COLORADO
Department of Health Care Policy & Financing

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

November 8, 2022
Open Session
1:00 pm – 5:00 pm

1. Call to Order

Today's meeting was held virtually via Zoom. The meeting was called to order at 1:02 pm by L Claus, Board Vice Chair.

2. Roll Call and Introductions

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

- **Members Present:** Alison Shmerling, MD, MPH (Chair); Liza Claus, PharmD (Vice Chair); Todd Brubaker, DO; Brian Jackson, MD, MA; Patricia Lanius, BSPharm, MHA; Ken MacIntyre, DO; Ingrid Pan, PharmD, Melissa Polvi, RN
- **Members Absent:** Shilpa Klocke, PharmD
- **HCPF Pharmacy Office Staff:** Jim Leonard, PharmD; Jeffrey Taylor, PharmD, Rachele Poissant, PharmD, Veronia Guirguis-Garcia, 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
- We ask that speakers and other attendees who are not on the Board or facilitating the meeting to remain off video with microphones muted.
- Ryan Tran and Johna Thaut, University of Colorado DUR pharmacy interns, will be managing technical aspects of Zoom during the second half of today's meeting.
- Stakeholders who have signed up in advance to provide testimony will have their microphones unmuted and may turn on video at the appropriate time.
- Speakers providing testimony, and other meeting guests, are asked to keep video turned off throughout the meeting so that Board members' votes can be easily seen and tracked.

Reminders for Board Members:

- Video and microphone for Board members will be turned ON.
- If you experience technical difficulties or your connection interrupted during the meeting, please leave the meeting and use the same Zoom meeting link to be readmitted, as that usually resolves the issue.

- Two meeting binders containing DUR documents and written stakeholder testimony were sent to all Board members. Use the icon on the left that looks like a ribbon to quickly navigate to specific documents. Board members were reminded to delete these binders immediately following the meeting.
- Voting may be conducted by raising your hand and/or by verbal "ayes" and "nays," abstentions, and recusals as determined by the Board Chair and/or Vice-Chair.

4. Colorado Department of Health Care Policy and Financing Updates

J Taylor provided updates from the Department:

- DUR Board membership Updates
  - Dr. Taylor thanked Ms. Patte Lanius and Dr. Todd Brubaker for their renewed 2-year appointments to the DUR Board
  - The Board welcomes Melissa Polvi, RN, the Board's new Industry Representative. The Industry Representative serves in a non-voting role with a 1 year term.
- Follow-up report to the Board's discussion in August 2022 regarding Magellan Rx pharmacists involved in prior authorization (PA) reviews and the potential for personal or religious beliefs preventing them from conducting PA reviews in an objective manner. The Department confirmed that the Magellan Call Center has a process in place that allows for objective pharmacist review of PAs.
- Toward the end of today's meeting, and following review of proposed criteria for the PDL, we will be reviewing proposed DUR criteria for specific Physician Administered Drugs. Within the PDL section, it is possible that some therapeutic classes may be moved <u>out</u> of Mass Review during today's meeting.
- For products and drug classes *currently* managed with DUR criteria posted on the PDL, Appendix P or Appendix Y, only <u>proposed changes</u> to the currently posted criteria will be read aloud.
- Two therapeutic classes included on the agenda, *Hepatitis C-Other Agents* and *Asthma- Other Agents* were created as placeholders only and we will not be reviewing any drugs in those classes today. The Board will be reviewing Hepatitis C Direct-Acting Antivirals and Ribavirin Products, and Asthma biologic agents (a subclass of Targeted Immune Modulators).
- Dr. Taylor provided some clarification about the types of PA criteria that will be reviewed during today's meeting. Three online documents are involved:
  - <u>Preferred Drug List (PDL)</u> – preferred and non-preferred pharmaceutical options within specific therapeutic drug classes
  - <u>Appendix P</u> – medications covered by the pharmacy benefit but not included in a PDL therapeutic drug class
  - <u>Appendix Y</u> – medications covered by the Physician Administered Drug (PAD) benefit. This document includes drugs that must be administered in a physician's office or outpatient clinical setting

  There will be some overlap involving some drugs that are managed under both the pharmacy and medical benefit. "Place of service" criteria language is included for some products to ensure that these medication are being billed appropriately. A summary document was shared on screen and also included in today's meeting binder for Board members' reference.

5. Final Approval of Minutes from August 9, 2022 Meeting

Vice Chair L Claus asked if there were any changes to propose to the minutes from the August 9, 2022 DUR Board meeting. With no discussion, B Jackson moved to approve the minutes as written. Seconded by T Brubaker. A Shmerling and L Claus recused. Motion passed.

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.

Melissa Polvi, Industry Representative, disclosed her conflicts of interest related to employment by Swedish Orphan Biovitrum (Sobi), a rare disease company that has responsibility for Synagis® (palivizumab), Orfadin® (nitisinone) Kineret® (anakinra) and Doptelet® (avatrombopag).

7. Clinical Updates and General Orders

- **FDA New Product & Safety Updates**
  J Rawlings highlighted recent updates from the FDA Drug Approvals report prepared by Michael Brace, DUR Intern. A Drug Safety Update was not presented this quarter, as no FDA Drug Safety Communications have been released since the last DUR Board meeting.

- **Quarterly Clinical Modules**
  R Page presented an update on last quarter's Quarterly Clinical Module, *Psychotropic Medication Use among Pediatric and Adolescent Members of Health First Colorado*. This module suggests some differences in psychotropic utilization in Colorado members under the age of 18 who are in foster care compared to members in that age group who are not in foster care. These findings are congruent with national estimates. Providers who care for patients under 18 years of age now receive an educational letter once each quarter if any their patients enrolled in Health First Colorado have pharmacy claims for 3 or more concomitant psychotropic medications.

  The Colorado Evidence-based Drug Utilization Review team is currently working on clinical modules to evaluate the use of stimulant medications and the use of gabapentinoids, particularly in the context of opioid overdose.

- **Retrospective DUR Report**
  R Page presented the RDUR summary and referred Board members to the meeting binder for details. Colorado Health First Colorado prescribers currently receive quarterly educational letters when their patients meet one or more the following RDUR parameters:
  - Two or more benzodiazepine claims concomitantly for ≥ 90 days during the last two quarters
  - Members who received an opioid, a benzodiazepine and a skeletal muscle relaxant concomitantly for 60 or more days (excluding individuals with a diagnosis of cancer or sickle cell disease)

- Members and providers associated with claims for opioids exceeding an average of 200 MME in a 30-day period
- Members with multiple claims for opioid prescriptions that total >150 MME (averaged over 30 days) and no naloxone fill within the 12 months prior to, or during, the current quarter
- Members under age 18 years with ≥ 3 pharmacy claims for psychotropic medications during the measurement quarter

- **Quarterly Drug Utilization Reports**
  Board members were referred to these reports in the meeting binder.

8. New Business

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

- Board members will be asked if they have potential conflicts of interest to disclose prior to reviewing therapeutic drug classes or individual products listed in the meeting agenda.
- For products and drug classes currently managed with posted DUR criteria, only proposed changes to the currently posted criteria will be read aloud.
- Time is permitted for stakeholder comment. All speakers have registered in advance, and each speaker will be given up to 3 minutes of time to present.
- There will be an opportunity for Board discussion, motions and votes.

J Rawlings proceeded with the review process of proposed criteria.

Proposed Criteria

Red indicates proposed deleted text

Yellow indicates proposed new text

Conflict of Interest Check

No Board members reported a conflict of interest for any of the drug classes being reviewed today from the beginning of the therapeutic classes listed in the agenda up to the Mass Review section.

1. Hepatitis C Virus Treatments

PA Required for all agents in this class

a. Direct Acting Antivirals (DAAs)

Preferred Agents
EPCLUSA (sofosbuvir/velpatasvir) 200 mg-50 mg, 150 mg-37.5 mg tablet, pellet pack
HARVONI (ledipasvir/sofosbuvir) 45mg-200mg tablet, pellet pack
Ledipasvir/Sofosbuvir 90 mg-400 mg tablet (*Asequa only)*
MAVYRET (glecaprevir/pibrentasvir) tablet, pellet pack
Sofosbuvir/Velpatasvir 400mg-100mg (*Asequa only)*
VOSEVI 2nd Line tablet (sofosbuvir/velpatasvir/voxilaprevir)

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

- HCV treatment is being prescribed either through consultation with an expert in hepatitis C treatment OR the primary care provider attests to having received sufficient education to safely prescribe the listed hepatitis C medications **AND**
- Prescriber attests that the member has been counseled about the importance of adherence to initial therapy to treat hepatitis C **AND**
- Physician attests to meeting one of the following:
  - Member has a diagnosis of chronic HCV infection (presence of HCV RNA viral load for ≥ 6 months) OR
  - Member has a diagnosis of acute HCV infection in the setting of solid organ transplant OR
  - Prescriber wishes to treat a member with acute HCV infection upon initial diagnosis and acknowledges that the rate of spontaneous resolution of acute infection has been considered as part of assessing the need to initiate antiviral therapy (acute HCV infection may spontaneously clear in 20-50% of patients)

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

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

- Assessment of member readiness for 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.

Vosevi tablet [2nd Line] (sofosbuvir/velpatasvir/ voxilaprevir)	May be approved for members 18 years or older with chronic HCV infection who are NC, have CC (Child-Pugh A) AND meet one of the following: • GT 1-6 and has previously failed treatment with a regimen containing an NS5A inhibitor (such as ledipasvir, daclatasvir, or ombitasvir) OR • GT 1a or 3 and has previously failed treatment with a regimen containing sofosbuvir without an NS5A inhibitor AND meet the applicable criteria below for re-treatment.

(GT-Genotype, NC-Non-Cirrhotic, CC-Compensated Cirrhosis)

Dosing Limitations:
Preferred products will be limited to appropriate days' duration for initial treatment regimen. Additional fills will require prior authorization meeting re-treatment criteria above.

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

b. Ribavirin

Preferred Agents
Ribavirin capsule
Ribavirin tablet

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

Stakeholder input:

Written testimony, R Bricker-Ford, PharmD, BCIDP, BCPS, AAHIVP – Clinical Pharmacist Specialist, Hepatology & Infectious Diseases, University of Colorado Hospital
Written testimony, S Rowan, MD – Associate Director HIV and Viral Hepatitis Prevention, Public Health Institute at Denver Health

Scheduled testimony presentations:

R Bricker-Ford, PharmD – Clinical Pharmacist Specialist, Hepatology & Infectious Diseases, University of Colorado Hospital
N Rose, Epclusa – Gilead Sciences, Inc.
N Rose, Mavyret – Gilead Sciences, Inc.
N Steinfurth – Executive Director, Live Health Connection
S Rowan, MD – Assoc Director HIV & Viral Hepatitis Prevention, Public Health Institute, Denver Health

Discussion

- Medications in this therapeutic class are categorized as non-maintenance drugs and are therefore currently limited to 30-day fills. A question was asked about the possibility of approving a 90-day supply for medications in this class as compared to the current 30-day supply. Board members felt this change would be a positive step toward removing barriers to treatment, maximizing the chances for successful completion of hepatitis C therapy, and allowing for the dispensing of full initial treatment courses. Consideration would need to be given to the medication waste that might be a factor in clinical situations such as medication intolerance or lack of adherence by members who are not ready for re-treatment.
- The Board also noted that the statement, "PA Required for all agents in this class" needs to be removed from the beginning of the Hepatitis C Virus Treatments section in the final version of the criteria.
- B Jackson moved that (1) the Department evaluate 90-day supply coverage for medications in the Hepatitis C therapeutic class, and (2) that the remaining criteria be accepted as written. Seconded by K MacIntyre. Motion passed unanimously.

2. Human Immunodeficiency Virus (HIV) Treatments

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

Preferred Agents

Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs)

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

Nucleoside/Nucleotide Reverse Transcriptase Inhibitors (NRTIs)

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

Protease Inhibitors (PIs)

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

Other Agents

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

VOCABRIA (cabotegravir) tablet

Combination Agents
No PA Required*

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

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

TAF – Tenofovir alafenamide
TDF – Tenofovir disoproxil fumarate

All products are preferred and do not require prior authorization.

Scheduled testimony presentations:

N Rose, Biktarvy – Gilead Sciences, Inc.
N Rose, Descovy – Gilead Sciences, Inc.

Discussion

A Shmerling moved to accept the proposed criteria as written. Seconded by B Jackson. Motion passed unanimously.

3. Intranasal Rhinitis Agents

Preferred Agents
- Azelastine 0.15%, 0.1% (137 mcg)
- Budesonide (OTC)
- Fluticasone (RX)
- Ipratropium
- Olopatadine spray
- 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).

Discussion
- P Lanius moved to accept the proposed criteria as written. Seconded by A Shmerling. Motion passed unanimously.

4. Targeted Immune Modulators

J Taylor oriented the Board to today's review of the large Targeted Immune Modulators class. This class is divided into seven subclasses based on clinical indications. The Asthma (biologics) and Atopic Dermatitis subclasses are new this quarter. Some biologic agents in this class will be reviewed for the preferred drug list (PDL) and some will be reviewed for the Appendix P and the Appendix Y later in the meeting agenda.

Stakeholder input:

Written testimony, TIMs/Cosentyx – P Wettestad, Novartis
Written testimony, TIMs/Otezla – J Wild, Amgen

Scheduled testimony presentations:

TIMs/Cosentyx – P Wettestad, Novartis
TIMs/Rinvoq – H Freml, AbbVie
TIMs/Skyrizi – H Freml, AbbVie
TIMs/Otezla – J Wild, Amgen
TIMs/Dupixent – T Nguyen, Sanofi
TIMs – ulcerative colitis/Zeposia – P Menacherry, Bristol Myers Squibb
TIMs – asthma/Xolair – E Pfeifer, Genentech

Conflict of Interest Check

No Board members reported conflict of interests for the products in this class that had not been previously disclosed during today's meeting.

a. Rheumatoid Arthritis (RA), Polyarticular Course Juvenile Idiopathic Arthritis (JIA), and Ankylosing Spondylitis

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

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

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

COSENTYX (secukinumab) may be approved when the following criteria are met:
- Medication is being prescribed for enthesitis-related arthritis, **AND**
- Member is ≥ 4 years of age and weighs ≥15 kg, **AND**
- Member has had trialed and failed‡ NSAID therapy **AND** ENBREL (etanercept) **AND** HUMIRA (adalimumab)

ILARIS (canakinumab) may receive approval if meeting the following:
- Medication is being prescribed for systemic juvenile idiopathic arthritis (sJIA) or Adult Onset Still's Disease (AOSD), **AND**
- Member has trialed and failed‡ KINERET (anakinra) **AND** ACTEMRA (tocilizumab)

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

KINERET (anakinra) may receive approval for:
- FDA-labeled indications following trial and failure‡ of HUMIRA or ENBREL **AND** XELJANZ IR **OR**
- Treatment of systemic juvenile idiopathic arthritis (sJIA) or Adult Onset Still's Disease (AOSD)

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

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 (tafacitinib) **oral solution** may be approved for members with a diagnosis of pJIA who require a weight-based dose for <40 kg following trial and failure‡ of HUMIRA or ENBREL.

‡Failure is defined as lack of efficacy with a three-month trial, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction. Note that trial and failure of preferred TNF-α inhibitors will not be required when prescribed for pJIA in members with documented clinical features of lupus.α

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

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

Discussion
- A recommendation was made to include infliximab (an IV physician-administered product) in the failure definition as a TNF inhibitor.
- It was noted that adalimumab biosimilars will become commercially available in early 2023. J Taylor confirmed that, as biosimilar products are released, the Department will be evaluating the impact and integration of those new products.
- I Pan moved to amend the current criteria for trial and failure of two TNF inhibitors for pJIA to indicate that members who have moderate to severe pJIA who have previously failed one TNF inhibitor will not be required to trial a second TNF inhibitor before moving to another product class. Seconded by B Jackson. Motion passed unanimously.
- I Pan moved to accept the criteria as amended. Seconded by T Brubaker. Motion passed unanimously.

b. Psoriatic Arthritis

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

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

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

COSENTYX (secukinumab) may be approved when the following criteria are met:
Medication is being prescribed for active psoriatic arthritis **AND**
- Member is ≥ 2 years of age and weighs ≥ 15 kg, **AND**
- Member has had a trial and failure‡ of all preferred agents: ENBREL (etanercept), HUMIRA (adalimumab), OTEZLA (apremilast), TALTZ (ixekizumab) **AND** XELJANZ IR (tofacitinib)

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

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

- Member has trial and failure‡ of HUMIRA (adalimumab) or ENBREL **AND** XELJANZ IR **AND** TALTZ or OTEZLA **AND**
- Prescriber acknowledges that loading dose administration prior to approval of STELARA for maintenance therapy using the above criteria should be avoided and will not result in an automatic approval of STELARA for maintenance therapy **AND**
- Prior authorization approval may be given for an initial 16 week supply and authorization approval for continuation may be provided based on clinical response.

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

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 HUMIRA (adalimumab) or ENBREL **AND** XELJANZ IR **AND** TALTZ or OTEZLA.

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

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

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
- A Shmerling moved to accept the criteria as written. Seconded by K MacIntyre. Motion passed unanimously.

c. Plaque Psoriasis

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

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

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

STELARA (ustekinumab) prefilled syringe for subcutaneous use may receive approval if meeting the following criteria:
- Member has trial and failure‡ of one indicated first line agent (HUMIRA, ENBREL) AND two indicated second line agents (TALTZ, OTEZLA) **AND**
- Prescriber acknowledges that loading dose administration prior to approval of STELARA for maintenance therapy using the above criteria should be avoided and will not result in an automatic approval of STELARA for maintenance therapy AND
- Prior authorization approval may be given for an initial 16-week supply and authorization approval for continuation may be provided based on clinical response.

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

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

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

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

Discussion

- B Jackson moved to accept the proposed criteria as written. Seconded by T Brubaker. Motion passed unanimously.

d. Crohn's Disease and Ulcerative Colitis

Preferred Agents
HUMIRA (adalimumab)
*XELJANZ IR (tofacitinib) tablet

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

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

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

SIMPONI may receive approval if meeting the following:

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

SKYRIZI (risankizumab) **syringe for subcutaneous use** and **on-body injector formulations** may receive approval if meeting the following criteria:

- The requested medication is being prescribed for use for treating moderately-to-severely active Crohn's disease AND
- Member is ≥ 18 years of age AND
- Member has trial and failure† of all indicated preferred agents AND
- Prescriber acknowledges that administration of IV induction therapy prior to approval of SKYRIZI prefilled syringe or on-body injector formulation using the above criteria should be avoided and will not result in an automatic approval of requests for these formulation.

Quantity limits for maintenance doing of Skyrizi on-body formulations:

- One 180 mg/1.2 mL single-dose prefilled cartridge with on-body injector every 8 weeks
  OR
- One 360 mg/2.4 mL single-dose prefilled cartridge with on-body injector every 8 weeks

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

- For treatment of moderately-to-severely active Crohn's disease, member has trial and failure† of all indicated preferred agents (HUMIRA) **OR** for treatment of moderately-to-severely active ulcerative colitis, member has trial and failure† of all indicated preferred agents (HUMIRA and XELJANZ IR) **AND**
- The member is ≥ 18 years of age **AND**
- Prescriber acknowledges that loading dose administration prior to approval of STELARA for maintenance therapy using the above criteria should be avoided and will not result in an automatic approval of STELARA for maintenance therapy **AND**
- Prior authorization approval may be given for an initial 16 week supply and authorization approval for continuation may be provided based on clinical response.

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

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

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

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

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

Discussion

- A Shmerling moved to accept the proposed criteria as written. Seconded by Lanius. Motion passed unanimously.

e. Asthma

Preferred Agents
Must meet eligibility criteria*
*FASENRA (benralizumab) syringe, pen
*XOLAIR (omalizumab) syringe

***FASENRA (benralizumab)** may be approved if the following criteria are met:

1. Member is ≥ 12 years of age **AND**
2. The requested medication is being prescribed for a member with severe asthma* with an eosinophilic phenotype, based on a blood eosinophil level of ≥ 150/mcL **AND**
3. The requested medication is being prescribed as add-on therapy to existing asthma regimen **AND**
4. The requested medication will not be used concomitantly with other biologic products indicated for asthma.

*Severe asthma is defined as uncontrolled symptoms despite adherence to a minimum of three months of treatment with a high dose inhaled corticosteroid plus a long-acting beta-2 agonist (LABA) or requires oral corticosteroid therapy.

***XOLAIR (omalizumab)** may be approved if the following criteria are met:

1. Member is ≥ 6 years of age **AND**
2. The requested medication is being prescribed for a member with moderate to severe persistent asthma** who has a positive skin test or in vitro reactivity to a perennial inhaled allergen and whose symptoms are inadequately controlled inhaled corticosteroids, **AND**
3. The requested medication is being prescribed as add-on therapy to existing asthma regimen AND
4. The requested medication will not be used concomitantly with other biologic products indicated for asthma.

**Moderate asthma is defined as being well controlled with low-or-medium dose inhaled corticosteroid therapy plus a long-acting beta-2 agonist (LABA). Severe asthma is defined as uncontrolled symptoms despite adherence to a minimum of three months of treatment with a high dose inhaled corticosteroid plus a long-acting beta-2 agonist (LABA) or requires oral corticosteroid therapy.

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

1. Member is 6 years of age or older AND
2. Member has a diagnosis of moderate to severe asthma (on medium to high dose inhaled corticosteroid and a long-acting beta agonist) with eosinophilic phenotype OR oral corticosteroid dependent asthma AND
3. Member has had at least one asthma exacerbation in the past year requiring systemic corticosteroids or emergency department visit or hospitalization OR dependence on daily oral corticosteroid therapy PLUS regular use of high dose inhaled corticosteroid PLUS an additional controller medication AND
4. Member has trialed and failed† both preferred agents (FASENRA and XOLAIR) AND
5. Medication is being prescribed as add-on therapy to existing regimen AND
6. Medication is being prescribed by or in conjunction consultation with a rheumatologist, allergist, or pulmonologist AND
7. For indication of moderate to severe asthma with eosinophilic phenotype:
    a. baseline lung function (FEV1) is provided and baseline eosinophils are greater than 300 cells/mcL AND
    b. Initial authorization will be for 12 weeks. Continued authorization will require prescriber attestation of improvement in FEV1 of 25% from baseline and will be for 12 months
8. For indication of oral corticosteroid dependent asthma:
    a. Dosing of the oral corticosteroid is provided AND
    b. Initial authorization will be 24 weeks. Continued authorization will require prescriber attestation of a reduction of oral corticosteroid by at least 50% and will be for 12 months

Nucala (mepolizumab) may be approved for severe asthma if meeting the following criteria:

1. Nucala (mepolizumab) may be approved as a pharmacy benefit when the medication is administered in the member's home by a healthcare professional with appropriate clinical monitoring or when administered in a long-term care facility. Medications administered in a physician's office must be billed as a medical expense **OR**
2. Nucala (mepolizumab) may be approved for patient self-administration with verification that the prescriber has determined that self-administration is clinically appropriate **AND**
3. The prescriber verifies that the member has been properly trained in subcutaneous injection technique and on the preparation and administration of Nucala (mepolizumab) per information contained in product package labeling **AND**
4. Member has trialed and failed† both preferred agents (FASENRA and XOLAIR)

All other non-preferred FDA-indicated biologic agents for asthma may receive approval following trial and failure† of both preferred agents (FASENRA, XOLAIR).

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

Members with current prior authorization approval on file for an asthma biologic agent may receive approval to continue therapy with that agent.

Discussion

- B Jackson moved 1) to modify the proposed asthma severity definitions, as they are not necessarily consistent with pediatric clinical practice and the fact that that some children with moderate-to-severe asthma symptoms can be adequately managed with an inhaled corticosteroid alone (without a LABA), (2) to add current *pediatric* asthma guideline-based definitions for both severe and moderate asthma to the definitions for adults, and (3) to consider removing the requirement for a positive skin test or in vitro reactivity to a perennial inhaled allergen in order to receive approval for Xolair (omalizumab), as many children who may benefit from treatment for allergy-induced asthma have not undergone formal allergy testing and a determination about allergic reactivity can often be made clinically without formal testing. Seconded by T Brubaker. Motion passed unanimously.
- B Jackson moved to accept the proposed criteria as amended. Seconded by T Brubaker. Motion passed unanimously.

f. Atopic Dermatitis

Preferred Agents
NONE

ADBRY (tralokinumab-ldrm) may be approved if the following criteria are met:

1. Member is ≥ 18 years of age AND
2. The requested drug is being prescribed for moderate-to-severe atopic dermatitis AND
3. Member has baseline Investigator Global Assessment (IGA) score for atopic dermatitis severity of at least 3 (Scored 0-4, 4 being most severe) OR moderate erythema and moderate papulation/infiltration AND
4. Member has been educated by provider regarding the elimination of exacerbating factors including aeroallergens, food allergens, and contact allergens AND
5. Member has been educated by provider regarding the appropriate use of emollients and moisturizers for promotion of skin hydration AND
6. Member has trialed and failed† the following agents:
    a. Two medium potency to very-high potency topical corticosteroids [such as mometasone furoate, betamethasone dipropionate] AND
    b. Two topical calcineurin inhibitors [such as pimecrolimus and tacrolimus]

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

Maximum Dose: 600 mg/2 weeks

Quantity Limit: Four 150 mg/mL prefilled syringes/2 weeks

Initial approval: 18 weeks

Reauthorization:

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

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

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

1. Member is 6 years of age or older AND
2. Member has a diagnosis of moderate to severe chronic atopic dermatitis AND
3. Member has baseline Investigator Global Assessment (IGA) score for atopic dermatitis severity of at least 3 (Scored 0-4, 4 being most severe) OR moderate erythema and moderate papulation/infiltration

AND

4. Member has been educated by provider regarding the elimination of exacerbating factors including aeroallergens, food allergens, and contact allergens AND
5. Member has been educated by provider regarding the appropriate use of emollients and moisturizers for promotion of skin hydration

AND

6. Member has trialed and failed‡ the following agents:
    a. Two medium potency to very-high potency topical corticosteroids [such as mometasone furoate, betamethasone dipropionate, or fluocinonide (see PDL for list of preferred products) AND
    b. Two topical calcineurin inhibitors (see PDL for list of preferred products) AND
7. Must be prescribed by or in conjunction consultation with a dermatologist, allergist/immunologist, or rheumatologist AND

Initial approval: 18 weeks

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

All other non-preferred agents indicated for the treatment of atopic dermatitis may receive approval when the following criteria are met:

- Member has a diagnosis of moderate to severe chronic atopic dermatitis **AND**
- Member has trialed and failed‡ the following agents:
    - Two medium potency to very-high potency topical corticosteroids (such as mometasone furoate, betamethasone dipropionate, or fluocinonide)
    - Two topical calcineurin inhibitors (such as pimecrolimus and tacrolimus) **AND**
- The medication must be prescribed by or in consultation with a dermatologist, allergist, immunologist.

Initial authorization: 18 weeks

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

Members with current prior authorization approval on file for a non-preferred agent may receive approval to continue therapy with that agent.

Discussion

- I Pan moved to (1) remove the extraneous word "AND" at the end of bullet point 7 of the Dupixent criteria, (2) add rheumatologist to the list of subspecialty prescribers in the non-preferred agents section, and (3) accept the proposed criteria as amended. Seconded by P Lanius. Motion passed unanimously.

g. Other Indications

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

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

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

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

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

- Medication is being prescribed for one of the following autoinflammatory periodic fever syndromes (approval for all other indications is subject to meeting 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.

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

Medication is being prescribed for eosinophilic esophagitis (EoE) (approval for other indications is subject to meeting non-preferred criteria listed below):

AND

1. For members that have a diagnosis of asthma and/or atopic dermatitis in addition to another indicated diagnosis for Dupixent (dupilumab), the member must meet criteria listed above for the respective diagnosis **AND**
2. Member is ≥12 years of age **AND**
3. Member weighs at least 40 kg **AND**
4. 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**

5. Member is following appropriate dietary therapy interventions **AND**
6. Member has trialed and failed† other treatment options for EoE, including:
    a. Proton pump inhibitor trial of at least eight weeks in duration if reflux is a contributing factor **AND/OR**
    b. Minimum four-week trial of local therapy with fluticasone (using a metered dose inhaler) sprayed into the mouth and then swallowed

AND

7. Medication is being prescribed by or in consultation with a gastroenterologist, allergist or immunologist

OR

Medication is being prescribed for Chronic Rhinosinusitis with Nasal Polyposis (approval for other indications is subject to meeting non-preferred criteria listed below):

AND

1. Member is ≥ 18 years of age AND
2. Medication is being prescribed as an add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP) AND
3. 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
4. Member has trialed and failed‡ therapy with three intranasal corticosteroids (see PDL Class) AND
5. Medication is being prescribed by or in conjunction consultation with a rheumatologist, allergist, ear/nose/throat specialist or pulmonologist AND
6. Dose of Dupixent (dupilumab) 300mg every 2 weeks is used AND
7. Initial authorization will be for 24 weeks, for additional 12-month approval member must meet the following criteria: o NC and NPS scores are provided and show a 20% reduction in symptoms AND
8. Member continues to use primary therapies such as intranasal corticosteroids
9. Quantity Limit: 2 syringes every 28 days after initial 14 days of therapy (first dose is twice the regular scheduled dose)

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

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

- Medication is being prescribed for one of the following autoinflammatory periodic fever syndromes (approval for all other indications is subject to meeting non-preferred criteria listed below):
    - Familial Mediterranean Fever (FMF)
    - Hyperimmunoglobulinemia D syndrome (HIDS)
    - Mevalonate Kinase Deficiency (MKD)
    - Neonatal onset multisystem inflammatory disease (NOMID)
    - TNF Receptor Associated Periodic Syndrome (TRAPS)
    - Cryopyrin-associated Autoinflammatory Syndrome (including Familial Cold Autoinflammatory Syndrome and Muckle-Wells Syndrome)

  AND
- Member has trialed and failed‡ colchicine.

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

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

  AND
- Member has trialed and failed‡ colchicine.

NUCALA (mepolizumab) may be approved for maintenance treatment of Chronic Rhinosinusitis with Nasal Polyps meeting the following criteria (approval for other indications is subject to meeting non-preferred criteria listed below):

1. Member is 18 years of age or older **AND**
2. Medication is being prescribed as an add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP) AND
3. 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
4. Member has trialed and failed‡ therapy with three intranasal corticosteroids (see PDL Class) AND
5. Medication is being prescribed by or in consultation with a rheumatologist, allergist, ear/nose/throat specialist or pulmonologist AND
6. Initial authorization will be for 24 weeks, for additional 12 month approval member must meet the following criteria: o NC and NPS scores are provided and show a 20% reduction in symptoms AND
7. Member continues to use primary therapies such as intranasal corticosteroids
8. Quantity Limit: 100 mg by subcutaneous injection every 4 weeks

***XOLAIR (omalizumab) syringe for subcutaneous injection** may be approved for maintenance treatment of Chronic Rhinosinusitis with Nasal Polyps meeting the following criteria (approval for other indications is subject to meeting non-preferred criteria listed below):

1. If administered for the treatment of chronic rhinosinusitis with nasal polyps:
    a. If the member has a concomitant diagnosis of asthma or chronic idiopathic urticaria, then criteria listed above for the respective diagnoses are met AND
    b. Member is 18 years of age or older AND
    c. Member has a pre-treatment IgE level greater than or equal to 30 IU per mL AND
    d. Member has tried and failed at least two intranasal corticosteroids (see Intranasal Rhinitis Agents PDL class). Failure is defined as lack of efficacy with a 2-week trial, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction, AND
    e. Member is currently adherent to intranasal corticosteroid therapy AND
    f. Member has a baseline bilateral endoscopic nasal polyps score indicating the need for treatment AND
    g. Xolair is being prescribed by or in consultation with a qualified subspecialist such as an allergist, ear/nose/throat specialist, immunologist, rheumatologist, or pulmonologist AND
    h. Reauthorization for the chronic rhinosinusitis with nasal polyps indication may be approved if member has shown clinical improvement as indicated by all of the following:
        i. Initial approval criteria were met at the time of initiation of therapy AND
        ii. Provider attests that member has documented improvement in bilateral endoscopic nasal polyps score, AND
        iii. Provider attests that member is being periodically reassessed for need for continued therapy based on disease severity and/or level of symptom control

Quantity Limits: Four 150 mg/mL pre-filled syringes or single-dose vials/14 days (600mg every 14 days)

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

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

Members currently taking COSENTYX (secukinumab) may receive approval to continue on that agent. Members with current one-year prior authorization approval on file for Dupixent, Xolair, or Nucala may receive approval to continue on that agent.

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

Discussion

- L Claus moved to (1) recommend that the Department review colchicine trial/failure footnotes specifically for Ilaris and Kineret to ensure appropriateness within the criteria, (2) change disease state title of the arthritis related TIMs subclass to include JIA (and not pJIA specifically) so that the subclass will be inclusive of both pJIA and sJIA, and (3) accept the proposed criteria as amended. Seconded by P Lanius. Motion passed unanimously.

6. Newer Hereditary Angioedema (HAE) Products

Preferred Agents

PA Required for all agents in this class

Prophylaxis:

HAEGARDA (C1 esterase inhibitor) vial

Treatment:

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

Medications Indicated for Routine Prophylaxis:
Members are restricted to coverage of one medication for routine prophylaxis at one time. Prior authorization approval will be for one year.

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

- Member has a diagnosis of HAE confirmed by laboratory tests obtained on two separate instances at least one month apart (C4 level, C1-INH level) **AND**
- Member has a documented history of at least one symptom of a moderate to severe HAE attack (moderate to severe abdominal pain, facial swelling, airway swelling) in the absence of hives or a medication known to cause angioedema **AND**

- Member meets at least one of the following:
  - Haegarda is being used for short-term prophylaxis to undergo a surgical procedure or major dental work **OR**
  - Haegarda is being used for long-term prophylaxis and member meets one of the following:
    - History of ≥1 attack per month resulting in documented ED admission or hospitalization **OR**
    - History of laryngeal attacks **OR**
    - History of ≥2 attacks per month involving the face, throat, or abdomen **AND**
    - Member is not taking medications that may exacerbate HAE including ACE inhibitors and estrogen-containing medications **AND**
- Member has received hepatitis A and hepatitis B vaccination **AND**
- Provider attests to performing annual testing or screening (as appropriate) for HBV, HCV, and HIV

Maximum Dose: 60 IU/kg

Minimum Age: 10 6 years

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

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

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

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

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

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

TAKHZYRO (lanadelumab-flyo) may be approved for members meeting the following criteria:

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

Minimum age: 12 years

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

Medications Indicated for Treatment of Acute Attacks:

Members are restricted to coverage of one medication for treatment of acute attacks at one time. Prior authorization approval will be for one year.

FIRAZYR (icatibant acetate) may be approved for members meeting the following criteria:

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

Minimum age: 18 years
Maximum dose: 30 mg

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

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

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

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

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

Minimum age: 13 years
Maximum dose: 4,200 Units/dose

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

Discussion
B Jackson moved to accept the proposed 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.*

Conflict of Interest Check
No Board members reported a conflict of interest for any drug classes or products being reviewed today within the Mass Review section.

7. Antiherpetic Agents – Oral, Topical

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

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

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

For members with a diagnosis of Bell's palsy, valacyclovir 1,000 mg three times daily may be approved for 7 days if member presents with severe facial palsy.

Acyclovir suspension may be approved for:

- Members under 5 years of age OR
- Members with a feeding tube OR
- Members meeting non-preferred criteria listed above.

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

Antiherpetic Agents

Preferred Agents, TOPICAL

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

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

XERESE (acyclovir/hydrocortisone) prior authorization 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 1,500 mg **OR** valacyclovir 2 grams twice daily (Failure is defined as significant drug-drug interaction, lack of efficacy, contraindication to or intolerable side effects)

9. Fluoroquinolones, Oral

Preferred
No PA Required (*if meeting eligibility criteria)
*CIPRO (ciprofloxacin) oral suspension
*Ciprofloxacin oral suspension
Ciprofloxacin tablet
Levofloxacin tablet
Moxifloxacin tablet

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

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

Levofloxacin solution may be approved for members < 5 years of age with prescriber attestation that member is unable to take Cipro (ciprofloxacin) crushed tablet or suspension OR for members < 5 years of age for treatment of pneumonia. For members ≥ 5 years of age, levofloxacin solution may be approved for members who require administration via feeding tube OR who have failed an adequate trial (7 days) of ciprofloxacin suspension. Failure is defined as lack of efficacy, allergy, intolerable side effects, significant drug-drug interaction, or contraindication to therapy.

10. Immune Globulins

Preferred Agents
PA Required for all agents in this class*
CUVITRU 20% SQ liquid
GAMMAGARD 10% IV/SQ liquid
GAMMAKED 10% IV/SQ liquid
GAMMAPLEX 5%, 10% IV liquid
GAMUNEX-C 10% IV/SQ liquid
HIZENTRA 20% SQ liquid
PRIVIGEN 10% IV liquid

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

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

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

Approved Conditions for Immune Globulin Use:

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

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

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).

11. Newer Generation Antihistamines

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

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

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

12. Newer Generation Antihistamine/Decongestant Combinations

Preferred Agents
Loratadine-D (OTC) tablet

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

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

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 *(removed from Mass Review – see criteria below)*

Preferred Agents
Methotrexate oral tablet, vial

OTREXUP, REDITREX or **RASUVO** may be approved if meeting the following criteria:
- Member has diagnosis of severe, active rheumatoid arthritis OR active polyarticular juvenile idiopathic arthritis (pJIA) OR inflammatory bowel disease (IBD) **AND**
- Member has trialed and failed preferred methotrexate tablet formulation (failure is defined as lack of efficacy, allergy, intolerable side effects, or inability to take oral product formulation) **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 on that agent.

15. Epinephrine Products

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

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

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

16. Respiratory Agents

a. Inhaled Anticholinergics

Preferred Agents
No PA Required (unless indicated*)

Solutions
Ipratropium solution (nebules)

Short-Acting Inhalation Devices
ATROVENT HFA (ipratropium)

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

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

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

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

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

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

b. Inhaled Anticholinergic Combinations

Preferred Agents
No PA Required (unless indicated*)

Solutions
Albuterol/ipratropium solution

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

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

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

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

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

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

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

c. Inhaled Beta-2 Agonists (short-acting)

Preferred Agents, Short-acting

Solutions
Albuterol solution for nebulizer

Inhalers
PROAIR BNR HFA (albuterol)
PROVENTIL BNR HFA (albuterol)
VENTOLIN BNR HFA (albuterol)

Non-preferred, short acting beta-2 agonists may be approved for members who have failed treatment with one preferred agent. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.

MDI formulation quantity limits: 2 inhalers / 30 days

d. Inhaled Beta-2 Agonists (long-acting)

Preferred Agents, Long-acting
***Must meet eligibility criteria**

Solutions
NONE

Inhalers
*SEREVENT DISKUS (salmeterol) inhaler

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

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

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

e. Inhaled Corticosteroids

Preferred Agents, Single Agents

Solutions
Budesonide nebules

Inhalers
ASMANEX Twisthaler (mometasone)
FLOVENT DISKUS (fluticasone)
FLOVENT HFA BNR (fluticasone)
PULMICORT FLEXHALER (budesonide)

Non-preferred inhaled corticosteroids may be approved in members with asthma who have failed an adequate trial of two preferred agents. An adequate trial is defined as at least 6 weeks. (Failure is defined

as: lack of efficacy with a 6-week trial, allergy, contraindication to, intolerable side effects, or significant drug-drug interactions.)

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

f. Inhaled Corticosteroids, Combinations

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

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

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

g. Phosphodiesterase Inhibitors (PDEIs)

Preferred Agents
NONE

DALIRESP (roflumilast) may be approved for members when the following criteria are met:
- Member has severe COPD associated with chronic bronchitis and a history of COPD exacerbations (2 or more per year) AND
- Member must be ≥ 18 years of age AND
- Member must have failed a trial of TWO of the following (Failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interaction):
  - A long-acting beta2 agonist
  - A preferred inhaled anticholinergic or anticholinergic combination product

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

Discussion
- Five Board members voted to keep Inhaled Antibiotics class in Mass Review and read the proposed criteria and written stakeholder input provided. P Lanius voted to remove this class for an individual review. See details in the Inhaled Antibiotics section below.
- I Pan requested that the Methotrexate Products class be pulled out of today's Mass Review. The Board agreed to pull this class out for further discussion. See details in the Methotrexate Products section below.
- K MacIntyre moved to accept criteria in the Mass Review section as written, except for Inhaled Antibiotics and Methotrexate products, which were reviewed individually. Seconded by L Claus. Motion passed unanimously.

7. Antibiotics, Inhaled

Preferred Agents

No PA Required

(*Must meet eligibility criteria)

Tobramycin inhalation solution (generic TOBI)

*CAYSTON (aztreonam) inhalation solution

***CAYSTON (aztreonam)** inhalation solution may be approved if the following criteria are met:

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

ARIKAYCE (amikacin) may be approved if the following criteria are met:

- Member has refractory *Mycobacterium avium* complex (MAC) lung disease with limited or no alternative treatment options available **AND**
- Member has trialed and failed 6 months of therapy with a 3-drug regimen that includes a macrolide (failure is defined as lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interactions).

All other non-preferred inhaled antibiotic agents may be approved if the following criteria are met:

- The member has a diagnosis of cystic fibrosis with known colonization of *Pseudomonas aeruginosa* in the lungs **AND**
- Member has history of trial and failure of preferred tobramycin solution for inhalation (failure is defined as lack of efficacy with a 4-week trial, contraindication to therapy, allergy, intolerable side effects or significant drug-drug interactions).

Table 1: Minimum Age, Maximum Dose, and Quantity Limitations

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

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

Stakeholder input:

Written testimony, Adina Rubenstein – Cystic Fibrosis Foundation

Discussion
- After further Board discussion and clarification by the Department, it was determined that the current criteria are appropriate, and no changes were proposed.
- K MacIntyre moved to accept the proposed criteria for Inhaled Antibiotics class as written. Seconded by B Jackson. Motion passed unanimously.

14. Methotrexate Products

Preferred Agents
Methotrexate oral tablet, vial

OTREXUP, REDITREX or **RASUVO** may be approved if meeting the following criteria:
- Member has diagnosis of severe, active rheumatoid arthritis OR active polyarticular juvenile idiopathic arthritis (pJIA) OR inflammatory bowel disease (IBD) **AND**
- Member has trialed and failed preferred methotrexate tablet formulation (failure is defined as lack of efficacy, allergy, intolerable side effects, or inability to take oral product formulation) **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 on that agent.

Discussion
- The Board discussed information that subcutaneous methotrexate has more data to support its use in pediatric patients as compared to methotrexate oral tablets.
- To better align these criteria with current polyarticular JIA treatment guidelines, I Pan moved to add a new bullet point under criteria for Otrexup/Reditrex/Rasuvo. "If the member has a diagnosis of pJIA and is less than 18 years of age, trial and failure of the preferred methotrexate oral tablet will not be required." Seconded by L Claus. Motion passed unanimously.
- I Pan moved to accept the proposed criteria for Methotrexate Products as amended. Seconded by L Claus. Motion passed unanimously.

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

Conflict of Interest Check
No Board members reported a conflict of interest for the three products being reviewed in this section.

1. **CIMZIA (certolizumab pegol) lyophilized powder for reconstitution (subcutaneous)**

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 on that agent.

New starts of CIMZIA may be approved only for the prefilled syringe for subcutaneous administration.

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

Discussion

- I Pan moved to delete the phrase "New starts of CIMZIA may be approved only for the prefilled syringe for subcutaneous administration" from these criteria, as that restriction may be misaligned and not apply when a prescriber is specifically requesting the lyophilized power formulation of Cimzia. Seconded by P Lanius. Motion passed unanimously.
- P Lanius moved to accept the proposed criteria as amended. Seconded by B Jackson. Motion passed unanimously.

2. **SKYRIZI (risankizumab) IV Injection**

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 use 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)

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

Discussion

- B Jackson moved to accept the proposed criteria as written. Seconded by I Pan. Motion passed unanimously.

3. RADICAVA (edaravone)

RADICAVA (edaravone) for IV Infusion may be approved if the following criteria are met:

1. Member is ≥ 18 years of age **AND**
2. RADICAVA is being administered in a long-term care facility or in a member's home by a home healthcare provider AND
3. Member has a "definite" or "probable" diagnosis of amyotrophic lateral sclerosis (ALS) based on medical history and diagnostic testing which may include imaging and nerve conduction conditions studies AND
4. Member meets ALL of the following:
    a. Member has a diagnosis of ALS for 2 or less years (for new starts only)
    b. Diagnosis has been established by or with the assistance of a neurologist with expertise in ALS using El Escorial or Airlie House diagnostic criteria (ALSFRS-R)
    c. Member has normal respiratory function as defined as having a percent predicated forced vital capacity of greater than or equal to 80%
    d. The ALSFRS-R score is greater than or equal to 2 for all items in the criteria.
    e. Member does not have severe renal impairment (CrCl < 30 mL/min) or end stage renal disease
    f. Member does not have moderate or severe hepatic impairment (Child-Pugh Class B or C) **AND**
    g. RADICAVA is prescribed by or in consultation with a neurologist

Radicava ORS (edaravone) **oral suspension** may be approved if the criterion below is met in addition to the criteria listed above:

- Prescriber attests that member is not a candidate for IV Radicava due to intolerable side effects, contraindication to therapy, or significant drug-drug interaction.

Length of Approval: 6 months

Quantity Limits: For patients initiating therapy, approval will include

- For IV formulation: 28 bags per 28 days (initial dose) for the first month and 20 bags per 28 days for the remainder of the 6 months
- Initiation of therapy with Radicava oral suspension (14 doses of 105 mg each (28-day supply):
    - Two cartons, each containing one 35 mL bottle of oral suspension
      or
    - One carton containing two 35 mL bottles of oral suspension
- Maintenance therapy with Radicava oral suspension (10 doses of 105 mg each, within 14 days)
    - One carton containing one 50 mL bottle

Renewal: Authorization may be reviewed every six months to confirm that current medical necessity criteria are met and that the medication is effective per improvement in ALSFRS-R score.

Discussion

- P Lanius observed that the phrase "contraindication to therapy" is not appropriate in the failure definition because the IV and oral products contain the same active ingredient.
- I Pan moved to accept the proposed criteria as amended. Seconded by L Claus. Motion passed unanimously.

Proposed Prior Authorization Criteria for Non-PDL Physician Administered Drug Products Managed Under the Pharmacy Benefit and Medical Benefit
(J-Codes listed for medical benefit management)

1. J1602 Simponi (golimumab)

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**
- Simponi IV injection is being administered by a healthcare professional in the member's home or in a long-term care facility AND
- Member has tried and failed‡ all preferred agents in the "Targeted Immune Modulators" PDL drug class that are FDA-labeled for use for the prescribed indication.
- 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.

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

SIMPONI (golimumab) **IV (Simponi Aria) and subcutaneous injection** may be approved if meeting the following criteria:

- Simponi IV injection is being administered by a healthcare professional in the member's home or in a long-term care facility AND

- Member has tried and failed‡ all preferred agents in the "Targeted Immune Modulators" PDL drug class that are FDA-labeled for use for the prescribed indication.
- 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 psoriatic arthritis AND has trialed and failed‡ (Humira or Enbrel) AND Xeljanz IR AND (Taltz or Otezla) **OR**
- If the request is for use of the subcutaneous formulation for treating moderately to severely active ulcerative colitis, all of the following criteria are met:
    - Member is ≥ 18 years of age **AND**
    - Member has trialed and failed‡ all preferred agents in the "Targeted Immune Modulators" PDL drug class that are FDA-labeled for use for the prescribed indication **AND**
    - Member has demonstrated corticosteroid dependence or has had an inadequate response to (or failed to tolerate) oral aminosalicylates, oral corticosteroids, azathioprine, or 6-mercaptopurine for inducing and maintaining clinical response, improving endoscopic appearance of the mucosa during induction, inducing clinical remission, or achieving and sustaining clinical remission in induction responders.

Members currently stabilized on a Simponi (golimumab) regimen that was initiated prior to 1/1/2023 may receive prior authorization approval for continuation of therapy without meeting the above criteria.

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

Discussion

- J Taylor clarified that the J code for Simponi (for medical benefit billing) happens to include both the IV and subcutaneous formulations.
- L Claus moved to accept the proposed criteria as written. Seconded by B Jackson. Motion passed unanimously.

2. J3357/J3558 Stelara (ustekinumab)

STELARA (ustekinumab) **IV injection** may be approved if meeting the following criteria:

- For billing under the pharmacy benefit, Stelara (ustekinumab) IV injection is being administered by a healthcare professional in the member's home or in a long-term care facility **AND**
- The member is ≥ 18 years of age **AND**
- The member has a diagnosis of moderate-to-severely active Crohn's disease or moderate-to-severely active ulcerative colitis **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 AND
- The request meets one of the following:
    - The member has trialed and failed‡ Entyvio (vedolizumab) or an infliximab-containing product (such as Renflexis) **OR**
    - The prescriber confirms that maintenance subcutaneous dosing regimen of Stelara (ustekinumab) will be dispensed by a pharmacy for self-administration by the member or for administration in the member's home or LTCF

  AND
- If meeting criteria listed above, prior authorization approval will be placed based on the following:
    - If maintenance subcutaneous therapy will be dispensed by a pharmacy for self-administration by the member or for administration in the member's home or LTCF, initial 16-week approval will be placed for both IV and subcutaneous formulations, and one-year prior authorization approval for subcutaneous maintenance therapy continuation may be provided based on clinical response **OR**
    - If maintenance subcutaneous therapy will be billed as a medical claim for administration in the doctor's office or other clinical setting, initial 16-week approval will be placed for the IV formulation.

- 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

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

3. J3558 Stelara (ustekinumab)

STELARA (ustekinumab) may be approved if meeting the following criteria based on indication for use:

Crohn's Disease or Ulcerative Colitis (IV and subcutaneous formulations):

- 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**
- 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 AND
- The request meets one of the following:
  - The member has trialed and failed‡ Entyvio (vedolizumab) or an infliximab-containing product (such as Renflexis) **OR**
  - The prescriber confirms that maintenance subcutaneous dosing regimen of Stelara (ustekinumab) will be dispensed by a pharmacy for self-administration by the member or for administration in the member's home or LTCF

  AND
- If meeting criteria listed above, prior authorization approval will be placed based on the following:
  - If maintenance subcutaneous therapy will be billed as a medical claim for administration in the doctor's office or other clinical setting, initial 16-week approval will be placed for both IV and subcutaneous formulations and one-year prior authorization approval for continuation of subcutaneous maintenance therapy may be provided based on clinical response **OR**
  - If maintenance subcutaneous therapy will be dispensed by a pharmacy for self-administration by the member or for administration in the member's home or LTCF, initial 16-week approval will be placed for the IV formulation.

Plaque Psoriasis (subcutaneous formulation):

- Member has trial and failure‡ of (HUMIRA or ENBREL) AND TALTZ AND 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.

Psoriatic Arthritis (subcutaneous formulation):

- Member has trial and failure‡ of (HUMIRA or ENBREL) AND XELJANZ IR AND (TALTZ or OTEZLA) **AND**
- Prior authorization approval may be given for an initial 16-week supply and authorization approval for continuation may be provided based on clinical response.

Members currently stabilized on a Stelara (ustekinumab) regimen that was initiated prior to 1/1/2023 may receive prior authorization approval for continuation of therapy without meeting the above criteria.

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

Discussion

- B Jackson moved to accept the proposed criteria as written. Seconded by L Claus. Motion passed unanimously.

4. J0129 Orencia (abatacept)

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**
- 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.

‡Failure is defined as lack of efficacy with a three-month trial, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction. Note that trial and failure of preferred TNF-α inhibitors will not be required when prescribed for pJIA in members with documented clinical features of lupus.

Discussion

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

5. J2356 Tezspire (tezepelumab-ekko)

Tezspire (tezepelumab-ekko) may be approved if all the following criteria are met:

a. Member is 12 years of age or older AND
b. Member has a diagnosis of severe asthma that is uncontrolled or inadequately controlled as demonstrated by
    i. 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
c. Medication is being administered as add-on therapy (not monotherapy) AND
d. Member is taking a high dose inhaled corticosteroid and a long-acting beta agonist AND
e. Medication will not be used in concomitantly with other biologics indicated for asthma AND
f. Member is not taking maintenance oral corticosteroids AND
g. Member has documented baseline FEV1

Reauthorization may be approved if member has shown clinical improvement as documented by one of the following

a. Improvement in lung function, measured in FEV1
b. 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

Maximum dose: 210 mg once every 4 weeks

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 without meeting the above criteria.

Scheduled testimony presentations:

J Wild/Tezspire – Amgen *Speaker yielded time*

Discussion

- T Brubaker moved to accept the proposed criteria as amended. Seconded by B Jackson. Motion passed unanimously.

6. J1427 Viltepso (viltoarsen)

Viltepso (viltolarsen) may be approved for members meeting the following criteria:

a. Medication is being administered in the member's home or in a long-term care facility by a healthcare professional AND
b. Member must have genetic testing confirming mutation of the Duchenne muscular dystrophy (DMD) gene that is amenable to exon 53 skipping AND
c. Medication is prescribed by or in consultation with a neurologist or a provider who specializes in treatment of DMD (i.e., pediatric neurologist, cardiologist or pulmonary specialist) AND
d. Serum cystatin C, urine dipstick, and urine protein-to-creatinine ratio should be measured before starting Viltepso (viltolarsen). Consider measurement of glomerular filtration rate prior to initiation of Viltepso (viltolarsen) AND
e. Members with known renal function impairment should be closely monitored during treatment with Viltepso (viltolarsen), as renal toxicity has occurred with similar drugs AND
f. If the member is ambulatory, functional level determination of baseline assessment of ambulatory function is required OR if not ambulatory, member must have a baseline Brooke Upper Extremity Function Scale score or Forced Vital Capacity (FVC) documented AND
g. Provider and patient or caregiver are aware that continued US FDA approval of Viltepso (viltolarsen) for Duchenne muscular dystrophy (DMD) may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Reauthorization: After 24 weeks of treatment with Viltepso (viltolarsen), member may receive approval to continue therapy for one year if the following criteria are met:

a. Member has shown no intolerable adverse effects related to Viltepso (viltolarsen) treatment at a dose of 80mg/kg IV once a week AND
b. Member has normal renal function or stable renal function if known impairment AND
c. Member demonstrates response to Viltepso (viltolarsen) treatment with clinical improvement in trajectory from baseline assessment in ambulatory function OR if not ambulatory, member demonstrates improvement from baseline on the Brooke Upper Extremity Function Scale or in Forced Vital Capacity (FVC).

Maximum dose: 80 mg/kg administered as an IV infusion once weekly *(documentation of patient's current weight with the date the weight was obtained*)

Initial authorization 6 months, continuation authorization is for 1 year

Members currently stabilized on a Viltepso (viltolarsen) regimen administered in a physician's office or clinical setting that was initiated prior to 1/1/2023 may receive prior authorization approval for continuation of therapy without meeting the above criteria.

Above coverage standards will continue to be reviewed and evaluated for any applicable changes due to the evolving nature of factors including disease course, available treatment options, and available peer-reviewed medical literature and clinical evidence.

Scheduled testimony presentations:

A Stratton, MD – Dept of Physical Medicine and Rehabilitation, Children's Hospital Colorado
J Chauhan – NS Pharma

Discussion

- The Board discussed the length of time needed to adequately evaluate medication efficacy in members who have DMD. J Taylor clarified that the Department's standard maximum approval period is 1 year.
- B Jackson moved to change prescriber-related language to "Medication is prescribed by or in consultation with a neurologist or a provider who specializes in treatment of DMD (i.e., neurologist, cardiologist, pulmonologist, or physical medicine and rehabilitation physician)." Seconded by T Brubaker. Motion passed unanimously.
- B Jackson moved that (1) the initial authorization period for Viltepso be increased from 6 months to 12 months, and (2) the reauthorization time period be changed from 24 weeks of treatment with Viltepso (viltolarsen) to 52 weeks of treatment. Seconded by T Brubaker. Motion passed unanimously.
- B Jackson moved to accept the proposed criteria as amended. Seconded by T Brubaker. Motion passed unanimously.

7. J0224 Oxlumo (lumasiran)

Oxlumo (lumasiran) may be approved if all the following criteria are met:

a. Medication is being administered in the member's home or in a long-term care facility by a healthcare professional AND
b. Member has a diagnosis of Primary hyperoxaluria type 1 (PH1) confirmed by either:
   i. Genetic testing that demonstrates a mutation of the alanine glyoxylate aminotransferase (AGXT) gene OR
   ii. Liver enzyme analysis demonstrating absent or significantly reduced AGXT
c. Medication is being prescribed by, or in consultation with a nephrologist, neurologist, or other healthcare provider with expertise in treating PH1
d. Member has documented baseline urinary oxalate excretion or plasma oxalate concentrations

Reauthorization: Member demonstrates response to medication as indicated by a positive clinical response from baseline urinary oxalate excretion or plasma oxalate concentration

Maximum dose: weight-based dosing regimen as shown in the following table *(documentation of patient's current weight with the date the weight was obtained)*

Body Weight	**Loading Dose**	**Maintenance Dose**
Less than 10 kg	6 mg/kg once monthly for three doses	3 mg/kg once monthly, beginning one month after the last loading dose
10 kg to less than 20 kg	6 mg/kg once monthly for three doses	6 mg/kg once every three months, beginning one month after the last loading dose
20 kg and above	3 mg/kg once monthly for three doses	3 mg/kg once every three months, beginning one month after the last loading dose

Members currently stabilized on a Oxlumo (lumasiran) regimen that was initiated prior to 1/1/2023 may receive prior authorization approval for continuation of therapy without meeting the above criteria.

Discussion

- R Poissant clarified that the date of the patients' weights need to be documented in order for the medical benefit to be administered and based appropriate weight-based dosing units.
- K MacIntyre moved to accept the proposed criteria as written. Seconded by T Brubaker. Motion passed unanimously.

8. J1428 Exondys 51 (eteplirsen)

Exondys 51 (eteplirsen) may be approved if the following criteria are met:

a. Medication is being administered in the member's home or in a long-term care facility by a healthcare professional AND
b. Member has a diagnosis of Duchenne Muscular Dystrophy (DMD) AND
c. Member must have genetic testing confirming mutation of the Duchenne Muscular Dystrophy (DMD) gene that is amenable to exon 51 skipping AND
d. Medication is prescribed by or in consultation with a neurologist or a provider who specializes in treatment of DMD (i.e., pediatric neurologist, cardiologist or pulmonary specialist) AND
e. The member must be on corticosteroids at baseline or has a contraindication to corticosteroids AND
f. If the member is ambulatory, functional level determination of baseline assessment of ambulatory function is required OR if not ambulatory, member must have a Brooke Upper Extremity Function Scale of five or less documented OR a Forced Vital Capacity (FVC) of 30% or more.

Reauthorization:

a. Member demonstrates response to Exondys 51 (eteplirsen) treatment with clinical improvement in trajectory from baseline assessment in ambulatory function OR if not ambulatory, member demonstrates improvement from baseline on the Brooke Upper Extremity Function Scale or in Forced Vital Capacity (FVC).

Maximum Dose: 30 mg/kg per week *(documentation of patient's current weight with the date the weight was obtained*)

Initial authorization 6 months, continuation authorization is for 1 year.

Above coverage standards will continue to be reviewed and evaluated for any applicable changes due to the evolving nature of factors including disease course, available treatment options, and available peer-reviewed medical literature and clinical evidence.

9. J1429 Vyondys 53 (golodirsen)

Vyondys 53 may be approved if all the following criteria are met:

a. Medication is being administered in the member's home or in a long-term care facility by a healthcare professional AND
b. Member has a diagnosis of Duchenne Muscular Dystrophy (DMD) AND
c. Member must have genetic testing confirming mutation of the Duchenne Muscular Dystrophy (DMD) gene that is amenable to exon 53 skipping AND
d. Medication is prescribed by or in consultation with a neurologist or a provider who specializes in treatment of DMD (i.e., pediatric neurologist, cardiologist or pulmonary specialist) AND
e. The member must be on corticosteroids at baseline or has a contraindication to corticosteroids AND
f. If the member is ambulatory, functional level determination of baseline assessment of ambulatory function is required OR if not ambulatory, member must have a Brooke Upper Extremity Function Scale of five or less documented OR a Forced Vital Capacity of 30% or more.

Reauthorization:

a. Member demonstrates response to Vyondys 53 (golodirsen) treatment with clinical improvement in trajectory from baseline assessment in ambulatory function OR if not ambulatory, member demonstrates improvement from baseline on the Brooke Upper Extremity Function Scale or in Forced Vital Capacity (FVC).

Maximum Dose: 30 mg/kg per week *(documentation of patient's current weight with the date the weight was obtained*)

Initial authorization 6 months, continuation authorization is for 1 year.

Above coverage standards will continue to be reviewed and evaluated for any applicable changes due to the evolving nature of factors including disease course, available treatment options, and available peer-reviewed medical literature and clinical evidence.

Stakeholder input:

Written testimony, Brian Denger, Parent Project Muscular Dystrophy
Written testimony, Lauren Stanford, Parent Project Muscular Dystrophy

Scheduled testimony presentations:

Anne Stratton, MD - Dept of Physical Medicine and Rehabilitation, Children's Hospital Colorado
Leslie Zanetti, Sarepta Therapeutics *Speaker yielded time*

Discussion

- The proposed criteria for Exondys 51 and Vyondys 53 were reviewed together.
- B Jackson moved to (1) change prescriber-related language to "Medication is prescribed by or in consultation with a neurologist or a provider who specializes in treatment of DMD (i.e., neurologist, cardiologist, pulmonologist, or physical medicine and rehabilitation physician)" for both Exondys 51 and Vyondys 53, (2) increase the initial authorization period for Exondys 51 and Vyondys 53 from 6 months to 12 months, and (3) include clinical stability as a reauthorization criterion for Exondys 51 and Vyondys 53. Seconded by I Pan. Motion passed unanimously.
- B Jackson moved to accept the criteria as amended. Seconded by L Claus. Motion passed unanimously.

D. Review of Proposed Changes to "High Cost Claims" Prior Authorization

- *Agenda item deferred due to time constraints*

E. Review of Maximum Dose for Buprenorphine-Containing Products Used to Treat Substance Use Disorder

- Products involved include
  - Buprenorphine SL tablet
  - Buprenorphine/naloxone SL film, SL tablet
  - Bunavail (buprenorphine/naloxone) buccal film
  - Suboxone (buprenorphine/naloxone) SL film (No PA required on brand for doses ≤ 24mg buprenorphine/day)
  - Zubsolv (buprenorphine/naloxone) SL tablet

- <u>Department's Proposed Change to Maximum Dose Criteria:</u>

  Maximum Dose: 24mg of buprenorphine/day*

  *Prior authorization requests for Suboxone (buprenorphine/naloxone) SL film doses exceeding 24mg buprenorphine/day will be eligible to undergo clinical review by a call center pharmacist on a case-by-case basis with provider submission of clinical information (such as documentation from medical chart notes) supporting the need for doses exceeding the 24mg/day maximum (eligible for 6-month approval for up to 32mg buprenorphine/day dosing).

  Prior authorization requests for buprenorphine SL tablet for members that are pregnant or unable to tolerate naloxone due to allergy or intolerable side effects will also be eligible for submission and review.

Scheduled testimony presentations:

Joshua Blum, MD - Medical Director, Denver Health Adult Outpatient Substance Use Disorder Services
Stephanie Stewart, MD, MPHS - Public Policy Chair, Colorado Society of Addiction Medicine (COSAM)

Discussion

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

11. Adjournment

A Shmerling reminded attendees that the next Board meeting is scheduled for Tuesday, February 7, 2023, from 1:00 to 5:00 pm on Zoom, and also reminded Board members to delete their meeting binders at the conclusion of today's meeting.

L Claus moved to adjourn the meeting, Seconded by I Pan. Motion passed unanimously. The meeting was adjourned at 5:10 pm.

Minutes respectfully submitted by Julia Rawlings, PharmD