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

May 9, 2023
Open Session
1:00 pm – 5:00 pm

1. Call to Order

Today's meeting was held virtually via Zoom. The meeting was called to order at 1:00 pm by B Jackson, 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 six voting members participating. Quorum is five voting members.

Members Present: Brian Jackson, MD, MA (Vice Chair); Todd Brubaker, DO; Shilpa Klocke, PharmD; Patricia Lanius, BSPharm, MHA; Ken MacIntyre, DO; Ingrid Pan, PharmD; Melissa Polvi, RN
Members Absent: Liza Claus, PharmD (Chair)
HCPF Pharmacy Office Staff: Jim Leonard, PharmD; Jeffrey Taylor, 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:

- Given the absence of Dr. Liza Claus due to a schedule conflict, today's meeting will be facilitated by Dr. Brian Jackson, Vice Chair.
- This meeting is being recorded for internal use by the Department.
- Kelly Gaebel, DUR Intern, is managing the Zoom technology for today's meeting.
- Speakers providing testimony and other meeting guests are asked to keep video and microphones turned off throughout the meeting so that Board members' votes can be easily seen and tracked. Stakeholders who have signed up in advance to provide testimony will be called upon at the appropriate times in the meeting agenda. Video and microphones for Board members will remain on throughout the meeting. Vice Chair Jackson will manage the voting process.
- 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.
- Board members need to delete the meeting binder and associated email at the conclusion of the meeting.

4. Colorado Department of Health Care Policy and Financing Updates

J Taylor provided updates from the Department:

- The Department recruits for physician and pharmacist Board members on a rolling basis based on the terms of service for current Board members. There is currently an opening for a physician Board member. If you are interested, please send an email along with a current CV to sspps.co-dur@cuanschutz.edu
- For products and drug classes currently managed with DUR criteria posted on the Preferred Drug List (PDL), Appendix P, or Appendix Y, only proposed changes to the currently posted criteria will be read aloud during the meeting.
- Full criteria for drugs managed under the pharmacy benefit on the PDL and Appendix P are available for public reference at http://hcpf.colorado.gov/pharmacy-resources. Full criteria for drugs managed under the medical benefit are available at http://hcpf.colorado/gov/physician-administered-drugs.

5. Final Approval of Minutes from the February 7, 2023 Meeting

- Vice Chair B Jackson asked the Board to review minutes from the February 7, 2023 meeting.
- K MacIntyre asked to confirm that the motion to require that Hetlioz (tasimelteon) be "prescribed by a sleep specialist or a practitioner who has sufficient education and experience to safely prescribe tasimelteon" was considered after the February meeting. Language proposed as part of this February motion is included in Hetlioz criteria on the current PDL.
- S Klocke moved to approve the minutes as written. Seconded by I Pan. Motion passed with five votes in favor. T Brubaker abstained due to not being available for this vote.

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, RN, Industry Representative, disclosed her conflicts of interest related to employment by Swedish Orphan Biovitrum (Sobi), a rare disease company.

7. Clinical Updates and General Orders

- **FDA New Product & Safety Updates**
  M Brace, DUR Intern, highlighted updates from the FDA Drug Approvals report prepared by Tracy Van, DUR Intern. This quarter's Safety Update included an FDA Communication from April 13 regarding safe opioid dosing and opioid-induced hyperalgesia (OIH). The FDA full safety communication is available in the meeting binder.

- **Quarterly Clinical Modules**
  R Page presented an update on last quarter's Quarterly Clinical Module, *Utilization of Gabapentin Medications among Members of Health First Colorado.* This module was undertaken after several new reports in the medical literature described an increased risk for overdose in those who take opioids and gabapentinoids concomitantly. Additional concomitant use of CNS depressants was also analyzed. Gabapentin and pregabalin are both Schedule 5 controlled substances in the states of Alabama, Kentucky, Michigan, North Dakota, Tennessee, Virginia and West Virginia.

  The Colorado Evidence-based Drug Utilization Review team is currently working on clinical modules to evaluate (1) The Health First Colorado Rx Review Program and pharmacy interventions resulting from retrospective medication list reviews, in particular those related to the management of heart failure, and (2) a utilization comparison of oral and long-acting injectable antipsychotic medications under both the pharmacy and medical benefits.

- **Retrospective DUR Report**
  R Page presented the RDUR summary and highlighted that the number of providers included in the report for members who have claims for 2 or more concomitant benzodiazepines is in a downward trend. Dr. Page referred Board members to today's meeting binder for more details.

- **Quarterly Drug Utilization Reports**
  R Page presented highlights from this quarter's drug utilization reports. Ventolin, gabapentin, amoxicillin, sertraline and omeprazole composed the top five drug products by claim count during the 1st quarter of 2023. Humira, Biktarvy, Trulicity, Trikafta, Dupixent and Suboxone were among the top product claims by cost. Board members were referred to utilization reports in the meeting binder for more details.

8. New Business

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

- Board members will be asked if they have potential conflicts of interest to verbally disclose prior to reviewing therapeutic drug classes or individual products listed in the meeting agenda.
- There will be an opportunity for Board discussion.
- Time will be permitted for stakeholder comment.
- The name of each Board member offering a motion, seconding a motion and the results of votes (including abstentions and recusals) will be captured.

R Page proceeded with the review process of proposed criteria.

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

Red indicates proposed deleted text

Yellow indicates proposed new text

1. Pulmonary Arterial Hypertension (PAH) Therapies

a. PAH: Phosphodiesterase Inhibitors (PDEIs)

Preferred Agents

***Must meet eligibility criteria**

*REVATIO[BNR] (sildenafil) oral suspension
*Sildenafil oral suspension
*Sildenafil tablet
*Tadalafil 20 mg tablet

***Eligibility criteria for preferred products:**

Preferred sildenafil and tadalafil tablet formulations may be approved for a diagnosis of pulmonary hypertension or right-sided heart failure.

REVATIO (sildenafil) suspension may be approved for a diagnosis of pulmonary hypertension for members < 5 years of age or members ≥ 5 years of age who are unable to take/swallow tablets.

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

- Member has a diagnosis of pulmonary hypertension **AND**
- Member has trialed and failed treatment with preferred sildenafil tablet **AND** preferred tadalafil tablet. Failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects, or significant drug-drug interaction.

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

b. PAH: Endothelin Receptor Antagonists

Preferred Agents

***Must meet eligibility criteria**

*Ambrisentan tablet
*Bosentan 62.5 mg, 125 mg tablet

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

Approval may be granted for a diagnosis of pulmonary hypertension. Member and prescriber should be enrolled in applicable REMS program for prescribed medication.

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

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

c. PAH: Prostanoids (Prostatacylin Analogues and Receptor Agonists)

Preferred Agents

***Must meet eligibility criteria**

*Epoprostenol vial
*FLOLAN (epoprostenol) vial
*ORENITRAM (treprostinil ER) tablet
*VENTAVIS (iloprost) inhalation solution

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

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

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

d. PAH: Guanylate Cyclase Stimulators

Preferred Agents

NONE

ADEMPAS (riociguat) may be approved for members who meet the following criteria:

- For members of childbearing potential:
  - Member is not pregnant and is able to receive monthly pregnancy tests while taking ADEMPAS and one month after stopping therapy **AND**
  - Member and their partners are utilizing one of the following contraceptive methods during treatment and for one month after stopping treatment (IUD, contraceptive implants, tubal sterilization, a hormone method with a barrier method, two barrier methods, vasectomy with a hormone method, or vasectomy with a barrier method)

  AND
- Member has a CrCl ≥ 15 mL/min and is not on dialysis **AND**
- Member does not have severe liver impairment (Child Pugh C) **AND**
- Prescriber attests to compliance with the ADEMPAS REMS Program **AND**
- Member has a diagnosis of persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH) (WHO Group 4) after surgical treatment or has inoperable CTEPH **OR**
- Member has a diagnosis of pulmonary hypertension and has failed treatment with a preferred product for pulmonary hypertension. (Failure is defined as a lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction).

Scheduled Speaker Testimony

- K Simpson, Tyvaso – United Therapeutics
- A Hale, Uptravi – Janssen

Discussion

- No Board members reported a conflict of interest for any products included in the Pulmonary Hypertension therapeutic drug class.
- I Pan moved to accept the criteria as written. Seconded by T Brubaker. Motion passed unanimously.

2. Anti-Psoriatics – Oral & Topical

a. Anti-Psoriatics - Oral

Preferred Agents

Acitretin capsule

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

b. Anti-Psoriatics - Topical

Preferred Agents
Calcipotriene cream, solution
Dovonex (calcipotriene) cream
Taclonex Scalp[BNR] (calcipotriene/betamethasone) suspension
Taclonex[BNR] (calcipotriene/betamethasone) ointment

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

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

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

Discussion
- No Board members reported a conflict of interest for any products included in this therapeutic class.
- S Klocke moved to accept the criteria as written. Seconded by K MacIntyre. Motion passed unanimously.

3. Immunomodulators – Topical

a. Immunomodulators – Atopic Dermatitis

Preferred Agents
Elidel[BNR] (pimecrolimus) cream
Protopic[BNR] (tacrolimus) ointment
Tacrolimus ointment

EUCRISA (crisaborole) may be approved if the following criteria are met:
- Member is at least 3 months of age and older AND
- Member has a diagnosis of mild to moderate atopic dermatitis AND
- Member has a history of failure, contraindication, or intolerance to at least two medium-to high-potency topical corticosteroids for a minimum of 2 weeks OR is not a candidate for topical corticosteroids AND
- Member must have tried and failed pimecrolimus and tacrolimus. Failure is defined as a lack of efficacy, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions AND
- Eucrisa (crisaborole) must be prescribed by or in consultation with a dermatologist or allergist/immunologist.

OPZELURA (ruxolitinib) may be approved if the following criteria are met:

- Member is ≥ 12 years of age AND
- Member is immunocompetent AND
- Member has a diagnosis of mild to moderate atopic dermatitis AND
- Member has a history of failure, contraindication, or intolerance to at least two medium-to high-potency topical corticosteroids for a minimum of 2 weeks OR is not a candidate for topical corticosteroids AND
- Member must have trialed and/or failed pimecrolimus and tacrolimus. Failure is defined as a lack of efficacy, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions AND
- Must be prescribed by or in consultation with a dermatologist or allergist/immunologist.
- Quantity limit: 60 grams/week

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

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

Note: Prior authorization requests for Opzelura (ruxolitinib) prescribed solely for treating nonsegmental vitiligo will not be approved.

b. Immunomodulators – Antineoplastic Agents

Preferred Agents

No PA Required (unless indicated*)

*Diclofenac 3% gel (generic Solaraze)
Fluorouracil 5% cream (generic Efudex)
Fluorouracil 2%, 5% solution

*Diclofenac 3% gel (generic Solaraze) may be approved if the member has a diagnosis of actinic keratosis (AK).

TARGRETIN (bexarotene) gel or **VALCHLOR (mechlorethamine) gel** may be approved for members who meet the following criteria:

- Member is ≥ 18 years of age **AND**
- Member has been diagnosed with Stage IA or IB cutaneous T-cell lymphoma (CTCL) **AND**
- Member has refractory or persistent CTCL disease after other therapies OR has not tolerated other therapies **AND**
- Member and partners have been counseled on appropriate use of contraception

Non-preferred agents may be approved for members who have failed an adequate trial of all preferred products FDA-approved for that indication. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.

c. Immunomodulators – Other Agents

Preferred Agents
Condylox (podofilox) gel
*Imiquimod (generic Aldara) cream
Podofilox solution

Veregen (sinecatechins) may be approved if the following criteria are met:
- Member has a diagnosis of external genital and/or perianal warts (*Condylomata acuminata*) AND
- Member is ≥ 18 years of age AND
- Member is immunocompetent AND
- Member has tried and failed two preferred products. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.

Zyclara (imiquimod) **2.5% cream** may be approved if the following criteria are met:
- Member has a diagnosis of clinically typical visible or palpable actinic keratoses (AK) of the full face or balding scalp AND
- Member is ≥ 18 years of age AND
- Member is immunocompetent AND
- Member has tried and failed one preferred product in the Antineoplastic Agents class (such as diclofenac gel or fluorouracil) AND the preferred imiquimod (generic Aldara) product. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.

Zyclara (imiquimod**) 3.75% cream** may be approved for:
- Treatment of clinically typical visible or palpable, actinic keratoses (AK) of the full face or balding scalp if the following criteria are met:
- Member is ≥ 18 years of age AND
- Member is immunocompetent AND
- Member has tried and failed one preferred product from the Antineoplastic Agents class (such as diclofenac gel or fluorouracil) AND the preferred imiquimod (generic Aldara) product. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.

OR

- Treatment of external genital and/or perianal warts (*Condylomata acuminata)* if the following criteria are met:
- Member is ≥ 12 years of age AND
- Member has tried and failed two preferred products. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.

HYFTOR (sirolimus) gel
- Member has a diagnosis of facial angiofibroma associated with tuberous sclerosis AND
- Member is ≥ 6 years of age AND
- Provider has evaluated, and member has received, all age-appropriate vaccinations as recommended by current immunization guidelines prior to initiating treatment with HYFTOR

Initial approval**:** 6 months

Reauthorization: An additional 6 months may be approved based on provider attestation that symptoms improved during the initial 6 months of treatment

Maximum dose: one 10 gram tube/28 days

All other non-preferred products may be approved for members who have trialed and failed all preferred products that are FDA-approved for use for the prescribed indication. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.

*Quantity Limits: Aldara cream has a quantity limit of 12 packets/28 days.

Discussion

- No Board members reported a conflict of interest for any products included in this therapeutic class.
- B Jackson moved to include in the reauthorization criteria a provider attestation that members continue to receive age-appropriate (non-live) vaccinations per ACIP guidelines while using Hyftor gel. Seconded by S Klocke. Motion passed unanimously.
- K MacIntyre moved to accept the criteria as amended. Seconded by P Lanius. Motion passed unanimously.

4. Bile Salts

Preferred Agents
Ursodiol capsule
Ursodiol tablet

Chenodal (chenodiol) and **Actigall** (ursodiol) may be approved for members who meet the following criteria:

- Member is >≥ 18 years of age AND
- Member has tried and failed therapy with a 12-month trial of a preferred ursodiol product (failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions).

Cholbam (cholic acid) may be approved for members who meet the following criteria:

- Bile acid synthesis disorders:
  - Member age must be greater than 3 weeks old AND
  - Member has a diagnosis for bile acid synthesis disorder due to single enzyme defect (Single Enzyme-Defect Disorders: Defective sterol nucleus synthesis, 3β-hydroxy-Δ-c27-steroid oxidoreductase deficiency, AKR1D1 deficiency, CYP7A1 deficiency, Defective side-chain synthesis, CYP27A1 deficiency (cerebrotendinous xanthomatosis), 2-methylacyl-CoA racemase deficiency (AMACR), 25-hydroxylation pathway (Smith–Lemli-Opitz).
- Peroxisomal disorder including Zellweger spectrum disorders:
  - Member age must be greater than 3 weeks old AND
  - Member has diagnosis of peroxisomal disorders (PDs) including Zellweger spectrum disorders AND
  - Member has manifestations of liver disease, steatorrhea or complications from decreased fat-soluble vitamin absorption.

Ocaliva (obeticholic acid), **Urso** (ursodiol), and **Urso Forte** (ursodiol) may be approved for members meeting the following criteria:

- Member is >≥ 18 years of age AND
- Medication is prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant provider AND
  - treatment of radiolucent, noncalcified gallbladder stones < 20 mm in greatest diameter AND elective cholecystectomy would be undertaken except for the presence of increased surgical risk due to systemic disease, advanced age, idiosyncratic reaction to general anesthesia, or for those patients who refuse surgery

OR

- prevention of gallstone formation in obese patients experiencing rapid weight loss

AND

- Member has the diagnosis of Primary Biliary Cholangitis as evidenced by two of the following at the time of diagnosis:
  - Evidence of cholestasis with an alkaline phosphatase elevation of at least 1.5 times the upper limit of normal
  - Presence of antimitochondrial antibody with titer of 1:40 or higher
  - Histologic evidence of nonsuppurative destruction cholangitis and destruction of interlobular bile ducts AND
- Due to risk of serious liver injury, mMember does not have Primary Biliary Cholangitis with advanced cirrhosis due to the risk of serious liver injury, AND
- Member has failed treatment with a preferred ursodiol product for at least 1 year 6 months with due to an inadequate response, OR Member has had intolerable side effects, drug-drug interaction, or allergy to preferred ursodiol formulations.

Reltone (ursodiol) may be approved for members meeting the following criteria:

- Member is ≥ 18 years of age AND
- Medication is prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant provider AND
- Reltone (ursodiol) is being prescribed for one of the following:
  - treatment of radiolucent, noncalcified gallbladder stones < 20 mm in greatest diameter AND elective cholecystectomy would be undertaken except for the presence of increased surgical risk due to systemic disease, advanced age, idiosyncratic reaction to general anesthesia, or for those patients who refuse surgery

  OR
  - prevention of gallstone formation in obese patients experiencing rapid weight loss

  AND
- No compelling reasons for the member to undergo cholecystectomy exist, including unremitting acute cholecystitis, cholangitis, biliary obstruction, gallstone pancreatitis, or biliary-gastrointestinal fistula, **AND**
- Member has failed treatment with a preferred ursodiol product for at least 6 months due to an inadequate response, intolerable side effects, drug-drug interaction, or allergy to inactive ingredients contained in the preferred ursodiol formulations.

Initial approval: 1 year

Reauthorization: May be reauthorized for 1 additional year with provider attestation that partial or complete stone dissolution was observed after completion of the initial year of Reltone therapy. Maximum cumulative approval per member is 24 months.

Ocaliva (obeticholic acid), **Urso** (ursodiol), and **Urso Forte** (ursodiol) may be approved for members meeting the following criteria:

- Member is ≥≥ 18 years of age AND
- Medication is prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant provider AND
- Member has the diagnosis of Primary Biliary Cholangitis as evidenced by two of the following at the time of diagnosis:
  - Evidence of cholestasis with an alkaline phosphatase elevation of at least 1.5 times the upper limit of normal
  - Presence of antimitochondrial antibody with titer of 1:40 or higher
  - Histologic evidence of nonsuppurative destruction cholangitis and destruction of interlobular bile

ducts AND

- Due to risk of serious liver injury, member does not have Primary Biliary Cholangitis with advanced cirrhosis, AND
- Member has failed treatment with a preferred ursodiol product for at least 1 year 6 months with due to an inadequate response, OR Member has had intolerable side effects, drug-drug interaction, or allergy to inactive ingredients contained in the preferred ursodiol formulations.

Requests for drug products that are FDA-indicated for the treatment of nonalcoholic steatohepatitis (NASH) must meet the follow criteria:

- A diagnosis of NASH has been confirmed through liver biopsy AND
- Member meets the FDA-labeled minimum age requirement for the prescribed product AND
- Member does not have significant liver disease other than NASH, AND
- The requested medication is being prescribed for use for the FDA-labeled indication and as outlined in product package labeling AND
- Medication is prescribed by a gastroenterologist, hepatologist, or liver transplant provider

All other nNon-preferred products prescribed for all other FDA-approved indications may receive approval for use for FDA-labeled indications as outlined in product package labeling.

Written Testimony
Letter, Livmarli - Mirum Pharmaceuticals

Discussion

- No Board members reported a conflict of interest for any products included in this therapeutic class.
- P Lanius moved to add "or in consultation with" to the phrase "prescribed by a gastroenterologist, hepatologist, or liver transplant provider" in the treatment of NASH section. Seconded by B Jackson. Motion passed with five votes in favor. T Brubaker abstained due to not being available for this vote.
- S Klocke moved to accept the criteria as amended. Seconded by K MacIntyre. Motion passed unanimously.

5. Antiemetics – Oral & Non-oral

a. Antiemetics – Oral

Preferred Agents

DICLEGIS DR[BNR] tablet (doxylamine/pyridoxine)
Meclizine (Rx) 12.5 mg, 25 mg tablet
Metoclopramide solution, tablet
Ondansetron ODT, tablet
Ondansetron oral suspension/ solution* (<5 years)
Prochlorperazine tablet
Promethazine syrup, tablet
Trimethobenzamide capsule

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

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

Doxylamine/pyridoxine tablet (generic) or **Bonjesta (doxylamine/pyridoxine)** may be approved for 9 months if meeting the following criteria:

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

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

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

Promethazine product formulations require prior authorization for members < 2 years of age due to risk of fatal respiratory depression.

b. Antiemetics – Non-oral

Preferred Agents

Prochlorperazine 25 mg suppository
Promethazine 12.5 mg, 25 mg suppository
Scopolamine patch

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

Discussion

- No Board members reported a conflict of interest for any products included in this therapeutic class.
- T Brubaker moved to remove the phrase "Ondansetron solution may be approved for members < 5 years and those members ≥ 5 years of age with a feeding tube" and replace it with add "Ondansetron solution may be approved for members who are unable to use ODT or tablet." Seconded by I Pan. Motion passed unanimously.
- The Board also discussed the use of granisetron as first-line therapy as part of pediatric oncology protocols and whether there should be a pathway for approval of that non-preferred agent for patients who are on those protocols. B Jackson suggested that the Department consult with an oncology specialist to determine whether this change would be appropriate.
- T Brubaker moved to accept the criteria as amended. Seconded by K MacIntyre. Motion passed unanimously.

6. GI Motility, Chronic

Preferred Agents

AMITIZA^{BNR} (lubiprostone) capsule
LINZESS (linaclotide) capsule
MOVANTIK (naloxegol) tablet

All agents will only be approved for FDA labeled indications and up to FDA approved maximum doses listed below.

Preferred agents may be approved if the member meets the following criteria:

- Has diagnosis of Irritable Bowel Syndrome – Constipation (IBS-C), Chronic Idiopathic Constipation (CIC), or Opioid Induced Constipation (OIC) in patients with opioids prescribed for noncancer pain **AND**
- Member does not have a diagnosis of GI obstruction **AND**
- For indication of OIC, member opioid use must exceed 4 weeks of treatment
- For indications of CIC, OIC, IBS-C; member must have documentation of adequate trial of two or more over-the-counter motility agents (polyethylene glycol, docusate or bisacodyl, for example). OR If the member cannot take oral medications, then the member must fail a 7-day trial with a non-phosphate enema (docusate or bisacodyl enema). Failure is defined as a lack of efficacy for a 7-day trial, allergy, intolerable side effects, contraindication to, or significant drug-drug interaction **AND**
- For indication of IBS-D, must have documentation of adequate trial and failure with loperamide and trial and failure with dicyclomine or hyoscyamine. Failure is defined as a lack of efficacy for a 7-day trial, allergy, intolerable side effects, contraindication to, or significant drug-drug interaction.

Non-preferred agents may be approved if the member meets the following criteria:

- Member meets all listed criteria for preferred agents **AND**
- Member has trialed and failed two preferred agents OR if the indication is OIC caused by methadone, then a non-preferred agent may be approved after an adequate trial of MOVANTIK (naloxegol). Failure is defined as a lack of efficacy for a 7-day trial, allergy, intolerable side effects, contraindication to, or significant drug-drug interaction **AND**
- If prescribed Viberzi (eluxadoline) or Lotronex (alosetron), member meets the additional criteria for those agents listed below.

VIBERZI (eluxadoline) may be approved for members who meet the following additional criteria:

- Diagnosis of Irritable Bowel Syndrome – Diarrhea (IBS-D) **AND**
- Member has a gallbladder **AND**
- Member does not have severe hepatic impairment (Child-Pugh C), history of severe constipation, known mechanical gastrointestinal obstruction, biliary duct obstruction, history of pancreatitis or structural disease of the pancreas **AND**
- Member does not drink more than 3 alcoholic drinks per day

LOTRONEX (alosetron) and generic alosetron may be approved for members who meet the following additional criteria:

- Member is a female with Irritable Bowel Syndrome – Diarrhea (IBS-D) with symptoms lasting 6 months or longer **AND**
- Member does not have severe hepatic impairment (Child-Pugh C), history of severe constipation or ischemic colitis, hypercoagulable state, Crohn's disease or ulcerative colitis, or known mechanical gastrointestinal obstruction.

Medication	FDA approved indication	FDA Max Dose
Amitiza (lubiprostone)	IBS-C (females only), CIC, OIC (not caused by methadone)	48 mcg/day
Linzess (linaclotide)	IBS-C, CIC	290 mcg/day
Movantik (naloxegol)	OIC	25 mg/day
Viberzi (eluxadoline)	IBS-D	200 mg/day
Relistor syringe subcutaneous injection (methylnaltrexone)	OIC	12 mg SQ/day

Relistor oral (methylnaltrexone)	OIC	450 mg/day
Lotronex (alosetron)	IBS-D (females only)	2 mg/day (females only)
Symproic (Naldemedine)	OIC	0.2 mg/day
Trulance (plecanatide)	CIC, IBS-C	3 mg/day
Motegrity (prucalopride)	CIC	2 mg/day

CIC – chronic idiopathic constipation, OIC – opioid induced constipation, IBS – irritable bowel syndrome, D – diarrhea predominant, C – constipation predominant

Discussion

- No Board members reported a conflict of interest for any products included in this therapeutic class.
- S Klocke moved to accept the criteria as written. Seconded by P Lanius. Motion passed with five votes in favor. T Brubaker abstained due to not being available for this vote.

7. Hemorrhoidal, Anorectal, and Related Topical Anesthetic Agents

a. Hydrocortisone single-agent products

Preferred Agents
Anusol-Hc (hydrocortisone) 2.5% cream
Cortifoam (hydrocortisone) 10% aerosol
Hydrocortisone 1% (Rx) cream/kit
Hydrocortisone 2.5% cream/kit
Hydrocortisone enema
Procto-Med HC (hydrocortisone) 2.5% cream
Procto-Pak (hydrocortisone) 1% cream
Proctosol-HC 2.5% (hydrocortisone) cream
Proctozone-HC 2.5% (hydrocortisone) cream

b. Lidocaine single-agent products

Preferred Agents
Lidocaine 5% ointment

Non-preferred products may be approved following trial and failure of therapy with 3 preferred products (failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions).

c. Other Agents and Combinations

Preferred Agents
Hydrocortisone-Pramoxine 1%/1% cream
Lidocaine-Hydrocortisone 3-0.5% cream
Lidocaine-Prilocaine 2.5%/2.5% cream *(all other manufacturers except Fougera)*
Proctofoam-HC (hydrocortisone-pramoxine) 1%-1% foam

Non-preferred products may be approved following trial and failure of therapy with 3 preferred products (failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions).

Discussion

- No Board members reported a conflict of interest for any products included in this therapeutic class.
- K MacIntyre moved to accept the criteria as written. Seconded by P Lanius. Motion passed unanimously.

8. Anticoagulants – Oral and Parenteral

a. Anticoagulants - Oral agents

Preferred Agents
ELIQUIS (apixaban) tablet
PRADAXA[BNR] (dabigatran) capsule
Warfarin tablet
XARELTO (rivaroxaban) 10 mg, 15 mg, 20 mg tablet, dose pack

SAVAYSA (edoxaban) may be approved if all the following criteria have been met:
- The member has failed therapy with two preferred agents. (Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction) **AND**
- Member is not on dialysis **AND**
- Member does not have CrCl > 95 mL/min **AND**
- The member has a diagnosis of deep vein thrombosis (DVT), pulmonary embolism (PE) **OR**
- The member has a diagnosis of non-valvular atrial fibrillation **AND**
- The member does not have a mechanical prosthetic heart valve

XARELTO 2.5 mg (rivaroxaban) may be approved for members meeting all of the following criteria:
- Xarelto 2.5 mg is being prescribed to reduce major CV events in members diagnosis of chronic coronary artery disease (CAD) or peripheral artery disease **AND**
- Xarelto 2.5 mg is being taken twice daily and in combination with aspirin 75-100 mg daily **AND**
- Member must not be receiving dual antiplatelet therapy, other non-aspirin antiplatelet therapy, or other oral anticoagulant **AND**
- Member must not have had an ischemic, non-lacunar stroke within the past month **AND**
- Member must not have had a hemorrhagic or lacunar stroke at any time

XARELTO (rivaroxaban) **oral suspension** may be approved without prior authorization for members < 5 years of age who require a rivaroxaban dose of less than 10 mg.

All other non-preferred oral agents require trial and failure of two preferred oral agents. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.

Continuation of Care: Members with current prior authorization approval on file for a non-preferred oral anticoagulant medication may continue to receive approval for that medication

b. Anticoagulants – Non-Oral agents

Preferred Agents
Enoxaparin syringe
Enoxaparin vial

Non-preferred parenteral anticoagulants may be approved if member has trial and failure of one preferred parenteral agent. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction

ARIXTRA (fondaparinux) may be approved if the following criteria have been met:
- Member is 18 years of age or older **AND**
- Member has a CrCl > 30 ml/min **AND**

- Member weighs > 50 kg **AND**
- Member has a documented history of heparin induced-thrombocytopenia **OR**
- Member has a contraindication to enoxaparin

Members currently stabilized on fondaparinux (Arixtra) or dalteparin (Fragmin) may receive prior authorization approval to continue receiving that medication.

Discussion

- No Board members reported a conflict of interest for any products included in this therapeutic class.
- The Board discussed Xarelto (rivaroxaban) oral suspension approval being limited to members < 5 years of age. B Jackson moved to edit this phrase to "Xarelto (rivaroxaban) oral suspension may be approved without prior authorization for members who require rivaroxaban doses of less than 10 mg or cannot tolerate tablets." Seconded by K MacIntyre. Motion passed unanimously.
- T Brubaker moved to accept the criteria as amended. Seconded by P Lanius. Motion passed unanimously.

9. Antiplatelet Agents

Preferred Agents
Aspirin/dipyridamole ER capsule
Brilinta (tigacrelor) tablet
Cilostazol tablet
Clopidogrel tablet
Dipyridamole tablet
Pentoxifylline ER tablet
Prasugrel tablet

Zontivity (vorapaxar) may be approved for patients with a diagnosis of myocardial infarction or peripheral artery disease without a history of stroke, transient ischemic attack, intracranial bleeding, or active pathological bleeding. Patients must also be taking aspirin and/or clopidogrel concomitantly.

Non-preferred products without criteria will be reviewed on a case-by-case basis.

Discussion

- No Board members reported a conflict of interest for any products included in this therapeutic class.
- K MacIntyre moved to accept the criteria as written. Seconded by P Lanius. Motion passed unanimously.

10. Colony Stimulating Factors

Preferred Agents
PA Required for all agents in this class*
Neupogen (filgrastim) vial, syringe
Nyvepria (pegfilgrastim-apgf) syringe

*Prior authorization for preferred agents may be approved if meeting the following criteria:

- Medication is being used for one of the following indications:
  - Patient with cancer receiving myelosuppressive chemotherapy –to reduce incidence of infection (febrile neutropenia) (Either the post nadir ANC is less than 10,000 cells/mm^3 or the risk of neutropenia for the member is calculated to be greater than 20%)
  - Acute Myeloid Leukemia (AML) patients receiving chemotherapy
  - Bone Marrow Transplant (BMT)

- Peripheral Blood Progenitor Cell Collection and Therapy
- Hematopoietic Syndrome of Acute Radiation Syndrome
- Severe Chronic Neutropenia (Evidence of neutropenia infection exists or ANC is below 750 cells/mm^3)

AND

- For **Nyvepria** (pegfilgrastim-apgf), the member meets the following criteria:
  - Member has trial and failure of Neupogen. Failure is defined as lack of efficacy, intolerable side effects, drug-drug interaction, or contraindication to Neupogen therapy. Trial and failure of Neupogen will not be required if meeting one of the following:
    - Member has limited access to caregiver or support system for assistance with medication administration **OR**
    - Member has inadequate access to healthcare facility or home care interventions.

Prior authorization for non-preferred agents may be approved if meeting the following criteria:

- Medication is being used for one of the following indications:
  - Patient with cancer receiving myelosuppressive chemotherapy –to reduce incidence of infection (febrile neutropenia) (Either the post nadir ANC is less than 10,000 cells/mm^3 or the risk of neutropenia for the member is calculated to be greater than 20%)
  - Acute Myeloid Leukemia (AML) patients receiving chemotherapy
  - Bone Marrow Transplant (BMT)
  - Peripheral Blood Progenitor Cell Collection and Therapy
  - Hematopoietic Syndrome of Acute Radiation Syndrome
  - Severe Chronic Neutropenia (Evidence of neutropenia infection exists or ANC is below 750 cells/mm^3)

  AND
- Member has history of trial and failure of Neupogen AND one other preferred agent. Failure is defined as a lack of efficacy with a 3-month trial, allergy, intolerable side effects, significant drug-drug interactions, or contraindication to therapy. Trial and failure of Neupogen will not be required if meeting one of the following:
  - Member has limited access to caregiver or support system for assistance with medication administration **OR**
  - Member has inadequate access to healthcare facility or home care interventions.

Discussion

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

11. Gender-Affirming Hormone Therapy (GAHT) Criteria

(Review of proposed changes to PDL GAHT criteria are only due to an update in the WPATH guidelines; drug class not undergoing full review)

Gender Transition/Affirming Hormone Therapy:

Preferred androgenic drugs may be approved for members meeting the following:

1. Female sex assigned at birth and has reached Tanner stage 2 of puberty > 16 years of age AND
2. Is undergoing female to male transition AND
3. Has a negative pregnancy test prior to initiation AND
4. Has baseline hematocrit < 50% or hematocrit < 54% for continuation of therapy.
4. Hematocrit (or hemoglobin) is being monitored in transgender and gender diverse members treated with testosterone

Discussion

- J Taylor explained that today's criteria review involves only the section of criteria within the Androgen Agents PDL class related to gender transition and affirming hormone therapy and not the entire androgen therapeutic class. This review is due to a recent update in the World Professional Association for Transgender Health (WPATH) standards of care.
- I Pan commended the State for incorporating the most recent guidelines and removing the age requirement.
- As an editorial change, B Jackson suggested removing "in transgender and gender diverse members treated with testosterone" from the phrase "Hematocrit (or hemoglobin) is being monitored in transgender and gender diverse members treated with testosterone."
- T Brubaker moved to accept the criteria as written. Seconded by K MacIntyre. Motion passed unanimously.

Pulled from Mass Review by the Department

19.c Lipotropics – Other Products

Preferred Agents
Ezetimibe tablet
Niacin ER tablet
*Omega-3 ethyl esters capsule (generic Lovaza)

Non-preferred lipotropic agents with a preferred product with same strength, dosage form, and active ingredient may be approved with adequate trial and/or failure of the preferred product with the same ingredient (such as preferred ezetimibe and Zetia) and 2 additional agents. (Failure is defined as: lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions).

*Omega-3 ethyl esters (generic Lovaza) may be approved for members who have a baseline triglyceride level ≥ 500 mg/dL

Lovaza (brand name) may be approved if meeting the following:
- Member has a baseline triglyceride level > 500 mg/dl AND
- Member has failed an adequate trial of omega-3 Ethyl Esters AND an adequate trial of gemfibrozil or fenofibrate (failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions)

Nexletol (bempedoic acid) or **Nexlizet** (bempedoic acid/ezetimibe) may be approved if meeting the following criteria:
- Member is ≥ 18 years of age **AND**
- Member is not pregnant **AND**
- Member is not receiving concurrent simvastatin > 20 mg daily or pravastatin > 40 mg daily **AND**
- Member has a diagnosis of either heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease (see definition below), **AND**

Conditions Which Define Clinical Atherosclerotic Cardiovascular Disease
• Acute Coronary Syndrome • History of Myocardial Infarction • Stable or Unstable Angina • Coronary or other Arterial Revascularization • Stroke • Transient Ischemic Attack • Peripheral Arterial Disease of Atherosclerotic Origin

- Member is concurrently adherent (> 80% of the past 180 days) on a maximally tolerated dose of a high intensity statin therapy (atorvastatin ≥ 40 mg daily **OR** rosuvastatin ≥ 20 mg daily [as a single-entity or as a combination product]) **AND** ezetimibe (as a single-entity or as a combination product) concomitantly for ≥ 8 continuous weeks), **AND**
- If intolerant to a statin due to side effects, member must have a one month documented trial with at least two other maximally-dosed statins in addition to ezetimibe. For members with a past or current incidence of rhabdomyolysis, a one-month trial and failure of a statin is not required, **AND**
- Member has a treated LDL > 70 mg/dL for a clinical history of ASCVD **OR** LDL > 100 mg/dL if familial hypercholesterolemia

Initial Approval: 1 year

Reauthorization: Reauthorization may be approved for 1 year with provider attestation of medication safety and efficacy during the initial treatment period

Vascepa (icosapent ethyl) may be approved if meeting the following:

- Member has a baseline triglyceride level > 500 mg/dl AND
- Member has failed an adequate trial of generic omega-3 ethyl esters AND an adequate trial of gemfibrozil or fenofibrate (failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions)
  OR
- Medication is being prescribed to reduce CV risk for members on maximally tolerated statin therapy with triglyceride levels ≥ 150 mg/dL and LDL-C levels between 41-100 mg/dL AND member meets one of the following:
  - Member is ≥ 45 years of age and has established atherosclerotic CV disease (e.g., coronary artery disease, cerebrovascular/carotid disease, peripheral arterial disease) OR
  - Member is ≥ 50 years of age with diabetes mellitus and has one or more of the following additional risk factors for CV disease:
    - Male ≥ 55 years of age or female ≥ 65 years of age
    - Cigarette smoker
    - Hypertension
    - HDL-C ≤ 40 mg/dL for men or ≤ 50 mg/dL for women
    - hsCRP >3.00 mg/L (0.3 mg/dL)
    - CrCl 30 to 59 mL/min
    - Retinopathy
    - Micro- or macroalbuminuria
    - ABI <0.9 without symptoms of intermittent claudication
- Maximum Dose: 4g daily

Minimum Age Limitations:
Nexletol (bempedoic acid): 18 years
Nexlizet (bempedoic acid/ezetimibe): 18 years

Discussion

- K MacIntyre moved to accept the criteria as written. Seconded by S Klocke. Motion passed with five votes in favor. T Brubaker abstained due to not being available for this vote.

Mass review drug classes*

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

12. Tetracyclines

Preferred Agents
- Doxycycline hyclate capsule
- Doxycycline hyclate tablet
- Doxycycline monohydrate 50 mg, 100 mg capsule
- Doxycycline monohydrate tablet
- Minocycline capsule

Prior authorization for non-preferred tetracycline agents may be approved if member has trialed/failed a preferred doxycycline product AND preferred minocycline. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.

Prior authorization for liquid oral tetracycline formulations may be approved if member has difficulty swallowing and cannot take solid oral dosage forms.

Nuzyra (omadacycline) prior authorization may be approved if member meets all of the following criteria: the above "non-preferred" prior authorization criteria and the following:

- Member has trialed and failed† therapy with a preferred doxycycline product and preferred minocycline OR clinical rationale is provided describing why these medications cannot be trialed (including resistance and sensitivity) AND
- Member has diagnosis of either Community Acquired Bacterial Pneumonia (CABP) or Acute Bacterial Skin and Skin Structure Infection (ABSSSI) or clinical rationale and supporting literature describing/supporting intended use AND one of the following:
    - If member diagnosis is ABSSSI, member must have trial and failure† of sulfamethoxazole/trimethoprim product in addition to preferred tetracyclines OR
    - If member diagnosis is CABP, member must have trial and failure† of either a beta-lactam antibiotic (amoxicillin/clavulanic acid) or a macrolide (azithromycin)

  AND
- Maximum duration of use is 14 days

†Failure is defined as lack of efficacy with 7-day trial, allergy, intolerable side effects, or significant drug-drug interaction.

13. Alpha Blockers

Preferred Agents
- Prazosin capsule

Non-preferred products may be approved following trial and failure of one preferred product (failure is defined as lack of efficacy with 4-week trial, allergy or intolerable side effects).

14. Beta Blockers – Single Agent, Antiarrhythmics & Combinations

a. Beta Blockers – Single Agent

Preferred Agents
- Acebutolol capsule
- Atenolol tablet
- Bisoprolol tablet
- Bystolic[BNR] (nebivolol) tablet
- Carvedilol IR tablet
- Carvedilol ER capsule
- Coreg CR[BNR] (carvedilol ER) capsule
- Labetalol tablet
- Metoprolol tartrate IR tablet
- Metoprolol succinate ER tablet
- Nadolol tablet
- Nevibolol tablet
- Pindolol tablet
- Propranolol IR tablet, solution
- Propranolol ER capsule

Non-preferred products may be approved following trial and failure with two preferred products (failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions).

HEMANGEOL (propranolol) oral solution may be approved for members between 5 weeks and 1 year of age with proliferating infantile hemangioma requiring systemic therapy.
Maximum dose: 1.7 mg/kg twice daily

KAPSPARGO SPRINKLE (metoprolol succinate) extended-release capsule may be approved for members ≥ 6 years of age that have difficulty swallowing or require medication administration via a feeding tube.
Maximum dose: 200 mg/day (adult); 50 mg/day (pediatric)

Members currently stabilized on timolol oral tablet non-preferred products may receive approval to continue on that product.

Table 1: Receptor Selectivity and Other Properties of Preferred Beta Blockers

	ß$_1$	ß$_2$	Alpha-1 receptor antagonist	Intrinsic sympathomimetic activity (ISA)
Acebutolol	X			X
Atenolol	X			
Betaxolol	X			
Bisoprolol	X			
Carvedilol	X	X	X	
Labetalol	X	X	X	
Metoprolol succinate	X			
Metoprolol tartrate	X			
Nadolol	X	X		
Nebivolol	X			

Pindolol	X	X		X
Propranolol	X	X		

b. Beta blockers – Antiarrhythmics

Preferred Agents

Sotalol tablet

SOTYLIZE (sotalol) oral solution may be approved for members 3 days to < 5 years of age. For members ≥ 5 years of age, SOTYLIZE (sotalol) oral solution may be approved for members who cannot swallow a sotalol tablet OR members that have trialed and failed therapy with one preferred product. (Failure is defined as allergy or intolerable side effects.)

Maximum dose: 320 mg/day

c. Beta blockers – Combinations

Preferred Agents

Atenolol/Chlorthalidone tablet
Bisoprolol/HCTZ tablet
Metoprolol/HCTZ tablet

Non-preferred products may be approved following trial and failure with two preferred products (failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions).

15. Calcium Channel Blockers – Dihydropyridine (DHP) and Non-Dihydropyridine

a. Calcium Channel Blockers – DHP

Preferred Agents

Amlodipine tablet
Felodipine ER tablet
Nifedipine IR capsule
Nifedipine ER tablet

Non-preferred products may be approved following trial and failure of two preferred agents. Failure is defined as lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interactions.

NYMALIZE (nimodipine) oral syringe may be approved for adult members (≥ 18 years of age) with subarachnoid hemorrhage who also have a feeding tube or have difficulty swallowing solid dosage forms.

Maximum dose: 360 mg/day for 21 days (6 syringes/day or 126 syringes/21 days)

KATERZIA (amlodipine) suspension may be approved if meeting the following:

- The member has a feeding tube or confirmed difficulty swallowing solid oral dosage forms OR cannot obtain the required dose through crushed amlodipine tablets AND
- For members < 6 years of age, the prescriber confirms that the member has already been receiving the medication following initiation in a hospital or other clinical setting

b. Calcium Channel Blockers – Non-DHP

Preferred Agents
Diltiazem IR tablet
Diltiazem CD/ER capsule
Verapamil IR, ER tablet
Verapamil ER 120 mg, 180 mg, 240 mg capsule

Non-preferred products may be approved following trial and failure of three preferred agents. Failure is defined as lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interactions.

16. Angiotensin Converting Enzyme (ACE) Inhibitors & Combinations

a. ACE Inhibitors – Single Agent

~~ Subclass pulled from Mass Review (see below) ~~

17. Angiotensin Receptor Blockers (ARBs) & Combinations

a. ARBs – Single Agent

Preferred Agents
Irbesartan tablet
Losartan tablet
Olmesartan tablet
Telmisartan tablet
Valsartan tablet

Non-preferred ACE inhibitors, ACE inhibitor combinations, ARBs, ARB combinations, renin inhibitors, and renin inhibitor combination products may be approved for members who have trialed and failed treatment with three preferred products (failure is defined as lack of efficacy with a 4-week trial, allergy, intolerable side effects, or significant drug-drug interaction).

***ENTRESTO** (sacubitril/valsartan) may be approved for members if the following criteria are met:

- Member age is 1 to 17 years of age and has a diagnosis of symptomatic heart failure with systemic left ventricular systolic dysfunction (LVSD) and/or has chronic heart failure with a below-normal left ventricular ejection fraction (LVEF) OR
- Member is ≥ 18 years of age and has a diagnosis of chronic heart failure.
- Diagnosis will be verified through automated verification (AutoPA) of the appropriate corresponding ICD-10 diagnosis codes related to the indicated use of the medication.

18. Renin Inhibitors & Combinations

Preferred Agents
NONE

Non-preferred renin inhibitors and renin inhibitor combination products may be approved for members who have failed treatment with three preferred products from the angiotensin modifier class (failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction).

Renin inhibitors and combinations will not be approved in patients with diabetes. Renin inhibitors are contraindicated when used in combination with an ACE-inhibitor, ACE-inhibitor combination, ARB, or ARB-combination.

19. Lipotropics – Bile Acid Sequestrants, Fibrates & Other Agents

a. Lipotropics – Bile Acid Sequestrants

Preferred Agents
Colesevelam tablet
Colestipol tablet
Cholestyramine packet, light packet, powder

Non-preferred bile acid sequestrants may be approved if the member has failed treatment with 2 preferred products in the last 12 months (failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions).

Non-preferred lipotropic agents with a preferred product with same strength, dosage form, and active ingredient may be approved with adequate trial and/or failure of the preferred product with the same ingredient (such as preferred ezetimibe and Zetia) and 2 additional agents. (Failure is defined as: lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions).

b. Lipotropics – Fibrates

Preferred Agents
Fenofibrate capsule, tablet (generic Lofibra/Tricor)
Gemfibrozil tablet

Non-preferred fibrates may be approved if the member has failed treatment with generic gemfibrozil or generic fenofibrate and niacin ER in the last 12 months (failure is defined as lack of efficacy with 4-week trial of each drug, allergy, intolerable side effects or significant drug-drug interactions).

Non-preferred lipotropic agents with a preferred product with same strength, dosage form, and active ingredient may be approved with adequate trial and/or failure of the preferred product with the same ingredient (such as preferred ezetimibe and Zetia) and 2 additional agents. (Failure is defined as: lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions).

c. Lipotropics – Other Products

~~ *Subclass pulled from Mass Review (see above)* ~~

20. Statins & Combinations

a. Statins – Single Agents

Preferred Agents
Atorvastatin tablet
Lovastatin tablet
Pravastatin tablet
Rosuvastatin tablet
Simvastatin tablet

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

Age Limitations: Altoprev will not be approved for members < 18 years of age. Fluvastatin will not be approved for members < 10 years of age. Livalo will not be approved for members < 8 years of age.

b. Statins – Combination Products

Preferred Agents
NONE

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

Age Limitations: Vytorin (ezetimibe/simvastatin) will not be approved for members < 18 years of age. Caduet (amlodipine/atorvastatin) will not be approved for members < 10 years of age.

21. Acne Agents – Topical

Preferred Agents
No PA Required (if age and diagnosis criteria are met*)
*Adapalene gel
*Adapalene/benzoyl peroxide gel (generic Epiduo)
*Clindamycin phosphate solution, medicated swab/pledget
*Clindamycin/benzoyl peroxide gel jar (generic Benzaclin)
*Clindamycin/benzoyl peroxide gel tube (generic Duac)
*Dapsone gel
*Erythromycin solution
*Erythromycin/Benzoyl peroxide gel (generic Benzamycin)
*Sulfacetamide sodium suspension
*RETIN-A^{BNR} (tretinoin) cream, gel

Authorization for all acne agents prescribed solely for cosmetic purposes will not be approved.

Preferred topical clindamycin and erythromycin products may be approved by AutoPA verification of ICD-10 diagnosis code for acne vulgaris, psoriasis, cystic acne, comedonal acne, disorders of keratinization, neoplasms, folliculitis, hidradenitis suppurativa, or perioral dermatitis (erythromycin only). Approval of preferred topical clindamycin and erythromycin products for other medically accepted indications may be considered following clinical prior authorization review by a call center pharmacist.

All other preferred topical acne agents may be approved if meeting the following criteria:

- For members > 25 years of age, may be approved following prescriber verification that the medication is not being utilized for cosmetic purposes AND prescriber verification that the indicated use is for acne vulgaris, psoriasis, cystic acne, disorders of keratinization, neoplasms, or comedonal acne. These medications are only eligible for prior authorization approval for the aforementioned diagnoses.
- For members ≤ 25 years of age, may be approved for a diagnosis of acne vulgaris, psoriasis, cystic acne, disorders of keratinization, neoplasms, or comedonal acne. Diagnosis will be verified through automated verification (AutoPA) of the appropriate corresponding ICD-10 diagnosis code related to the indicated use of the medication.

Non-preferred topical products may be approved for members meeting all of the following criteria:

- Member has trialed/failed three preferred topical products with different mechanisms (such as tretinoin, antibiotic). Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction AND
- Prescriber verification that the medication is being prescribed for one of the following diagnoses: acne vulgaris, psoriasis, cystic acne, disorders of keratinization, neoplasms, or comedonal acne.

22. Acne Agents – Oral Isotretinoins

Preferred Agents
Amnesteem capsule
Claravis capsule
Isotretinoin 10 mg, 20 mg, 30 mg, 40 mg capsule *(all manufacturers except Amneal)*

Preferred products may be approved for adults and children ≥ 12 years of age for treating severe acne vulgaris or for treating moderate acne vulgaris in members unresponsive to conventional therapy.

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

- Member has trialed/failed one preferred agent (failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction) AND
- Member is an adult or child ≥ 12 years of age with severe, recalcitrant nodulocystic acne and has been unresponsive to conventional therapy

23. Rosacea Agents

Preferred Agents
Finacea[BNR] (azelaic acid) gel, foam
Metronidazole cream, lotion
Metronidazole 0.75% gel

Prior authorization for non-preferred products in this class may be approved if member meets the following criteria:

- Member has a diagnosis of persistent (non-transient) facial erythema with inflammatory papules and pustules due to rosacea AND
- Prescriber attests that medication is not being used solely for cosmetic purposes AND
- Member has tried and failed two preferred agents of different mechanisms of action (Failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects)

*Doxycycline monohydrate DR (generic Oracea) may be approved if the following criteria are met:

- Member has taken generic doxycycline for a minimum of three months and failed therapy in the last 6 months. Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions AND
- Member has history of an adequate trial/failure (8 weeks) of 2 other preferred agents (oral or topical). Failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions AND
- Member is ≥ 18 years of age and has been diagnosed with rosacea with inflammatory lesions (papules and pustules)

24. Topical Steroids – Low, Medium, High & Very High Potency

a. Topical Steroids – Low Potency

Preferred Agents

Hydrocortisone (Rx) cream, ointment, lotion
Derma-Smoothe-FS [BNR] (fluocinolone) 0.01% oil
Desonide 0.05% cream, ointment
Fluocinolone 0.01% cream

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

b. Topical Steroids – Medium Potency

Preferred Agents

Betamethasone dipropionate 0.05% lotion
Betamethasone valerate 0.1% cream, ointment
Fluocinolone 0.025% cream
Fluticasone 0.05% cream, 0.005% ointment
Mometasone 0.1% cream, 0.1% ointment, 0.1% solution
Triamcinolone acetonide 0.025% cream, 0.1% cream, 0.025% ointment, 0.05% ointment, 0.1% ointment, 0.025% lotion, 0.1% lotion
Triamcinolone 0.1% dental paste

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

c. Topical Steroids – High Potency

Preferred Agents

No PA Required (*unless exceeds duration of therapy)

*Betamethasone dipropionate/propylene glycol (augmented) 0.05% cream
*Fluocinonide 0.05% cream, 0.05% gel, 0.05% solution, 0.05% ointment
*Triamcinolone acetonide 0.5% cream, 0.5% ointment

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

*All High Potency topical corticosteroids will require prior authorization beyond 4 weeks of therapy. The provider will be encouraged to transition to a medium or low potency topical steroid after this time has elapsed.

**Claims for compounded products containing high-potency topical steroids will be limited to a maximum of 60 grams or 60 mL of a high-potency ingredient per 4-week treatment period. Claims exceeding this quantity limit will require prior authorization with prescriber's justification for use of the product at the prescribed dose.

d. Topical Steroids – Very High Potency

Preferred Agents

No PA Required (unless exceeds duration of therapy*)
*Betamethasone dipropionate/propylene glycol (augmented) 0.05% ointment
*Clobetasol 0.05% cream, 0.05% gel, 0.05% ointment, 0.05% solution
*Fluocinonide 0.1% cream

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

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

25. *H. Pylori* Treatments

Preferred Agents
PYLERA[BNR] capsule (bismuth subcitrate/metronidazole tetracycline)

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

26. Pancreatic Enzymes

Preferred Agents
Creon (pancrelipase) capsule
Zenpep (pancrelipase) capsule

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

27. Proton Pump Inhibitors

Preferred Agents
Dexilant[BNR] (dexlansoprazole) capsule
Esomeprazole DR capsule (RX)
Lansoprazole DR capsules (RX)
Nexium[BNR] (esomeprazole) oral suspension packet
Omeprazole DR capsule (RX)
Pantoprazole tablet
Protonix[BNR] (pantoprazole DR) packet for DR Oral Suspension
Lansoprazole ODT (lansoprazole) *(for members under 2 years)*

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

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

- Member has a qualifying diagnosis (below) AND
- Member has trialed and failed therapy with three preferred agents within the last 24 months. (Failure is defined as: lack of efficacy following 4-week trial, allergy, intolerable side effects, or significant drug-drug interaction) AND
- Member has been diagnosed using one of the following diagnostic methods:
    - Diagnosis made by GI specialist
    - Endoscopy
    - X-ray
    - Biopsy
    - Blood test
    - Breath Test

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

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

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

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

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

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

28. Non-Biologic Ulcerative Colitis Treatments – Oral & Rectal

a. Non-Biologic UC Treatments – Oral

Preferred Agents
Apriso[BNR] (mesalamine ER) capsule
Lialda[BNR] (mesalamine DR) tablet
Pentasa[BNR] (mesalamine) capsule
Sulfasalazine IR and DR tablet

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

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

b. Non-Biologic UC Treatments – Rectal

Preferred Agents
Mesalamine suppository (generic Canasa)
Mesalamine 4gm/60 ml enema (generic SF Rowasa)

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

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

29. Erythropoiesis Stimulating Agents

Preferred Agents
PA Required for all agents in this class*
Epogen[BNR] (epoetin alfa) vial
Procrit (epoetin alfa) vial
Retacrit[BNR] (epoetin alfa-epbx)

*Prior Authorization is required for all products and may be approved if meeting the following:

- Medication is being administered in the member's home or in a long-term care facility **AND**
- Member meets one of the following:
  - A diagnosis of cancer, currently receiving chemotherapy, with chemotherapy-induced anemia, and hemoglobin† of 10g/dL or lower **OR**

- A diagnosis of chronic renal failure, and hemoglobin† below 10g/dL **OR**
- A diagnosis of hepatitis C, currently taking ribavirin and failed response to a reduction of ribavirin dose, and hemoglobin† less than 10g/dL (or less than 11g/dL if symptomatic) **OR**
- A diagnosis of HIV, currently taking zidovudine, hemoglobin† less than 10g/dL, and serum erythropoietin level of 500 mU/mL or less **OR**
- Member is undergoing elective, noncardiac, nonvascular surgery and medication is given to reduce receipt of allogenic red blood cell transfusions, hemoglobin† is greater than 10g/dL, but less than or equal to 13g/dL and high risk for perioperative blood loss. Member is not willing or unable to donate autologous blood pre-operatively

AND

- For any non-preferred product, member has trialed and failed treatment with one preferred product. Failure is defined as lack of efficacy with a 6-week trial, allergy, intolerable side effects, or significant drug-drug interaction.

†Hemoglobin results must be from the last 30 days.

Discussion

- No voting Board members reported a conflict of interest for any products included in this therapeutic class.
- K MacIntyre moved to accept all criteria as written in Mass Review, except for the ACE Inhibitor Single Agent subclass, which will be removed from Mass Review and reviewed separately. Seconded by I Pan. Motion passed unanimously.

Pulled from Mass Review by the Board

16.a Angiotensin Converting Enzyme (ACE) Inhibitors – Single Agent

Preferred Agents
Benazepril tablet
Enalapril tablet
Fosinopril tablet
Lisinopril tablet
Quinapril tablet
Ramipril tablet

Non-preferred ACE inhibitors, ACE inhibitor combinations, ARBs, ARB combinations, renin inhibitors, and renin inhibitor combination products may be approved for members who have trialed and failed treatment with three preferred products (failure is defined as lack of efficacy with a 4-week trial, allergy, intolerable side effects, or significant drug-drug interaction).

***Enalapril solution** may be approved without trial and failure of three preferred agents for members under the age of 5 years OR members who cannot swallow a whole or crushed tablet.

QBRELIS (lisinopril) solution may be approved for members 6 years of age or older who cannot swallow a whole or crushed tablet and have trialed and failed Epaned (enalapril) solution. Failure is defined as lack of efficacy with a 4-week trial, allergy, intolerable side effects, or significant drug-drug interaction.

Discussion

- I Pan moved to edit the statement "Enalapril solution may be approved without trial and failure of three preferred agents for members under the age of 5 years OR members who cannot swallow a whole or crushed tablet" to "Enalapril solution may be approved without trial and failure of three preferred agents for members who cannot swallow a whole or crushed tablet." B Jackson seconded. Motion passed unanimously.

- I Pan moved to accept the criteria for this subclass as amended. Seconded by K MacIntyre. Motion passed unanimously.

B. Proposed Coverage Criteria for Non-PDL Products

No voting Board members reported a conflict of interest for any of the products included in the Non-PDL Section of the meeting agenda.

1. BRIUMVI (ublituximab) intravenous solution
-- Pharmacy and medical benefit

Briumvi (ublituximab) may be approved if the following criteria are met:

1. For claims billed through the pharmacy benefit, prescriber verifies that the medication is being administered by a healthcare professional in the member's home or in a long-term care facility **AND**
2. Member is ≥ 18 years of age **AND**
3. Member has a relapsing form of multiple sclerosis (MS) **AND**
4. Member has experienced at least one relapse in the prior year or two relapses in the prior two years **AND**
5. Member has had trial and failure of any two high efficacy disease modifying therapies (such as ofatumumab, fingolimod, rituximab, ocrelizumab, alemtuzumab). Failure is defined as allergy, intolerable side effects, significant drug-drug interaction, or lack of efficacy. Lack of efficacy is defined as one of the following:
    a. On MRI, presence of any new spinal lesions, cerebellar or brainstem lesions, or change in brain atrophy **OR**
    b. Signs and symptoms on clinical exam consistent with functional limitations that last one month or longer

    AND
6. Member does not have active hepatitis B virus (HBV) infection **AND**
7. Briumvi (ublituximab) is prescribed by or in consultation with a neurologist or a physician that specializes in the treatment of multiple sclerosis **AND**
8. Member does not low serum immunoglobulins, based on quantitative tests performed before initiating treatment, **AND**
9. Prescriber attests that appropriate premedication will be administered prior to each Briumvi (ublituximab) infusion. For members with known psychiatric conditions, prescriber acknowledges that consultation with the member's behavioral health provider will be conducted prior to the member's receiving treatment with a high dose corticosteroid as part of the Briumvi premedication procedure, **AND**
10. For members of childbearing potential:
    a. Member is not pregnant and is able to receive a pregnancy test prior to each Briumvi (ublituximab) infusion **AND**
    b. Member has been counseled regarding the use of highly effective contraceptive methods while receiving treatment with Briumvi and for at least 6 months after stopping Briumvi

Quantity limit: Four 150 mg/6 mL single-dose vials for the first 2 weeks (initial dose), and three 150 mg/6 mL single-dose vials every 24 weeks thereafter

Exemption: If member is currently receiving and stabilized on Briumvi (ublituximab), they may receive prior authorization approval to continue therapy.

Scheduled Speaker Testimony

- E Stevenson – TG Therapeutics

Discussion

- Proposed criteria were read aloud by Dr. Garcia.
- S Klocke moved to (1) remove bullet point 9, as the corticosteroid dose used as pre-medication for ublituximab is unlikely to contribute to psychiatric symptoms, (2) remove bullet point 10 as currently written to "Members of childbearing potential have received counseling regarding the potential risks of use during pregnancy," (3) add the word "have" to the phrase "Member does not low serum immunoglobulins" in bullet point 8, and (4) consider adding preconception counseling such as "Members of childbearing potential have received counseling regarding the potential risks of use during pregnancy," to the existing PA criteria for Ocrevis and Tysabri. Seconded by K MacIntyre. Motion passed with five votes in favor. T Brubaker abstained due to not being available for this vote.
- S Klocke moved to accept criteria as amended. Seconded by K MacIntyre. Motion passed with five votes in favor. T Brubaker abstained due to not being available for this vote.

2. ROLVEDON (eflapegrastim-xnst) prefilled syringe for subcutaneous injection

-- Pharmacy benefit

ROLVEDON (eflapegrastim-xnst) may be approved if the following criteria are met:

1. For claims billed through the pharmacy benefit, prescriber verifies that the medication is being administered by a healthcare professional in the member's home or in a long-term care facility **AND**
2. Member is ≥ 18 years of age **AND**
3. Member has been diagnosed with a non-myeloid malignancy and is receiving myelosuppressive anti-cancer drugs associated with clinically significant incidence of febrile neutropenia, **AND**
4. Member is receiving Rolvedon (eflapegrastim-xnst) to decrease the incidence of infection, as manifested by febrile neutropenia **AND**
5. Member does not have mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation **AND**
6. Rolvedon is being prescribed by or in consultation with an oncologist, hematologist, or critical care provider **AND**
7. Member has failed† an adequate trial of one preferred product in the Colony Stimulating Factor therapeutic class on the Preferred Drug List (PDL) OR prescriber attests to clinical necessity for use of the requested agent.

Approval: 1 year
Maximum dose: 13.2 mg/14 days
Quantity limit: one 13.2 mg prefilled syringe/14 days

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

Discussion

- Proposed criteria were read aloud by R Tran, DUR Intern.
- S Klocke moved to accept the criteria as written. Seconded by T Brubaker. Motion passed unanimously.

3. LEQEMBI (lecanemab-irmb) intravenous solution

--Pharmacy and medical benefit

Leqembi (lecanemab-irmb) may be approved if the member meets ALL of the following criteria:

1. For claims billed through the pharmacy benefit, prescriber verifies that the medication is being administered by a healthcare professional in the member's home or in a long-term care facility **AND**
2. Member has documented diagnosis of mild cognitive impairment or mild dementia stage of Alzheimer's disease, the population in which treatment was initiated in clinical trials, as evidenced by ALL of the following:
   a. Positron Emission Tomography (PET) scan OR lumbar puncture positive for amyloid beta plaque
   b. Clinical Dementia Rating global score (CDR-GS) of 0.5 or 1 (available at https://otm.wustl.edu/cdr-terms-agreement/)
   c. Mini-Mental State Examination (MMSE) score of 24-30 OR Montreal Cognitive Assessment (moCA) Test score of 19-25

   AND
3. Member is ≥ 50 years of age AND
4. The prescriber attests that member has been counseled on the approval and safety status of Leqembi (lecanemab-irmb) being approved under accelerated approval based on reduction in amyloid beta plaques AND
5. Prior to initiation of Leqembi (lecanemab-irmb), the prescriber attests that the member meets ALL of the following:
   a. Member has had a brain MRI within the prior one year to treatment initiation, showing no signs or history of localized superficial siderosis, ≥ 10 brain microhemorrhages, and/or brain hemorrhage > 1 cm
   b. Attestation that MRI will be completed prior to the 5th, 7th and 14th infusions

   AND
6. Member does not have any of the following:
   a. Any medical or neurological condition other than Alzheimer's Disease that might be a contributing cause of the subject's cognitive impairment including (but not limited to) stroke/vascular dementia, tumor, dementia with Lewy bodies [DLB], frontotemporal dementia [FTD] or normal pressure hydrocephalus
   b. Contraindications to PET, CT scan, or MRI
   c. History of or increased risk of amyloid related imaging abnormalities ARIA-edema (ARIA-E) or ARIA-hemosiderin deposition (ARIA-H)
   d. History of unstable angina, myocardial infarction, chronic heart failure, or clinically significant conduction abnormalities, stroke, transient ischemic attack (TIA), or unexplained loss of consciousness within 1 year prior to initiation of Leqembi (lecanemab-irmb)
   e. History of bleeding abnormalities or taking any form of anticoagulation therapy

   AND
7. Leqembi (lecanemab-irmb) is prescribed by or in consultation with a neurologist **AND**
8. The prescribed regimen meets FDA-approved labeled dosing of 10 mg/kg, diluted then administered as an intravenous infusion over approximately one hour, every two weeks.

Initial approval period: 6 months

Subsequent approval: an additional 6 months of Leqembi (lecanemab-irmb) therapy may be approved with provider attestation that a follow-up MRI will be (or has been) completed prior to the 14th infusion

Maximum dose: 10 mg/kg IV every 2 weeks

The 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. If request is for use outside of stated coverage standards, support with peer reviewed medical literature and/or subsequent clinical rationale shall be provided and will be evaluated at the time of request.

Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trial(s).

Written Testimony

- Handout, Coral Cosway, Alzheimer's Association of Colorado

Discussion

- Proposed criteria were read aloud by Dr. Garcia.
- K MacIntyre moved to remove "the population in which treatment was initiated in clinical trials" from bullet point 2 "Member has documented diagnosis of mild cognitive impairment or mild dementia stage of Alzheimer's disease, the population in which treatment was initiated in clinical trials, as evidenced by ALL of the following:" Seconded by S Klocke. Motion passed unanimously.
- S Klocke also suggested that the same recommendation from the motion above be applied to the current criteria for Aduhelm (aducanumab).
- B Jackson moved to remove "PET" from, bullet 6.b that currently reads "Contraindications to PET, CT scan, or MRI." Seconded by S Klocke. Motion passed unanimously.
- P Lanius moved to remove bullet point 8 which reads "The prescribed regimen meets FDA-approved labeled dosing of 10 mg/kg, diluted then administered as an intravenous infusion over approximately one hour, every two weeks" since this information is also included in the Maximum Dose section. Seconded by S Klocke. Motion passed with five votes in favor. T Brubaker abstained due to not being available for this vote.
- K MacIntyre moved to accept criteria as amended. Seconded by S Klocke. Motion passed with five votes in favor. T Brubaker abstained due to not being available for this vote.

4. TZIELD (teplizumab-mzwv) single-dose vial for intravenous infusion

-- Pharmacy benefit

TZIELD (teplizumab-mzwv) may be approved if the following criteria are met:

1. For claims billed through the pharmacy benefit, prescriber verifies that the medication is being administered by a healthcare professional in the member's home or in a long-term care facility **AND**
2. Member is ≥ 8 years of age AND
3. Member has a diagnosis of Stage 2 type 1 diabetes, AND
4. The member's clinical history does not suggest type 2 diabetes, AND
5. The requested medication is being prescribed in consultation with an endocrinologist AND
6. Prescriber attests that patient will be monitored for Cytokine Release Syndrome (CRS) AND
7. Prescriber attests that appropriate premedication will be administered prior to each TZIELD (teplizumab-mzwv) infusion, AND
8. Prescriber attests that lymphocyte counts and liver function tests will be closely monitored during the treatment period, AND
9. Member has no serious infections at time of starting therapy AND
10. Member is not pregnant or planning to become pregnant

Dosing limit: Approval will be placed to allow for one 14-day course of treatment

Scheduled Speaker Testimony

- J Aldridge – Prevention Bio

Discussion

- Proposed criteria were read aloud by R Tran, DUR Intern.
- S Klocke moved to accept the criteria as written. Seconded by I Pan. Motion passed unanimously.

5. **Mifeprex** (mifepristone) is excluded from coverage under the pharmacy benefit. may be approved if meeting the following criteria:
   - The requested medication is being billed as a pharmacy claim for administration by the patient (Note that submission of this request applies to pharmacy claims billing only. Medication administered by a healthcare professional in the office, clinic, or outpatient hospital setting should be billed through the medical benefit in accordance with claim billing processes outlined for medical) **AND**
   - The requested medication is being prescribed as federally allowed for use for one of the following:
     - Abortion to save the life of the mother **OR**
     - Abortion for sexual assault (rape) or incest **OR**
     - Use for non-viable pregnancy (pregnancy loss, miscarriage, or anembryonic service)

   AND
   - The prescriber submits all required information contained within the posted "Certification Statement" form associated with the services provided in relation to this request to the Magellan Pharmacy helpdesk by fax at 1-800-424-5725 for review and approval (forms are located at https://hcpf.colorado.gov/provider-forms under "Claim Forms and Attachments"). Prior authorization approval will allow for one full treatment course of both mifepristone and misoprostol.

6. **Cytotec** (misoprostol) – (Effective 07/18/19 06/01/23) Prior authorization may be approved for members meeting the following:
   - Misoprostol is not being prescribed for use related to termination of pregnancy AND
   - The requested medication is being prescribed for use for one of the following:
     - Prophylaxis for reducing risk of NSAID-induced gastric ulcers in patients at high risk of complications from gastric ulceration **OR**
     - Use for other off-label indications supported by clinical compendia, peer-reviewed medical literature, and medical necessity.

   AND
   - For requests for use for termination of pregnancy or non-viable pregnancy, the request meets the following:
     - The requested medication is being billed as a pharmacy claim for administration by the patient (note that this request applies to pharmacy claims billing only. Medication administered by a healthcare professional in the office, clinic, or outpatient hospital setting should be billed through the medical benefit in accordance with claims billing processes outlined for medical) **AND**
     - The prescriber submits all required information contained within the posted "Certification Statement" form associated with the services provided in relation to this request to the Magellan Pharmacy helpdesk by fax at 1-800-424-5725 for review and approval (forms are located at https://hcpf.colorado.gov/provider-forms under "Claim Forms and Attachments"). Prior authorization approval will allow for one full treatment course of misoprostol.

Discussion

- Proposed criteria for Mifeprex (mifepristone) and Cytotec (misoprostol) were reviewed as one section.
- Dr. Taylor commented the Department is aware of the evolving political landscape regarding coverage of abortion related services and the associated medications. The Department's leadership feels it is important to bring these drug utilization criteria through the public process to ensure a public forum and transparency regarding these types of policies.
- HCPF Forms related to abortion services are available at https://hcpf.colorado.gov/provider-forms → Claim Forms and Attachments → Women's Health → Certification Statement Forms. Three certification forms currently in use for in-office administration under the medical benefit: (1) Abortion to save the life of the mother,

(2) Abortion for sexual assault (rape) or incest, and (3) Use for non-viable pregnancy (pregnancy loss, miscarriage, or anembryonic service). Today's discussion is related to a January 2023 FDA update to the REMS program for these medications that allows certified pharmacies to dispense mifepristone and misoprostol in the outpatient setting. In the new pharmacy benefit workflow, these same forms will be sent to the pharmacy desk rather than the medical utilization management team. The proposed criteria changes for these two medications would be implemented on June 1, 2023.

- A lengthy discussion included plans to communicate the new coverage policy to Heath First Colorado providers, plans to post the new criteria publicly on Appendix P, the difference between evidence-based FDA labeled indications for mifepristone and misoprostol and their off-label use for abortion related services under the FDA REMS, tracking and reporting requirements regarding the use of these two medications under both the medical and pharmacy benefits, and permitted coverages according to the federal Hyde Amendment statute.
- K MacIntyre moved to accept these criteria as written. There was no second, and Dr. MacIntyre later withdrew this initial motion. After further Board discussion, K MacIntyre moved that mifepristone and misoprostol criteria be returned to the Department for further evaluation. Seconded by S Klocke. Motion passed unanimously.

C. Adjournment

Vice Chair Jackson reminded attendees that the next Board meeting is tentatively scheduled for Tuesday, August 8, 2023, from 1:00 to 5:00 pm and also reminded Board members to delete their meeting binders and the associated email at the conclusion of today's meeting.

I Pan moved to adjourn the meeting, Seconded by K MacIntyre. Motion passed unanimously. The meeting was adjourned at 3:52 pm.

Minutes respectfully submitted by Julia Rawlings, PharmD