergens **AND**
- Member has been educated by provider regarding the appropriate use of emollients and moisturizers for promotion of skin hydration **AND**
- Member has trialed and failed‡ the following agents:
  - Two One medium potency to very-high potency topical corticosteroids (such as mometasone furoate, betamethasone dipropionate) **AND**
  - Two One topical calcineurin inhibitors (such as pimecrolimus and tacrolimus)

AND
- The requested drug is being prescribed by, or in consultation with, a dermatologist, allergist/immunologist, or rheumatologist.

Maximum Dose: 600 mg/2 weeks

Quantity Limit: Four 150 mg/mL prefilled syringes/2 weeks
Initial approval: 18 weeks One year

Reauthorization:

- Additional one year approval for continuation may be granted with prescriber attestation that member has a 16-week IGA score showing improvement by at least 2 points from baseline OR has demonstrated clinically significant improvement due to treatment with the requested medication AND
- If clear or almost clear skin has been achieved after 16 weeks of treatment with, provider attests to considering a dose reduction to 300 mg every 4 weeks.

DUPIXENT (dupilumab): may be approved for members meeting the following criteria:

- Member is 6 years of age or older **AND**
- Member has a diagnosis of moderate to severe chronic atopic dermatitis **AND**
- Member has baseline Investigator Global Assessment (IGA) score for atopic dermatitis severity of at least 3 (Scored 0-4, 4 being most severe) OR moderate erythema and moderate papulation/infiltration **AND**
- Member has been educated by provider regarding the elimination of exacerbating factors including aeroallergens, food allergens, and contact allergens **AND**
- Member has been educated by provider regarding the appropriate use of emollients and moisturizers for promotion of skin hydration **AND**
- Member has trialed and failed‡ the following agents:
  - Two One medium potency to very-high potency topical corticosteroids [such as mometasone furoate, betamethasone dipropionate, or fluocinonide (see PDL for list of preferred products) **AND**
  - Two One topical calcineurin inhibitors (see PDL for list of preferred products such as pimecrolimus and tacrolimus) **AND**
- Must be prescribed by or in conjunction consultation with a dermatologist, allergist/immunologist, or rheumatologist AND

Quantity Limit: 2 syringes every 28 days after initial 14 days of therapy (first dose is twice the regular scheduled dose)

Initial approval: 18 weeks One year

Reauthorization: Dupixent may be authorized for 12 months with prescriber attestation to 16-week IGA score showing improvement by at least 2 points from baseline OR clinically significant improvement with Dupixent regimen.

All other n Non-preferred agents indicated for the treatment of atopic dermatitis may receive approval if meeting the following:

- Member has a diagnosis of moderate to severe chronic atopic dermatitis **AND**
- Member has trialed and failed‡ therapy with two preferred agents for the prescribed indication **AND**
- Member has trialed and failed‡ the following agents:
  - Two One medium potency to very-high potency topical corticosteroids (such as mometasone furoate, betamethasone dipropionate, or fluocinonide)
  - Two One topical calcineurin inhibitors (such as pimecrolimus and tacrolimus)

  AND
- The medication is being prescribed by or in consultation with a dermatologist, allergist, immunologist, or rheumatologist.

Initial authorization: 18 weeks One year

Reauthorization: may be approved for 12 months with prescriber attestation to 16-week IGA score showing improvement by at least 2 points from baseline OR clinically significant improvement with regimen.

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

Members currently taking a preferred agent may receive approval to continue therapy with that agent.

Members with current prior authorization approval on file for a non-preferred agent:

- Will be subject to meeting reauthorization criteria listed above for the prescribed agent **OR**
- If reauthorization criteria are not listed above, may receive approval for continuation of therapy with the prescribed agent.

g. Other indications

Preferred Agents
(If diagnosis met, No PA required)
(Must meet eligibility criteria*)
*DUPIXENT (dupilumab) SC pen, syringe
ENBREL (etanercept)
HADLIMA (adalimumab- bwwd) Pushtouch, syringe
HUMIRA (adalimumab)
OTEZLA (apremilast) tablet
XELJANZ IR (tofacitinib) tablet
*XOLAIR (omalizumab) syringe

***For information on IV infused Targeted Immune Modulators please see Appendix P**

HADLIMA, HUMIRA, ENBREL, OTEZLA 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

***DUPIXENT (dupilumab)** may receive approval if meeting the following criteria based on prescribed indication:

- For members that have a diagnosis of asthma and/or atopic dermatitis in addition to another indicated diagnosis for Dupixent (dupilumab), the member must meet criteria listed for the respective diagnosis **AND**
- Request meets the following based on prescribed indication:

Chronic Rhinosinusitis with Nasal Polyposis or Prurigo Nodularis:

- Member is ≥ 18 years of age **AND**
- Medication is being prescribed as an add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP) **AND**
- Member has a baseline bilateral endoscopic nasal polyps score (NPS; scale 0-8) **AND** nasal congestion/obstruction score (NC; scale 0-3) averaged over 28-day period **AND**
- Member has trialed and failed‡ therapy with at least two three intranasal corticosteroids regimens (see PDL Class) **AND**
- Medication is being prescribed by or in consultation with a rheumatologist, allergist, ear/nose/throat specialist or pulmonologist **AND**
- Dose of 300mg every 2 weeks is used **AND**

- Initial authorization will be for 24 weeks, for additional 12-month approval member must meet the following criteria:
  - NC and NPS scores are provided and show a 20% reduction in symptoms **AND**
  - Member continues to use primary therapies such as intranasal corticosteroids.

Eosinophilic Esophagitis (EoE):

- Member is ≥ 12 years of age **AND**
- Member weighs at least 40 kg **AND**
- Member has a diagnosis of eosinophilic esophagitis (EoE) with ≥ 15 intraepithelial eosinophils per high-power field (eos/hpf), with or without a history of esophageal dilations **AND**
- Member is following appropriate dietary therapy interventions **AND**
- Medication is being prescribed by or in consultation with a gastroenterologist, allergist or immunologist **AND**
- Member has trialed and failed‡ other treatment options for EoE including:
  - Proton pump inhibitor trial of at least eight weeks in duration if reflux is a contributing factor **AND/OR**
  - Minimum four-week trial of local therapy with Fluticasone (using a metered dose inhaler) sprayed into the mouth and then swallowed or budesonide slurry.

Other Indications:

- Approval for other indications is subject to meeting non-preferred criteria listed below.

***Xolair (omalizumab)** may receive approval if meeting the following based on prescribed indication:

Chronic Rhinosinusitis with Nasal Polyps:

- If the member has a concomitant diagnosis of asthma or chronic idiopathic urticaria, then criteria listed for the respective diagnosis are met **AND**
- Member is 18 years of age or older **AND**
- Medication is being prescribed as add-on maintenance treatment of chronic rhinosinusitis with nasal polyps (CRSwNP) in adult patients 18 years of age and older with inadequate response to nasal corticosteroids **AND**
- Member has a pre-treatment IgE level greater than or equal to 30 IU per mL **AND**
- Member has tried and failed‡ therapy with at least two intranasal corticosteroids regimens (see Intranasal Rhinitis Agents PDL class). Failure is defined as lack of efficacy with a 2-week trial, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction **AND**
- Member is currently adherent to intranasal corticosteroid therapy **AND**
- Member has a baseline bilateral endoscopic nasal polyps score indicating the need for treatment **AND**
- The requested medication is being prescribed by or in consultation with a qualified subspecialist such as an allergist, ear/nose/throat specialist, immunologist, rheumatologist, or pulmonologist **AND**
- Maximum dose for nasal polyps is 600 mg subcutaneously every 2 weeks

Chronic Idiopathic Urticaria (CIU):

- Member is 12 years of age or older **AND**
- Member is diagnosed with chronic idiopathic urticaria **AND**
- Member is symptomatic despite H1 antihistamine treatment **AND**
- Member has tried and failed‡ at least three of the following:
  - High-dose second generation H1 antihistamine
  - H2 antihistamine
  - First-generation antihistamine

  - Leukotriene receptor antagonist
  - Hydroxyzine or doxepin (must include)

AND

- Prescriber attests that the need for continued therapy will be periodically reassessed (as the appropriate duration of Xolair therapy for CIU has currently not been evaluated).

Non-Preferred Agents:

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 non-preferred criteria listed below):
  - 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 non-preferred criteria listed below):
  - Familial Mediterranean Fever (FMF)
  - Hyperimmunoglobulinemia D syndrome (HIDS)
  - Mevalonate Kinase Deficiency (MKD)
  - Neonatal onset multisystem inflammatory disease (NOMID)
  - 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 below):
  - Neonatal onset multisystem inflammatory disease (NOMID).
  - Familial Mediterranean Fever (FMF)

  AND
- Member has trialed and failed‡ colchicine.

NUCALA (mepolizumab) may receive approval if meeting the following based on prescribed indication (for any FDA-labeled indications that are not listed, approval is subject to meeting non-preferred criteria listed below):

Chronic Rhinosinusitis with Nasal Polyps:

- Member is 18 years of age or older **AND**
- Medication is being prescribed as an add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP) **AND**

- Member has a baseline bilateral endoscopic nasal polyps score (NPS; scale 0-8) **AND** nasal congestion/obstruction score (NC; scale 0-3) averaged over 28-day period **AND**
- Member has trialed and failed‡ therapy with three intranasal corticosteroids (see PDL Class) **AND**
- Medication is being prescribed by or in consultation with a rheumatologist, allergist, ear/nose/throat specialist or pulmonologist **AND**
- Initial authorization will be for 24 weeks, for additional 12-month approval member must meet the following criteria:
    - NC and NPS scores are provided and show a 20% reduction in symptoms from baseline **AND**
    - Member continues to use primary therapies such as intranasal corticosteroids.

Eosinophilic Granulomatosis with polyangiitis (EGPA):

- Member is 18 years of age or older **AND**
- Member has been diagnosed with relapsing or refractory EGPA at least 6 months prior to request as demonstrated by ALL the following:
    - Member has a diagnosis of asthma **AND**
    - Member has a blood eosinophil count of greater than or equal to 1000 cells/mcL or a blood eosinophil level of 10%

AND

- Member has the presence of two of the following EGPA characteristics:
    - Histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil-rich granulomatous inflammation
    - Neuropathy
    - Pulmonary infiltrates
    - Sinonasal abnormality
    - Cardiomyopathy
    - Glomerulonephritis
    - Alveolar hemorrhage
    - Palpable purpura
    - Antineutrophil cytoplasmic antibody (ANCA) positive

AND

- Member is on a stable dose of corticosteroids for at least 4 weeks prior to request AND
- Dose of 300 mg once every 4 week is being prescribed.

Hypereosinophilic Syndrome (HES):

- Member is 12 years of age or older **AND**
- Member has a diagnosis for HES for at least 6 months that is nonhematologic secondary HES **AND**
- Member has a blood eosinophil count of greater than or equal to 1000 cells/mcL **AND**
- Member has a history of two or more HES flares (defined as worsening clinical symptoms or blood eosinophil counts requiring an increase in therapy) **AND**

- Member has been on stable dose of HES therapy for at least 4 weeks, at time of request, including at least one of the following:
    - Oral corticosteroids
    - Immunosuppressive therapy
    - Cytotoxic therapy

AND

- Dose of 300 mg once every 4 weeks is being prescribed.

All other non-preferred agents indications may receive approval for FDA-labeled indications use following trial and failure‡ of all indicated preferred agents (including preferred agents with strong evidence supporting indicated use from clinically recognized guideline compendia). (Enbrel, Humira, Xeljanz IR, Taltz, Otezla, Xolair).

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

Members currently taking Cosentyx may receive approval to continue on that agent. Members with current prior authorization approval on file for Xolair, Dupixent, or Nucala will be subject to meeting reauthorization criteria above when listed for the prescribed indication OR if reauthorization criteria is are not listed for the prescribed indication, may receive approval for continuation of therapy.

Note: Prior authorization requests for OLUMIANT (baricitinib) prescribed solely for treating alopecia areata will not be approved.

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.

Scheduled Speaker Testimony
S Hall – Genetech, Xolair *(yielded speaking time)*
H Freml – AbbVie, Rinvoq
H Freml – AbbVie, Skyrizi
CA Dubé – AstraXeneca *(yielded speaking time)*
P Wettestad – Novartis, Cosentyx
P Wettestad – Novartis, Ilaris
V Ng – LEO Pharma, Adbry *(yielded speaking time)*

Submitted Written Testimony
AbbVie – Rinvoq
AbbVie – Skyrizi
Novartis – Cosentyx
Novartis – Ilaris

Discussion

- I Pan moved that new criteria be added to allow access to Xeljanz® oral solution for members who are unable to swallow tablets since National Institute for Occupational Safety and Health (NIOSH) hazardous drug handling guidelines recommend against crushing the oral tablets to compound a liquid formulation. Seconded by P Lanius. Motion passed unanimously.
- I Pan offered a recommendation, in order to avoid potential confusion, to consider removing to the statement "For information on IV infused Targeted Immune Modulators please see Appendix P" in TIMs subclasses (such as Atopic Dermatitis) in which IV therapy is not used.
- I Pan mentioned that a new section of DUR criteria may need to be created based on recent FDA approval or Orencia® (abatacept) for the indication of pediatric psoriatic arthritis for pediatric patients. Potential criteria might include Orencia may be approved for members ≥ 2 years of age who have trialed and failed the preferred products. T Brubaker moved to pursue this recommendation. Seconded by I Pan. Motion passed unanimously.
- I Pan noted that Hadlima® (adalimumab-bwwd) is not currently FDA approved for two specific indications: pediatric uveitis and pediatric ulcerative colitis. The reference product, Humira®, may be used in these cases.
- T Brubaker moved to accept the proposed criteria as amended. Seconded by I Pan. Motion passed unanimously.

4. Newer Hereditary Angioedema (HAE) Products

Preferred Agents

Prophylaxis:
HAEGARDA (C1 esterase inhibitor) vial

Treatment:
BERINERT (C1 esterase inhibitor) kit
FIRAZYR (icatibant)
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: 6 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: 2 years

Maximum dose: The recommended starting dose is 300 mg 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: 30 mg

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: 4,200 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.

Scheduled Speaker Testimony
Lindsey Noble – Biocryst, Orladeyo

Discussion

- K MacIntyre moved to accept the proposed criteria as written. Seconded by S Klocke. 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.*

5. Antibiotics, Inhaled

Preferred Agents
No PA Required (*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			
Drug Name	**Minimum Age**	**Maximum Dose**	**Quantity Limit (Based on day supply limitation for pack size dispensed)**
ARIKAYCE (amikacin)	≥ 18 years	590 mg once daily	Not applicable
BETHKIS (tobramycin)	Age ≥ 6 years	300 mg twice daily	28-day supply per 56-day period
CAYSTON (aztreonam)	≥ 7 years	225 75 mg three times daily	28-day supply per 56-day period
KITABIS PAK (tobramycin)	Age ≥ 6 years	300 mg twice daily	28-day supply per 56-day period
TOBI † (tobramycin)	Age ≥ 6 years	300 mg twice daily	28-day supply per 56-day period
TOBI PODHALER (tobramycin)	Age ≥ 6 years	112 mg twice daily	28-day supply per 56-day period
† Limitations apply to brand product formulation only			

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

6. Antiherpetic Agents *(The Board pulled this class out of Mass Review for further discussion)*

a. 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 may 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/day daily	3,200 mg/day daily
Famciclovir	2,000 mg/day	
Valacyclovir	4,000 mg/day daily	Age 2-11 years: 3,000 mg/day daily Age ≥ 12 years: 4,000 mg /day daily

b. Topical

Preferred Agents
Acyclovir cream (*Teva only*)
Acyclovir ointment
DENAVIR (penciclovir) cream[BNR]

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 may 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 is 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 1500 mg OR valacyclovir 2 grams twice daily (Failure is defined as significant drug-drug interaction, lack of efficacy, contraindication to or intolerable side effects)

7. Fluroquinolones, Oral *(The Board pulled this class out of Mass Review for further discussion)*

Preferred Agents
No PA Required
(*if meeting eligibility criteria)
*CIPRO[BNR] (ciprofloxacin) oral suspension
*Ciprofloxacin oral suspension
Ciprofloxacin tablet
Levofloxacin tablet
Moxifloxacin 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.

8. Immune Globulins

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

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/mm3
- 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 preoperative therapy for undergoing elective splenectomy with platelet count < 20,000/mcL
    - Members with active bleeding & platelet count <30,000/mcL
    - Pregnant members with platelet counts <10,000/mcL in the third trimester
    - Pregnant members with platelet count 10,000 to 30,000/mcL who are bleeding
- Multisystem Inflammatory Syndrome in Children (MIS-C)

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 subcutaneous admin	12.6 grams every 2 weeks
Flebogamma DIF – IV admin	600 mg/kg every 3 weeks
Gammaplex 5% -- IV admin Infusion	800 mg/kg every 3 weeks
Gammagard liquid – SQ subcutaneous or IV admin	2.4 grams/kg/month
Gammaked – SQ subcutaneous or IV admin	600 mg/kg every 3 weeks
Gamunex-C – SQ subcutaneous or IV admin	600 mg/kg every 3 weeks
Hizentra – SQ subcutaneous admin	0.4 g/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	2 g/kg over 2 to 5 consecutive days

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).

9. Antihistamines

a. Newer Generation – single ingredient products

Preferred Agents
Cetirizine (OTC) tablet, syrup/solution (OTC/RX)
Desloratadine tablet (RX)
Levocetirizine tablet (RX/OTC)
Loratadine tablet (OTC), syrup/solution (OTC)

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.

b. Antihistamine/Decongestant Combinations

Preferred Agents
Loratadine-D (OTC) tablet

Non-preferred antihistamine/decongestant combinations may be approved for members who have failed treatment with the preferred product 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.

10. Intranasal Rhinitis

Preferred Agents
- Azelastine 0.15%, 137 mcg
- Budesonide (OTC)
- DYMISTA[BNR] (azelastine/fluticasone) spray
- Fluticasone (RX)
- Ipratropium
- Olopatadine
- Triamcinolone acetonide (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).

11. Leukotriene Modifiers

Preferred Agents
- Montelukast tablet, chewable

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.

12. Methotrexate Products

Preferred Agents
- Methotrexate oral tablet, vial

OTREXUP, REDITREX 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, inability to take oral product formulation, or member has a diagnosis of pJIA and provider has determined that the subcutaneous formulation is necessary to optimize methotrexate therapy) **AND**

- Member (or parent/caregiver) 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 **OR**
- Member has a diagnosis of active polyarticular juvenile idiopathic arthritis (pJIA) 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

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.

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

13. Epinephrine Products

Preferred Agents
EPIPEN[BNR] 0.3 mg/0.3 ml (epinephrine) auto-injector
EPIPEN JR[BNR] 0.15 mg/0.15 ml, (epinephrine) auto-injector

Non-preferred products may 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

14. Respiratory Agents

a. Inhaled Anticholinergics & Combinations

Preferred Agents
No PA Required (Unless indicated*)

Solutions
Ipratropium solution nebules
Albuterol/ipratropium solution nebules

Short-Acting Inhalation Devices
ATROVENT HFA (ipratropium)
COMBIVENT RESPIMAT (albuterol/ipratropium)

Long-Acting Inhalation Devices
SPIRIVA Handihaler[BNR] (tiotropium)
*SPIRIVA RESPIMAT (tiotropium)
ANORO ELLIPTA (umeclidinium/vilanterol)

***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 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.

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).

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

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

b. Inhaled Beta-2 Agonists (Short-Acting - SABA)

Preferred Agents

Solutions
- Albuterol solution, for nebulizer

Inhalers
- PROAIR[BNR] HFA (albuterol)
- PROVENTIL[BNR] HFA (albuterol)
- VENTOLIN[BNR] HFA (albuterol)

Non-preferred short acting beta-2 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

c. Inhaled Beta-2 Agonists (Long-Acting - LABA)

Preferred Agents
***Must meet eligibility criteria**

Solutions
NONE

Inhalers
*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.

d. Inhaled Corticosteroids & Combinations

Preferred Agents
Solutions
Budesonide nebules

Inhalers
ADVAIR DISKUS[BNR] (fluticasone/salmeterol)
ADVAIR HFA[BNR] (fluticasone/salmeterol)
ARNUITY ELLIPTA (fluticasone furoate)
ASMANEX Twisthaler (mometasone)
DULERA (mometasone/formoterol)
FLOVENT DISKUS (fluticasone)
FLOVENT HFA[BNR] (fluticasone)
PULMICORT FLEXHALER (budesonide)
SYMBICORT[BNR] (budesonide/formoterol) inhaler
*TRELEGY ELLIPTA (fluticasone/umeclidinium/vilanterol)

***TRELEGY ELLIPTA** (fluticasone furoate/umeclidinium/vilanterol) may be approved if the member has trialed/failed three one preferred agent. 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.
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

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.)

e. Phosphodiesterase Inhibitors (PDEIs)

Preferred Agents

NONE

Roflumilast tablet

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 beta2 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 of Mass Review Section

- The Board pulled the Antiherpetics and Fluoroquinolone therapeutic classes out of Mass Review for further discussion.
- There were no potential conflict of interest disclosures related to the Mass Review section.
- I Pan moved to remove the statement, "For members with a diagnosis of Bell's palsy, valacyclovir 1,000 mg three times daily may be approved for 7 days if member presents with severe facial palsy" since valacyclovir is now a preferred agent. Seconded by T Brubaker. Motion passed unanimously.
- T Brubaker moved to add "or inability to swallow a solid dosage form" or similar standard language after the preferred product notation "Acyclovir suspension *(members under 5 years or with a feeding tube)* under Oral Antiherpetics.
- I Pan moved to add "based on culture and sensitivity testing, levofloxacin oral solution may be approved without the need to trial and fail ciprofloxacin oral suspension. Seconded by P Lanius. Motion passed with six votes in favor. B Jackson, who had just joined the Board meeting, abstained from this vote.
- S Klocke moved to accept criteria in the Mass Review section of the agenda as amended. Seconded by K MacIntyre. Motion passed with six votes in favor. B Jackson, who had just joined the Board meeting, abstained from this vote.

Proposed Coverage Criteria for Non-PDL Products
Managed Under the Pharmacy Benefit

R Page proceeded with the review process of proposed criteria for Non-PDL Products and asked if any Board members had conflicts of interest related to the seven products on today's agenda. No Board members reported a potential conflict of interest.

1. Filspari (sparsentan)

Filspari (sparsentan) may be approved if the following criteria are met:

1. Member is ≥ 18 years of age AND
2. Member has a diagnosis of primary immunoglobulin A nephropathy (IgAN) and is at risk of rapid disease progression, AND
3. Member has a urine protein-to-creatinine ratio of ≥1.5 g/g AND
4. Member is not pregnant AND
5. Member does not have heart failure AND
6. Member has tried and failed† maximally tolerated dose of an immunosuppressant (such as corticosteroids, mycophenolate, tacrolimus, cyclosporine, leflunomide, cyclophosphamide, and azathioprine) **AND**
7. Member has tried and failed† maximally tolerated doses of an ACE inhibitor, angiotensin receptor blocker (ARB) or angiotensin receptor/neprilysin inhibitor (ARNI) **AND**
8. Member is not concurrently taking any of the following medications:
    a. ACE inhibitor
    b. Angiotensin receptor blocker (ARB)
    c. Endothelin receptor antagonist (such as ambrisentan, atrasentan, bosentan, BQ-123, edonentan, macitentan, sitaxentan, tezosentan, or zibotentan)
    d. Direct renin inhibitor (such as aliskiren)
    e. Angiotensin receptor/neprilysin inhibitor (ARNI)

    AND
9. Member's medication profile has been reviewed for drug interactions between Filspari (sparsentan) and strong/moderate CYP3A inhibitors, strong CYP3A inducers, CYP2B6 substrates, and other agents that may result in clinically significant interacting drugs, according to product labeling **AND**
10. Prior to initiation of Filspari (sparsentan) therapy, the member's hepatic aminotransferases (ALT, AST) are not greater than 3 times the upper limit of normal **AND**
11. Requested medication is being prescribed by or in consultation with a nephrologist or immunologist **AND**
12. Provider and patient or caregiver are aware that continued US FDA approval of Filspari (sparsentan) to slow kidney function decline in patients with IgAN may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

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

Maximum dose: 400 mg daily

Quantity limit: 30 tablets/30 days

Continuation of Therapy: Members who are currently stabilized on the requested medication may receive approval to continue treatment on that medication

Discussion

- S Klocke moved to accept criteria as written. Seconded by B Jackson. Motion passed unanimously.

2. Skyclarys (omaveloxolone)

Skyclarys (omaveloxolone) may be approved if the following criteria are met:

1. Member is ≥ 16 years of age **AND**
2. Member has a diagnosis of Friedreich's ataxia meeting the following criteria:
   - Genetic testing confirming loss-of-function mutations in the frataxin (*FXN*) gene **AND**
   - Confirmatory neuroimaging with MRI
3. Requested product is being prescribed by or in consultation with a neurologist or physical medicine and rehabilitation physician **AND**
4. Member does not have severe hepatic impairment (Child-Pugh Class C) **AND**
5. If the member is ambulatory, a baseline neuromuscular assessment that includes all of the following elements has been performed and documented:
   - Bulbar function (swallowing or speaking)
   - Upper limb coordination
   - Lower limb coordination
   - Upright stability
6. Member is not concurrently taking any of the following medications:
   - moderate or strong CYP3A4 inhibitor
   - moderate or strong CYP3A4 inducer

Initial approval: 6 months

Reauthorization: Reauthorization approval may be received for 1 year with provider attestation that:

1. The member has a demonstrated response to Skyclarys treatment by showing significant clinical improvement or no decline in bulbar function, upper and lower limb coordination, and upright stability
   AND
2. Member is being monitored for clinically significant adverse effects such as:
   - Elevated ALT or AST (>5 times the ULN) with no evidence of liver dysfunction
   - Elevated ALT or AST (>3 times the ULN) with evidence of liver dysfunction (such as elevated bilirubin)
   - Elevated B-type natriuretic peptide (BNP)
   - Lipid abnormalities

Maximum dose with normal hepatic function: 150 mg/day

Maximum dose with hepatic impairment: 100 mg/day

Quantity limit: 90 capsules/30 days

Scheduled Speaker Testimony
R Jaramillo —Reata Pharmaceuticals, Inc
J Farmer – Friedreich's Ataxia Research Alliance
C Bolinger – Member of the Public/Patient Advocate

Submitted Written Testimony
R Jaramillo, Reata Pharmaceuticals, Inc.

Discussion

- L Claus moved to delete the bullet point, “Confirmatory neuroimaging with MRI.” Seconded by T Brubaker. Motion passed unanimously.

3. S Klocke moved to amend the reauthorization criteria, as described below, to take both medication safety and efficacy parameters into account. Motion seconded by B Jackson. Motion passed with six votes in favor. P Lanius abstained.
   - Initial authorization is for 6 months
     Reauthorization may be approved for 1 year with provider attestation that member is being monitored for clinically significant adverse effects such as:
     - Elevated ALT or AST (>5 times the ULN) with no evidence of liver dysfunction
     - Elevated ALT or AST (>3 times the ULN) with evidence of liver dysfunction (such as elevated bilirubin)
     - Elevated B-type natriuretic peptide (BNP)
     - Lipid abnormalities
   2. Subsequent reauthorizations may be approved for 1 year with provider attestation that:
      a. The member has a demonstrated response to Skyclarys treatment by showing significant clinical improvement or no decline in bulbar function, upper and lower limb coordination, and upright stability
         AND
      b. Member is being monitored for clinically significant adverse effects such as:
      c. Elevated ALT or AST (>5 times the ULN) with no evidence of liver dysfunction
      d. Elevated ALT or AST (>3 times the ULN) with evidence of liver dysfunction (such as elevated bilirubin)
      e. Elevated B-type natriuretic peptide (BNP)
      f. Lipid abnormalities

1. K MacIntyre moved to accept these criteria as amended. Seconded by B Jackson. Motion passed unanimously.

3. Elfabrio (pegunigalsidase alfa)

Elfabrio (pegunigalsidase alfa) may be approved if the following criteria are met:

1. For billing under the pharmacy benefit, medication is being administered in the member's home or in a long term care facility by a healthcare professional **AND**
2. Member is ≥ 18 years of age **AND**
3. Member has a confirmed diagnosis of Fabry disease **AND**
4. The medication is being prescribed by or in consultation with a neurologist **AND**
5. Member has an eGFR ≥ 30 mL/min **AND**
6. Member has been counseled regarding use of highly effective contraceptive method(s) while receiving treatment

Approval: 1 year

Maximum dose: 1 mg/kg every two weeks, based on actual body weight

Scheduled Speaker Testimony
Paola Mascia – Chiesi

Discussion
- B Jackson moved to add metabolic disease provider to the list of prescribers. Seconded by K MacIntyre. Motion passed unanimously.
- S Klocke moved to accept the proposed criteria as amended. Seconded by B Jackson. Motion passed unanimously.

4. Vyjuvek (beremagene geperpavec-svdt)

Vyjuvek (beremagene geperpavec-svdt) may be approved if the following criteria are met:

1. For billing under the pharmacy benefit, medication is being administered in the member's home or in a long term care facility by a healthcare professional **AND**
2. Member is ≥ 6 months of age, **AND**
3. Member has a documented diagnosis of dystrophic epidermolysis bullosa **AND**
4. Member must have undergone genetic testing confirming mutation(s) in the *collagen type VII alpha 1 chain (COL7A1)* gene **AND**
5. The requested medication is being prescribed by a provider who has expertise in treating dystrophic epidermolysis bullosa **AND**
6. Member has been counseled regarding use of highly effective contraceptive method(s) while receiving treatment

Quantity limit: one 1 mL vial of biological suspension plus one 1.5 mL excipient gel vial per week

Initial approval: 1 year

Reauthorization: Prescribing provider attests that clinical condition is improving on Vyjevek therapy

Scheduled Speaker Testimony
Karen Ward – Krystal Biotech

Discussion

- L Claus moved to amend bullet point 5 to say, "The requested medication is being prescribed by or in consultation with a provider who has expertise in treating dystrophic epidermolysis bullosa." Seconded by I Pan. Motion passed unanimously.
- T Brubaker moved to accept the criteria as amended. Seconded by B Jackson. Motion passed unanimously.

5. Rystiggo (rozanolixizumab)

Rystiggo (rozanolixizumab) may be approved if the following criteria are met:

1. For billing under the pharmacy benefit, medication is being administered in the member's home or in a long term care facility by a healthcare professional **AND**
2. Member is ≥ 18 years of age **AND**
3. Member has a diagnosis of generalized myasthenia gravis that falls within Myasthenia Gravis Foundation of America (MGFA) Class II to IV disease, **AND**
4. Member has a positive serologic test for anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibodies **AND**
5. Requested product is being prescribed by or in consultation with a neurologist **AND**
6. A baseline Quantitative Myasthenia Gravis (QMG) assessment has been documented, **AND**
7. Patient has a MG-Activities of Daily Living (MG-ADL) total score of ≥6, **AND**
8. Patient has failed† treatment over at least 1 year with at least 2 immunosuppressive therapies (such as azathioprine, cyclosporine, tacrolimus, mycophenolate), or has failed at least 1 immunosuppressive therapy and required chronic therapeutic plasma exchange or intravenous immunoglobulin (IVIG)

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

Initial Approval: 6 months

Reauthorization: Prescriber attests that member has experienced a positive clinical response to rozanolixizumab based on documented Quantitative Myasthenia Gravis (QMG) assessment **AND/OR** MG-Activities of Daily Living (MG-ADL) score

Maximum dose: 840 mg (6 mL) by subcutaneous infusion every 6 weeks

Quantity limit: three 280 mg/2 mL single-dose vials every 6 weeks

Continuation of Therapy: Members who are currently stabilized on the requested medication may receive approval to continue treatment on that medication

Discussion

- S Klocke moved to apply the following changes to the proposed criteria. Seconded by I Pan. Motion passed with six votes in favor. T Brubaker abstained due to not being available for this vote.
    1. Amend bullet 3 to include Myasthenia Gravis Foundation of America (MGFA) Class II to IVa disease" since patients in Class IVb were not studied.
    2. Amend bullet 7 to "Patient has a MG-Activities of Daily Living (MG-ADL) total score of ≥3" as was applied in the clinical studies.
    3. Add a bullet point 9 "As a safety precaution, avoid concomitant use of Rystiggo (rozanolixizumab) with IVIG, other immunoglobuins, or a C5 complement inhibitor (such as such as Ultomiris® (ravulizumab) or Soliris® (eculizumab).
    4. Request that the Department review current DUR criteria for Ultomiris (ravulizumab), Soliris (eculizumab) and Vyvgart® (efgartigimod) to further evaluate MGFA Classification in consideration of applying Class IVa rather than IV, and evaluate MG-ADL scores for potential alignment, if appropriate.
    5. Based on the clinical trial inclusion criteria, consider including a minimum serum IgG level of 5.5 g/L to initiate therapy as part of the final DUR criteria for this product.

6. Ycanth (cantharidin)

Ycanth (cantharidin) may be approved if the following criteria are met:

1. For billing under the pharmacy benefit, medication is being administered in the member's home or in a long term care facility by a healthcare professional **AND**
2. Member is ≥ 2 years of age **AND**
3. Member has a diagnosis of molluscum contagiosum **AND**
4. Requested product is being prescribed by a dermatologist **AND**
5. Member has tried and failed an adequate trial with topical podofilox. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction, **AND**
6. Member has undergone a surgical intervention (such as cryotherapy, surgical scraping, laser therapy) with inadequate resolution **OR** provider has determined that member is not a good candidate for any of these procedures.

Quantity limit: 6 single-use applicators/9 weeks

Discussion

- B Jackson moved to amend bullet point 4 to "Requested product is being prescribed by or in consultation with a dermatologist" and to accept the criteria as amended. I Pan seconded. Motion passed with six votes in favor. T Brubaker abstained due to not being available for this vote.

6. Xdemvy (lotilaner)

Xdemvy (lotilaner) may be approved if the following criteria are met:

1. Member is ≥ 18 years of age **AND**
2. Member has a documented diagnosis of moderate to severe Demodex blepharitis confirmed through microscopic examination **AND**
3. Requested product is being prescribed by or in consultation with an ophthalmologist or optometrist **AND**
4. Member has failed to experience clinical improvement of Demodex blepharitis with regular lid hygiene practices including warm compresses, lid massage, eyelid washing for at least two months **AND**
5. Member has tried and failed therapy with two of the following:
    a. Ivermectin
    b. Topical metronidazole
    c. Permethrin

    AND
6. Member has been advised that Xdemvy (lotilaner) solution may discolor soft contact lenses

Quantity limit: approval will be given for one course of therapy (1 drop in each eye every 12 hours for 6 weeks), or one 10 mL bottle

Discussion

1. B Jackson moved to accept criteria as written. Seconded by K MacIntyre. Motion passed unanimously. T Brubaker abstained due to not being available for this vote.

C. Adjournment

Board Chair Claus reminded attendees that the next Board meeting is tentatively scheduled for Tuesday, February 13, 2024, from 1:00 to 5:00 pm. She also reminded Board members to delete their meeting binders and associated emails at the conclusion of today's meeting.

L Claus moved to adjourn the meeting, Seconded by S Klocke. Motion passed unanimously.

The meeting was adjourned at 3:51 pm.

Minutes respectfully submitted by Julia Rawlings, PharmD