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 12, 2024
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 1:02 pm by B Jackson, Board Chair.

2. Roll Call and Introductions

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

Members Present: Brian Jackson, MD, MA (Chair); Liza Claus, PharmD (Vice Chair); Todd Brubaker, DO; Shilpa Klocke, PharmD; Kenneth MacIntyre, DO; Ingrid Pan, PharmD, Mary Shefchyk, MBA

Members Absent: Marshal Ash, DO

HCPF Pharmacy Office: Veronia Garcia, PharmD; Jim Leonard, PharmD; Rachele Poissant, PharmD, Jeffrey Taylor, PharmD

CO-DUR Team: Robert Page, PharmD, MSPH; Julia Rawlings, PharmD

Lisa Rothgery, MD, HCPF Chief Medical Officer

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 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.
- 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.

4. Colorado Department of Health Care Policy and Financing Updates

V Garcia provided updates from the Department:

- DUR Board membership update:
  - Congratulations to our new industry representative Mary Shefchyk, who is joining the DUR Board today for a one-year term in a non-voting role.
- Two updates as of 1/1/2025:
  - Three new Humira® biosimilars will be preferred by Health First Colorado. The preferred products include Cyltezo®, adalimumab-aaty, and adalimumab-adbm. These products join Hadlima™ as preferred Humira biosimilars on Health First Colorado's Preferred Drug List. Cyltezo will be the first preferred Humira biosimilar that is directly interchangeable with Humira.
  - 340B pharmacies may submit Paxlovid™ products through the Health First Colorado (Colorado's Medicaid Program) pharmacy benefit instead of the Pfizer PAXCESS™ Patient Support Program.
- 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.

- **Final Approval of Minutes from the August 13, 2024 Meeting**
  - Chair B Jackson asked the Board to review minutes from the August 13, 2024 meeting.
  - L Claus moved to approve the minutes as written. Seconded by T Brubaker. Motion passed with five votes in favor. B Jackson abstained, as he did not attend the August meeting.

- **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.

  Mary Shefchyk, MBA, Industry Representative, disclosed her conflicts of interest related to employment as a Colorado account manager for Novo Nordisk.

7. Clinical Updates and General Orders

- **FDA Drug Safety Communications**
  J Rawlings presented the FDA Drug Safety report prepared by Population Health intern N DeLeon. The report described an added warning about rare but serious liver injury that may occur with the use of Veozah (fezolinetant).

- **FDA New Product Update**
  J Rawlings presented the FDA Drug Approvals report prepared by Population Health interns M Harris and J Hayden.

- **Quarterly Clinical Modules**
  R Page presented an executive summary of last quarter's clinical module analysis, *Frequent Emergency Department Utilization Among Health First Colorado Members*, that was delivered to the Department on September 30.

  Dr. Page also presented follow-up reporting for a May 2023 policy change involving liquid opioid-containing cough and cold products. For promethazine with codeine products, which constituted nearly 97% of the claims examined, the mean number of prescription claims in the three years pre-intervention was 424 compared to 95 claims observed during the 13-month post-intervention period. This reflects a 78% decrease in prescription claims and a substantial impact on utilization within this medication subclass.

- **Retrospective DUR (RDUR) Report**
  R Page presented the quarterly RDUR summary.

- **Quarterly Drug Utilization Reports**
  R Page presented highlights from this quarter's drug utilization reports. Board members were referred to utilization reports in the meeting binder for more details.

8. New Business

J Taylor provided a brief overview of today's new business section of the agenda.

- Today's agenda includes a review of the Targeted Immune Modulators (TIMs), which are divided into seven subclasses by indications for use. Given the degree of indication crossovers among subclasses, we will ask today's registered speakers to present testimony at the beginning of the general TIMs class rather than within each subclass section of the agenda.
- The agenda also includes eight products with brand new proposed criteria for Appendix P (pharmacy benefit), along with one product with new proposed criteria for both Appendix P and Appendix Y (medical benefit).
- There are two speakers registered to provide testimony for drug classes included in the Mass Review section of the agenda. These two sections, inhaled corticosteroids and hereditary angioedema agents, will be pulled from Mass Review and undergo full review after the Phosphodiesterase Inhibitors.

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.
- 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.
- There will be an opportunity for Board discussion.

R Page proceeded with the review process for this quarter's proposed criteria.

1. Human Immunodeficiency Virus (HIV) Treatments

Effective 01/14/22, oOral products indicated for HIV pre-exposure prophylaxis (PrEP) or post-exposure prophylaxis (PEP) are eligible for coverage with a written prescription by an enrolled pharmacist. Additional information regarding pharmacist enrollment can be found at https://hcpf.colorado.gov/pharm-serv

a. Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs)

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

All products are preferred and do not require prior authorization.

b. 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
- Tenofovir disoproxil fumarate (TDF) tablet
- VIREAD (TDF) oral powder, tablet
- ZIAGEN (abacavir) solution, tablet
- Zidovudine capsule, syrup, tablet

*TDF – Tenofovir disoproxil fumarate

All products are preferred and do not require prior authorization.

c. Protease Inhibitors (PIs)

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

All products are preferred and do not require prior authorization.

d. 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

All products are preferred and do not require prior authorization.

e. Combination Agents

Preferred Agents

No PA Required*
*Dispense as written (DAW) should be indicated on the prescription

Abacavir/Lamivudine tablet
ATRIPLA (efavirenz/Emtricitabine/TDF) 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
TRIUMEQ (abacavir/dolutegravir/ lamivudine) tablet
TRIUMEQ PD (abacavir/dolutegravir) tablet for suspension
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

- No Board members reported potential conflicts of interest for this therapeutic class.
- K MacIntyre moved to accept the criteria as written. Seconded by S Klocke. Motion passed unanimously.

2. Immune Globulins

Preferred Agents

PA Required for all agents in this class*

CUVITRU 20% SQ liquid
GAMMAGARD 10% IV/SQ liquid
GAMUNEX-C 10% IV/SQ liquid
HIZENTRA 20% SQ syringe
PRIVIGEN 10% IV liquid

If immune globulin is being administered in a long-term care facility or in a member's home by a home healthcare provider, it should be billed as a pharmacy claim. All other claims must be submitted through the medical benefit.

Preferred agents may be approved for members meeting at least one of the approved conditions listed below for prescribed doses not exceeding maximum (Table 1).

Non-preferred agents may be approved for members meeting the following:

- Member meets at least one of the approved conditions listed below AND
- Member has history of trial and failure of two preferred agents (failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions) AND
- Prescribed dose does not exceed listed maximum (Table 1)

Approved Conditions for Immune Globulin Use:

- Primary Humoral Immunodeficiency disorders including:
  - Common Variable Immunodeficiency (CVID)
  - Severe Combined Immunodeficiency (SCID)
  - X-Linked Agammaglobulinemia
  - X-Linked with Hyperimmunoglobulin M (IgM) Immunodeficiency
  - Wiskott-Aldrich Syndrome
  - Members < 13 years of age with pediatric Human Immunodeficiency Virus (HIV) and CD-4 count > 200/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 – subcutaneous admin	12 grams protein/site for up to four sites weekly (48 grams/week)
Flebogamma DIF – IV admin	600 mg/kg every 3 weeks
Gammaplex 5% – IV admin	800 mg/kg every 3 weeks 1 gram/kg for 2 consecutive days
Gammagard liquid – subcutaneous or IV admin	2.4 grams/kg/month
Gammaked – subcutaneous or IV admin	600 mg/kg every 3 weeks
Gamunex-C –subcutaneous or IV admin	600 mg/kg every 3 weeks
Hizentra – subcutaneous admin	0.4 g/kg per week
Octagam – IV admin	600 mg/kg every 3 to 4 weeks 2 grams/kg every 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).

Discussion

- No Board members reported potential conflicts of interest for this therapeutic class.
- T Brubaker moved to accept the criteria as written. Seconded by L Claus. Motion passed unanimously.

3. 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.

Discussion

- No Board members reported potential conflicts of interest for this therapeutic class.
- S Klocke moved to accept the criteria as written. Seconded by T Brubaker. Motion passed unanimously.

4. Targeted Immune Modulators Therapeutic Drug Class

Preferred agents
Adalimumab biosimilar products
Adalimumab-aaty
Adalimumab-adbm
CYLTEZO (adalimumab-adbm)
HADLIMA (adalimumab- bwwd) Pushtouch, syringe
ADBRY (tralokinumab-ldrm), syringe, auto-injector
DUPIXENT (dupilumab)
ENBREL (etanercept)
FASENRA (benralizumab) pen
HUMIRA (adalimumab)
OTEZLA (apremilast) tablet
KEVZARA (sarilumab)
TALTZ (ixekizumab)
TEZSPIRE (tezepelumab-ekko) pen
TYENNE (tocilizumab-aazg) syringe, auto-injector
XELJANZ IR (tofacitinib) tablet
XOLAIR (omalizumab) syringe

Note: Product formulations in the physician administered drug (PAD) category are located on Appendix P

Scheduled Speaker Testimony
M Turkington, Bimzelx – UCB Pharmaceuticals
B Jones, Rinvoq – AbbVie
B Jones, Skyrizi - AbbVie
R Williams, Otezla – Amgen
M Sohal, Simlandi - Teva

Conflict of Interest Disclosures for the TIMs Class
Dr. Pan disclosed that she serves on an advisory board for Sobi Pharmaceuticals for another biologic product that is not included in the Targeted Immune Modulators class. This was determined to not be an actual conflict of interest for today's review of the medications in this class.

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)
Adalimumab biosimilar products
Adalimumab-aaty
Adalimumab-adbm
CYLTEZO (adalimumab-adbm)
HADLIMA (adalimumab- bwwd) Pushtouch, syringe
ENBREL (etanercept)
HUMIRA (adalimumab)
*KEVZARA (sarilumab) pen, syringe
*TALTZ (ixekizumab) 80 mg syringe
*TYENNE (tocilizumab-aazg) syringe, auto-injector
XELJANZ IR (tofacitinib) tablet

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

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

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

***TYENNE (tocilizumab-aazg)** may receive approval for use for FDA-labeled indications following trial and failure‡ of a preferred adalimumab product, or ENBREL **AND** XELJANZ IR.

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

Non-Preferred Agents:

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, a preferred adalimumab product

KINERET (anakinra) may receive approval for:
- FDA-labeled indications following trial and failure‡ of HADLIMA, HUMIRA, a preferred adalimumab product **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 TYENNE (tocilizumab)
- Quantity Limits (effective 2/15/2024):
  - Cryopyrin-associated periodic syndrome: 600 mg (4 mL) every 8 weeks
  - All other indications: 300 mg (2 mL) every 4 weeks

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 when the following criteria are met:
- Member has 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, a preferred adalimumab product **OR** ENBREL **OR**
- Member cannot swallow a tofacitinib tablet

All other non-preferred agents may receive approval for FDA-labeled indications following trial and failure‡ of all preferred agents that are FDA-indicated or have strong evidence supporting use for the prescribed indication from clinically recognized guideline compendia (only one preferred adalimumab product trial required).

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.

Continuation of therapy: Members with current prior authorization approval on file for a preferred or non-preferred agent may receive approval for continuation of therapy with the prescribed agent.

Members currently taking COSENTYX or XELJANZ oral solution may receive approval to continue on that agent.

‡Failure is defined as lack of efficacy, 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

Discussion
- I Pan moved that the Department consider clarification and rewording of the tocilizumab trial and failure step within the Ilaris criteria and, in general, standardize the language used for referring to biosimilar products in this and other TIMs subclasses. Seconded by L Claus. Motion passed unanimously.
- K MacIntyre moved to accept the criteria as amended. Seconded by S Klocke. Motion passed unanimously.

b. Psoriatic Arthritis

Preferred agents
No PA Required (If diagnosis met)
(*Must meet eligibility criteria)
Adalimumab biosimilar products
Adalimumab-aaty
Adalimumab-adbm
CYLTEZO (adalimumab-adbm)
HADLIMA (adalimumab- bwwd) Pushtouch, syringe
ENBREL (etanercept)
HUMIRA (adalimumab)
*OTEZLA (apremilast) tablet
*TALTZ (ixekizumab) 80 mg syringe
XELJANZ IR (tofacitinib) tablet

Note: Product formulations in the physician administered drug (PAD) category are located on Appendix P

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

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

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

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

Non-Preferred Agents:

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, a preferred adalimumab product 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, a preferred adalimumab product 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, a preferred adalimumab product **OR** ENBREL **AND** XELJANZ IR **AND** TALTZ or OTEZLA.

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

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

Continuation of therapy: Members with current prior authorization approval on file for a preferred or non-preferred agent may receive approval for continuation of therapy with the prescribed agent.

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

Discussion

- I Pan noted that Taltz and Otezla are not currently approved for pediatric psoriatic arthritis. After some discussion it was determined that pediatric use would be viewed as a "contraindicated" (as in not FDA-indicated based on the labeled age range for use), and the failure definition for this subclass would also capture those circumstances. B Jackson suggested that "lack of an FDA indication" might be considered for some failure definitions in the future.
- B Jackson suggested the use of parentheses or bullet points to improve the readability of trial and failure requirements that include several different products or combinations of TIMs products (such as …OR ENBREL AND XELJANZ IR AND TALTZ or OTEZLA) in this and other sections of the TIMs class.
- S Klocke moved to accept the criteria as written. Seconded by I Pan Motion. Motion passed unanimously.

c. Plaque Psoriasis

Preferred agents
No PA Required (If diagnosis met)
(*Must meet eligibility criteria)
Adalimumab biosimilar products
Adalimumab-aaty
Adalimumab-adbm
CYLTEZO (adalimumab-adbm)
HADLIMA (adalimumab- bwwd) Pushtouch, syringe
ENBREL (etanercept)
HUMIRA (adalimumab)
*OTEZLA (apremilast) tablet
*TALTZ (ixekizumab) 80 mg syringe

Note: Product formulations in the physician administered drug (PAD) category are located on Appendix P

First line preferred agents (HADLIMA, HUMIRA, preferred adalimumab products, 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, a preferred adalimumab product OR ENBREL.

Non-Preferred Agents:

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, a preferred adalimumab product, 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, a preferred adalimumab product, ENBREL) AND two second line agents (TALTZ, OTEZLA).

‡Failure is defined as lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction.
Members currently taking COSENTYX may receive approval to continue on that agent.

Continuation of therapy: Members with current prior authorization approval on file for a preferred or non-preferred agent may receive approval for continuation of therapy with the prescribed agent.

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

Discussion

- L Claus moved to accept the criteria as written. Seconded by T Brubaker. Motion passed unanimously.

d. Crohn's Disease and Ulcerative Colitis

Preferred agents
No PA Required (If diagnosis met)
(*Must meet eligibility criteria)
Adalimumab biosimilar products
Adalimumab-aaty
Adalimumab-adbm
CYLTEZO (adalimumab-adbm)
HADLIMA (adalimumab- bwwd) Pushtouch, syringe
HUMIRA (adalimumab)
*XELJANZ IR (tofacitinib) tablet

Note: Product formulations in the physician administered drug (PAD) category are located on Appendix P

Preferred agents (HADLIMA/ HUMIRA preferred adalimumab products, XELJANZ IR) may receive approval for Crohn's disease and ulcerative colitis indications.

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

Non-Preferred Agents:

ENTYVIO (vedolizumab) pen for subcutaneous injection may receive approval if the following criteria are met:

- 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 **AND**
- Member is ≥ 18 years of age **AND**
- Prescriber acknowledges that administration of IV induction therapy prior to approval of ENTYVIO (vedolizumab) pen for subcutaneous injection using the above criteria should be avoided and will not result in an automatic approval of requests for these formulations.

OMVOH (mirikizumab-mrkz) pen for subcutaneous injection may receive approval if the following criteria are met:

- The requested medication is being prescribed for treatment of moderately-to-severely active ulcerative colitis **AND**
- Member is ≥ 18 years of age **AND**

- Member has trial and failure‡ of one preferred adalimumab product AND XELJANZ IR AND ENTYVIO (vedolizumab) **AND**
- Prescriber acknowledges that administration of IV induction therapy prior to approval of OMVOH (mirikizumab-mrkz) pen for subcutaneous injection using the above criteria should be avoided and will not result in an automatic approval of requests for these formulations.

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 ANDOR for treatment of moderately-to-severely active ulcerative colitis, AND
- Member is ≥ 18 years of age AND
- For treatment of moderately-to-severely active Crohn's disease, member has trial and failure‡ of one preferred adalimumab product and ENTYVIO (vedolizumab) **OR** for treatment of moderately-to-severely active ulcerative colitis, member has trial and failure‡ of one preferred adalimumab product and XELJANZ IR and ENTYVIO (vedolizumab) AND
- Prescriber acknowledges that administration of IV induction therapy prior to approval of SKYRIZI (risankizumab) 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/1.2 mL 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 and ENTYVIO (vedolizumab) **OR** for treatment of moderately-to-severely active ulcerative colitis, member has trial and failure‡ of one preferred adalimumab product and XELJANZ IR and ENTYVIO (vedolizumab) 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.

TREMFYA (guselkumab) pen for subcutaneous injection may receive approval if the following criteria are met:
- For treatment of moderately-to-severely active ulcerative colitis, member has trial and failure‡ of one preferred adalimumab product and XELJANZ IR **AND**
- Member is ≥ 18 years of age **AND**
- Prescriber acknowledges that administration of IV induction therapy prior to approval of TREMFYA (guselkumab) pen for subcutaneous injection using the above criteria should be avoided and will not result in an automatic approval of requests for these formulations.

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:
- 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.

Members with current prior authorization approval on file for a preferred or non-preferred agent may receive approval for continuation of therapy with the prescribed agent.

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

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

Discussion

- S Klocke moved to accept the criteria as written. Seconded by K MacIntyre. Motion passed with five votes in favor. T Brubaker abstained, as he was unavailable for this vote.

e. Asthma

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

Note: Product formulations in the physician administered drug (PAD) category are located on Appendix P

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

DUPIXENT (dupilumab):

- Member is 6 years of age or older **AND**
- Member has 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**
- Medication is being prescribed as add-on therapy to existing asthma regimen.

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

FASENRA (benralizumab):
- Member is ≥ 6 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.

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

XOLAIR (omalizumab) may receive approval if meeting the following based on prescribed indication:
- 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.

Non-Preferred Agents**:**
Non-preferred FDA-indicated biologic agents for asthma may receive approval if meeting the following:
- 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) is limited to 100 mg every 4 weeks (members ≥ 12 years of age) or 40 mg every 4 weeks (members 6-11 years of age).

‡Failure is defined as a lack of efficacy, 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.

Continuation of therapy: Members with current prior authorization approval on file for a preferred or non-preferred agent may receive approval for continuation of therapy with the prescribed agent.

Members with current prior authorization approval on file for a non-preferred agent may receive approval for continuation of therapy with the prescribed agent.

Discussion

- K MacIntyre moved to accept the criteria as written. Seconded by L Claus. Motion passed with five votes in favor. T Brubaker abstained, as he was unavailable for this vote.

f. Atopic Dermatitis

Preferred agents
No PA Required
(*Must meet eligibility criteria)
*ADBRY (tralokinumab-ldrm) syringe, autoinjector
*DUPIXENT (dupilumab) pen, syringe

Note: Product formulations in the physician administered drug (PAD) category are located on Appendix P

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

ADBRY (tralokinumab-ldrm):

- The requested drug is being prescribed for moderate-to-severe atopic dermatitis **AND**
- Member has trialed and failed‡ the following agents:
  - One medium potency to very-high potency topical corticosteroid (such as mometasone furoate, betamethasone dipropionate) **AND**
  - One topical calcineurin inhibitor (such as pimecrolimus or tacrolimus)

Maximum Dose: 600 mg/2 weeks
Quantity Limit: Four 150 mg/mL prefilled syringes/2 weeks
Approval: One year

DUPIXENT (dupilumab):

- Member has a diagnosis of moderate to severe atopic dermatitis **AND**
- Member has trialed and failed‡ the following agents:
  - One medium potency to very-high potency topical corticosteroid [such as mometasone furoate, betamethasone dipropionate, or fluocinonide (see PDL for list of preferred products) **AND**
  - One topical calcineurin inhibitor (such as pimecrolimus or tacrolimus)

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

Approval: One year
Non-Preferred Agents:
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:
  - One medium potency to very-high potency topical corticosteroid (such as mometasone furoate, betamethasone dipropionate, or fluocinonide)
  - One topical calcineurin inhibitor (such as pimecrolimus and tacrolimus)

AND

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

Approval: One year

‡Failure is defined as a lack of efficacy, 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.

Continuation of therapy: Members with current prior authorization approval on file for a preferred or non-preferred agent may receive approval for continuation of therapy with the prescribed agent.

Members with current prior authorization approval on file for a non-preferred agent may receive approval for continuation of therapy with the prescribed agent.

Discussion

- L Claus moved to accept the criteria as written. Seconded by S Klocke. Motion passed with five votes in favor. T Brubaker abstained, as he was unavailable for this vote.

g. Other indications

Preferred agents
If diagnosis met, No PA Required (If diagnosis met)
(*Must meet eligibility criteria*)

Adalimumab biosimilar products
Adalimumab-aaty
Adalimumab-adbm
CYLTEZO (adalimumab-adbm)
HADLIMA (adalimumab- bwwd) Pushtouch, syringe
*DUPIXENT (dupilumab) pen, syringe
ENBREL (etanercept)
*FASENRA (benralizumab) pen
HUMIRA (adalimumab)
*KEVZARA (sarilumab)
OTEZLA (apremilast) tablet
*TYENNE (tocilizumab-aazg) syringe, auto-injector
XELJANZ IR (tofacitinib) tablet
*XOLAIR (omalizumab) syringe, autoinjector

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

Chronic Obstructive Pulmonary Disease

- Member is ≥ 18 years of age **AND**
- Medication is being prescribed by or in consultation with a pulmonologist or allergist **AND**
- Requested medication is being prescribed as an add-on maintenance treatment for inadequately controlled chronic obstructive pulmonary disease (COPD) **AND**
- Member's COPD is an eosinophilic phenotype based on a blood eosinophil level of ≥ 300 cells/mcL **AND**

- Member is receiving, and will continue, standard maintenance triple therapy for COPD (inhaled corticosteroid, long-acting muscarinic agent, long-acting beta agonist) as recommended by the current Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines **AND**
- Member has experienced at least 2 moderate-to-severe COPD exacerbations during the past 12 months

Chronic Rhinosinusitis with Nasal Polyposis
- Member is ≥ 12 years of age **AND**
- Medication is being prescribed as an add-on maintenance treatment in adult patients withfor inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP) **AND**
- Member has trialed and failed‡ therapy with at least two intranasal corticosteroid regimens

Eosinophilic Esophagitis (EoE):
- Member is ≥ 1 year of age **AND**
- Member weighs at least 15 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‡ one of the following treatment options for EoE:
    - Proton pump inhibitor trial of at least eight weeks in duration if reflux is a contributing factor **OR**
    - Minimum four-week trial of local therapy with a corticosteroid medicationfluticasone (using a metered dose inhaler) sprayed into the mouth and then swallowed or budesonide slurry.

Prurigo Nodularis**:**
- Member is ≥ 18 years of age **AND**
- Medication is being prescribed as treatment for prurigo nodularis **AND**
- Member has trialed and failed‡ therapy with at least two corticosteroid regimens (topical or intralesional injection).

***FASENRA (benralizumab)** pen may receive approval if meeting the following based on prescribed indication:

Eosinophilic granulomatosis with polyangiitis (EGPA)
- Member meets FDA-labeled indication, dose, age, and role in therapy as outlined in product package labeling.

***KEVZARA (sarilumab)** may receive approval if meeting the following based on prescribed indication:

Polymyalgia Rheumatica**:**
- Member has had an inadequate response to corticosteroids or who cannot tolerate corticosteroid taper.

***TYENNE (tocilizumab-aazg)** may receive approval for use for FDA-labeled indications following trial and failure‡ of a preferred adalimumab product or ENBREL **AND** XELJANZ IR (when FDA indicated).

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

Chronic Rhinosinusitis with Nasal Polyps:
- 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 tried and failed‡ therapy with at least two intranasal corticosteroid regimens

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).

IgE-Mediated Food Allergy:
- Medication is being prescribed for reduction of allergic reactions (Type I), including anaphylaxis, that may occur with accidental exposure to one or more foods in adult and pediatric patients aged 1 year and older with IgE-mediated food allergy.

All other preferred agents (HADLIMA, HUMIRA, preferred adalimumab products, ENBREL, OTEZLA, KEVZARA) may receive approval for use for FDA-labeled indications.

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 (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)
- Symptomatic treatment of adult patients with gout flares in whom NSAIDs and colchicine are contraindicated, are not tolerated, or do not provide an adequate response, and in whom repeated courses of corticosteroids are not appropriate (limited to four 150 mg doses per one year approval)

AND

- Member has trialed and failed‡ colchicine.

Quantity Limits (effective 2/15/2024):

- Cryopyrin-associated periodic syndrome:
  - 600 mg (4 mL) every 8 weeks
  - All other indications: 300 mg (2 mL) every 4 weeks

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 in this subclass category 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 weeks 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 agent indications may receive approval for FDA-labeled use following trial and failure‡ of all preferred agents that are FDA-indicated or have strong evidence supporting use for the prescribed indication from clinically recognized guideline compendia (only one preferred adalimumab product trial required).

‡Failure is defined as lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction. Members currently taking a preferred agent may receive approval to continue therapy with that agent.

Members with current prior authorization approval on file for preferred or non-preferred agents will be subject to meeting reauthorization criteria above when listed for the prescribed indication **OR** if reauthorization criteria are not listed for the prescribed indication, may receive approval for continuation of therapy.

Continuation of therapy: Members with current prior authorization approval on file for a preferred or non-preferred agent may receive approval for continuation of therapy with the prescribed agent.

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.

Discussion

- K MacIntyre moved to accept the criteria as written. Seconded by S Klocke. Motion passed with five votes in favor. T Brubaker abstained, as he was unavailable for this vote.

5. Respiratory Agents

a. Inhaled Beta$_2$ Agonists

i. Short-acting

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

AIRSUPRA (budesonide/albuterol)
Airsupra minimum age: 18 years old

ii. Long-acting

Preferred Agents

Solutions

NONE

Inhalers

SEREVENT DISKUS (salmeterol) inhaler

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.

iii. Phosphodiesterase inhibitors

Preferred Agents

Roflumilast tablet

Requests for use of the non-preferred brand product formulation may be approved if meeting criteria outlined in the Appendix P “Generic Mandate” section.

Discussion

- No Board members reported potential conflicts of interest for the Respiratory Agents therapeutic class.
- K MacIntyre moved to accept the criteria as written. Seconded by S Klocke. Motion passed with five votes in favor. T Brubaker abstained, as he was unavailable for this vote.

6. Newer Hereditary Angioedema (HAE) Products *(pulled from Mass Review)*

Preferred Agents
PA Required for all agents in this class

Prophylaxis
CINRYZE (C1 Esterase Inhibitor) vial
HAEGARDA (C1 esterase inhibitor) vial

Treatment:
BERINERT (C1 esterase inhibitor) kit, vial
FIRAZYR[BNR] (icatibant acetate) syringe

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 Type I or Type II confirmed by laboratory tests obtained on two separate instances at least one month apart (C4 level, C1-INH level) OR has a diagnosis of HAE Type III based on clinical observation **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 Type I or Type II confirmed by laboratory tests obtained on two separate instances at least one month apart (C4 level, C1-INH level) OR has a diagnosis of HAE Type III based on clinical observation **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 Type I or Type II confirmed by laboratory tests obtained on two separate instances at least one month apart (C4 level, C1-INH level) OR has a diagnosis of HAE Type III based on clinical observation **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 Type I or Type II confirmed by laboratory tests obtained on two separate instances at least one month apart (C4 level, C1-INH level) OR has a diagnosis of HAE Type III based on clinical observation **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 Type I or Type II confirmed by laboratory tests obtained on two separate instances at least one month apart (C4 level, C1-INH level) OR has a diagnosis of HAE Type III based on clinical observation **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 Type I or Type II confirmed by laboratory tests obtained on two separate instances at least one month apart (C4 level, C1-INH level) OR has a diagnosis of HAE Type III based on clinical observation **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
Max 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 Type I or Type II confirmed by laboratory tests obtained on two separate instances at least one month apart (C4 level, C1-INH level) OR has a diagnosis of HAE Type III based on clinical observation **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
R Rivera, Ruconest – Pharming pharmaceuticals

Discussion

- No Board members reported potential conflicts of interest for this therapeutic class.
- J Taylor noted that the Department is proposing adding HAE Type III to criteria for all agents in this class. The Department is also proposing removal of the Hepatitis A and Hepatitis B vaccination requirement from criteria for all agents in this class.
- L Claus moved to remove the bullet point "Provider attests to performing annual testing or screening (as appropriate) for HBV, HCV and HIV" from the Ruconest criteria, and assess other agents in this class with the same statement to confirm that it is still necessary based on current FDA labeling. Seconded by S Klocke. Motion passed with five votes in favor. T Brubaker abstained, as he was unavailable for this vote.
- L Claus moved to accept the criteria as amended. Seconded by I Pan. Motion passed with five votes in favor. T Brubaker abstained, as he was unavailable for this vote.

15.c Inhaled Corticosteroids *(pulled from Mass Review)*

Preferred Agents

Solutions
Budesonide nebules

Inhalers
ARNUITY ELLIPTA (fluticasone furoate)
ASMANEX HFA (mometasone furoate) inhaler
ASMANEX Twisthaler (mometasone)
FLOVENT^{BNR} DISKUS (fluticasone)
FLOVENT^{BNR} HFA (fluticasone)
PULMICORT FLEXHALER (budesonide)
QVAR REDIHALER (beclomethasone)

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, or dexterity/coordination limitations (per provider notes) that significantly impact appropriate use of a specific dosage form.)

***FLUTICASONE PROPIONATE HFA** is available to members may be approved without prior authorization for members with a diagnosis of eosinophilic esophagitis (EoE) **OR** for members ≤ 12 years of age. 12 years and under without prior authorization.

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

Quantity Limits:
Pulmicort Flexhaler: 2 inhalers / 30 days

Scheduled Speaker Testimony
S White, Children's Hospital Colorado – *yielded time*

Written Testimony
S White, Children's Hospital Colorado

Discussion

- No Board members reported potential conflicts of interest for this therapeutic class.
- L Claus asked about brand-name Flovent continuing to be listed on the preferred agents list even though is no longer available on the market. J Taylor clarified that discontinued products are often left on the PDL for a period of time to allow pharmacies to deplete any stock they have on hand and not require PA approval to dispense those units. He also acknowledged that the Department has received additional stakeholder input that leaving discontinued products on the preferred list may be misleading since in reality those products may not be available to dispense. G Miller confirmed that the Department plans to remove Flovent brand name product from the PDL with the 1/1/2025 update.
- L Claus moved to accept the criteria as written. Seconded by I Pan. Motion passed with five votes in favor. T Brubaker abstained, as he was unavailable for this vote.

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.

J Taylor introduced the Mass Review section and noted that no substantive criteria changes are being proposed for the drug products included in this section.

6. 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	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.

7. Antiherpetic Agents

a. Oral

Preferred Agents
Acyclovir tablet, capsule
*Acyclovir suspension *(members under 18 years or cannot swallow a solid dosage form)*
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.

*Acyclovir suspension does not require prior authorization for members < 18 years of age and may be approved for members ≥ 18 years of age who cannot swallow an oral dosage form.

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

b. Topical

Preferred Agents
- Acyclovir cream *(Teva only)*
- Acyclovir ointment
- DENAVIR (penciclovir) cream
- *Penciclovir cream

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

Xerese (acyclovir/hydrocortisone) prior authorization 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)

8. Fluoroquinolones, Oral

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

***CIPRO suspension** does not require prior authorization for members < 18 years of age and may be approved for members ≥ 18 years of age

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 with prescriber attestation that member:

- is unable to take Cipro (ciprofloxacin) crushed tablet or suspension OR
- is < 5 years of age and being treated for pneumonia OR
- has 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.

9. Hepatitis C Virus Treatments

a. Direct Acting Antivirals (DAAs)

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 *(Asegua only)*
MAVYRET (glecaprevir/pibrentasvir) tablet, pellet pack
Sofosbuvir/Velpatasvir 400 mg/100 mg *(Asegua only)*
*VOSEVI tablet (sofosbuvir/velpatasvir/voxila previr)

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. Ribavirin

Preferred Agents
Ribavirin capsule
Ribavirin tablet

Preferred products are eligible for up to a 90-day supply fill.

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

10. Antihistamines

a. Newer Generation

Preferred Agents
Cetirizine tablet (OTC) 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.

11. Intranasal Rhinitis Agents

Preferred Agents
Azelastine 137 mcg
Budesonide (OTC)
DYMISTA[BNR] (azelastine/fluticasone)

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).

12. 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.

13. Epinephrine Products

Preferred Agents
*Epinephrine 0.15 mg/0.15 mL, 0.3mg/0.3mL auto-injector *(Mylan only)*
EPIPEN 0.3 mg/0.3 mL epinephrine) auto-injector
EPIPEN JR 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. Newer Hereditary Angioedema (HAE) Products *(see above – pulled from Mass Review)*

15. Respiratory Agents

a. Inhaled Anticholinergics

Preferred Agents
No PA Required (Unless indicated*)

Solutions
Ipratropium solution

Short-Acting Inhalation Devices
ATROVENT HFA (ipratropium)

Long-Acting Inhalation Devices
SPIRIVA Handihaler[BNR] (tiotropium)
*SPIRIVA RESPIMAT (tiotropium)

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

***SPIRIVA RESPIMAT (tiotropium) 2.5 mcg** may be approved for members with a diagnosis of COPD who have trialed and failed SPIRIVA HANDIHALER. Failure is defined as intolerable side effects or inability to use dry powder inhaler (DPI) formulation.

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

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

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

b. Inhaled Anticholinergic Combinations

Preferred Agents

Solutions
Ipratropium/Albuterol solution

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

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

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

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

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

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

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

c. Inhaled Corticosteroids *(see above – pulled from Mass Review)*

d. Inhaled Corticosteroid Combinations

Preferred Agents
(*Must meet eligibility criteria)
ADVAIR[BNR] DISKUS (fluticasone/salmeterol)
ADVAIR[BNR] HFA (fluticasone/salmeterol)
AIRDUO RESPICLICK[BNR] (fluticasone/salmeterol)
DULERA (mometasone/formoterol)
SYMBICORT[BNR] (budesonide/formoterol) inhaler
*TRELEGY ELLIPTA (fluticasone furoate/umeclidinium/vilanterol)

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

Discussion
- No Board members reported potential conflicts of interest for the Mass Review section.
- S Klocke moved to accept the criteria as written. Seconded by K MacIntyre. Motion passed with five votes in favor. T Brubaker abstained, as he was unavailable for this vote.

Proposed Coverage Criteria for Non-PDL Products

1. Kisunla (donanemab-azbt) IV solution

Kisunla (donanemab-azbt) may be approved if the member meets ALL the following criteria:

1. For claims billed through the pharmacy benefit, prescriber verifies that the medication is being administered by a healthcare professional in the member's home or in a long-term care facility **AND**
2. Member has documented diagnosis of mild cognitive impairment or mild dementia stage of Alzheimer's disease, the population in which treatment was initiated in clinical trials, as evidenced by ALL the following:
   a. Positron Emission Tomography (PET) scan OR lumbar punctuation positive for amyloid beta plaque
   b. Mini-Mental State Examination (MMSE) score of 20-28 OR Montreal Cognitive Assessment MoCA Test score of 19-25
   c. Progressive change in memory function for at least 6 months
   AND
3. Member is 60 years of age or older **AND**
4. Prior to initiation of medication, the prescriber attests that the member meets ALL the following:
   a. Member has had a baseline brain MRI within the prior one year to treatment initiation, showing no signs or history of microhemorrhages and/or superficial siderosis
   b. Attestation that MRI will be completed prior to the 2nd, 3rd, 4th, and 7th infusions

c. Member is negative for apolipoprotein E ε4 (ApoE ε4) homozygotes
AND

5. Medication is prescribed by or in consultation with a neurologist

Initial approval period: 6 months

Second prior authorization approvals: an additional 6 months of therapy may be approved with provider attestation that a follow-up MRI will be (or has been) completed prior to the 7th infusion

Subsequent prior authorization approvals: may be approved if provider attests that the member has demonstrated a positive clinical response to treatment

Maximum dose: 700 mg every 4 weeks for the first 3 doses, followed by 1,400 mg every 4 weeks

Written Testimony
S White, Children's Hospital Colorado

Discussion

- R Poissant noted that these proposed criteria will apply to both the pharmacy and medical benefit since Kinsula is an IV formulation.
- No Board members reported potential conflicts of interest for this product.
- S Klocke noted that "punctuation" in bullet point 2.a should be edited to "puncture."
- S Klocke moved to add safety criteria that is more in alignment with current criteria for Leqembi (lecanemab-irmb) on Appendix P, given a higher risk of amyloid-related imaging abnormalities (ARIA) associated with donanemab-azbt use. Seconded by I Pan. Motion passed with five votes in favor. T Brubaker abstained, as he was unavailable for this vote.
- K MacIntyre noted that availability of PET scans for members can be very limited. After some discussion, the Board recommended leaving the reference to PET scans in the criteria because FDA approval for this drug required that type of imaging, and availability of PET scans could change in the future.
- K MacIntyre also for confirmation that the number of MRIs required by the criteria are also required safety interventions based on FDA product labeling. R Poissant and S Klocke confirmed this is the case, especially during the first 12 weeks of therapy, due to a high risk of ARIA.
- S Klocke moved to also add "Member is negative for apolipoprotein E ε4 (ApoE ε4) homozygotes" to existing criteria for lacanemab-irmb on Appendix P. Seconded by K MacIntyre. Motion passed with five votes in favor. T Brubaker abstained, as he was unavailable for this vote.
- S Klocke moved to accept the criteria as amended. Seconded by T Brubaker. Motion passed with five votes in favor and with K MacIntyre opposed.

2. **Miplyffa (arimoclomol citrate)** oral capsule

Miplyffa (arimoclomol citrate) may be approved if the following criteria are met:

1. Member is ≥ 2 years of age **AND**
2. Member has a documented diagnosis of Niemann-Pick disease type C, molecularly confirmed by genetic testing **AND**
3. Member is concurrently being treated with miglustat **AND**
4. Requested medication is being prescribed by a neurologist or other provider specializing in the treatment of Niemann-Pick disease type C **AND**
5. Prescriber attests that the member will be assessed using the NPC Clinical Severity Scale (NPCCSS) prior to initiating Miplyffa (arimoclomol citrate) therapy, **AND**

6. For members with renal impairment (eGFR ≥ 15 to < 50 mL/min) the dose of Miplyffa (arimoclomol citrate) will be adjusted according to product labeling **AND**
7. Members of child-bearing potential been counseled that Miplyffa (arimoclomol citrate) may cause embryo-fetal harm and to consider pregnancy planning and prevention **AND**
8. Members are limited to one prior authorization approval on file for Miplyffa (arimoclomol citrate) OR Aqneursa (levacetylleucine).

Maximum dose: 372 mg/day

Maximum quantity: 90 tablets/30 days

Approval: 6 months

Reauthorization:
Members may receive approval to continue therapy for 6 months if ALL of the following criteria are met:

- Based on ongoing response to treatment, the provider attests there is medical necessity justifying continuation of drug therapy **AND**
- Member has demonstrated response to treatment based on quantitative scores using the same scale(s) previously used to assess Miplyffa (arimoclomol citrate) treatment (see bullet point 5 of the initial authorization criteria), **AND**
- A brief explanation, including the provider name, must be submitted if a provider other than the one who initially performed the neurologic exam completes any follow-up exam(s) **AND**
- A brief explanation must be submitted if an exam scale other than the scale used for initial authorization is used for reassessment

Discussion

- No Board members reported potential conflicts of interest for this product.
- B Jackson moved to accept the criteria as written. Seconded by T Brubaker. Motion passed unanimously.

3. **Aqneursa (levacetylleucine)** granules for oral suspension

Aqneursa (levacetylleucine) may be approved if the following criteria are met:

1. Member weighs ≥ 15 kg **AND**
2. Member has a documented diagnosis of Niemann-Pick disease type C, molecularly confirmed by genetic testing **AND**
3. Requested medication is being prescribed by a neurologist or other provider specializing in the treatment of Niemann-Pick disease type C **AND**
4. A baseline assessment of disability has been documented using a version of the NPC Clinical Severity Scale (NPCCSS) prior to initiating Aqneursa (levacetylleucine) therapy, **AND**
5. Member is not pregnant **AND**
6. If member is breastfeeding, the developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Aqneursa (levacetylleucine) **AND** any potential adverse effects on the breastfed infant or from the underlying maternal condition, **AND**
7. Members of childbearing potential been counseled that Aqneursa (levacetylleucine) may cause fetal harm and to use effective contraception during treatment and for 7 days after the last dose of Aqneursa, if therapy is discontinued.
8. Members are limited to one prior authorization approval on file for Miplyffa (arimoclomol citrate) OR Aqneursa (levacetylleucine).

Maximum dose: 4 grams/day

Maximum quantity: 112 unit-dose 1-gram packets/28 days

Approval: 6 months

Reauthorization:
Members may receive approval to continue therapy for 6 months if the following criteria are met:

- Based on ongoing response to treatment, the provider attests there is medical necessity justifying continuation of drug therapy **AND**
- Member has demonstrated response to treatment based on quantitative scores using the same scale(s) previously used to assess Aqneursa treatment (see bullet point 5 of the initial authorization criteria), **AND**
- A brief explanation, including the provider name, must be submitted if a provider other than the one who initially performed the neurologic exam completes any follow-up exam(s) **AND**
- A brief explanation must be submitted if an exam scale other than the scale used for initial authorization is used for reassessment

Scheduled Speaker Testimony
J Raymond, Aqneursa – IntraBio, Inc.

Discussion

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

4. **Duvyzat (givinostat)** oral suspension

1. Member is ≥ 6 years of age **AND**
2. Member has a diagnosis of Duchenne Muscular Dystrophy (DMD) and is ambulatory **AND**
3. Member is on a stable dose of corticosteroids **AND**
4. Requested medication is being prescribed by or in consultation with a neurologist or a provider who specializes in treatment of DMD (such as a cardiologist, pulmonologist, or physical medicine and rehabilitation physician) **AND**
5. Prescriber confirms that prior to initiating Duvyzat (givinostat) therapy, muscle function has been assessed and documented based on the 4-step Climb Test (4SC) **AND**
6. Prescriber confirms that a baseline triglyceride level has been drawn prior to initiation of Duvyzat (givinostat) and that triglycerides will be monitored at 1 month, 3 months, 6 months, and then every 6 months thereafter following initiation of therapy **AND**
7. Prescriber confirms that a baseline platelet count of >150 x 10^9/L has been confirmed prior to initiation of Duvyzat (givinostat) and that blood counts will be monitored every 2 weeks for the first 2 months of treatment, then monthly for the first 3 months, and every 3 months thereafter **AND**
8. Prescriber confirms that a baseline ECG has been performed if member has underlying cardiac disease OR if member is taking concurrently taking medication(s) that cause QT prolongation **AND**
9. Prescriber acknowledges that Duvyzat (givinostat) should be discontinued if the following clinical situations arise:
   a. Hematological abnormalities worsen despite Duvyzat (givinostat) dose modification(s) per product labeling **OR**
   b. Triglycerides remain elevated despite adequate dietary intervention and Duvyzat (givinostat) dose modification(s) per product labeling **OR**

c. Moderate or severe diarrhea persists despite Duvyzat (givinostat) dose modification(s) per product labeling
d. QTc interval is > 500 ms OR the QTc change from pre-treatment baseline is > 60 ms

Maximum dose: 53.2 mg (6 mL) twice daily

Initial Approval: 6 months

Reauthorization:
The member may receive approval to continue therapy for one year if the following criteria are met:
- Member has shown no clinically significant or intolerable adverse effects related to Duvyzat (givinostat) treatment **AND**
- Member demonstrates response to Duvyzat (givinostat) treatment with clinical improvement in trajectory from baseline assessment in ambulatory function based on the 4-step Climb Test (4SC)

Discussion
- No Board members reported potential conflicts of interest for this product.
- B Jackson moved to change "ambulatory function based on the 4-step Climb Test (4SC)" to "ambulatory function based on the 4-step Climb Test (4SC) or similar motor function test used for DMD." Seconded by T Brubaker. Motion passed unanimously.
- T Brubaker moved to accept the criteria as amended. Seconded by B Jackson. Motion passed unanimously.

5. OTC Multivitamin + Iron (Poly-Vi-Sol + Iron) Oral Drops

Poly-Vi-Sol with Iron OTC drops may be approved if the following criteria are met:
1. Member is < 1 year of age AND
2. Member is being treated for a diagnosis of anemia of prematurity OR is considered clinically "at risk" and requiring supplementation with an oral iron-containing multivitamin medication.

Length of Approval: 1 year

Discussion
- No Board members reported potential conflicts of interest for this product.
- J Taylor confirmed that "at risk" is intended to be broadly interpreted when a member <1 year of age has a clinical need for approval of this product.
- I Pan moved to accept the criteria as amended. Seconded by T Brubaker. Motion passed unanimously.

6. **Iqirvo (elafibranor)** oral tablet

Iqirvo (elafibranor) may be approved if the following criteria are met:
1. Member is > 18 years of age **AND**
2. Member has a diagnosis of primary biliary cholangitis and meets one of the following:
   a. Combined therapy: Requested medication will be used in combination with ursodiol (ursodeoxycholic acid) if the member had an inadequate response (lack of efficacy) following at least one year of treatment with ursodiol (ursodeoxycholic acid) alone
   OR

b. Monotherapy: Requested medication will be used as monotherapy in members who have trialed and failed ursodiol (ursodeoxycholic acid) therapy. Failure is defined as allergy, intolerable side effects, or significant drug-drug interaction

AND

3. Medication is prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant provider **AND**
4. Laboratory tests to evaluate ALT, AST, alkaline phosphatase and total bilirubin will be performed at baseline and during treatment with Iqirvo (elafibranor), according to product labeling, **AND**
5. Prior to initiating therapy, the member does NOT have an elevated creatine phosphokinase (CPK) and/or signs/symptoms of muscle pain or myopathy, and prescriber attests that these parameters will be monitored throughout treatment with Iqirvo (elafibranor), **AND**
6. Member does not have complete biliary obstruction, cirrhosis, or other types of liver disease, **AND**
7. Members without serologic evidence of immunity have received hepatitis A and hepatitis B vaccinations **AND**
8. Prescriber has considered the risk of fracture in members treated with Iqirvo (elafibranor) **AND**
9. Prescriber has counseled member to abstain from alcohol or avoid heavy alcohol use **AND**
10. Prescriber attests that a pre-treatment pregnancy test will be performed, and that members of reproductive potential will be advised to switch to effective non-hormonal contraceptives OR add a barrier method when using hormonal contraceptives and for at least 3 weeks after last dose of Iqirvo (elafibranor), **AND**
11. Prescriber attests that members of reproductive potential will be advised to avoid breastfeeding during treatment and for 3 weeks after last dose of Iqirvo (elafibranor) **AND**
12. Prescriber attests the member has been counseled that the approval and safety status of Iqirvo (elafibranor) is based on reduction of alkaline phosphatase. Improvement in survival or prevention of liver decompensation events have not been demonstrated. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

Maximum dose: 80 mg/day
Maximum quantity: 30 tablets/30 days

Approval: 6 months

Reauthorization:
Member may receive approval for one year with provider attestation that a biochemical response (such as an alkaline phosphatase level less than 1.67-times the upper limit of normal) has been observed after 6 months of therapy.

Discussion

- No Board members reported potential conflicts of interest for this product.
- J Rawlings noted that the approved age will be edited to greater than or equal to 18 years of age.
- B Jackson moved to accept the criteria as amended. Seconded by K MacIntyre. Motion passed unanimously.

7. **Livdelzi (seladelpar)** oral capsule

Livdelzi (seladelpar) may be approved if the following criteria are met:
1. Member is > 18 years of age **AND**
2. Member has a diagnosis of primary biliary cholangitis and meets one of the following:
   a. Combined therapy: Requested medication will be used in combination with ursodiol (ursodeoxycholic acid) if the member had an inadequate response (lack of efficacy) following at least one year of treatment with ursodiol (ursodeoxycholic acid) alone
   OR

b. Monotherapy: Requested medication will be used as monotherapy in members who have trialed and failed ursodiol (ursodeoxycholic acid) therapy. Failure is defined as allergy, intolerable side effects, or significant drug-drug interaction

AND

3. Medication is prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant provider **AND**
4. Laboratory tests to evaluate ALT, AST, alkaline phosphatase and total bilirubin will be performed at baseline and during treatment with Livdelzi (seladelpar), according to product labeling, **AND**
5. Prior to initiating therapy, the member does NOT have an elevated creatine phosphokinase (CPK) and/or signs/symptoms of muscle pain or myopathy, and prescriber attests that these parameters will be monitored throughout treatment with Livdelzi (seladelpar), **AND**
6. Member does not have complete biliary obstruction, cirrhosis, or other types of liver disease, **AND**
7. Members without serologic evidence of immunity have received hepatitis A and hepatitis B vaccinations **AND**
8. Prescriber has considered the risk of fracture in patients treated with the requested product **AND**
9. Due to the risk of adverse reactions that maybe be associated with significant increases in Livdelzi (seladelpar) exposure, member is not taking an OAT3 inhibitor (such as gemfibrozil, probenecid, teriflunomide) OR a strong CYP2C9 inhibitor (such as fluconazole, fluorouracil, gemfibrozil, metronidazole), and member's medication profile has been reviewed for other potential clinically significant drug interactions according to product labeling, **AND**
10. Prescriber attests the member has been counseled that the approval and safety status of Livdelzi (seladelpar) is based on reduction of alkaline phosphatase. Improvement in survival or prevention of liver decompensation events have not been demonstrated. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

Maximum dose: 10 mg/day

Maximum quantity: 30 tablets/30 days

Approval: 6 months

Reauthorization:
Member may receive approval for one year with provider attestation that a biochemical response (such as an alkaline phosphatase level less than 1.67-times the upper limit of normal) has been observed after 6 months of therapy.

Discussion

- No Board members reported potential conflicts of interest for this product.
- J Rawlings noted that the indicated age will be edited to greater than or equal to 18 years of age.
- S Klocke moved to accept the criteria as amended. Seconded by I Pan. Motion passed unanimously.

8. **Xolremdi (mavorixafor)** oral capsule

Xolremdi (mavorixafor) may be approved if the following criteria are met:
1. Member is ≥ 12 years of age **AND**
2. Member has a diagnosis of WHIM syndrome (warts, hypogammaglobulinemia, infections, myelokathexis) **AND**
3. Diagnosis of WHIM is based on a genotype-confirmed pathogenic variant in the *CXCR4* gene **AND**
4. Member has a confirmed absolute neutrophil count of ≤ 400 cells/µL **AND**
5. The requested drug is being prescribed by a provider specializing in the treatment of WHIM (such as an immunologist, geneticist, hematologist or dermatologist) **AND**
6. Member has a recent creatinine clearance of 30 mL/min or greater **AND**

7. Member does not moderate to severe hepatic impairment **AND**
8. Provider attests that QTc interval will be assessed at baseline and monitored during treatment as clinically indicated **AND**
9. Prescriber attests that members of reproductive potential will be advised to use effective contraception while on Xolremdi (mavorixaflor) therapy **AND**
10. Prescriber attests that members of reproductive potential will be advised that breastfeeding is not recommended during treatment and for 3 weeks after last dose of Xolremdi (mavorixaflor) **AND**
11. Due to the risk of adverse reactions that maybe be associated with significant increases in Xolremdi (mavorixafor) exposure, member is not concurrently taking a medication that is highly dependent on CYP2D6 for clearance (such as dextromethorphan, fluoxetine, nortriptyline, oxycodone, paroxetine, quinidine) OR a strong CYP3A4 inducer (such as carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifampin, rifabutin, rifapentine, dexamethasone, efavirenz, etravirine, nevirapine, darunavir/ritonavir, ritonavir, St John's Wort) AND member's medication profile has been reviewed for other potential clinically significant drug interactions according to product labeling.
12. Member is not being treated with any other CXCR4 antagonists, **AND**
13. Member has been counseled to take Xolremdi (mavorixaflor) on an empty stomach after an overnight fast, and at least 30 minutes before food, AND counseled that Xolremdi (mavorixaflor) capsules should not be cut, crushed or chewed.

Maximum dose: 400 mg/day

Maximum quantity: 120 capsules (100 mg strength)/30 days

Initial approval: 1 year

Reauthorization:
Provider attests to the efficacy of treatment based on a sustained increase in absolute neutrophil count with ongoing monitoring

Discussion

- No Board members reported potential conflicts of interest for this product.
- J Rawlings proposed the addition of infectious disease provider to the list of subspecialists in bullet point 5. The Board concurred with that recommendation.
- S Klocke moved to accept the criteria as amended. Seconded by B Jackson. Motion passed unanimously.

9. Vafseo (vadadustat) oral tablet

Vafseo (vadadustat) may be approved if the following criteria are met:

1. Member is ≥ 18 years of age **AND**
2. Member has a diagnosis of anemia due to chronic kidney disease (CKD) and has been receiving dialysis for at least three months, **AND**
3. Member does not have uncontrolled hypertension, **AND**
4. Member does not have cirrhosis or acute, active liver disease **AND**
5. Member does not have any known, active malignancies **AND**
6. Member has trialed and failed at least one month of treatment with an erythropoiesis-stimulating agent (ESA) **AND**
7. Laboratory tests to evaluate ALT, AST, alkaline phosphatase, total bilirubin, hemoglobin and iron status will be performed at baseline and during treatment with Vafseo (vadadustat), according to product labeling, **AND**

8. Prescriber has counseled members who are taking an oral iron supplement, other products containing iron, or a phosphate binder that Vafseo (vadadustat) should be administered at least 1 hour before taking these products to avoid reducing the effectiveness of Vafseo (vadadustat) **AND**
9. Prescriber attests that member's medication profile has been reviewed for clinically significant drug interactions, including:
   - BCRP substrates (such as sulfasalazine, ciprofloxacin, acyclovir, nitrofurantoin, zidovudine): Monitor patients more frequently for adverse reactions and consider dose reduction of the BCRP substrate drug
   - OAT1 inhibitors (such as probenecid, rifampicin) and OAT3 inhibitors (such as gemfibrozil, probenecid, teriflunomide): Closely monitor for too large or too rapid an increase in hemoglobin response and for adverse reactions

   AND
10. Regarding concurrent statin therapy, provider attests that:
    - If member is concurrently taking simvastatin, the dose of the statin will be limited to 20 mg/day **OR**
    - If member is concurrently taking rosuvastatin, the dose of the statin will be limited to 5 mg/day

    AND
11. The requested medication is not being prescribed as a substitute for red blood cell transfusions in patients who require immediate correction of anemia **AND**
12. The requested medication is not being prescribed for treatment of anemia of chronic kidney disease in patients who are not on dialysis **AND**
13. Member has been counseled that Vafseo (vadadustat) tablets should not be cut, crushed or chewed.

Maximum dose: 600 mg/day

Approval: 6 months

Reauthorization:
Reauthorization for 6 months may be approved with documentation of lab results that indicate a clinically meaningful increase in hemoglobin level since initiation of treatment with Vafseo (vadadustat).

Note: Vafseo (vadadustat) should not be continued beyond 24 weeks of therapy if a clinically meaningful increase in hemoglobin level has not been achieved. Alternative explanations for an inadequate response should be sought and treated before re-starting therapy.

Discussion

- No Board members reported potential conflicts of interest for this product.
- L Claus moved to make the following edits. Seconded by I Pan. Motion passed unanimously.
  - Regarding concurrent statin therapy, provider attests that:
    - If member is concurrently taking simvastatin, the dose of the statin simvastatin will be limited to 20 mg/day **OR**
    - If member is concurrently taking rosuvastatin, the dose of the statin rosuvastatin will be limited to 5 mg/day
- K MacIntyre moved to accept the criteria as amended. Seconded by T Brubaker. Motion passed unanimously.

C. Adjournment

Vice Chair Claus reminded attendees that the next Board meeting is scheduled for Tuesday, February 11, 2025, 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 and the meeting was adjourned at 4:09 pm.

Minutes prepared by Julia Rawlings, PharmD, Secretary