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 4, 2025
Open Session
1:00 pm – 5:00 pm

1. Call to Order

Today's meeting was held virtually via Zoom. The meeting was called to order at 1:01 pm by B Jackson, Vice Chair.

2. Roll Call and Introductions

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

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

Members Absent: Marshal Ash, DO

HCPF Pharmacy Office: Jim Leonard, PharmD; Jeffrey Taylor, PharmD

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

3. Virtual Meeting Information and General Announcements

J Rawlings shared several announcements:

- This meeting is being recorded for internal use by the Department.
- Video and microphone for Board members will be turned ON. Speakers who will be 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. Stakeholders who have signed up in advance will be invited to provide testimony at the appropriate time on the meeting agenda.
- Board members may vote by raising hands and/or by verbal "ayes" and "nays," abstentions, and recusals as determined today by the Chair and Vice Chair.

4. Colorado Department of Health Care Policy and Financing Updates

J Taylor provided some updates from the Department

- The Department continues to transition components of its Pharmacy Benefit Management System (PBMS) from Prime Therapeutics (formerly Magellan Rx) to MedImpact. This quarter you will notice a new format for the market share tables in the meeting binder.
- Board members may have noticed that the Retrospective DUR educational outreach graphs and the quarterly utilization reports are not included in today's meeting binder. These reports are unavailable this quarter due to some technical difficulties. However, the most recent data sets indicate that numbers in all categories have stayed consistent with prior quarters.
- During today's review of products and therapeutic drug classes currently managed with prior authorization criteria, only proposed changes to the currently posted criteria will be read aloud.

5. Final Approval of Minutes from the August 12, 2025 Meeting

- Vice Chair B Jackson asked Board members to review minutes from the August 12, 2025 meeting. T Brubaker moved to approve the minutes as written. Seconded by S Klocke. Motion passed with seven votes in favor. Dr. Claus abstained, as she did not attend the August meeting.

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

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

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

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

7. Clinical Updates and General Orders

- **FDA Drug Safety Communications**
  B McCarty, Population Health Intern, presented two FDA Drug Safety Communications:
  1. FDA's removal of the risk evaluation and mitigation strategy (REMS) for clozapine effective June 13, 2025
  2. A new FDA recommendation from August 28 regarding additional and earlier MRI monitoring for patients with Alzheimer's disease who are taking Leqembi (lecanemab)

- **FDA New Drug Approvals Report**
  T Smith, Population Health Intern, presented this quarter's FDA Drug Approvals summary report.

- **Quarterly Clinical Module Summary**
  R Page presented a summary of last quarter's clinical module analysis entitled *Evaluation of RAAS inhibitors in Patients with Chronic Kidney Disease and Heart Failure with Preserved Ejection Fraction: A focus on finerenone and its placement on the PDL*. The full module was delivered to the Department on September 30, 2025.

8. New Business

J Taylor provided several agenda updates:

- The Targeted Immune Modulators include seven therapeutically divided subclasses and comprise the largest class on the Colorado PDL. The Board may either conduct motions and votes to cover the Targeted Immune Modulators class as a whole or review criteria individually by subclass. Five speakers have registered in advance to provide testimony during today's class review.

- Section C of today's agenda includes a review of specific to IV and physician-administered Targeted Immune Modulators that are currently managed on Appendix P. Speakers who provide testimony related to Targeted Immune Modulators on the PDL will not be recalled to provide additional testimony for these Appendix P products.
- Lucentis (ranibizumab), Ranibizumab-Containing Biosimilar Products, and Rituxan Hycela (rituximab/hyaluronidase) listed in Section D of the meeting agenda will not be reviewed today.
- The PDL drug class Inhaled Antibiotics will be pulled from Mass Review and undergo a full review, based on receipt of written testimony regarding this drug class from the Cystic Fibrosis Foundation.

J Rawlings introduced the process to evaluate proposed criteria for PDL drug classes and products scheduled for November Board review.

- Board members present will be asked about any potential conflicts of interest to disclose prior to reviewing the therapeutic drug classes and products listed in the meeting agenda.
- Time is 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.
- To facilitate recordkeeping, it is helpful for Board members to state their names as they make motions and offer seconds.

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

Proposed deletions are highlighted in red. Proposed additions are highlighted in yellow.

1. Epinephrine Products

Preferred agents
AUVI-Q auto-injector
*Epinephrine 0.15mg/0.15ml, 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
NEFFY nasal spray

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

Scheduled Speaker Testimony
K Schreur, Neffy – ARS Pharma

Written Testimony
Neffy information sheet - ARS Pharma

Discussion

- No Board members reported a potential conflict of interest for this therapeutic class.
- S Klocke moved to accept the criteria as written. Seconded by I Pan. Motion passed unanimously.

2. 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/voxilaprevir)

***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.

Scheduled Speaker Testimony
M Harmon, Mavyret – *unavailable*
N Rose, Epclusa - Gilead

b. Ribavirin Products

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.

Discussion

- No Board members reported a potential conflict of interest for this therapeutic class.
- I Pan moved to accept the criteria as written. Seconded by K MacIntyre. Motion passed unanimously.

3. Human Immunodeficiency Virus (HIV) Treatments

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

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

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

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
YEZTUGO (lenacapavir)

e. Combination Agents

Preferred Agents

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/rilpivirine/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

All products are preferred and do not require prior authorization.

Scheduled Speaker Testimony

N Rose, Biktarvy – Gilead
N Rose, Yeztugo - Gilead
P Amato, Cabenuva – Viiv Healthcare
P Amato, Apretude – Viiv Healthcare

Written Testimony
Cabenuva – Viiv Healthcare
Apretude – Viiv Healthcare

Discussion

- No Board members reported a potential conflict of interest for this therapeutic class.
- S Klocke moved to accept the criteria as written. Seconded by L Claus. Motion passed with six votes in favor. T Brubaker abstained, as he was unavailable for this vote.

4. Immune Globulins

Preferred agents
PA Required for all agents in this class*
BIVIGAM 10% IV liquid
CUTAQUIG 16.5% SQ liquid
CUVITRU 20% SQ liquid
GAMMAGARD 10% IV/SQ liquid
GAMMAKED 10% IV/SQ liquid
GAMUNEX-C 10% IV/SQ liquid
HIZENTRA 20% SQ syringe, vial
PRIVIGEN 10% IV liquid

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

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

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

Approved Conditions for Immune Globulin Use:
- Primary Humoral Immunodeficiency disorders including:
  - Common Variable Immunodeficiency (CVID)
  - Severe Combined Immunodeficiency (SCID)
  - X-Linked Agammaglobulinemia
  - X-Linked with Hyperimmunoglobulin M (IgM) Immunodeficiency
  - Wiskott-Aldrich Syndrome
  - Members < 13 years of age with pediatric Human Immunodeficiency Virus (HIV) and CD-4 count > 200/mm^3
- Neurological disorders including:
  - Guillain-Barré Syndrome
  - Relapsing-Remitting Multiple Sclerosis
  - Chronic Inflammatory Demyelinating Polyneuropathy
  - Myasthenia Gravis
  - Polymyositis and Dermatomyositis
  - Multifocal Motor Neuropathy

- Kawasaki Syndrome
- Chronic Lymphocytic Leukemia (CLL)
- Autoimmune Neutropenia (AN) with absolute neutrophil count < 800 mm and history of recurrent bacterial infections
- Autoimmune Hemolytic Anemia (AHA)
- Liver or Intestinal Transplant
- Immune Thrombocytopenia Purpura (ITP) including:
    - Requiring 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	
Alyglo – IV admin	800 mg/kg every 3 to 4 weeks
Asceniv – IV admin	800 mg/kg every 3 to 4 weeks
Bivigam – IV admin	800 mg/kg every 3 to 4 weeks
Cutaquig – subcutaneous admin	See product labeling
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	1 gram/kg for 2 consecutive days (ITP) 800 mg/kg every 3 to 4 weeks (PI)
Gammagard liquid — subcutaneous or IV admin	2.4 grams/kg/month (IV for MMN) 2 grams/kg over 2 to 5 consecutive days (IV for CIDP) 600 mg/kg every 3 weeks (IV for PI)
Gammaked – subcutaneous or IV admin	2 grams/kg over 2 consecutive days (IV for ITP, CIDP) 600 mg/kg every 3 weeks (IV for PI)
Gamunex-C – subcutaneous or IV admin	2 grams/kg over 2 to 5 consecutive days (IV for ITP, CIDP) 600 mg/kg every 3 weeks (IV for PI)
Hizentra – subcutaneous admin	0.4 grams/kg per week over 2 consecutive days (CIDP)
Hyqvia – subcutaneous admin	600 mg/kg every 3 weeks
Octagam – IV admin	2 grams/kg every 4 weeksover 2 to 5 consecutive days (ITP, DM) 600 mg/kg every 3 weeks (PI)

Panzyga – IV admin	2 grams/kg every 3 weeksover 2 consecutive days (ITP, CIDP) 600 mg/kg every 3 weeks (PI)
Privigen – IV admin	2 grams/kg over 2 to 5 consecutive days (ITP, CIDP) 800 mg/kg every 3 weeks (PI)
Xembify – subcutaneous admin	150 mg/kg/day for 5 consecutive days (PI loading dose)

CIDP=Chronic Inflammatory Demyelinating Polyneuropathy; DM=Dermatomyositis; ITP= Chronic Immune Thrombocytopenic Purpura; MMN=Multifocal Motor Neuropathy; PI=Primary Humoral Immunodeficiency

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

Discussion

- No Board members reported a potential conflict of interest for this therapeutic class.
- I Pan moved to ask the Department to review whether measles post-exposure prophylaxis should be added to the criteria as an indication for the use of immune globulin (IVIG). Seconded by S Cho. Motion passed with six votes in favor. T Brubaker abstained, as he was unavailable for this vote.
- I Pan moved to accept the criteria as amended. Seconded by L Claus. Motion passed with six votes in favor. T Brubaker abstained, as he was unavailable for this vote.

5. Newer Hereditary Angioedema (HAE) Products

a. HAE Prophylaxis

Preferred agents
PA Required for all agents in this class
CINRYZE (C1 esterase inhibitor) kit
HAEGARDA (C1 esterase inhibitor) vial
ORLADEYO (berotralstat) capsule
TAKHZYRO (lanadelumab-flyo) vial, 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.

Preferred products **HAEGARDA** (C1 esterase inhibitor - human), **ORLADEYO** (berotralstat), and **TAKHZYRO** (lanadelumab-flyo) may be approved if the following criteria are met:

- Member has a diagnosis of Type I HAE (Hereditary Angioedema with deficient C1-inhibitor) or Type II HAE (Hereditary Angioedema with dysfunctional C1-inhibitor) 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 with normal C1-inhibitor and based on clinical presentation 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:

- Requested product is being used for short-term prophylaxis to undergo a surgical procedure or major dental work **OR**
    - Requested product 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
    - The request meets minimum age and maximum dose limits listed in **Table 1**

AND

- For **HAEGARDA**: Prescriber acknowledges that the member will receive information and/or counseling regarding the information from the FDA-labeled package insert outlining transmission of infectious agents with a medication made from human blood.
- For **ORLADEYO** (berotralstat): Appropriate drug interaction interventions will be made for members using concomitant medications that may require dose adjustments (such as cyclosporine, fentanyl, pimozide, digoxin).
- For **TAKHZYRO** (lanadelumab-flyo): 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.

Non-preferred agents for routine prophylaxis may be approved if the member has trialed and failed at least two preferred agents indicated for routine prophylaxis. Failure is defined as lack of efficacy, allergy, intolerable side effect, or a significant drug-drug interaction.

Table 1. FDA-approved Minimum Age and Maximum Dose

	Minimum Age	Maximum Dose
CINRYZE (C1 esterase inhibitor-human)	6 years	2,000 units IV every 3 or 4 days
HAEGARDA (C1 esterase inhibitor-human)	6 years	60 units/kg twice weekly
ORLADEYO (berotralstat)	12 years	150 mg once daily
TAKHZYRO (lanadelumab-flyo)	2 years	300 mg every 2 weeks

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

- Member has a diagnosis of HAE Type I HAE (Hereditary Angioedema with deficient C1-inhibitor) or Type II HAE (Hereditary Angioedema with dysfunctional C1-inhibitor) 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 with normal C1-inhibitor Type III based on clinical presentation 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

- Prescriber acknowledges that the member will receive information and/or counseling regarding the information from the FDA-labeled package insert outlining transmission of infectious agents with a medication made from human blood.

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 presentation 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**
  - Prescriber acknowledges that the member will receive information and/or counseling regarding the information from the FDA-labeled package insert outlining transmission of infectious agents with a medication made from human blood.

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 presentation 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 presentation 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: 2 years

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

Scheduled Speaker Testimony
J Martin, Orladeyo – AbbVie

Discussion

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

b. HAE Treatment

Preferred agents
BERINERT (C1 esterase inhibitor) kit, vial
FIRAZYR (icatibant acetate) syringe[BNR]
ICATIBANT syringe

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.

Preferred products **BERINERT** (C1 esterase inhibitor) or **generic ICATIBANT** may be approved if the following criteria are met:

- Member has a diagnosis of Type I HAE (Hereditary Angioedema with deficient C1-inhibitor) or Type II HAE (Hereditary Angioedema with dysfunctional C1-inhibitor) 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 with normal C1-inhibitor based on clinical presentation **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**
- The request meets minimum age and maximum dose limits listed in **Table 2**

AND

- For **BERINERT** (C1 esterase inhibitor): Prescriber acknowledges that the member will receive information and/or counseling regarding the information from the FDA-labeled package insert outlining transmission of infectious agents with a medication made from human blood.

RUCONEST (C1 esterase inhibitor - recombinant) may be approved if the following criteria are met:

- Member meets all of the preferred product criteria above **AND**
- Member has a history of trial and failure of BERINERT (C1 esterase inhibitor). Failure is defined as lack of efficacy, allergy, intolerable side effects, or a significant drug-drug interaction

All other non-preferred agents for acute treatment may be approved if the member has trialed and failed at least two preferred products for acute treatment. Failure is defined as lack of efficacy, allergy, intolerable side effect, or a significant drug-drug interaction.

Table 2. FDA-approved Minimum Age and Maximum Dose

	Minimum Age	Maximum Dose
BERINERT (C1 esterase inhibitor)	5 years	20 units/kg
FIRAZYR (icatibant acetate)	18 years	30 mg
Generic ICATIBANT	18 years	30 mg
RUCONEST (C1 esterase inhibitor-recombinant)	13 years	4,200 Units

FIRAZYR (icatibant acetate) or **RUCONEST** (C1 esterase inhibitor - recombinant) 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 presentation **AND**
- Member has a documented history of at least one symptom of a moderate to severe HAE attack (moderate to severe abdominal pain, facial swelling, airway swelling) in the absence of hives or a medication known to cause angioedema **AND**
- Member is not taking medications that may exacerbate HAE including ACE inhibitors and estrogen-containing medications

Minimum age: 18 years
Maximum dose: 30mg

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

- Member has a diagnosis of HAE 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 presentation 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

- Prescriber acknowledges that the member will receive information and/or counseling regarding the information from the FDA-labeled package insert outlining transmission of infectious agents with a medication made from human blood.
  Minimum age: 6 years
  Maximum dose: 20 IU/kg

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

- Member has a history of trial and failure of Firazyr OR Berinert. Failure is defined as lack of efficacy, allergy, intolerable side effects, or a significant drug-drug interaction **AND**
- Member has a diagnosis of HAE 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 presentation **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: 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.

Discussion

- No Board members reported a potential conflict of interest for this therapeutic class.
- S Cho moved to accepted the criteria as written. Seconded by K MacIntyre. Motion passed with six votes in favor. T Brubaker abstained, as he was unavailable for this vote.

6. Respiratory Agents

a. Inhaled β_2 Agonists (short acting)

Preferred agents

Solutions

Albuterol solution for nebulizer

Inhalers

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

b. Inhaled ß$_2$ Agonists (long acting)

Preferred agents

Solutions
Budesonide nebules

Inhalers
ARNUITY ELLIPTA[BNR] (fluticasone furoate)
ASMANEX HFA (mometasone furoate) inhaler
ASMANEX Twisthaler (mometasone)
PULMICORT FLEXHALER (budesonide)
QVAR REDIHALER (beclomethasone)

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.

c. Inhaled Anticholinergics and Combinations

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.

d. 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)[BNR]

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.

e. Inhaled Corticosteroids and Combinations

Preferred agents

Solutions

Budesonide nebules

Inhalers

ARNUITY ELLIPTA[BNR] (fluticasone furoate)
ASMANEX HFA (mometasone furoate) inhaler
ASMANEX Twisthaler (mometasone)
PULMICORT FLEXHALER (budesonide)
QVAR REDIHALER (beclomethasone)

f. Inhaled Corticosteroid Combinations

Preferred agents

No PA Required (*Must meet eligibility criteria)

ADVAIR DISKUS[BNR] (fluticasone/salmeterol)
ADVAIR HFA[BNR] (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 a potential conflict of interest for this therapeutic class.
- L Claus moved to request that the Department ensure appropriate guideline-supported trial and failure criteria for Trelegy Ellipta for the management of COPD to "may be approved if the member has trialed and failed one preferred agent from the Inhaled Anticholinergic Combinations or the Inhaled Corticosteroid Combinations subclass. Seconded by S Klocke. Motion passed with six 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 six votes in favor. T Brubaker abstained, as he was unavailable for this vote.

7. Targeted Immune Modulators

Summary of Preferred Agents:

adalimumab-aacf (CF) single-dose syringe
adalimumab-aaty auto-injector
adalimumb-adbm 2-pen kit
ADBRY (tralokinumab-ldrm) syringe, auto-injector
AMJEVITA (adalimumab-atto) syringe, auto-injector
Cyltezo (adalimumab-adbm) pen, syringe
DUPIXENT (dupilumab) pen, syringe
ENBREL (etanercept) Mini, SureClick pen, syringe, vial
FASENRA (benralizumab) pen
HADLIMA (adalimumab- bwwd)
HUMIRA (adalimumab)
IMULDOSA (ustekinumab-srlf) syringe
OTEZLA (apremilast) tablet
KEVZARA (sarilumab) pen, syringe
SELARSDI (ustekinumab-aekn) syringe
STEQEYMA (ustekinumab-stba) syringe
TALTZ (ixekizumab) syringe, auto-injector
TEZSPIRE (tezepelumab-ekko) pen
TYENNE (tocilizumab-aazg) pen, syringe
XELJANZ IR (tofacitinib) tablet
XELJANZ XR tablet
XOLAIR (omalizumab) syringe, auto-injector
YUFLYMA (adalimumab-aaty) syringe, auto-injector

Scheduled Speaker Testimony
M Harmon, Rinvoq – AbbVie
M Harmon, Skyrizi - AbbVie
E Tauchman, Bimzelx – UCB Pharmaceuticals
K Chang, Dupixent – Sanofi
N Kamyabi, Nemluvio – Galderma

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-aacf (CF) single-dose syringe
adalimumab-aaty auto-injector
adalimumb-adbm 2-pen kit
AMJEVITA (adalimumab-atto) syringe, auto-injector
CYLTEZO (adalimumab-adbm) pen, syringe
ENBREL (etanercept) Mini, SureClick pen, syringe, vial
HADLIMA (adalimumab-bwwd) Pushtouch, syringe
HUMIRA (adalimumab)
*KEVZARA (sarilumab) pen, syringe
*TALTZ (ixekizumab) syringe, auto-injector
*TYENNE (tocilizumab-aazg) pen, syringe
XELJANZ IR (tofacitinib) tablet
XELJANZ XR (tofacitinib) tablet
YUFLYMA (adalimumab-aaty) syringe, auto-injector

First line preferred agents (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:
- A preferred adalimumab product **OR**
- ENBREL.

***KEVZARA (sarilumab)** may receive approval for use for FDA-labeled indications following trial and failure‡ of:
- 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 be approved if meeting general non-preferred criteria listed belowreceive approval for:**OR**

- FDA-labeled indications following trial and failure‡ of all indicated preferred agents OR
- For tTreatment 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 a preferred adalimumab product
  -

Humira brand and non-preferred adalimumab agents may receive approval if meeting the following:

- The request meets one of the following:
  - The prescribed agent is a preferred adalimumab product
    OR
  - If the prescribed agent is brand Humira or a non-preferred adalimumab product, then the member has trialed and failed at least one preferred adalimumab product. Failure is defined as lack of efficacy or intolerable side effects with the preferred adalimumab product.
    AND
- The general non-preferred criteria listed below are met

KINERET (anakinra) may receive approval for:

- Treatment of systemic juvenile idiopathic arthritis (sJIA) or Adult-Onset Still's Disease (AOSD) **OR**
- Treatment of rheumatoid arthritis following trial and failure‡ of
  - A preferred adalimumab product or ENBREL **AND**
  - XELJANZ IR

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‡ a tocilizumab product.

Quantity Limit: 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 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 the following preferred agents when that are FDA-indicated or havehaving strong evidence supporting use for the prescribed indication from clinically recognized guideline compendia: (only one preferred adalimumab product trial required).

- Adalimumab or ENBREL (TNF inhibitor) **AND**
- XELJANZ (JAK inhibitor) **AND**
- TYENNE, KEVZARA or TALTZ (IL inhibitor)

Non-preferred agents that are being prescribed per FDA labeling 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 currently taking a preferred agent may receive approval to continue therapy with that agent. Members with current prior authorization approval on file for a non-preferred agent that does not have a preferred biosimilar 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 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

- No Board members reported a potential conflict of interest for this therapeutic class.
- I Pan moved to change the bullet under Cosentyx (secukinumab) regarding enthesitis-related arthritis from "Member has trialed and failed‡ NSAID therapy and ENBREL **and** a preferred adalimumab product" to "Member has trialed and failed‡ NSAID therapy and ENBREL **or** a preferred adalimumab product" to avoid stepping through two TNF inhibitors. Seconded by S Cho. Motion passed with six votes in favor. T Brubaker abstained, as he was unavailable for this vote.
- S Klocke moved to add a quantity limit for Xeljanz XR, in addition to Xeljanz IR, based on dose-related boxed warning safety precautions in the product labeling. Seconded by S Cho. Motion passed with six votes in favor. T Brubaker abstained, as he was unavailable for this vote. (J Taylor confirmed that this motion would also be considered for Xeljanz quantity limit statements in subsequent Targeted Immune Modulator subclasses being reviewed during today's meeting.)
- I Pan moved to accept the criteria as amended. Seconded by K MacIntyre. Motion passed with six votes in favor. T Brubaker abstained, as he was unavailable for this vote.

b. Psoriatic Arthritis

Preferred agents
No PA Required (If diagnosis met)
(*Must meet eligibility criteria)
adalimumab-aacf (CF) single-dose syringe
adalimumab-aaty auto-injector
adalimumb-adbm 2-pen kit
AMJEVITA (adalimumab-atto) syringe, auto-injector
CYLTEZO (adalimumab-adbm) pen, syringe
ENBREL (etanercept) Mini, SureClick pen, syringe, vial
HADLIMA (adalimumab-bwwd) Pushtouch, syringe
HUMIRA (adalimumab)
**IMULDOSA (ustekinumab-srlf) syringe
*OTEZLA (apremilast) tablet
** SELARSDI (ustekinumab-aekn) syringe
** STEQEYMA (ustekinumab-stba) syringe
*TALTZ (ixekizumab) syringe, auto-injector
XELJANZ IR (tofacitinib) tablet
XELJANZ XR (tofacitinib) tablet
YUFLYMA (adalimumab-aaty) syringe, auto-injector

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

***OTEZLA (apremilast)** may receive approval for psoriatic arthritis indication following trial and failure‡ of:

- A preferred adalimumab product or ENBREL **AND**
- XELJANZ IR or TALTZ or a preferred ustekinumab product.

***TALTZ (ixekizumab)** may receive approval for psoriatic arthritis indication following trial and failure‡ of:

- A preferred adalimumab product or ENBREL **AND**
- XELJANZ IR or OTEZLA or a preferred ustekinumab product.

Preferred **USTEKINUMAB biosimilars IMULDOSA (ustekinumab-srlf), SELARSDI (ustekinumab-aekn), and STEQEYMA (ustekinumab-stba) may receive approval for psoriatic arthritis indication following trial and failure‡ of:

- A preferred adalimumab product or ENBREL **AND**
- XELJANZ, TALTZ 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:

- A preferred adalimumab product or ENBREL **AND**
- XELJANZ IR **AND**
- TALTZ or OTEZLA.

Humira brand and non-preferred adalimumab agents may receive approval if meeting the following:

- The request meets one of the following:
  - The prescribed agent is a preferred adalimumab product
    OR
  - If the prescribed agent is brand Humira or a non-preferred adalimumab product, then the member has trialed and failed at least one preferred adalimumab product. Failure is defined as lack of efficacy or intolerable side effects with the preferred adalimumab product.
    AND
- The general non-preferred criteria listed below are met

Stelara brand and non-preferred ustekinumab agents may receive approval if meeting the following:

- The request meets one of the following:
  - The prescribed agent is a preferred ustekinumab product
    OR
  - If the prescribed agent is brand Stelara or a non-preferred ustekinumab product, then the member has trialed and failed at least one preferred ustekinumab product. Failure is defined as lack of efficacy or intolerable side effects with the preferred ustekinumab product.
    AND
- The general non-preferred criteria listed below are met.

USTEKINUMAB (Stelara brand/generic biosimilar agents) syringe for subcutaneous use may receive approval if meeting the following:

- The request meets one of the following:
  - The prescribed agent is one of the following favored U stekinumab products: Imuldosa, Otulfi, Pyzchiva, Selarsdi, Steqeyma, Ustekinumab (generic Stelara biosimilars), Ustekinumab-AEKN, Yesintek
    OR
  - If the prescribed agent is brand Stelara or product that is not favored Ustekinumab product, then the member has trialed and failed‡ at least one favored Ustekinumab product. **AND**
    - Member has trial and failure‡ of:
    - 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:

- A preferred adalimumab product or ENBREL **AND**
- Two other preferred products (XELJANZ, TALTZ, OTEZLA, ustekinumab)
- 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.

Continuation of therapy: Members currently taking a preferred agent may receive approval to continue therapy with that agent. Members with current prior authorization approval on file for a non-preferred agent that does not have a preferred biosimilar 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

- No Board members reported a potential conflict of interest for this therapeutic class.
- I Pan suggested that the Department consider creating some claims messaging at the point of sale to assist pharmacy teams as they select specific ustekinumab products to submit for prior authorization approval. (J Taylor confirmed that this motion would also be considered for Xeljanz quantity limit statements in subsequent Targeted Immune Modulator subclasses being reviewed during today's meeting.)
- K MacIntyre moved to accept the criteria as written. Seconded by S Cho. Motion passed with six votes in favor. T Brubaker abstained, as he was unavailable for this vote.

c. Plaque Psoriasis

Preferred agents
No PA Required (If diagnosis met)
(*Must meet eligibility criteria)
Adalimumab-aacf (CF) single-dose syringe
Adalimumab-aaty auto-injector
Adalimumab-adbm 2-pen kit
AMJEVITA (adalimumab-atto) syringe, auto-injector
CYLTEZO (adalimumab-adbm) pen, syringe
ENBREL (etanercept) Mini, SureClick pen, syringe, vial
HADLIMA (adalimumab-bwwd) Pushtouch, syringe
HUMIRA (adalimumab)
**IMULDOSA (ustekinumab-srlf) syringe
*OTEZLA (apremilast) tablet
**SELARSDI (ustekinumab-aekn) syringe
**STEQEYMA (ustekinumab-stba) syringe
*TALTZ (ixekizumab) syringe, auto-injector
TYENNE (tocilizumab-aazg) pen, syringe
YUFLYMA (adalimumab-aaty) syringe, auto-injector

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

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

Non-Preferred Agents:

Humira brand and non-preferred adalimumab agents may receive approval if meeting the following:

- The request meets one of the following:
  - The prescribed agent is a preferred adalimumab product
    OR
  - If the prescribed agent is brand Humira or a non-preferred adalimumab product, then the member has trialed and failed at least one preferred adalimumab product. Failure is defined as lack of efficacy or intolerable side effects with the preferred adalimumab product.
    AND
- The general non-preferred criteria listed below are met.

Stelara brand and non-preferred ustekinumab agents) may receive approval if meeting the following:

- The request meets one of the following:
  - The prescribed agent is a preferred ustekinumab product
    OR
  - If the prescribed agent is brand Stelara or a non-preferred ustekinumab product, then the member has trialed and failed at least one preferred ustekinumab product. Failure is defined as lack of efficacy or intolerable side effects with the preferred ustekinumab product.

AND

- The general non-preferred criteria listed below are met.

USTEKINUMAB (Stelara brand/generic and non-preferred ustekinumab biosimilar agents) may receive approval if meeting the following:

- The request meets one of the following:
  - The prescribed agent is a preferred one of the following favored U ustekinumab products: Imuldosa, Otulfi, Pyzchiva, Selarsdi, Steqeyma, Ustekinumab (generic Stelara biosimilars), Ustekinumab-AEKN, Yesintek

  OR

  - If the prescribed agent is brand Stelara or a non-preferred ustekinumab product that is not favored Ustekinumab product, then the member has trialed and failed‡ at least one favored Ustekinumab product. Failure is defined as lack of efficacy or intolerable side effects with the preferred ustekinumab product.

AND

- The general non-preferred criteria listed below are met.

AND

- Member has trial and failure‡ of one indicated first line agent (preferred adalimumab products, 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 (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.

Continuation of therapy: Members currently taking a preferred agent may receive approval to continue therapy with that agent. Members with current prior authorization approval on file for a non-preferred agent that does not have a preferred biosimilar 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

- No Board members reported a potential conflict of interest for this therapeutic class.
- S Cho moved to change the paragraph that begins "All other non-preferred agents may receive approval…" to say "AND two second line agents (TALTZ, OTEZLA, or a preferred ustekinumab product)." Seconded by S Klocke. Motion passed unanimously, as T Brubaker was able to return to the meeting for this vote.
- I Pan noted that the biosimilar TYENNE (tocilizumab-aazg) is included as a preferred agent in this subclass even though it does not have an FDA indication for plaque psoriasis. Additionally, on the current PDL, the list of non-preferred agents for this subclass includes Orencia (abatacept); however, it does not have an FDA-approved indication for plaque psoriasis.
- S Cho moved to accept the criteria as amended. Seconded by I Pan. Motion passed unanimously.

d. Crohn's Disease and Ulcerative Colitis

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

Adalimumab-aacf (CF) single-dose syringe
Adalimumab-aaty auto-injector
Adalimumab-adbm 2-pen kit
AMJEVITA (adalimumab-atto) syringe, auto-injector
CYLTEZO (adalimumab-adbm) pen, syringe
HADLIMA (adalimumab-bwwd) Pushtouch, syringe
HUMIRA (adalimumab)
IMULDOSA (ustekinumab-srlf) syringe
SELARSDI (ustekinumab-aekn) syringe
STEQEYMA (ustekinumab-stba) syringe
*XELJANZ IR (tofacitinib) tablet
XELJANZ XR (tofacitinib) tablet
YUFLYMA (adalimumab-aaty) syringe, auto-injector

Preferred agents (preferred adalimumab products, preferred ustekinumab 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 for Crohn's Disease:

Humira brand and non-preferred adalimumab agents may receive approval if meeting the following:

- The request meets one of the following:
  - The prescribed agent is a preferred adalimumab product
    OR
  - If the prescribed agent is brand Humira or a non-preferred adalimumab product, then the member has trialed and failed at least one preferred adalimumab product. Failure is defined as lack of efficacy or intolerable side effects with the preferred adalimumab product.
    AND
- The general non-preferred criteria listed below are met.

Stelara brand and non-preferred ustekinumab agents may receive approval if meeting the following:

- The request meets one of the following:
  - The prescribed agent is a preferred ustekinumab product
    OR
  - If the prescribed agent is brand Stelara or a non-preferred ustekinumab product, then the member has trialed and failed at least one preferred ustekinumab product. Failure is defined as lack of efficacy or intolerable side effects with the preferred ustekinumab product.
    AND
- The general non-preferred criteria listed below are met.

USTEKINUMAB (Stelara brand/generic biosimilar agents) syringe for subcutaneous use may receive approval if meeting the following:

- The request meets one of the following:

- The prescribed agent is one of the following favored U stekinumab products: Imuldosa, Otulfi, Pyzchiva, Selarsdi, Steqeyma, Ustekinumab (generic Stelara biosimilars), Ustekinumab-AEKN, Yesintek
  OR
- If the prescribed agent is brand Stelara or product that is not favored Ustekinumab product, then the member has trialed and failed‡ at least one favored Ustekinumab product. **AND**
  - Member has trial and failure‡ of:
  - 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 FDA-labeled indications if meeting the following:

- The requested medication is being prescribed for treating moderately-to-severely active Crohn's disease 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 **AND** one preferred ustekinumab product.

Non-Preferred Agents for Ulcerative Colitis:

Humira brand and non-preferred adalimumab agents may receive approval if meeting the following:

- The request meets one of the following:
  - The prescribed agent is a preferred adalimumab product
    OR
  - If the prescribed agent is brand Humira or a non-preferred adalimumab product, then the member has trialed and failed at least one preferred adalimumab product. Failure is defined as lack of efficacy or intolerable side effects with the preferred adalimumab product.
    AND
- The general non-preferred criteria listed below are met.

Stelara brand and non-preferred ustekinumab agents may receive approval if meeting the following:

- The request meets one of the following:
  - The prescribed agent is a preferred ustekinumab product
    OR
  - If the prescribed agent is brand Stelara or a non-preferred ustekinumab product, then the member has trialed and failed at least one preferred ustekinumab product. Failure is defined as lack of efficacy or intolerable side effects with the preferred ustekinumab product.
    AND
- The general non-preferred criteria listed below are met.

USTEKINUMAB (Stelara brand/generic biosimilar agents) syringe for subcutaneous use may receive approval if meeting the following:

- The request meets one of the following:

- The prescribed agent is one of the following favored U stekinumab products: Imuldosa, Otulfi, Pyzchiva, Selarsdi, Steqeyma, Ustekinumab (generic Stelara biosimilars), Ustekinumab-AEKN, Yesintek
  OR
- If the prescribed agent is brand Stelara or product that is not favored Ustekinumab product, then the member has trialed and failed‡ at least one favored Ustekinumab product. **AND**
  - Member has trial and failure‡ of:
  - 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.

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 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 ulcerative colitis, member has trial and failure‡ of:
  - One preferred adalimumab product orand XELJANZ IR **AND**
  - One preferred ustekinumab product.

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 two preferred adalimumab products **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 or for treating moderate-to-severely ulcerative colitis **AND**
- Member is ≥ 18 years of age **AND**
- Request meets one of the following based on prescribed indication:

  - 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/1.2mL prefilled cartridge every 8 weeks.

USTEKINUMAB (Stelara brand/generic and biosimilar agents) syringe for subcutaneous use may receive approval if meeting the following:

- The request meets one of the following:
  - The prescribed agent is one of the following favored Ustekinumab products: Imuldosa, Otulfi, Pyzchiva, Selarsdi, Steqeyma, Ustekinumab (generic Stelara biosimilars), Ustekinumab-AEKN, Yesintek
  OR
  - If the prescribed agent is brand Stelara or a product that is not favored Ustekinumab product, then the member has trialed and failed‡ at least one favored Ustekinumab product

AND

- The requested medication is being prescribed for use for treating moderately-to-severely active Crohn's disease or for treating moderately-to-severely active ulcerative colitis **AND**
- Request meets one of the following based on prescribed indication:
  - 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 ustekinumab for maintenance therapy using the above criteria should be avoided and will not result in an automatic approval of ustekinumab 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.

Continuation of therapy: Members currently taking a preferred agent may receive approval to continue therapy with that agent. Members with current prior authorization approval on file for a non-preferred agent that does not have a preferred biosimilar 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

- No Board members reported a potential conflict of interest for this therapeutic class.
- S Cho moved to change the failure definition for this subclass to say "Note that trial and failure of Xeljanz" so that both the IR and XR formulations are included. Seconded by S Klocke. Motion passed unanimously.
- I Pan moved to accept the criteria as amended. Seconded by T Brubaker. Motion passed unanimously.

e. Asthma

Preferred agents

PA Required (*Must meet eligibility criteria)

*DUPIXENT (dupilumab) pen, syringe
*FASENRA (benralizumab) pen
*TEZSPIRE (tezepelumab-ekko) pen
*XOLAIR (omalizumab) syringe, auto-injector

*Preferred products (Dupixent, Fasenra, Tezspire, Xolair) 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)

***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

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

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

***XOLAIR (omalizumab)** 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.

Continuation of therapy: Members currently taking a preferred agent may receive approval to continue therapy with that agent. Members with current prior authorization approval on file for a non-preferred agent that does not have a preferred biosimilar may receive approval for continuation of therapy with the prescribed agent.

Discussion

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

f. Atopic Dermatitis

Preferred agents

(*Must meet eligibility criteria)

*ADBRY (tralokinumab-ldrm) syringe, auto-injector
*DUPIXENT (dupilumab) pen, syringe

*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

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)

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‡ the following agents:
  - One medium potency to very-high potency topical corticosteroid (such as mometasone furoate, betamethasone dipropionate, or fluocinonide) **AND**
  - One topical calcineurin inhibitor (such as pimecrolimus and tacrolimus) **AND**
  - Opzelura (ruxolitinib) topical cream

  AND
- Member has trialed and failed‡ therapy with two preferred agents for the prescribed indication

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.

Continuation of therapy: Members currently taking a preferred agent may receive approval to continue therapy with that agent. Members with current prior authorization approval on file for a non-preferred agent that does not have a preferred biosimilar 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

- No Board members reported a potential conflict of interest for this therapeutic class.
- S Klocke moved to consolidate or add more information to the trial and failure steps included in the non-preferred agents section, particularly by adding the names of two preferred agents in bullet point 3, to make the criteria more clear. Seconded by L Claus. Motion passed unanimously.
- B Jackson moved to restore rheumatologists to the list of subspecialists included in the non-preferred agents section. Seconded by I Pan. Motion passed with six votes in favor. T Brubaker abstained, as he was unavailable for this vote.
- I Pan noted that topical calcineurin inhibitors and topical ruxolitinib are not approved to treat patients who are less than 2 years of age. J Taylor confirmed that situations involving members <2 years of age would fall under the current failure definition for this subclass.
- I Pan suggested that, for consistency, the Department remove the phrase "Approval: One year" in the Non-Preferred Agents section.
- S Cho moved to accept the criteria as amended. Seconded by K MacIntyre. Motion passed unanimously.

g. Other indications

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

*DUPIXENT (dupilumab) pen, syringe
ENBREL (etanercept) Mini, SureClick pen, syringe, vial
*FASENRA (benralizumab) pen
HUMIRA (adalimumab)
*KEVZARA (sarilumab) pen, syringe
*OTEZLA (apremilast) tablet
*TYENNE (tocilizumab-aazg)
*XOLAIR (omalizumab) syringe, auto-injector

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

Bullous Pemphigoid

- Member is 18 years of age or older **AND**
- Member is diagnosed with Bullous Pemphigoid **AND**

- Member has trialed and failed‡ one of the following therapies:
  - High-potency topical corticosteroid
  - Oral prednisone
  - Doxycycline

Chronic Idiopathic Spontaneous Urticaria

- Member is 12 years of age or older **AND**
- Member is diagnosed with chronic idiopathic spontaneous 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

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 ≥ 300150 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 OR 1 severe COPD exacerbation 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 for 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 medication

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)** may be approved for the treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).

***KEVZARA (sarilumab)** treatment of adult patients with polymyalgia rheumatica who have had an inadequate response to corticosteroids or who cannot tolerate corticosteroid taper.

***OTEZLA (apremilast)** treatment of adult patients with oral ulcers associated with Behçet's Disease.

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

***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 Spontaneous 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 (preferred adalimumab products, ENBREL, OTEZLA) 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:
    - Cryopyrin-associated periodic syndrome: 600 mg (4mL) every 8 weeks
    - All other indications: 300 mg (2mL) 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):

Maintenance Treatment of COPD

- Member is 18 years of age or older **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**
- Medication is being prescribed by or in consultation with a pulmonologist or allergist **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 COPD exacerbations OR 1 severe exacerbation during the past 12 months **AND**
- Member has trialed and failed‡ therapy with Dupixent (dupilumab).

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 has trialed and failed‡ Fasenra (benralizumab) **AND**
- Dose of NUCALA (mepolizumab) 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.

Continuation of therapy: Members currently taking a preferred agent may receive approval to continue therapy with that agent. Members with current prior authorization approval on file for a non-preferred agent that does not have a preferred biosimilar may receive approval for continuation of therapy with the prescribed agent.

Note: Prior authorization requests for agents 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

- No Board members reported a potential conflict of interest for this therapeutic class.
- S Klocke suggested that the Department remove the reference to the current Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines, since specific guidelines are not usually included in PDL criteria sets.
- S Cho moved to approve the criteria as written. Seconded by B Jackson. Motion passed unanimously.

8. Inhaled Antibiotics (pulled out of mass review)

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*			

Written Testimony

Cystic Fibrosis Foundation National Office

Discussion

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

Mass review drug classes*

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

8. Inhaled Antibiotics
(Reviewed above - pulled out of mass review)

9. 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[BNR] (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)

10. Antihistamine/Decongestant Combinations

Preferred agents
Cetirizine-pseudoephedrine ER (OTC) tablet
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. Oral Fluoroquinolones

Preferred agents
No PA Required (*if meeting eligibility criteria)
*CIPRO (ciprofloxacin) oral suspension[BNR]
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.

12. Intranasal Rhinitis Agents

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

13. 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.

14. Methotrexate Products

Preferred agents
Methotrexate 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.

15. Newer Generation Antihistamines

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.

16. Phosphodiesterase Inhibitors (PDEIs)

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 a potential conflict of interest within the Mass Review section.
- I Pan noted that brand Dymista (azelastine/ fluticasone) has been discontinued by the manufacturer and that will impact product availability for that preferred agent.
- I Pan moved to add a fourth bullet to the Levofloxacin Solution section in the Oral Fluroquinolones class to allow for members 6 months of age or older who are being treated for fever in the setting of chemotherapy-induced neutropenia without trial and failure of ciprofloxacin. Seconded by L Claus. Motion passed with five votes in favor. S Klocke was opposed. T Brubaker abstained, as he was unavailable for this vote.
- B Jackson moved to accept the criteria as amended. Seconded by S Cho. Motion passed with six votes in favor. T Brubaker abstained, as he was unavailable for this vote.

Proposed Criteria Changes for Designated PDL Non-Preferred Products Not Undergoing Full PDL Drug Class Review

1. Review of Proposed Changes to Zepbound (tirzepatide) Non-Preferred Drug Criteria

ZEPBOUND (tirzepatide) may be approved if the following criteria are met:

Initial Authorization:

1. Member is 18 years of age or older AND
2. Member has a documented diagnosis of moderate to severe obstructive sleep apnea (OSA) AND
3. Member has a BMI ≥30 kg/m^2 indicating obesity documented in medical chart notes AND
4. Diagnosis of OSA is confirmed by a sleep test that is approved by the Food and Drug Administration (FDA) as a diagnostic device AND
5. A polysomnogram has been performed at baseline with a documented result of Apnea-Hypopnea Index (AHI) ≥15 events/hour (submission of sleep study documentation required) AND
6. Member is not pregnant or planning to become pregnant AND
7. Member has been counseled regarding the risk of medullary thyroid cancer (MTC) with the use of Zepbound (tirzepatide) and does not have a personal or family history of MTC or Multiple Endocrine Neoplasia syndrome type 2 (MEN 2) AND
8. The requested medication is being prescribed by or in consultation with a neurologist, pulmonologist, otolaryngologist, or other sleep medicine specialist
   AND
9. Member has been counseled regarding and is engaged in implementation of lifestyle interventions (diet modification and exercise) to promote weight loss AND
10. Member has failed a 6-month trial of continuous positive airway pressure (CPAP) or has a contraindication to the use of PAP therapy.

Reauthorization:

Reauthorization for one year may be approved if meeting the following criteria:

1. Member has previous PA approval on file (requests for members that do not have a historic PA approval on file will be subject to meeting "Initial Authorization" criteria listed above) AND
2. Prescriber attests that an in-person clinical re-evaluation of OSA from baseline has been performed by the treating practitioner AND
3. Clinical improvement in OSA symptoms has been documented in clinical chart notes AND
4. Adherence to use of Zepbound (tirzepatide) regimen has been evaluated by the treating practitioner.

2. Review of Proposed Changes to Continuation of Therapy Criteria for GLP-1 Analogue Non-Preferred Drugs

Glucagon-like Peptide-1 Receptor Agonists (GLP-1 Analogues)

Continuation of therapy: Members that are currently stabilized on a non-preferred product may receive approval for continuation of therapy with that product.

Continuation of therapy: Members that are currently stabilized on therapy with Mounjaro (tirzepatide) 7.5 mg, 10 mg or 15 mg strengths may receive approval for continuation of therapy with that product strength.

Discussion

- No Board members reported a potential conflict of interest for the GLP-1 analogues class.
- S Klocke moved to accept the criteria as written. Seconded by T Brubaker. Motion passed with six votes in favor. B Jackson abstained, as he had to leave the meeting for meet another obligation.

Proposed Coverage Criteria for Non-PDL Products

1. Kerendia (finerenone)

Kerendia (finerenone) may be approved if the following criteria are met:

- Member meets the following criteria based on prescribed indication:

Chronic Kidney Disease with T2DM:

- Member is ≥ 18 years of age AND
- Member has a diagnosis of chronic kidney disease associated with type 2 diabetes and both of the following:
  - Urinary albumin-to-creatinine ratio > 30 mg/day
  - eGFR ≥ 25 mL/min/1.73m^2

  AND
- Member is receiving concomitant therapy with either a maximally tolerated ACE inhibitor or ARB unless member has trialed and failed at least 30 days of an ACE inhibitor or ARB therapy or has an allergy, intolerance, or contraindication AND
- Members with an eGFR >20 mL/min/1.73m^2 are receiving concomitant therapy with a SGLT2 Inhibitor, unless member has an allergy, intolerance, or contraindication to a SGLT2 inhibitor AND
- Provider attests that serum potassium is <5 mEq/L prior to initiation of therapy AND that serum potassium will be monitored.

Heart Failure with Preserved or Mid-Range Ejection Fraction:

- Member is 18 years of age or older AND
- Member has a diagnosis of heart failure with preserved or mid-range ejection fraction (LVEF ≥ 40%) with NYHA class II-IV and meets all of the following:
  - Member has trialed and failed spironolactone or eplerenone. Failure is defined as lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction AND
  - Members with an eGFR >20 mL/min/1.73m^2 are receiving therapy with a preferred SGLT2 inhibitor, unless member has an allergy, intolerance, or contraindication AND
  - Member has had at least one prior hospitalization for worsening heart failure.

Maximum dose: 20 mg/day

Maximum quantity: 30 tablets/month

Continuation of therapy: Members who have been previously stabilized on Kerendia (finerenone) may receive approval to continue the medication.

Scheduled Speaker Testimony
P Patel – Bayer

Written Testimony
Kerendia - Bayer

Discussion

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

2. Brinsupri (brensocatib)

Brinsupri (brensocatib) may be approved if the following criteria are met:

1. Member is ≥12 years of age **AND**
2. Member has a diagnosis of bronchiectasis **AND**
3. Member does not have cystic fibrosis **AND**
4. Member will be monitored for dermatologic adverse reactions, including rash, dry skin, and hyperkeratosis **AND**
5. Member will be monitored for gingival and periodontal adverse reactions and referred to dental care services while taking Brinsupri (brensocatib) **AND**
6. Member has received counseling to not receive any live attenuated vaccines while receiving Brinsupri (brensocatib) and for two weeks after Brinsupri (brensocatib) therapy is discontinued **AND**
7. Requested medication is being prescribed by or in consultation with a pulmonologist or infectious disease specialist **AND**
8. Member meets ONE of the following:
    a. Member is 12 to 17 years of age with at least one pulmonary exacerbation in the last 12 months that resulted in the prescription of an antibiotic agent
    OR
    b. Member is ≥ 18 years of age and has had at least two pulmonary exacerbations in the last 12 months that resulted in the prescription of an antibiotic agent.

Maximum dose: 25 mg/day

Maximum quantity: 30 tablets/30 days

Scheduled Speaker Testimony
S Andes – Insmed

Written Testimony
Brinsupri - Insmed

Discussion

- No Board members reported a potential conflict of interest for this product.
- K MacIntyre moved to accept the criteria as written. Seconded by T Brubaker. Motion passed unanimously.

3. Wayrilz (rilzabrutinib)

Wayrilz (rilzabrutinib) may be approved if the following criteria are met:

1. Member is ≥18 years of age **AND**
2. Member has a diagnosis of persistent or chronic immune thrombocytopenia (ITP) **AND**
3. Member's degree of thrombocytopenia and clinical condition increase the risk for bleeding as demonstrated by a baseline platelet count within the past 28 days of less platelet count of ≤ 30,000/mm^3 **AND**
4. Member does not have severe renal impairment (CrCl <46 mL/min) **AND**
5. Member has had bilirubin and hepatic transaminases drawn at baseline **AND**
6. Member does not have moderate or severe hepatic impairment **AND**
7. Prescriber is aware that Wayrilz (rilzabrutinib) may increase the risk of severe and potentially life-threatening hepatotoxicity and that hepatic function must be monitored before and during therapy **AND**
8. Member is not pregnant or breastfeeding **AND**

9. Requested medication is being prescribed by a hematologist **AND**
10. Member has had an insufficient response to corticosteroids, immunoglobulins, or splenectomy **AND**
11. Member has trial and failure of Promacta (eltrombopag) or rituximab. Failure is defined as a lack of efficacy, allergy, intolerable side effects, or significant drug-drug interactions **AND**
12. Member will be monitored for signs and symptoms of infection and treated appropriately if needed **AND**
13. Member has received counseling to avoid the use of proton pump inhibitors and to take Wayrilz (rilzabrutnib) tablets at least 2 hours before doses of antacid or histamine H2 receptor antagonists AND that Wayrilz (rilzabrutnib) tablets should not be split, chewed, or crushed.

Maximum dose: 800 mg/day

Maximum quantity: 60 tablets/30 days

Initial approval: Initial prior authorization approval will be granted for 6 months

Reauthorization: Reauthorization approval for one year with verification of documented durable platelet count response, defined as:

- Platelet count ≥50 x 10^9/L (50,000/mm^3)
  OR
- Platelet count between 30 × 10^9/L (30,000/mm^3) and <50 × 10^9/L (50,000/mm^3) AND at least doubled from baseline in the absence of rescue therapy

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

Scheduled Speaker Testimony
K Chang – Sanofi

Discussion

- No Board members reported a potential conflict of interest for this product.
- Criteria were verbally presented by Z Ghafoori, who acknowledged that bullet point 3 will be corrected to say, "Member's degree of thrombocytopenia and clinical condition increase the risk for bleeding as demonstrated by a baseline platelet count within the past 28 days of ≤30,000/mm^3" **AND**
- S Klocke moved to accept the criteria as corrected. Seconded by K MacIntyre. Motion passed unanimously.

4. Blujepa (gepotidacin)

Blujepa (gepotidacin) may be approved if the following criteria are met:

1. Member is female and ≥12 years of age **AND**
2. Member weighs at least 40 kg **AND**
3. Member has a diagnosis of uncomplicated UTI proven or strongly suspected to be caused by *E. coli, K. pneumoniae, Citrobacter freundii complex (CFC), S. saprophyticus or E. faecalis* **AND**
4. Member does not have severe renal impairment (eGFR <30 mL/min) and is not receiving dialysis **AND**
5. Member does not have severe hepatic impairment (Child-Pugh Class C) **AND**
6. Member has tried and failed‡ treatment with three of the following:
   a. Ciprofloxacin
   b. Fosfomycin
   c. Levofloxacin
   d. Nitrofurantoin
   e. Sulfamethoxazole-trimethoprim

AND

7. Medication is being prescribed by or in consultation with an infectious disease specialist **AND**
8. Member has received counseling to take Bluejepa (gepotidacin) tablets after a meal to reduce stomach upset.

Maximum dose: 3,000 mg/day

Maximum quantity: 20 tablets per 5-day treatment course

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

Discussion

- No Board members reported a potential conflict of interest for this product.
- I Pan moved to accept the criteria as written. Seconded by T Brubaker. Motion passed unanimously.

5. Orlynvah (sulopenem etzadroxil/probenecid)

Orlynvah (sulopenem etzadroxil/probenecid) may be approved if the following criteria are met:

1. Member is female and ≥18 years of age **AND**
2. Member has a diagnosis of uncomplicated UTI proven or strongly suspected to be caused by *E. coli, K. pneumoniae or P. mirabilis* **AND**
3. Member has tried and failed‡ treatment with three of the following:
    - Ciprofloxacin
    - Fosfomycin
    - Levofloxacin
    - Nitrofurantoin
    - Sulfamethoxazole-trimethoprim

    AND
4. Member does not have a known blood dyscrasia **AND**
5. Member does not have known uric acid kidney stones **AND**
6. Member does not have a history of hypersensitivity to beta-lactam antibiotics **AND**
7. Member is not receiving any products that contain ketorolac or ketoprofen **AND**
8. Member does not have severe renal impairment (CrCl <15 mL/min) and is not receiving dialysis **AND**
9. If member has a known history of gout, provider attests that appropriate therapy of gout has been instituted **AND**
10. Medication is being prescribed by or in consultation with an infectious disease specialist

Maximum dose: 2 tablets/day

Maximum quantity: 10 tablets per 5-day treatment course

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

Discussion

- No Board members reported a potential conflict of interest for this product.
- K MacIntyre moved to accept the criteria as written. Seconded by T Brubaker. Motion passed unanimously.

6. Targeted Immune Modulators

IV and Physician-Administered Product Formulations Containing: abatacept, certolizumab, golimumab, infliximab, mepolizumab, mirikizumab, omalizumab, risankizumab, rituximab, secukinumab, spesolimab, tocilizumab, ustekinumab, vedolizumab

INFLIXIMAB (Remicade brand/generic and biosimilar products) **IV injection** may be approved if meeting the following criteria:

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

  AND
- The request meets one of the following:
  - The prescribed infliximab agent is Renflexis (infliximab-abda) OR
  - If the prescribed agent is brand Remicade or a biosimilar other than an infliximab product formulation other than Renflexis, then the member has trialed and failed Renflexis. Failure is defined as lack of efficacy or intolerable side effects with the preferred infliximab product formulation. if the prescribed infliximab agent is Remicade or a biosimilar other than Renflexis, then the member has trialed and failed Renflexis

  AND
- The member meets one of the following, based on prescribed indication:
  - For continuation of infliximab therapy that was initiated in the hospital setting for treating severe ulcerative colitis, no additional medication trial is required OR
  - For treatment of moderate to severe hidradenitis suppurativa, no additional medication trial is required OR
  - For all other prescribed indications, the member has trialed and failed‡ all preferred agents in the Targeted Immune Modulators PDL drug class that are FDA labeled for use for the prescribed indication (with only one preferred TNF inhibitor trial required).

Infliximab Maximum Dose: 10 mg/kg

Prior authorization requests for pharmacy benefit coverage of all other products included in the "Targeted Immune Modulator IV and Physician-Administered Products" category may be approved if meeting the following criteria:

- For billing under the pharmacy benefit, the prescriber confirms that the medication is being administered by a healthcare professional in the member's home or in a long-term care facility AND
- The requested medication is being prescribed for an FDA-labeled indicated use AND
- The request meets one of the following:
  - The request meets criteria listed on the Preferred Drug List (PDL) in the "Targeted Immune Modulators" drug class for the product ingredient name for the prescribed indication (see PDL "Targeted Immune Modulators" at https://hcpf.colorado.gov/pharmacy-resources#PDLP) OR
  - For products that do not have criteria listed for the product name on the PDL in the "Targeted Immune Modulators" drug class for the prescribed indication, no additional criteria apply.

ACTEMRA (tocilizumab) **IV injection** and biosimilar formulations (Tyenne, Tofidence) may be approved if meeting the following criteria:

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

Maximum Dose: 800 mg per infusion for cytokine release syndrome (CRS) or rheumatoid arthritis; and 162 mg once weekly for other indications

CIMZIA (certolizumab pegol) **lyophilized powder for reconstitution** may be approved if meeting the following criteria:

- For billing under the pharmacy benefit, the medication is being administered by a healthcare professional in the member's home or in a long-term care facility AND
- The requested medication is being prescribed for use for an FDA-labeled indication (per product package labeling) AND
- The member has trialed and failed† all preferred agents in the Targeted Immune Modulators PDL drug class that are FDA labeled for use for the prescribed indication (with only one preferred TNF inhibitor trial required).

Members currently receiving subcutaneous injections of CIMZIA from a health care professional using the lyophilized powder for injection dosage form may receive approval to continue therapy with that agent.

COSENTYX (secukinumab) **IV injection** may be approved if meeting the following:

- For billing under the pharmacy benefit, the medication is being administered by a healthcare professional in the member's home or in a long-term care facility AND
- Request meets criteria listed for Cosentyx (secukinumab) on the Health First Colorado Preferred Drug List (PDL) for the requested FDA-approved indication.

ENTYVIO (vedolizumab) **IV injection** may be approved if meeting the following criteria:

- If billing under the pharmacy benefit, the medication is being administered in the member's home or in a long-term care facility AND
- The member is ≥ 18 years of age with moderately-to-severely active ulcerative colitis or moderately-to-severely active Crohn's disease AND
- The member has had an inadequate response with, is intolerance to, or had demonstrated dependence on corticosteroids AND
- The member is not receiving Entyvio (vedolizumab) in combination with Cimzia, Enbrel, Humira, infliximab, Simponi or Tysabri AND

For Members Treating Crohn's Disease:

- Entyvio (vedolizumab) is initiated and titrated per FDA-labeled dosing for Crohn's disease AND
- The member meets one of the following:
  - The member has trialed and failed‡ therapy with Humira (adalimumab) or an infliximab-containing product (such as Renflexis) OR
  - The member is ≥ 65 years of age with increased risk of serious infection

For Members Treating Ulcerative Colitis:

- Entyvio (vedolizumab) is initiated and titrated per FDA-labeled dosing for ulcerative colitis AND
- The member meets one of the following:

- The member has trialed and failed‡ therapy with Humira (adalimumab) or Simponi (golimumab) or an infliximab-containing product (such as Renflexis) OR
- The member is ≥ 65 years of age with increased risk of serious infection.

FASENRA (mepolizumab) **prefilled syringe** formulation may be approved if meeting the following:

- For billing under the pharmacy benefit, the medication is being administered by a healthcare professional in the member's home or in a long-term care facility AND
- Request meets all criteria listed for FASENRA (mepolizumab) on the Health First Colorado Preferred Drug List (PDL) for the requested indication.

Members currently receiving subcutaneous injections of FASENRA (mepolizumab) from a health care professional using the prefilled syringe formulation may receive approval to continue therapy with that agent.

NUCALA (mepolizumab) **lypholized powder vial for injection** may be approved if meeting the following:

- For billing under the pharmacy benefit, the medication is being administered by a healthcare professional in the member's home or in a long-term care facility AND
- Request meets criteria listed for NUCALA (mepolizumab) on the Health First Colorado Preferred Drug List (PDL) for the requested indication.

Members currently receiving subcutaneous injections of NUCALA (mepolizumab) from a health care professional using the lyophilized powder vial for injection may receive approval if meeting reauthorization criteria.

OMVOH (mirikizumab-mrkz) **IV injection** may be approved if meeting the following:

- For billing under the pharmacy benefit, the medication is being administered by a healthcare professional in the member's home or in a long-term care facility AND
- Request meets criteria listed for Omvoh (mirikizumab-mrkz) on the Health First Colorado Preferred Drug List (PDL) for the requested FDA-approved indication.

ORENCIA (abatacept) **IV injection** may be approved if meeting the following criteria:

- For billing under the pharmacy benefit, the medication is being administered by a healthcare professional in the member's home or in a long-term care facility AND
- The request meets one of the following:
  - Member has a diagnosis of moderate to severe rheumatoid arthritis or polyarticular juvenile idiopathic arthritis (pJIA) AND has trialed and failed* all preferred agents in the "Targeted Immune Modulators" PDL drug class that are FDA-labeled for use for the prescribed indication OR
  - Member is an adult with a diagnosis of psoriatic arthritis AND has trialed and failed‡ Humira or Enbrel AND Xeljanz IR AND Taltz or Otezla OR
  - The requested medication is being prescribed for the prophylaxis of acute graft versus host disease (aGVHD) in combination with a calcineurin inhibitor and methotrexate in patients undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated-donor.

RITUXAN (rituximab**) IV and subcutaneous injection** may be approved for administration in a long-term care facility or in a member's home by a home healthcare provider AND for members who meet one of the following:

- Have diagnosis of moderate to severe rheumatoid arthritis AND have tried and failed both Enbrel and Humira OR
- Have diagnosis of chronic lymphocytic leukemia OR
- Have a diagnosis of Non-Hodgkins Lymphoma OR

- Have a diagnosis of pemphigus vulgaris (PV) OR
- Have a diagnosis of multiple sclerosis.

SIMPONI (golimumab) **IV injection (Simponi Aria)** may be approved if meeting the following criteria:
- For billing under the pharmacy benefit, the medication is being administered by a healthcare professional in the member's home or in a long-term care facility **AND**
- The request meets one of the following:
  - Member has a diagnosis of moderate to severe rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, or ankylosing spondylitis AND has trialed and failed‡ all preferred agents in the "Targeted Immune Modulators" PDL drug class that are FDA-labeled for use for the prescribed indication OR
  - Member is an adult with a diagnosis of psoriatic arthritis AND has trialed and failed‡ Humira or Enbrel AND Xeljanz IR AND Taltz or Otezla.

SPEVIGO (spesolimab) **IV injection** may be approved if meeting the following criteria:
- Medication is being administered in the member's home or in a long-term care facility by a healthcare professional AND
- Member is 12 years of age and older and weighing at least 40 kg AND
- Member is experiencing a generalized pustular psoriasis (GPP) flare AND
- Member has previously tried and failed‡ two of the following: oral cyclosporine, infliximab-containing product, adalimumab-containing product, or etanercept.

Dosing Limit: 2700mg/90 days (900mg per submitted claim)

SKYRIZI (risankizumab) **IV injection** may be approved if meeting the following criteria:
- For billing under the pharmacy benefit, the medication is being administered by a healthcare professional in the member's home or in a long-term care facility AND
- Member is ≥ 18 years of age AND
- The requested medication is being prescribed for induction dosing for moderately-to-severely active Crohn's disease AND
- The member has trialed and failed† all preferred agents in the Targeted Immune Modulators PDL drug class that are FDA-labeled for use for the prescribed indication (Humira).

TEZSPIRE (tezepelumab-ekko) **vial and pre-filled syringe** formulations may be approved if the following criteria are met (note: criteria for self-administered pre-filled pen formulation is located on Health First Colorado Preferred Drug List (PDL)):
- For billing under the pharmacy benefit, the medication is being administered by a healthcare professional in the member's home or in a long-term care facility AND
- Member is 12 years of age or older AND
- Member has a diagnosis of severe asthma that is uncontrolled or inadequately controlled as demonstrated by 2 or more asthma exacerbations requiring use of oral or systemic corticosteroids and/or hospitalizations and/or ER visits in the year prior to medication initiation AND
- The requested medication is being administered as add-on therapy (not monotherapy) AND
- Member is taking a high dose inhaled corticosteroid and a long-acting beta agonist AND
- The requested medication will not be used in concomitantly with other biologics indicated for asthma AND
- Member is not taking maintenance oral corticosteroids AND
- Member has documented baseline FEV1.

Reauthorization may be approved if member has shown clinical improvement as documented by one of the following:
- Improvement in lung function, measured in FEV1 OR

- Reduction in the number of asthma exacerbations, defined as a decrease in use of oral or systemic corticosteroids and/or reduced asthma related hospitalizations and/or ER visits.

Members currently stabilized on a Tezspire (tezepelumab-ekko) regimen that was initiated prior to 1/1/2023 may receive prior authorization approval for continuation of therapy.

Maximum Dose: 210 mg once every 4 weeks

USTEKINUMAB (Stelara brand/generic and biosimilar agents) **IV injection** may be approved if meeting the following criteria:

- For billing under the pharmacy benefit, the requested medication is being administered by a healthcare professional in the member's home or in a long-term care facility AND
- The request meets one of the following:
  - The prescribed agent is one of the following favored ustekinumab products when available in IV formulation: Imuldosa, Otulfi, Pyzchiva, Selarsdi, Steqeyma, Ustekinumab (generic Stelara), Ustekinumab-AEKN, Yesintek OR
  - If the prescribed ustekinumab IV agent is a product that is not a favored ustekinumab IV product, then the member has trialed and failed‡ at least one favored ustekinumab IV product AND
- Prescriber acknowledges that loading dose administration prior to approval of ustekinumab IV should be avoided and will not result in an automatic approval of ustekinumab for maintenance therapy AND
- Request meets the following based on prescribed indication for treatment:
  - If administered for Crohn's disease or Ulcerative Colitis:
    - The member has a diagnosis of moderate-to-severely active Crohn's disease or moderate-to-severely active ulcerative colitis AND
    - The 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
    - Prior authorization approval may be given for an initial 16-week supply and authorization approval for continuation may be provided based on clinical response.
  - If administered for psoriatic arthritis:
    - Member has trial and failure‡ of the following:
      - 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 course and authorization approval for continuation may be provided based on clinical response.
  - If administered for plaque psoriasis:
    - Member has trial and failure‡ of the following:
      - A preferred adalimumab product or ENBREL AND
      - TALTZ AND
      - OTEZLA

      AND
    - Prior authorization approval may be given for an initial 16-week course and authorization approval for continuation may be provided based on clinical response.

Maximum Dose: 520 mg initial IV dose for members weighing > 85 Kg (187 pounds)
Quantity Limit: For initial IV infusion, four 130 mg/26 mL single-dose vials

XOLAIR (omalizumab) **lypholized powder vial for injection** may be approved if meeting the following:

- For billing under the pharmacy benefit, the medication is being administered by a healthcare professional in the member's home or in a long-term care facility AND
- Request meets criteria listed for XOLAIR (omalizumab) on the Health First Colorado Preferred Drug List (PDL) for the requested indication.

Members currently receiving subcutaneous injections of XOLAIR (omalizumab) from a health care professional using the lyophilized powder vial for injection may receive approval to continue therapy with that agent.

‡Failure is defined as lack of efficacy with a three-month trial, allergy, intolerable side effects, contraindication to therapy, or significant drug-drug interaction. Trial and failure of Xeljanz IR will not be required when the requested medication is prescribed for ulcerative colitis for members ≥ 50 years of age that have an additional CV risk factor. Trial and failure of preferred TNF inhibitors will not be required when the requested medication is prescribed for pJIA in members with documented clinical features of lupus.

Discussion

- No Board members reported a potential conflict of interest for this product.
- S Klocke moved to accept the criteria as written. Seconded by I Pan. Motion passed unanimously.

7. Clemsza (clemastine fumarate)

Clemsza (clemastine fumarate) oral tablets may be approved if the following criteria are met:

1. Member is ≥12 years of age **AND**
2. Member is not breastfeeding **AND**
3. Member is not being treated for lower respiratory tract symptoms, including asthma **AND**
4. Member is not taking a monoamine oxidase inhibitor (MAOI) **AND**
5. Prescriber attests that member is unable to use an alternative generic clemastine product (other than IPG Pharmaceuticals Clemsza) and clinical justification is provided supporting that no alternative generic clemastine product can be used **AND**
6. Member has tried and failed at least three of the following (failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions):
   - Cetirizine
   - Cyproheptadine
   - Diphenhydramine
   - Fexofenadine
   - Levocetirizine
   - Loratadine

Maximum dose: 8.04 mg/day

Maximum quantity: 90 tablets/30 days

Discussion

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

8. Ertaczo (sertaconazole nitrate)

Ertaczo (sertaconazole nitrate cream) may be approved if the following criteria are met:

1. Member is ≥ 12 years of age **AND**
2. Member is immunocompetent **AND**
3. Member has a diagnosis of interdigital tinea pedis caused by *Trichophyton rubrum, Trichophyton mentagrophytes*, or *Epidermophyton floccosum* **AND**
4. Medication is being prescribed by or in consultation with a dermatologist or infectious disease specialist **AND**
5. Member has trialed and failed‡ at least three of the following (Failure is defined as lack of efficacy, allergy, intolerable side effect, or significant drug-drug interaction):
    - clotrimazole
    - miconazole
    - terbinafine
    - tolnaftate
    - ketoconazole
    - itraconazole
    - fluconazole

    AND
6. Member has been counseled to dry the affected area(s) thoroughly before application of Ertaczo (sertaconazole) cream after bathing.

‡Failure is defined as lack of efficacy with an 4-week trial, allergy, intolerable side effects, or significant drug-drug interaction.

Approval duration: 6 months

Quantity limit: one 60 gram tube/30 days

Discussion

- No Board members reported a potential conflict of interest for this product.
- K MacIntyre moved to accept the criteria as written. Seconded by T Brubaker. Motion passed unanimously.

Medical Benefit Only Review
Proposed Coverage Criteria for PAD Products Managed Under the Medical Benefit

1. Neupogen and filgrastim-containing products

FILGRASTIM (Neupogen brand/generic and filgrastim biosimilar agents) may receive approval if meeting the following:

- The prescribed agent is one of the following favored filgrastim products:
    - Granix (tbo-filgrastim)
    - Nivestym (filgrastim-aafi)

    OR
- If the prescribed agent is brand Neupogen or a filgrastim product formulation that is not a favored product, then the member has trialed and failed at least one favored filgrastim product. Failure is defined as lack of efficacy or intolerable side effects with the favored filgrastim product formulation.

2. **Neulasta** and **pegfilgrastim-containing biosimilar products**

PEGFILGRASTIM (Neulasta brand/generic and pegfilgrastim biosimilar agents) may receive approval if meeting the following:

- The prescribed agent is Ziextenzo (pegfilgrastim-bmez), the favored pegfilgrastim product,
  OR
- If the prescribed agent is brand Neulasta or a pegfilgrastim product formulation that is not a favored product, then the member has trialed and failed at least one favored pegfilgrastim product. Failure is defined as lack of efficacy or intolerable side effects with the favored pegfilgrastim product formulation.

3. **Rituxan (rituximab)** and **rituximab-containing biosimilar products**

RITUXIMAB (Rituxan brand/generic and rituximab biosimilar agents) may receive approval if meeting the following:

- The prescribed agent is one of the following favored rituximab products:
  - Ruxience (rituximab-pvvr)
  - Riabni (rituximab-arrx)
  - Truxima (rituximab-abbs)

  OR
- If the prescribed agent is brand Rituxan or a rituximab product formulation that is not a favored product, then the member has trialed and failed at least one favored rituximab product. Failure is defined as lack of efficacy or intolerable side effects with the favored rituximab product formulation.

Discussion

- No Board members reported a potential conflict of interest for these products.
- S Klocke moved to accept the criteria as written. Seconded by S Cho. Motion passed unanimously.

C. Adjournment

Board Chair Claus reminded attendees that the next Board meeting is scheduled for Tuesday, February 10, 2026, 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.

K MacIntyre moved to adjourn the meeting. Seconded by S Klocke. Motion passed unanimously and the meeting was adjourned at 4:38 pm.

Minutes prepared by Julia Rawlings, PharmD, Secretary