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 10, 2022
Open Session
1:00 pm – 5:00 pm

1. Call to Order

Today's meeting was held virtually via Zoom. The meeting was called to order at 1:01 pm by A Shmerling, Board Chair.

2. Roll Call and Introductions

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

- **Members Present:** Alison Shmerling, MD, MPH (Chair); Liza Claus, PharmD (Vice Chair); Todd Brubaker, DO; Patricia Lanius, BSPharm, MHA; Brian Jackson, MD, MA; Shilpa Klocke, PharmD; Ingrid Pan, PharmD, Ken MacIntyre, DO
- **Members Absent:** None
- **Medicaid Pharmacy Staff:** Jim Leonard, PharmD; Jeffrey Taylor, PharmD
- **CO-DUR Team**: Robert Page, PharmD, MSPH; Julia Rawlings, PharmD

3. Virtual Meeting Information and General Announcements

J Rawlings shared several announcements:

- This meeting is being recorded for internal use by the Department
- We ask that speakers and other attendees who are not on the Board or facilitating the meeting to remain off-video with microphones muted.
- Ryan Tran, University of Colorado DUR pharmacy intern, will be managing the technical aspects of today's Zoom meeting.
- Stakeholders who have signed up in advance to provide testimony will have their microphones unmuted and may turn on video at the appropriate time.
- Speakers providing testimony, and other meeting guests, are asked to keep video turned off throughout the meeting so that we can more easily see and track Board members' votes.

Reminders for Board Members:

- Video and microphone for Board members will be turned ON. To facilitate the voting process, keeping your video turned on as much as possible during the meeting is encouraged.
- If you experience technical difficulties or your connection interrupted during the meeting, please leave the meeting and use the same Zoom meeting link to be readmitted, as that usually resolves the issue.

- Two meeting binders containing DUR documents and written stakeholder testimony were sent to all Board members. Use the icon on the left that looks like a ribbon to quickly navigate to specific documents.
- Shaded rows on the market share tables indicate the current preferred products on the PDL.
- An important reminder to all Board members to DELETE the meeting binders immediately following this meeting.
- Voting may be conducted by raising your hand and/or by verbal "ayes" and "nays," abstentions, and recusals as determined by the Board Chair and/or Vice-Chair.

4. Colorado Department of Health Care Policy and Financing Updates

J Taylor provided updates from the Department:

- DUR Board membership updates
  a. Recently ended terms: Dr. Miro Anguelov, Dr. Lyle Laird, and Dr. Scott VanEyk
  b. New Board Members appointed this quarter:
     - Dr. Ingrid Pan (Rheumatology Pharmacy Specialty at Children's Hospital Colorado)
     - Dr. Ken MacIntyre (Psychiatry Medical Specialty – MHCD)
  c. Thank you to Dr. Liza Claus for renewing her appointment until 2024
  d. The Board currently has an opening for an Industry Representative. The Industry Representative serves for one year in a *non-voting* role and does not need to be a physician or pharmacist by training. Please send an email with your CV to jeffrey.taylor@state.co.us if you are interested in applying for this position.

- For products and drug classes currently managed with DUR criteria posted on the PDL or Appendix P, only proposed changes to the currently posted criteria will be read aloud.

- The current PDL and Appendix P are available on the Department's Pharmacy Resources page at https://hcpf.colorado.gov/pharmacy-resources

- Items included in today's proposed criteria may be moved either into or out of mass review, depending on whether any speakers have signed up to provide testimony for specific drug classes or if any edits have been made to the proposed criteria.

- The remaining Board meetings for 2022 are tentatively scheduled to be held virtually on May 10, August 9, and November 8. All meetings will be held on Zoom from 1:00 to 5:00 pm. Board members should have already received calendar invitations for these two dates. If you have not yet received these invitations, please let J Rawlings know.

5. Final Approval of Minutes from February 8, 2022 Meeting

Board Chair A. Shmerling asked if there were any changes to propose for minutes from the February 8 DUR Board meeting. With no discussion, a motion to approve the minutes as written made by L Claus and seconded by P Lanius. The motion passed unanimously.

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

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

Rules for Speaker Testimony: Presentations shall be restricted to products being reviewed for prior authorization criteria. Presentations shall be limited to a maximum of three minutes per drug product. Only one presentation per product will be permitted for a manufacturer. Presenters 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 at the time they are speaking.

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

7. Clinical Updates and General Orders

- **FDA New Product & Safety Updates**

  DUR Intern Thao Anh Mai presented FDA Safety information (3/30/2022) about the importance of thyroid monitoring in babies and young children (through 3 years of age) who receive injections of iodine-containing contrast media (ICM) for medical imaging.

  DUR Intern Ryan Tran presented a summary of recent FDA drug approvals.

- **Retrospective DUR Reports**

  R Page presented the RDUR summary.

  - There was a slight increase during 1Q2022 in the number of members <18 years of age who received two or more antipsychotic medications concomitantly for 45 or days or more.
  - Data regarding the number of members who had two or more benzodiazepine claims concomitantly for ≥ 90 days has leveled off and remained fairly consistent in both the number of providers and members.
  - The number of members who received an opioid, a benzodiazepine and a skeletal muscle relaxant concomitantly for 60 or more days (excluding individuals with a diagnosis of cancer or sickle cell disease) decreased from 4Q2021 to 1Q2022.
  - The number of members and providers associated with claims for opioids exceeding an average of 200 MME in a 30-day period continues to trend downward.
  - Members with multiple claims for opioid prescriptions that total >150 MME (averaged over 30 days) and no naloxone fill within the 12 months prior to or during the current quarter decreased from 4Q2021 to 1Q2022.

- **Quarterly Drug Utilization Reports**

  Board members were referred to these reports in the meeting binder. R Page highlighted that the top drugs in 1Q2022 by number of claims were Proair HFA, gabapentin, sertraline, omeprazole, amoxicillin, trazodone, lisinopril, ibuprofen, atorvastatin and levothyroxine. Top drugs by cost were Humira®, Trikafta®, Biktarvy®, Trulicity®, Latuda®, Novolog®, Lidoderm®, Suboxone® and ProAir® HFA.

- **Quarterly Clinical Modules**

R Page presented an update on Quarterly Clinical Modules, complex clinical modules created by the CO-DUR team based on the needs of the Department and to assist with policy development.

- **Analysis of the First Health Colorado DUR Pain Management Consultation Service**
  (final module delivered to the Department on 3/31/2022)
  - The current Opioid Consult Service has been in existence for about five years. This module updates our initial assessment since 10/31/2019.
  - Between March 2, 2017 to September 30, 2021, 2,877 members have triggered at least one completed opioid consult.
  - Members receiving high dose opioids had an average of about 1.5 completed consults during the study period, while opioid naïve members had an average of one completed consult.
  - As expected, 21% members receiving high dose opioids had a prior high dose consult. Of note, about 1,373 members has a consult initiated for an "other" reason in which 59.8% were triggered by an opioid fill exceeding the 14-day prescription limit and 20.25% in which the opioid fill did not meet the Department's preferred criteria.

  Conclusions/Recommendations
  - Access to a pain specialist in Colorado is extremely limited, particularly for our Health First Colorado members.
  - A major need for provider education in the primary care setting still exists.
  - Due to high demand by provider stakeholders, more than one physician, as well as inclusion of other health care disciplines, such as nurse practitioners and pharmacists to assist in therapeutic plan development are needed for sustainability.

8. New Business

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

- Board members will be asked if they have potential conflicts of interest to disclose prior to reviewing the therapeutic drug classes or individual products listed in the meeting agenda.
- For products and drug classes being newly managed and undergoing review, all proposed criteria will be read aloud during the meeting. For products and drug classes that are currently managed with DUR criteria posted on the PDL and Appendix P, only proposed changes to the currently posted criteria will be read aloud.
- Time is permitted for stakeholder comment. All speakers have registered in advance, and each will be given up to 3 minutes of time to present.
- There will be an opportunity for Board discussion.
- Then we will capture for the minutes all motions made by the Board:
  - Name of the member who makes the motion
  - Name of the member who 2nds the motion
  - Abstentions, recusals, and voting results
  - To facilitate recordkeeping for this meeting, a reminder to Board members to please clearly and state your name when making motions and offering seconds

R Page proceeded with the review process of proposed criteria.

Proposed Criteria

Red indicates proposed deleted text

Yellow indicates proposed new text

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

1. Tetracyclines

Preferred Agents
Doxycycline hyclate tablets, capsules
Doxycycline monohydrate 50 mg, 75 mg, 100 mg capsule
Doxycycline monohydrate tablets
Minocycline capsules

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.)

Discussion

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

2. Angiotensin Modifiers

a. Angiotensin Converting Enzyme (ACE) Inhibitors, single agent

Preferred Agents – ACE Inhibitors
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).

***Epaned** (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.

b. Angiotensin Converting Enzyme (ACE) Inhibitor Combinations

Preferred Agents – ACE Inhibitor Combination Products
- Amlodipine/Benazepril capsule
- Enalapril/HCTZ tablet
- Lisinopril/HCTZ 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).

c. Angiotensin Receptor Blockers (ARBs)

Preferred Agents – ARBs
- 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 product 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).

d. Angiotensin Receptor Blocker (ARB) Combinations

Preferred Agents – ARB Combination Products
No PA Required (unless indicated*)
- Amlodipine/olmesartan tablet
- Amlodipine/valsartan tablet
- Irbesartan/HCTZ tablet
- Losartan/HCTZ tablet
- Olmesartan/HCTZ tablet
- Valsartan/HCTZ tablet
- ENTRESTO (sacubitril/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 is ≥ 1 year of age 1 to 17 years 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.

Discussion

- All four sub-classes of angiotensin modifiers were reviewed as one section.
- B Jackson moved to accept the proposed criteria as written. Seconded by S Klocke. Motion passed unanimously.

3. Pulmonary Arterial Hypertension (PAH) Therapies

a. Phosphodiesterase Inhibitors (PDEIs)

Preferred Agents
***Must meet eligibility criteria**
*REVATIO[BNR] (sildenafil) oral suspension
*Sildenafil (generic Revatio) 20 mg tablet
*Tadalafil (generic Adcirca) 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. Endothelin Receptor Antagonists

Preferred Agents
***Must meet eligibility criteria**
*Ambrisentan tablet
*TRACLEER[BNR] 62.5 mg, 125 mg (bosentan) 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. Prostanoids Prostacyclin Analogues and Receptor Agonists

Preferred Agents, Prostanoids
***Must meet eligibility criteria**
*Epoprostenol (generic Flolan) 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. Guanylate Cyclase (sGC) 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).

Stakeholder input:
Written testimony, Tyvaso – United Therapeutics

Scheduled testimony presentations:
Z Rideman, Tyvaso – United Therapeutics

Discussion
- All four sub-classes of Pulmonary Arterial Hypertension Therapies were reviewed as one section.
- L Claus moved to accept the proposed criteria as written. Seconded by S Klocke. Motion passed unanimously.

4. Statins & Combinations

a. Statins

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 and lovastatin will not be approved for members < 10 years of age.
- Livalo will not be approved for members < 8 years of age.

b. Statin Combinations

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.

Discussion
- Statin and Statin Combinations were reviewed as one section.
- L Claus moved to accept the proposed criteria as written. Seconded by K MacIntyre. Motion passed unanimously.

5. Acne Agents, Topical (new sub-class divisions on the PDL, DUR criteria at end of class)

a. **Antibiotics and Antibiotic Combinations**

Preferred Agents, Antibiotics and Antibiotic Combinations
No PA Required (if age and diagnosis criteria are met*)
*Clindamycin phosphate solution, medicated swab
*Clindamycin/benzoyl peroxide gel jar (generic Benzaclin)
*Clindamycin/benzoyl peroxide (generic Duac)
*Erythromycin solution
*Erythromycin/benzoyl peroxide

b. **Retinoids & Retinoid Combination Products**

Preferred Agents, Retinoids & Retinoid Combination Products
No PA Required (if age and diagnosis criteria are met*)
*Adapalene gel
*Adapalene/benzoyl peroxide (generic Epiduo)
*DIFFERIN^{BNR} (adapalene) gel pump
*RETIN-A^{BNR} (tretinoin) cream, gel

c. **Other Products**

Preferred Agents, Other products
No PA Required (if age and diagnosis criteria are met*)
*Dapsone gel
*Sulfacetamide sodium suspension

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.

Discussion

- S Klocke moved to accept the proposed criteria for all topical acne agents as written. Seconded by T Brubaker. Motion passed unanimously.

6. Anti-Psoriatics

a. Anti-Psoriatics, topical

Preferred Agents, topical
Calcipotriene solution
DOVONEX[BNR] (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 requesting 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.

b. Anti-Psoriatics, oral

Preferred Agents, oral
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.

Discussion

- K MacIntyre moved to accept the proposed criteria for all anti-psoriatic agents as written. Seconded by T Brubaker. Motion passed unanimously.

7. Immunomodulators, Topical

a. Atopic Dermatitis

Preferred Agents
ELIDEL[BNR] (pimecrolimus) cream
Tacrolimus ointment

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.

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 conjunction with a dermatologist or allergist/immunologist.

Quantity limit: 60 grams/week

b. 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. **Other Agents** (new sub-class on the PDL)

Preferred Agents
CONDYLOX (podofilox) gel
Imiquimod cream (generic ALDARA)
Podofilox solution

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.

Veregen (sinecatechins) may be approved if the following criteria are met:

- Member is ≥ 18 years of age AND
- Member is immunocompetent AND
- Member has a diagnosis of external genital and/or perianal warts *(Condylomata acuminata)* AND
- Member has tried and failed two preferred products in the Topical Immunomodulators therapeutic class. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.

Zyclara (imiquimod) **2.5% or 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 two preferred products in the Topical Immunomodulators therapeutic class. 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 the 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 in the Topical Immunomodulators therapeutic class. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.

Discussion

- A Shmerling asked about the comparatively straightforward contraception counseling requirement for Targretin (bexarotene) gel when contraception criteria for other agents on the PDL are often more specific.
- L Claus moved to accept the proposed criteria for all topical immunomodulator agents as written. Seconded by S Klocke. B Jackson abstained. Motion passed, with seven members voting in favor.

8. Topical Steroids

a. 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. 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, 0.1% 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. High potency

Preferred Agents
No PA Required (*unless exceeds duration of therapy, **unless a compounded product claim)
*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.

**Compound claims are limited to 60 grams or 60 mL per 4-week treatment period. Claims exceeding quantity limit will require prior authorization with prescriber's justification for use of the product at the prescribed dose.

d. 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.

Discussion
- All sub-classes of topical steroids were reviewed as one section.
- T Brubaker raised a concern that not every Colorado town has access to a compounding pharmacy to readily obtain products for severe eczema and other skin conditions.
- I Pan added that in her experience she is not aware of many members who have experienced barriers to obtaining compounded pharmaceutical products, as her team tries to use commercially-available products whenever possible.
- J Taylor clarified that the intent of the new criteria related to compounded products would be to limit quantities of high potency steroid-containing compounds in order to help ensure appropriate utilization of high-potency topical products.
- B Jackson moved to accept the proposed criteria as written. Seconded by K MacIntyre. Motion passed unanimously.

9. Antiemetics

a. Antiemetics, oral

Preferred Agents
No PA Required (unless exceeds duration of therapy*)
DICLEGIS DR[BNR] tablet (doxylamine/pyridoxine)
Meclizine (Rx) 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.

b. Antiemetics, non-oral

Preferred Agents
Prochlorperazine 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

- Both sub-classes of antiemetic agents were reviewed as one section.
- S Klocke moved to accept the proposed criteria a written. Seconded by P Lanius. Motion passed unanimously.

10. *H. pylori* treatments

Preferred Agents
PYLERA tablet (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.

Discussion

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

11. Pancreatic Enzymes

Preferred Agents
CREON (pancrelipase) capsule
PANCREAZE (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.)

Members currently stabilized on a Non-preferred pancreatic enzyme may receive approval to continue on that agent for one year if medically necessary.

Discussion

- S Klocke asked about prior authorization process for pancreatic enzymes if the "approval to continue" statement is deleted. J Taylor explained that preferred products in this therapeutic class have not undergone any changes for a long time. What the Department is proposing is to no longer automatically approve PAs for members who are stabilized on non-preferred pancreatic enzyme products. PAs for non-preferred products would need to be resubmitted as current 12-month approvals expire.
- P Lanius moved to accept the proposed criteria as written. Seconded by B Jackson. T Brubaker was unavailable for this vote (abstention). Motion passed, with seven members voting in favor.

12. Anticoagulants

a. Anticoagulants, oral

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

BEVYXXA (betrixaban) may be approved if all the following criteria have been met:
- The member has trialed and 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**
- The member is need of prophylaxis for DVT following hospitalization for an acute medical illness who are at risk for thromboembolic events due to limited mobility **AND**
- The member does not have a mechanical prosthetic heart valve

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 2.5mg (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 for members < 5 years of age without prior authorization. For members ≥ 5 years of age, XARELTO (rivaroxaban) oral suspension may be approved for members who cannot swallow a whole or crushed tablet.

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, parenteral

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
- Both anticoagulant sub-classes were reviewed as one section.
- A Shmerling asked about the cut off of 5 year of age regarding the ability to swallow tablets. Five years may be a little too young for this delineation. T Brubaker agreed that 5 years may be a bit young. B Jackson noted that for members >5 years, DUR criteria usually offer coverage for non-solid dosage forms with prescriber attestation that the member cannot use a solid dosage form.
- A Shmerling asked if data could be analyzed to determine whether members older than five years require repeated prior authorization reviews in order to obtain needed medications. Could the minimum age be adjusted to 6 or 7 years on the PDL to globally decrease the volume of PA requests involving non-solid dosage forms for pediatric members?

- J Taylor mentioned that in addition to age-specific cut-offs, the Department considers alternative preferred dosage forms within a drug class that may be used by pediatric members, such as products that can be crushed and/or sprinkled on soft food.
- J Rawlings offered that Bevyxxa (betrixaban) was voluntarily removed from the market by the manufacturer in April 2020 for business reasons.
- K MacIntyre asked if the new clinical guidelines regarding aspirin use would potentially affect this set of criteria. R Page explained that the new guidelines would not affect therapy for primary prevention of cardiovascular events.
- L Claus moved to accept the proposed criteria as written. Seconded by K MacIntyre. Motion passed unanimously.

13. Antiplatelet Agents

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

Patients taking **Brilinta (ticagrelor)** must also be taking a maintenance dose of aspirin not exceeding 100 mg/day.

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
- This drug class was moved out of mass review during today's meeting.
- S Klocke asked about the inclusion of dipyridamole, not in combination with aspirin, as a preferred anti-platelet agent, and if it would be possible for the Department to take a look at utilization of this product in more detail regarding its appropriate use. J Taylor explained that utilization of dipyridamole tablets is extremely low in Colorado.
- R Page added that dipyridamole tablets are used for "Persantine" stress tests in cardiology departments.
- L Claus moved to accept the proposed as written. Seconded by B Jackson. Motion passed unanimously.

14. Colony Stimulating Factors

Preferred Agents
PA Required for all agents in this class*
NEUPOGEN (filgrastim) vial, syringe
NYVEPRIA (pegfilgrastim-apgf) syringe
UDENYCA (pegfilgrastim-cbqv)
ZIEXTENZO (pegfilgrastim-bmez)

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

Medication is being used for one of the following indications:

Cancer patient 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 Udenyca (pegfilgrastim-cbqv) or Ziextenzo (pegfilgrastim-bmez), 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:

Cancer patient 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

- This drug class was moved out of mass review during today's meeting.
- I Pan asked if biosimilar Nyvepria (pegfilgrastim-apgf) prefilled syringes can be manipulated to obtain smaller doses for pediatric members. J Taylor confirmed that the Department would take this question into consideration as the DUR criteria are being finalized.
- B Jackson moved to accept the proposed criteria as written. Seconded by S Klocke. Motion passed unanimously.

Mass review drug classes*

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

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

1. 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).

2. Beta Blockers – Single Agent, Anti-Arrhythmics & Combinations

a. Beta blockers, single agent

Preferred Agents
Acebutolol capsule
Atenolol tablet
Bisoprolol tablet
BYSTOLIC[BNR] (nebivolol) tablet
Carvedilol IR tablet
Carvedilol ER capsule
Labetalol tablet
Metoprolol tartrate tablet
Metoprolol succinate ER tablet
Nadolol 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: 200mg/day (adult); 50mg/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, Anti-arrhythmics

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).

3. Calcium Channel Blockers – DHPs & Non-DHPs

a. Dihydropyridines (DHPs)

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 **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. Non-Dihydropyridines (Non-DHPs)

Preferred Agents
Diltiazem IR tablet
Diltiazem 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.

4. Angiotensin Modifiers - 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.

5. Lipotropics

a. 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 will 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. 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 will 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. Other Lipotropics

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 will 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)

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 ≥ 150mg/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

6. Acne Agents, Oral Isotretinoin

Preferred Agents
PA Required for all agents
AMNESTEEM capsule
CLARAVIS capsule
Isotretinoin capsule 10 mg, 20 mg, 30 mg, 40 mg *(all 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 two preferred agents (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.

Therapy completion: Members currently taking AMNESTEEM or CLARAVIS may continue on those products after 7/1/22 in order to finish their current course of treatment (15 to 20 weeks total).

7. Rosacea Agents

Preferred Agents
FINACEA[BNR] (azelaic acid) gel
METROGEL[BNR] (metronidazole)
Metronidazole cream, lotionFepan
Metronidazole gel 0.75% gel
MIRVASO (brimonidine) gel pump

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)

***Oracea (doxycycline monohydrate DR)** 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)

8. Androgenic Agents - Topical, Injectable & Oral

Preferred Agents
ANDRODERM (testosterone) patch
ANDROGEL[BNR] (testosterone) gel 1.62% pump
ANDROGEL[BNR] (testosterone) gel packet
Testosterone cypionate vial
Testosterone 1% gel packet

Injectable testosterone cypionate is a pharmacy benefit when self-administered. Administration in an office setting is a medical benefit.

Hypogonadotropic or Primary Hypogonadism (may be secondary to Klinefelter Syndrome):

Preferred products may be approved for members meeting the following:

- Member is a male patient > 16 years of age with a documented diagnosis of hypogonadotropic or primary hypogonadism OR ≥ 12 years of age with a diagnosis of hypogonadotropic or primary hypogonadism secondary to Klinefelter Syndrome (all other diagnoses will require manual review) **AND**
- Member has two documented low serum testosterone levels below the lower limit of normal range for testing laboratory prior to initiation of therapy **AND**
- Member does not have a diagnosis of breast or prostate cancer **AND**
- If the member is > 40 years of age, has prostate-specific antigen (PSA) < 4 ng/mL or has no palpable prostate nodule **AND**
- Member has baseline hematocrit < 50%

Reauthorization Criteria (requests for renewal of a currently expiring prior authorization for a preferred product may be approved for members meeting the following criteria):

- Member is a male patient > 16 years of age with a documented diagnosis of hypogonadotropic or primary hypogonadism **OR** ≥ 12 years of age with a diagnosis of hypogonadotropic or primary hypogonadism secondary to Klinefelter Syndrome **AND**
- Serum testosterone is being regularly monitored (at least annually) to achieve total testosterone level in the middle tertile of the normal reference range **AND**
- Member does not have a diagnosis of breast or prostate cancer **AND**
- Member has a hematocrit < 54%

Gender Transition/Affirming Hormone Therapy:

1. Preferred androgenic drugs may be approved for members meeting the following:
2. Female sex assigned at birth > 16 years of age **AND**
3. Is undergoing female to male transition **AND**
4. Has a negative pregnancy test prior to initiation **AND**
5. Has baseline hematocrit < 50% or hematocrit < 54% for continuation of therapy

Non-Preferred Products:

Non-preferred topical androgenic agents may be approved for patients meeting the above criteria with trial and failed‡ therapy with two preferred topical androgen formulations.

Non-preferred injectable androgenic agents may be approved for patients meeting the above criteria with trial and failed‡ therapy with a preferred injectable androgenic drug.

Prior authorization for oral androgen agents (tablet, capsule, buccal) may be approved if member has trialed and failed‡ therapy with a preferred topical agent AND testosterone cypionate injection.

‡Failure is defined as lack of efficacy with 8 week trial, allergy, intolerable side effects, contraindication to, or significant drug-drug interaction.

For all agents and diagnoses, members < 16 years of age will require a manual prior authorization review by a pharmacist (with exception of members ≥ 12 years of age with a diagnosis of hypogonadotropic or primary hypogonadism secondary to Klinefelter Syndrome).

9. 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**
- 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 with an inadequate response **OR**
- Member has had intolerable side effects, drug-drug interaction, or allergy to preferred ursodiol formulations.

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

10. GI Motility, Chronic

Preferred Agents
PA Required for all agents in this class
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 bisocodyl, for example). OR If the member cannot take oral medications, then the member must fail a 7-day trial with a nonphosphate enema (docusate or bisocodyl 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.

11. 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% cream (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

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).

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 and Combination Products

Preferred Agents
- Hydrocortisone-Hydrocortisone 3-0.5% cream
- Lidocaine-Prilocaine Cream 2.5%-2.5% cream
- 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).

12. Proton Pump Inhibitors

Preferred Agents
- Esomeprazole DR capsule (RX)
- Lansoprazole DR capsules (RX)
- NEXIUM[BNR] (esomeprazole) oral suspension packet
- Omeprazole DR capsule (RX)
- Pantoprazole tablet
- 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 trailed 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.

13. Non-Biologic Ulcerative Colitis Agents

Preferred Agents
APRISO[BNR] (mesalamine ER) capsule
LIALDA[BNR] (mesalamine DR) tablet
Mesalamine 4gm/60 ml sulfate-free enema (generic SF ROWASA)
Mesalamine suppository (generic CANASA)
PENTASA (mesalamine) capsule
Sulfasalazine IR tablet, 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.

14. Phosphate Binders

Preferred Agents
Calcium acetate capsule
PHOSLYRA (calcium acetate)
RENAGEL[BNR] (sevelamer HCl 800mg tablet)
RENVELA[BNR] (sevelamer carbonate) tablet, powder pack
Sevelamer HCl 800mg tablet

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

- Member has diagnosis of end stage renal disease AND
- Member has elevated serum phosphorus [> 4.5 mg/dL or > 1.46 mmol/L] AND
- Provider attests to member avoidance of high phosphate containing foods from diet AND
- Member has trialed and failed‡ one preferred agent (lanthanum products require trial and failure‡ of a preferred sevelamer product).

Auryxia (ferric citrate) may be approved if the member meets all the following criteria:

- Member is diagnosed with end-stage renal disease, receiving dialysis, and has elevated serum phosphate (> 4.5 mg/dL or > 1.46 mmol/L). AND
- Provider attests to counseling member regarding avoiding high phosphate containing foods from diet AND
- Member has trialed and failed‡ three preferred agents with different mechanisms of action prescribed for hyperphosphatemia in end stage renal disease
  OR
- Member is diagnosed with chronic kidney disease with iron deficiency anemia and is not receiving dialysis AND
- Member has tried and failed‡ at least two different iron supplement product formulations (OTC or RX)

Velphoro (sucroferric oxyhydroxide tablet, chewable) may be approved if the member meets all of the following criteria:

- Member is diagnosed with chronic kidney disease and receiving dialysis and has elevated serum phosphate (> 4.5 mg/dL or > 1.46 mmol/L). AND
- Provider attests to counseling member regarding avoiding high phosphate containing foods from diet AND
- Member has trialed and failed‡ two preferred agents, one of which must be a preferred sevelamer product

Maximum Dose: Velphoro 3,000 mg daily

Members currently stabilized on a non-preferred lanthanum product may receive approval to continue therapy with that product.

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

Note: Medications administered in a dialysis unit or clinic are billed through the Health First Colorado medical benefit or Medicare with members with dual eligibility.

15. Erythropoiesis Stimulating Agents

Preferred Agents
PA Required for all agents in this class*
PROCRIT (epoetin alfa) vial
RETACRIT (epoetin alfa-epbx) (*Pfizer only)*

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

1. Medication is being administered in the member's home or in a long-term care facility **AND**
2. Member meets one of the following:
    a. A diagnosis of cancer, currently receiving chemotherapy, with chemotherapy-induced anemia, and hemoglobin† of 10 g/dL or lower **OR**
    b. A diagnosis of chronic renal failure, and hemoglobin† below 10 g/dL **OR**
    c. A diagnosis of hepatitis C, currently taking ribavirin and failed response to a reduction of ribavirin dose, and hemoglobin† less than 10 g/dL (or less than 11 g/dL if symptomatic) **OR**
    d. A diagnosis of HIV, currently taking zidovudine, hemoglobin† less than 10g/dL, and serum erythropoietin level of 500 (mU/mL) or less **OR**
    e. Member is undergoing elective, noncardiac, nonvascular surgery and medication is given to reduce receipt of allogenic red blood cell transfusions, hemoglobin† is greater than 10 g/dL, but less than or equal to 13 g/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.

16. Benign Prostatic Hyperplasia (BPH) Agents

Preferred Agents
Alfuzosin ER tablet
Doxazosin tablet
Dutasteride capsule
Finasteride tablet
Tamsulosin capsule
Terazosin capsule

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

- Member has tried and failed‡ three preferred agents AND
- For combinations agents, member has tried and failed‡ each of the individual agents within the combination agent and one other preferred agent.

‡Failure is defined as lack of efficacy with 8-week trial, allergy, intolerable side effects, contraindication to, or significant drug-drug interaction.

***CIALIS (tadalafil)** may be approved for members with a documented diagnosis of BPH who have failed a trial of finasteride (at least 3 months in duration) AND either a trial of a nonselective alpha blocker (therapeutic dose for at least two months) OR a trial of tamsulosin (therapeutic dose for at least one month).

Documentation of BPH diagnosis will require BOTH of the following:

- AUA Prostate Symptom Score ≥ 8 **AND**
- Results of a digital rectal exam.

Cialis (tadalafil) will not be approved for any patient continuing alpha-blocker therapy as this combination is contraindicated in this population.

Doses exceeding 5 mg per day of Cialis (tadalafil) will not be approved.

Discussion concerning therapeutic classes included in Mass Review

- Erythropoiesis Stimulating Agents and Benign Prostatic Hyperplasia (BPH) Agents were added to mass review during today's meeting.
- B Jackson asked if oral tretinoin products were being transitioned to generic products this quarter. J Taylor explained that new preferred agents include Absorica and Absorica LD (branded products) and generic products.
- I Pan asked about the statement within criteria for Katerzia (amlodipine) oral suspension "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." This product is also initiated at very low doses in the outpatient setting for children < 6 years of age who have Raynaud's disease/syndrome and also cannot use a solid dosage form of amlodipine.
- A Shmerling moved to add language, "If member is less than 6 years of age, the prescriber confirms that the member has already been receiving amlodipine following initiation in a hospital or other clinical setting OR indication is for Raynaud's."
- B Jackson noted product labeling Katerzia states that is indicated for children 6 years and older for the treatment of hypertension; however, he agrees that it is appropriate to start low doses of this medication in the outpatient setting under certain circumstances.
- B Jackson moved to add "OR indication is for Raynaud's to the second bullet of Katerzia criteria, and also request that the Department explore other literature-supported uses of amlodipine that may need to be included in this recommended criteria edit. Seconded by I Pan. S Klocke abstained. Motion passed, with seven members voting in favor.
- I Pan asked why compounded lansoprazole oral suspension is not reflected on the preferred drug list. J Taylor clarified that it is possible this product does not participate in the federal Medicaid Drug Rebate Program (MDRP).
- S Klocke moved to accept all other proposed criteria for the therapeutic classes included in today's mass review. Seconded by L Claus. Motion passed unanimously.

Prior Authorization and Utilization Management Criteria for other Selected Products

Conflict of Interest Check
No Board members reported a conflict of interest for any of the drug classes being reviewed today in this section (Besremi, Vyvgart, Leqvio, Adbry, Istruisa, Recorlev, and Dojolvi).

BESREMi (ropeginterferon alfa-2b) may be approved if the following criteria are met:

1. Member is ≥ 18 years of age AND
2. BESREMi is being prescribed for the treatment of polycythemia vera, AND
3. BESREMi is being prescribed by a hematologist AND
4. Member does NOT meet any of the following:
    a. History of, or presence of, severe psychiatric disorders, particularly severe depression, suicidal ideation, or history of suicide attempt
    b. Moderate or severe hepatic impairment
    c. History of, or presence of, active serious or untreated autoimmune disease
    d. The member is an immunosuppressed transplant recipient

    AND
5. Prescriber attests that complete blood counts (CBCs) will be checked at least every 2 weeks during the titration phase and at least every 3 to 6 months during the maintenance phase after the patient's optimal dose is established, AND
6. Prescriber attests that a pre-treatment pregnancy test will be performed, and that members of reproductive potential will be advised to use effective contraception during treatment with BESREMi and for at least 8 weeks after the final dose.

Maximum Dose: 500 mcg every two weeks
Quantity Limit: Four 500 mcg/mL prefilled syringes/30 days

Reauthorization: If hematological stability has been achieved after at least 1 year of therapy on a two week dosing interval of BESREMi , provider attests to considering an expanded dosing interval of every 4 weeks.

Discussion
- K MacIntyre noted that, given the propensity of this class to cause psychiatric disturbances, he would recommend adding baseline and follow-up requirements to assess psychiatric issues for members on Besremi therapy.
- P Lanius asked about the quantity limit of 30 days versus 28 days. J Taylor explained that the system will be able to accommodate either a 30 or 28 day quantity limit in this case.
- K MacIntyre moved to add a bullet point to these criteria that states “Provider attests that quarterly assessment of psychiatric well-being will be performed.” Seconded by L Claus. Motion passed unanimously.
- I Pan moved to accept all other proposed criteria for Besremi as written. Seconded by L Claus. Motion passed unanimously.

VYVGART (efgartigimod alfa) may be approved if the following criteria are met:

1. VYVGART 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. VYVGART is being prescribed for treatment of generalized myasthenia gravis that is anti-acetylcholine receptor (AChR) antibody positive AND

4. VYVGART is being prescribed by or in consultation with a neurologist or rheumatologist.

Maximum Dose: 1,200 mg IV every week for 4 weeks

Quantity Limit: Twelve 400 mg/20 mL single-dose vials/30 days

Discussion

- S Klocke asked if reauthorization criteria are indicated for this product. J Taylor explained that in this the same criteria (above) would apply for both initial and subsequent authorizations. After further discussion, S Klocke moved to add language to require that an MG-ADL assessment be conducted at baseline (with a score ≥ 5 and greater than 50% of the MG-ADL being non-ocular related) AND prior to reauthorization to demonstrate a stable MG-ADL score or better after one year of therapy with Vyvgart. Seconded by K MacIntyre. Claus and Shmerling abstained. Motion passed, with six members voting in favor.
- S Klocke moved to accept all other proposed criteria for Besremi as written. Seconded by K MacIntyre. Motion passed unanimously.

LEQVIO (inclisiran) may be approved if the following criteria are met:

1. To bill for LEQVIO under the pharmacy benefit, the drug is being administered by a healthcare professional in the member's home or in a long-term care facility, AND
2. Prescriber acknowledges that LEQVIO (inclisiran) doses administered by a healthcare provider in the doctor's office or clinic are to be billed through the Health First Colorado medical benefit through the standard buy-and-bill process AND
3. Member is ≥ 18 years of age, AND
4. LEQVIO is being prescribed as an adjunct to diet and maximally tolerated statin therapy with ezetimibe for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD), defined below, who require additional lowering of low-density lipoprotein cholesterol (LDL-C)

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

5. LEQVIO is being prescribed by, or in consultation with, a cardiologist, Certified Lipid Specialist (CLS) or an endocrinologist, AND
6. Member is concurrently adherent (>80% of the past 180 days) on maximally tolerated dose of statin therapy (see table below), which should include a 30-day trial of either atorvastatin OR rosuvastatin. If intolerant to a statin due to side effects, member must have a one month documented trial with at least two other statins. For members with a past or current incidence of rhabdomyolysis, one month trial and failure of two statins is not required AND
7. Member must be concurrently treated (in addition to maximally tolerated statin) with ezetimibe AND have a treated LDL > 70 mg/dl for a clinical history of ASCVD or LDL > 100 mg/dl if familial hypercholesterolemia.

Maximum Daily Statin Doses
Atorvastatin 80 mg
Fluvastatin 80 mg
Lovastatin 80 mg
Pravastatin 80 mg
Rosuvastatin 40 mg
Simvastatin 40 mg (80 mg not used in practice)

Maximum Dose: 284 mg/90 days

Quantity Limit: One 284 mg/1.5 mL prefilled syringe/90 days

Initial Authorization: 3 months

Reauthorization: Additional one year approval for continuation may be granted with provider attestation of safety and efficacy with initial medication therapy

Stakeholder input:
Written testimony, Leqvio – Novartis

Scheduled testimony presentations:
P Wettestad, Leqvio – Novartis

Discussion
- L Claus asked if language should be added to exclude members from the requirement to take concomitant ezetimibe if they have trialed and failed that agent, have an intolerance to that product, etc.
- B Jackson moved to accept the proposed criteria for Leqvio as written. Seconded by L Claus. Motion passed unanimously.

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

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

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

Initial Authorization: 18 weeks

Reauthorization: Additional one year approval for continuation may be granted with prescriber attestation that member has a 16-week IGA score showing improvement by at least 2 points OR has demonstrated clinically significant improvement due to treatment with ADBRY.

Stakeholder input:

Written testimony, Adbry – LEO Pharma, Inc.

Scheduled testimony presentations:

V Ng, Adbry – LEO Pharma, Inc.

Discussion

- J Rawlings noted that the standard failure definition needs to be added to bullet point six.
- S Klocke moved to accept all other proposed criteria for Adbry as written. Seconded by L Claus. Motion passed unanimously.

ISTURISA (osilodrostat) may be approved if the following criteria are met:

1. Member is ≥ 18 years of age, AND
2. Member has a diagnosis of Cushing's disease AND
3. Pituitary surgery is not an option or the member had surgery and it was not curative, AND
4. ISTURISA is being prescribed by, or in consultation with, an endocrinologist AND
5. For initial dose titrations:
    a. If the member has moderate hepatic impairment, the starting dose is 1 mg twice daily **OR**
    b. If the member has severe hepatic impairment, the starting dose is 1 mg once daily in the evening.

Maximum Dose: 60 mg/day

Initial Authorization: 12 months

Discussion

- B Jackson moved to accept the proposed criteria for Adbry as written. Seconded by K MacIntyre. Motion passed unanimously.

RECORLEV (levoketoconazole) may be approved if the following criteria are met:

1. Member is ≥ 18 years of age, AND
2. Member has a diagnosis of endogenous hypercortisolemia with Cushing's syndrome AND
3. Pituitary surgery is not an option or the member had surgery and it was not curative, AND
4. RECORLEV is NOT being prescribed to treat a fungal infection, AND
5. Member does not concomitantly take a proton pump inhibitor, H2-receptor antagonist, sucralfate, or have excessive alcohol intake AND
6. RECORLEV is being prescribed by, or in consultation with, an endocrinologist AND
7. Member does not have cirrhosis, acute liver disease, poorly controlled chronic liver disease, extensive metastatic liver disease, recurrent symptomatic cholelithiasis, or a prior history of azole antifungal-induced liver injury AND
8. Provider attests that the member's care plan will include frequent monitoring for significant adverse events (such as hepatotoxicity, QTc prolongation, hypercortisolism, low serum testosterone and major drug-drug interactions) as described in product labeling

Maximum Dose: 1,200 mg/day

Initial Authorization: 12 months

Stakeholder input:
Written testimony, Recorlev – Xeris Pharmaceuticals

Scheduled testimony presentations:
V Patel, Recorlev – Xeris Pharmaceuticals

Discussion
- K MacIntyre moved to accept the proposed criteria for Recorlev as written. Seconded by T Brubaker. Motion passed unanimously.

DOJOLVI (triheptanoin) may be approved if the following criteria are met:

1. Member has a molecularly-confirmed diagnosis of long-chain fatty acid oxidation disorder (LC-FAOD) AND
2. DOJOLVI is being prescribed by an endocrinologist, geneticist or LC-FAOD expert, AND
3. Member is experiencing symptoms of deficiency exhibited by the presence of at least one of the following:
   - Severe neonatal hypoglycemia
   - Hepatomegaly
   - Cardiomyopathy
   - Exercise intolerance
   - Frequent episodes of myalgia
   - Recurrent rhabdomyolysis induced by exercise, fasting or illness

Initial Authorization: 12 months

Stakeholder input:
Written testimony, Dojolvi, Xeris Pharmaceuticals

Scheduled testimony presentations:
R Kong, Dojolvi – Xeris Pharmaceuticals

Discussion
- K MacIntyre clarified with R Kong that this product is classified as a drug and not a medical food.
- J Rawlings asked Board members if they wanted to consider adding criteria to address the significant drug interaction between Dojolvi and pancreatic lipase inhibitors (such as orlistat).
- B Jackson agreed that the pancreatic lipase inhibitor interaction should be added, along with avoiding administration of Dojolvi in patients with pancreatic insufficiency.
- B Jackson moved include additional criteria for Dojolvi to 1) add a reference to the pancreatic lipase inhibitor drug interaction, 2) avoid in patients with pancreatic insufficiency, 3) avoid drug administration through PVC feeding tubes, 4) add metabolic physicians and medical nutrition physicians to the list of approved prescribers, and 5) include consultation with a dietician as one of the required aspects for use of Dojolvi. Seconded by T Brubaker. Motion passed unanimously.
- B Jackson moved to accept all other Dojolvi criteria as written. Seconded by L Claus. Motion passed unanimously.

Adjournment

A Shmerling reminded the Board that the next meeting is scheduled for Tuesday, August 9, from 1:00 to 5:00 pm on Zoom. Dr. Shmerling also reminded all Board members to delete the meeting binder at the conclusion of today's meeting.

L Claus moved to adjourn the meeting, seconded by S Klocke. Motion passed unanimously. The meeting was adjourned at 4:02 pm.

Minutes respectfully submitted by Julia Rawlings, PharmD