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 6, 2025
Open Session
1:00 pm – 5:00 pm

1. Call to Order

Today's meeting was held virtually via Zoom. The meeting was called to order at 1:00 pm by B Jackson, Vice Chair.

2. Roll Call and Introductions

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

Members Present: Liza Claus, PharmD (Chair) *joined at 2:00 pm*; Brian Jackson, MD, MA (Vice Chair); Todd Brubaker, DO; Stephanie Cho, PharmD; Shilpa Klocke, PharmD; Kenneth MacIntyre, DO; Ingrid Pan, PharmD; Marshal Ash, DO; Mary Shefchyk, MBA

Members Absent: None

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

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

Lisa Rothgery, MD, HCPF Chief Medical Officer

3. Virtual Meeting Information and General Announcements

J Rawlings shared several announcements:

- This meeting is being recorded for internal use by the Department
- Stakeholders who have signed up in advance will be invited to provide testimony at the appropriate time on the meeting agenda.
- If you experience technical difficulties during the meeting, please leave the meeting and use the same Zoom link to be readmitted, as that usually resolves the issue.
- Video and microphone for Board members will be turned on.
- Speakers providing testimony and our other meeting guests are asked to keep video turned off during the meeting so that we can more easily track Board member comments and votes.
- Voting may be conducted by raising your hand and/or by verbal "ayes" and "nays," abstentions, and recusals as determined today by the Chair or Vice Chair.

4. Colorado Department of Health Care Policy and Financing Updates

- V Garcia welcomed Dr. Stephanie Cho to her first meeting as a member of the DUR Board.

5. Final Approval of Minutes from the February 11, 2025 Meeting

- Vice Chair B Jackson asked the Board to review minutes from the February 11, 2025 meeting. I Pan moved to approve the minutes as written. Seconded by S Klocke. 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. Persons must sign up no later than 24 hours in advance with the DUR Account Manager in order to speak at the DUR Board Meeting. Persons will be called in the order in which they signed in for each set of prior authorization criteria. Presentations must be limited to verbal comments. No visual aids, other than designated handouts are permitted. Persons giving oral presentations must verbally disclose all relationships to pharmaceutical manufacturers.

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

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

7. Clinical Updates and General Orders

- **FDA Drug Safety Communications**
  There were no new FDA Drug Safety Communications to report this quarter.

- **FDA New Product Update**
  N Gyasi, Population Health Intern, presented the FDA Drug Approvals report prepared this quarter by intern Jennifer Hayden.

- **Quarterly Clinical Modules**
  R Page presented an executive summary of last quarter's clinical module analysis entitled *Targeted Immune Modulators 2024: An Update from the 2021 Analysis of Select Biological Products* that was delivered to the Department on March 31.

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

- **Quarterly Drug Utilization Reports**
  Board members were referred to utilization reports in the meeting binder for this quarter's details,

8. New Business

J Taylor provided three agenda updates:

1. Long-acting injectable buprenorphine products will be reviewed today for addition to the PDL. Since these products (Subclocade® and Briaxi®) are currently managed on the Department's Appendix P with prior authorization criteria previously reviewed by the DUR Board and subsequently finalized, only proposed updates to those criteria will be reviewed during today's meeting.
2. The Topical Antipsoriatics therapeutic class will be pulled from Mass Review today and reviewed immediately after the Topical Immunomodulators class. There are products that both of these drug classes have in common and this change in the agenda order will help facilitate the criteria review for those products.
3. The Bile Salts therapeutic class has preemptively been pulled from Mass Review and into the full review process due to some proposed criteria changes. The Bile Salts will be reviewed just after the Proton Pump Inhibitor class.

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

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

1. Buprenorphine, Injectable *(New therapeutic class on the PDL)*

Preferred Agents
(*Must meet eligibility criteria)
*BRIXADI (buprenorphine) syringe
*SUBLOCADE (buprenorphine) syringe

***BRIXADI** or **SUBLOCADE** (buprenorphine ER injection) may be approved if the following criteria are met:

- The requested medication is being dispensed directly to the healthcare professional (medication should not be dispensed directly to the member) **AND**
- Provider attests to member's enrollment in a complete treatment program, including counseling and psychosocial support **AND**
- Member must have documented diagnosis of moderate to severe opioid use disorder **AND**
- (SUBLOCADE only) Member must have initiated therapy with a transmucosal buprenorphine-containing product and had dose adjustment for a minimum of 7 days.

Maximum doses:

BRIXADI	128 mg/month
SUBLOCADE:	600 mg/month during 1st month of induction therapy 300 mg/month maintenance dose thereafter

Scheduled Speaker Testimony
M Penner, Sublocade – Indivior

Discussion

- No Board members reported potential conflicts of interest for this therapeutic class.
- S Klocke moved to edit the fourth bullet point that begins with "(SUBLOCADE only) to (1) include both usual and rapid induction with transmucosal buprenorphine-containing product

(based on recent product labeling updates), and (2) add BRIXADI to the same bullet point since its labeling also includes similar induction directions for use. Seconded by I Pan. Motion passed unanimously.

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

2. Tetracyclines

Preferred Agents
Doxycycline hyclate capsules
Doxycycline hyclate tablets
Doxycycline monohydrate 50mg, 100mg 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 is unable to take a solid oral dosage form.

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

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

3. Pulmonary Hypertension Therapies

a. Phosphodiesterase Inhibitors

Preferred Agents
***Must meet eligibility criteria**
*Sildenafil tablet, oral suspension
*Tadalafil 20mg 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.

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 oral tablet 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.

Non-preferred oral liquid products may be approved if meeting the following:
- Member has a diagnosis of pulmonary hypertension **AND**
- Request meets one of the following:
  - Member has trialed and failed treatment with one preferred oral liquid formulation (failure is defined as lack of efficacy with a 4-week trial, allergy, intolerable side effects, or significant drug-drug interaction) **OR**
  - Prescriber verifies that the member is unable to take a solid oral dosage form that there is clinical necessity for use of a regimen with a less frequent dosing interval.

b. Endothelin Receptor Antagonists

Preferred Agents
***Must meet eligibility criteria**
*Ambrisentan tablet
*Bosentan 62.5mg, 125mg 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 the medication.

c. Prostacyclin Analogues and Receptor Agonists

Preferred Agents
(*Must meet eligibility criteria)
*FLOLAN (epoprostenol) vial
*ORENITRAM (treprostinil ER) tablet, titration kit
*REMODULIN (treprostinil) vial
*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 Stimulator

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**
- Member has a diagnosis of persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH) (WHO Group 4) after surgical treatment or has inoperable CTEPH **OR**
- Member has a diagnosis of pulmonary hypertension and has failed treatment with a preferred product for pulmonary hypertension. (Failure is defined as a lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction).

Scheduled Speaker Testimony
K Simpson, Tyvaso – United Therapeutics
A Hale, Uptravi – Johnson & Johnson

Discussion

- No Board members reported potential conflicts of interest for this therapeutic class.
- I Pan moved for the Department to conduct a review to ensure that the PAH therapeutic class includes standard language to allow for approval of liquid formulations for members who are unable to take/swallow solid oral dosage forms. Seconded by M. Ash. Motion passed unanimously.
- T Brubaker moved to accept the criteria as amended. Seconded by S Klocke. Motion passed unanimously.

4. Statins and Combinations

a. Statins, single agents

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

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

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

b. Statin Combinations

Preferred Agents
- Simvastatin/Ezetimibe tablet

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 and generic ezetimibe/simvastatin will not be approved for members < 18 years of age. Caduet and generic amlodipine/atorvastatin will not be approved for members < 10 years of age

Discussion
- No Board members reported potential conflicts of interest for this therapeutic class.
- I Pan moved for the Department to conduct a review to ensure that the Statins, Single Agents section includes standard language to allow for approval of liquid formulations for members who are unable to take/swallow solid oral dosage forms. Seconded by M. S Cho. Motion passed unanimously.
- S Klocke moved to accept the criteria as amended. Seconded by K MacIntyre. Motion passed unanimously.

5. Movement Disorder Agents

Preferred Agents
(*Must meet eligibility criteria)
- *Austedo (deutetrabenazine) tablet
- *Austedo (deutetrabenazine) XR tablet, titration pack
- *Ingrezza (valbenazine) capsule, initiation pack
- *Tetrabenazine tablet

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

- Member is ≥18 years of age **AND**
- Member has been diagnosed with tardive dyskinesia or chorea associated with Huntington's disease **AND**
- If the member has hepatic impairment, FDA labeling for use has been evaluated **AND**
- For chorea associated with Huntington's disease:
    - Member has been evaluated for untreated or inadequately treated depression and member has been counseled regarding the risks of depression and suicidality associated with agents in this therapeutic class.

  AND
- For tardive dyskinesia:
    - If applicable, the need for ongoing treatment with 1st and 2nd generation antipsychotics, metoclopramide, or prochlorperazine has been evaluated AND
    - A baseline Abnormal Involuntary Movement Scale (AIMS) has been performed.

Xenazine (tetrabenazine)
Maximum dose 50 mg/day (PA available for extensive metabolizers of CYP2D6)

Ingrezza (valbenazine)
Quantity limits:

- 40 mg: 1.767 capsules/day
- 60 mg: 1 capsule/day
- 80 mg: 1 capsule/day

Austedo (deutetrabenazine)
Maximum dose: 48 mg/day

Non-preferred Movement Disorder Agents may be approved for members ≥18 years of age after trial and failure of two preferred products. Failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interaction.

Scheduled Speaker Testimony
R Kong, Ingrezza – Neurocrine Biosciences
M Sohal, Austedo - Teva

Discussion

- No Board members reported potential conflicts of interest for this therapeutic class.
- R Kong clarified that the non-sprinkle capsule formulation of Ingrezza (valbenazine), based on off-label information, may be opened and sprinkled on soft food such as applesauce, yogurt or pudding as long as the granules inside the oral capsules are crushed first. The advantage of the new sprinkle formulation is that the extra step to crush the granules is eliminated.
- I Pan moved for the Department to conduct a review of the PDL to ensure that "contraindication" is included in failure definitions. Seconded by K MacIntyre. Motion passed unanimously.
- K MacIntyre moved to accept the criteria as amended. Seconded by T Brubaker. Motion passed unanimously.

6. Acne Agents, Topical

Preferred Agents

No PA Required (if age and diagnosis criteria are met*)

*Adapalene gel
*Adapalene/benzoyl peroxide gel (generic Epiduo), gel pump (generic Epiduo Forte)
*Clindamycin phosphate gel, lotion, solution, medicated swab/pledget
*Clindamycin/benzoyl peroxide gel jar (generic Benzaclin)
*Clindamycin/benzoyl peroxide gel tube (generic Duac)
*Dapsone gel
*Erythromycin solution
*Erythromycin/Benzoyl peroxide gel (generic Benzamycin)
*Sulfacetamide sodium suspension
*Sulfacetamide sodium/sulfur cleanser
*RETIN-A^{BNR} (tretinoin) cream, gel

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

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

- No Board members reported potential conflicts of interest for this therapeutic class.
- J Taylor explained that Medicaid programs are not permitted to pay for drugs used solely for cosmetic purposes.
- T Brubaker moved to accept the criteria as written. Seconded by S Cho. Motion passed unanimously.

7. Immunomodulators, Topical

a. Atopic Dermatitis

Preferred Agents
(*Must meet eligibility criteria)
ELIDEL (pimecrolimus) cream[BNR]
***EUCRISA** (crisaborole) ointment
***OPZELURA** (ruxolitinib) cream
Tacrolimus ointment

***EUCRISA** (crisaborole) may be approved if the following criteria are met:

- Member is at least 3 months of age and older AND
- Member has a diagnosis of mild to moderate atopic dermatitis AND
- Member has a history of failure, contraindication, or intolerance to at least two medium-to high-potency topical corticosteroids for a minimum of 2 weeks OR is not a candidate for topical corticosteroids AND
- Eucrisa (crisaborole) must be is being prescribed by or in consultation with a dermatologist or allergist/immunologist AND
- Member must havehas tried and failed‡ pimecrolimus and tacrolimusone preferred agent. Failure is defined as a lack of efficacy, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions. AND

***OPZELURA** (ruxolitinib) cream may be approved if the following criteria are met based on prescribed indication:

Atopic Dermatitis

- Member is ≥ 12 years of age AND
- Member is immunocompetent AND
- Member has a diagnosis of mild to moderate atopic dermatitis AND
- Member has body surface area (BSA) involvement of ≤20% AND
- Medication is being prescribed by or in consultation with a dermatologist or allergist/immunologist 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 havehas trialed and failed‡ one preferred agent AND one medium potency to very high potency topical corticosteroid (such as mometasone furoate, betamethasone dipropionate, or fluocinonide) or prescriber verifies that member is not a candidate for topical corticosteroids.
    AND
- Member is not using Opzelura (ruxolitinib) cream along with a strong inhibitor of CYP3A4 (such as fluconazole ≥ 200 mg/day, ketoconazole, itraconazole, voriconazole, ritonavir) due to the potential for increased systemic exposure to ruxolitinib.

Nonsegmental Vitiligo

- Member is ≥ 12 years of age AND
- Member is immunocompetent AND
- Member has a diagnosis of stable nonsegmental vitiligo, defined as no increase in the size of existing lesions and the absence of new lesions in the previous 3 to 6 months, AND
- Medication is being prescribed by or in consultation with a dermatologist AND
- Member will be applying Opzelura (ruxolitinib) to ≤10% of body surface area (BSA) per application 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 failed twice-daily pimecrolimus OR tacrolimus. Failure is defined as a lack of efficacy, allergy, intolerable side effects, contraindication to, or significant drug-drug interaction AND
- Member must havehas trialed and failed‡ one preferred agent AND one medium potency to very high potency topical corticosteroid (such as mometasone furoate, betamethasone dipropionate, or fluocinonide) or prescriber verifies that member is not a candidate for topical corticosteroids.

  AND
- Member is not using Opzelura (ruxolitinib) cream along with a strong inhibitor of CYP3A4 (such as fluconazole ≥ 200 mg/day, ketoconazole, itraconazole, voriconazole, ritonavir) due to the potential for increased systemic exposure to ruxolitinib.

Quantity limit: 60 grams/week

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

‡Failure is defined as a lack of efficacy with a 2-week trial, allergy, intolerable side effects, contraindication to, or significant drug-drug interaction

b. Topical 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 Topical Immunomodulator Agents

Preferred Agents
Imiquimod (generic Aldara) cream
Podofilox gel, solution

Hyftor (sirolimus) gel

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

Initial approval: 6 months

Reauthorization: An additional 6 months may be approved based on provider attestation that symptoms improved during the initial 6 months of treatment and the provider has assessed use of all vaccinations recommended by current immunization guidelines.

Maximum dose: one 10-gram tube/28 days

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

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

Zyclara (imiquimod) **2.5% cream** may be approved if the following criteria are met:

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

Zyclara (imiquimod) **3.75% cream** may be approved for:

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

  OR

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

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

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

Scheduled Speaker Testimony:
J Leung, Opzelura – Incyte – *yielded time*
B Stephenson, Zoryve 0.15% Cream – Arcutis
B Stephenson, Zoryve 0.3% Foam – Arcutis
A Larsen, MD, FAAD, Opzelura – Monarch Dermatology

Written Testimony
Zoryve (roflumilast) Summary Document - Arcutis
Letter, Opzelura - A Larsen, MD, FAAD

Discussion

- No Board members reported potential conflicts of interest for this therapeutic class.
- J Taylor acknowledged that prior authorization criteria for Zoryve 0.3% used to treat seborrheic dermatitis are currently, and *incorrectly* included under the Topical Antipsoriatics therapeutic class on the PDL. Zoryve 0.3% foam for seborrheic dermatitis will be relocated to the Atopic Dermatitis subclass of Topical Immunomodulators as part of this quarter's review and update.
- I Pan noted that brand-name Elidil® (pimecrolimus) cream may no longer be available and asked that the Department to explore that possibly since it is currently listed as brand-name-required preferred agent in this class.
- S Cho moved to edit the criteria for Eucrisa (crisaborole) to include trial and failure of one preferred agent OR a medium-to-very high potency topical corticosteroid. Seconded by S Klocke. Motion passed with seven votes in favor. L Claus abstained, as she was not present for the full discussion of this therapeutic class.
- S Klocke moved to accept the criteria as amended. Seconded by T Brubaker. Motion passed unanimously.

19.b Antipsoriatics, Topical

Preferred Agents
Calcipotriene cream, solution, foam, ointment
Calcipotriene/Betamethasone DP ointment
TACLONEX SCALP[BNR] (calcipotriene/betamethasone) suspension
TACLONEX (calcipotriene/betamethasone) ointment

ZORYVE (roflumilast) may receive approval if meeting the following based on prescribed indication:

Seborrheic dermatitis (0.3% foam formulation)

- Member is ≥ 9 years of age AND
- Member has a diagnosis of seborrheic dermatitis AND
- Member does not have moderate or severe hepatic impairment (Child-Pugh B or C) AND
- Medication is being prescribed by or in consultation with a dermatologist AND
- If the affected area is limited to the scalp:
    - Prescriber attests that member has been counseled regarding alternative treatment options, including over-the-counter (OTC) antifungal shampoo (such as selenium sulfide, zinc pyrithione) and OTC coal tar shampoo, when appropriate)
      AND
    - Member has documented trial and failure (with a minimum 2-week treatment period) of at least one prescription product for seborrheic dermatitis, such as ketoconazole 2% antifungal shampoo or a topical corticosteroid. Failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interaction.

- If the affected area includes the face or body:
    - Member has documented trial and failure (with a minimum 2-week treatment period) with at least one product from ALL of the following categories (Failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interaction):
        - Topical antifungal (such as ketoconazole, ciclopirox)
        - Topical corticosteroid
        - Topical calcineurin inhibitor (such as pimecrolimus, tacrolimus)

      AND
        - Member has been counseled that Zoryve foam is flammable. Fire, flame, or smoking during and immediately following application must be avoided.

Plaque psoriasis (0.3% cream formulation)

- Member is ≥ 6 years of age AND
- Member has a diagnosis of plaque psoriasis AND
- Member has body surface area (BSA) involvement of ≤20% AND
- Member does not have moderate or severe hepatic impairment (Child-Pugh B or C) AND
- Medication is being prescribed by or in consultation with a dermatologist AND
- If the affected area is limited to the scalp:
    - Prescriber attests that member has been counseled regarding alternative treatment options, including over-the-counter (OTC) emollients, vitamin D analogs, and coal tar shampoo when appropriate

      AND
    - Member has documented trial and failure (with a minimum 2-week treatment period) of a topical corticosteroid. Failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interaction.

- If the affected area includes the face or body:
    - Member has documented trial and failure (with a minimum 2-week treatment period) of at least one product from ALL of the following categories. (Failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interaction):
        - Topical corticosteroid
        - Topical calcineurin inhibitor (such as pimecrolimus, tacrolimus)

Quantity limit: Foam or cream - 60 grams/30 days

Initial approval: Foam or cream: 8 weeks

Reauthorization: Reauthorization for one year may be approved based on provider attestation that member's symptoms improved during the initial 8 weeks of treatment and continuation of therapy is justified

Prior authorization for all other non-preferred topical agents may be approved with failure of two preferred topical agents. If non-preferred topical agent being requested 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. Members may not apply Zoryve (roflumilast) cream to >20% of affected body surface area, as safety and efficacy have not been established.

Scheduled Speaker Testimony:
B Stephenson, Zoryve 0.3% Cream – Arcutis

Written Testimony:
Zoryve (roflumilast) Summary Document – Arcutis

Discussion

- No Board members reported potential conflicts of interest for this therapeutic class.
- S Cho moved to add "Member has been counseled that Zoryve foam is flammable. Fire, flame, or smoking during and immediately following application must be avoided" in the "If the affected area is limited to the scalp" section of the criteria. Seconded by T Brubaker. Motion passed unanimously.
- S Cho moved to accept the criteria as amended. Seconded by T Brubaker. Motion passed unanimously.

8. Antiemetics

a. Antiemetics, Oral

Preferred Agents
DICLEGIS DR[BNR] tablet (doxylamine/pyridoxine)
Meclizine (Rx) 12.5 mg, 25 mg tablet
Metoclopramide solution, tablet
Ondansetron ODT; 4mg, 8mg tablet
Ondansetron oral suspension/ solution
Prochlorperazine tablet
Promethazine syrup, tablet

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

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

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

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

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

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

b. Antiemetics, Non-oral

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

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

Discussion
- No Board members reported potential conflicts of interest for this therapeutic class.
- L Claus moved to accept the criteria as amended. Seconded by K MacIntyre. Motion passed unanimously.

9. *H. pylori* treatments

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

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

Discussion
- No Board members reported potential conflicts of interest for this therapeutic class.
- T Brubaker moved to accept the criteria as amended. Seconded by K MacIntyre. Motion passed unanimously.

10. Proton Pump Inhibitors

Preferred Agents
Esomeprazole DR packet for oral suspension, capsule (RX)
Lansoprazole DR capsules (RX)
Lansoprazole ODT (lansoprazole) *(for members under 2 years)*
Omeprazole DR capsule (RX)
Pantoprazole tablet
PROTONIX (pantoprazole DR) packet for oral suspension[BNR]

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) be trialed in order to reduce long-term PPI use.

Prior authorization for non-preferred proton pump inhibitors may be approved if all of the following criteria are met:
- Member has a qualifying diagnosis (below) AND
- Member has trialed and failed therapy with three preferred agents within the last 24 months. (Failure is defined as: lack of efficacy following 4-week trial, allergy, intolerable side effects, or significant drug-drug interaction) AND
- Member has been diagnosed using one of the following diagnostic methods:
    - Diagnosis made by GI specialist
    - Endoscopy
    - X-ray

- Biopsy
- Blood test
- Breath Test

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

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

Adult members with GERD on once daily, high-dose PPI therapy who continue to experience symptoms may receive initial prior authorization approval for a 4-week trial of twice daily, high-dose PPI therapy. Continuation of the twice daily dosing regimen for GERD beyond 4 weeks will require additional prior authorization approval verifying adequate member response to the dosing regimen and approval may be placed for one year. If a member with symptomatic GERD does not respond to twice daily, high-dose PPI therapy, this should be considered a treatment failure.
Pediatric members (< 18 years of age) on once daily dosing of a PPI who continue to experience symptoms may receive one-year prior authorization approval for twice daily PPI therapy.

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

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

Continuation of Care: Members currently taking Dexilant (dexlansoprazole) capsules may continue to receive approval for that medication.

Scheduled Speaker Testimony:
A Nguyen (for H Morris), Konvomep – Azurity

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

22. Bile Salts (pulled out of Mass Review)

Preferred Agents
Ursodiol tablet
Ursodiol capsule

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).

Chenodal (chenodiol) 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). If chenodiol is being prescribed for treatment of cerebrotendinous xanthomatosis (CTX), no trial and failure of ursodiol is required.

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, 3ß-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) 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 without cirrhosis OR a diagnosis of primary biliary cholangitis with compensated cirrhosis with no evidence of portal hypertension AND
- Member has failed treatment with a preferred ursodiol product for at least 6 months due to an inadequate response, intolerable side effects, drug-drug interaction, or allergy to preferred ursodiol formulations.

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

- Member is ≥ 18 years of age AND
- The requested medication is prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant provider AND
- The requested medication is being prescribed for one of the following:
  - Treatment of radiolucent, noncalcified gallbladder stones < 20 mm in greatest diameter AND elective cholecystectomy would be undertaken except for the presence of increased surgical risk due to systemic disease, advanced age, idiosyncratic reaction to general anesthesia, or for those patients who refuse surgery OR
  - Prevention of gallstone formation in obese patients experiencing rapid weight loss

  AND

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

Initial approval: 1 year

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

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
- Member has failed treatment with a preferred ursodiol product for at least 6 months due to an inadequate response, intolerable side effects, drug-drug interaction, or allergy to inactive ingredients contained in the preferred ursodiol formulations.

Requests for drug products that are FDA-indicated for the treatment of nonalcoholic steatohepatitis (NASH) may be approved if meeting the following:=

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

Non-preferred products prescribed for FDA-labeled indications not identified above may receive approval for use as outlined in product package labeling.

Discussion

- No Board members reported potential conflicts of interest for this therapeutic class.
- I Pan moved for the Department to conduct a review of the PDL to ensure that "contraindication" is included in failure definitions. Seconded by M Ash. Motion passed unanimously.
- K MacIntyre moved to accept the criteria as amended. Seconded by L Claus. 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.

10. 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).

11. Beta Blockers

a. Beta Blockers, Single Agents

Preferred Agents
(*Must meet eligibility criteria)
Acebutolol capsule
Atenolol tablet
Bisoprolol tablet
Carvedilol IR tablet
*Hemangeol (propranolol) solution
Labetalol tablet
Metoprolol tartrate tablet
Metoprolol succinate ER tablet
Nadolol tablet
Nebivolol tablet
Propranolol IR tablet, solution
Propranolol ER capsule

***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

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).

INNOPRAN XL (propranolol ER) capsule brand product formulation may be approved if meeting the following:

- Request meets non-preferred criteria listed above AND
- Member has trialed and failed therapy with a generic propranolol ER capsule formulation OR prescriber provides clinical rationale supporting why generic propranolol ER capsule product formulations cannot be trialed. Failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions.

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.

Members currently stabilized on the non-preferred Bystolic (nebivolol) tablets may receive approval to continue on that product.

Members currently stabilized on the non-preferred carvedilol ER capsules 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, Antiarrhythmic Agents

Preferred Agents

Sotolol 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 are unable to take a solid oral dosage form 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 Blocker 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).

12. Calcium Channel Blockers

a. Dihydropyridines

Preferred Agents
- Amlodipine tablet
- Felodipine ER tablet
- Nifedipine ER tablet
- Nifedipine IR capsule

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.

Nimodipine oral capsule oral capsule may be approved for adult members (≥ 18 years of age) with subarachnoid hemorrhage

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

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

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

b. Non-Dihydropyridines

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

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

13. Angiotensin Converting Enzyme (ACE) Inhibitors and Combinations

a. ACE Inhibitors, Single Agents

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

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

***Enalapril solution** may be approved without trial and failure of three preferred agents for members who are unable to take a solid oral dosage form.

***QBRELIS (lisinopril) solution** may be approved for members 6 years of age or older who are unable to take a solid oral dosage form 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. ACE Inhibitor Combinations

Preferred Agents
- Amlodipine/Benazepril capsule
- Benazepril/HCTZ tablet
- Enalapril/HCTZ tablet
- Lisinopril/HCTZ tablet
- Quinapril/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).

14. Angiotensin Receptor Blockers (ARBs) and Combinations

a. Angiotensin Receptor Blockers (ARBs), Single Agents

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

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

b. Angiotensin Receptor Blocker (ARB) Combinations

Preferred Agents
No PA Required (Unless indicated*)
*ENTRESTO (sacubitril/valsartan) tablet[BNR]
- Irbesartan/HCTZ tablet
- Losartan/HCTZ tablet
- Olmesartan/Amlodipine tablet
- Olmesartan/HCTZ tablet
- Telmisartan/HCTZ tablet
- Valsartan/Amlodipine tablet
- Valsartan/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).

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

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

15. Renin Inhibitors and 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.

16. 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 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
Fenofibric acid DR (generic Trilipix) capsule
Fenofibrate capsule, tablet (generic Lofibra/Tricor)
Gemfibrozil tablet

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

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

c. Other lipotropics

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

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

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

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

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

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

- Member is concurrently adherent (> 80% of the past 180 days) on a maximally tolerated dose of a high intensity statin therapy (atorvastatin ≥ 40 mg daily OR rosuvastatin ≥ 20 mg daily [as a single-entity or as a combination product]) AND ezetimibe (as a single-entity or as a combination product) concomitantly for ≥ 8 continuous weeks), AND

- If intolerant to a statin due to side effects, member must have a one month documented trial with at least two other maximally dosed statins in addition to ezetimibe. For members with a

past or current incidence of rhabdomyolysis, a one-month trial and failure of a statin is not required, AND
- Member has a treated LDL > 70 mg/dL for a clinical history of ASCVD OR LDL > 100 mg/dL if familial hypercholesterolemia

Initial Approval: 1 year

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

17. Acne Agents, Oral Isotretinoins

Preferred Agents
AMNESTEEM capsule
CLARAVIS capsule
Isotretinoin 10 mg, 20 mg, 30 mg, 40 mg capsule *(Mayne-Pharma, Upsher-Smith, Zydus only)*
ZENATANE capsule

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

Non-preferred products may be approved for members meeting the following:
- Member has trialed/failed one preferred agent (failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction) AND
- Member is an adult or child ≥ 12 years of age with severe, recalcitrant nodulocystic acne and has been unresponsive to conventional therapy.

19.b Antipsoriatics, Topical

(Reviewed above - pulled out of mass review)

20. Rosacea Agents

Preferred Agents
Azelaic acid gel *(Sandoz only)*
FINACEA (azelaic acid) gel
FINACEA (azelaic acid) foam
Metronidazole cream, lotion
Metronidazole 0.75% gel

Prior authorization for non-preferred products in this class may be approved if meeting the following criteria for the prescribed diagnosis:

Rosacea:
- 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)

Demodex Blepharitis:

- Requests for non-preferred topical ivermectin cream may be approved for treatment of moderate to severe Demodex blepharitis

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

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

21. Topical Steroids

a. Topical Steroids, Low Potency

Preferred Agents

DERMA-SMOOTHE-FS (fluocinolone) 0.01% body oil/scalp oil[BNR]
Desonide 0.05% cream, ointment
Fluocinolone 0.01% cream
Fluocinolone 0.1% solution
Hydrocortisone (Rx) cream, lotion, ointment

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

b. Topical Steroids, Medium Potency

Preferred Agents

Betamethasone dipropionate 0.05% cream, lotion, ointment
Betamethasone valerate 0.1% cream, ointment
Fluocinolone 0.025% cream, 0.05% cream, 0.005% ointment
Fluticasone cream, ointment
Hydrocortisone valerate 0.2% cream
Mometasone 0.1% cream, 0.1% ointment, 0.1% solution
Triamcinolone acetonide 0.025% cream, 0.1% cream, 0.025% ointment, 0.05% ointment, 0.1% ointment, 0.025% lotion, 0.1% lotion
Triamcinolone 0.1% dental paste

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

c. Topical Steroids, High Potency

Preferred Agents

No PA Required (*unless exceeds duration of therapy)

*Betamethasone dipropionate 0.05% ointment
*Betamethasone dipropionate/propylene glycol (augmented) 0.05% cream

*Fluocinonide 0.05% cream, 0.05% gel, 0.05% solution, 0.05% ointment
*Triamcinolone acetonide 0.5% cream, 0.5% ointment

Non-preferred High Potency topical corticosteroids may be approved following adequate trial and failure of two preferred agents in the High Potency class (failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions).
*All High Potency topical corticosteroids will require prior authorization beyond 4 weeks of therapy. The provider will be encouraged to transition to a medium or low potency topical steroid after this time has elapsed.

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

d. Topical Steroids, Very High Potency

Preferred Agents
No PA Required (Unless exceeds duration of therapy*)
*Betamethasone dipropionate/propylene glycol (augmented) ,0.05% lotion
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.

22. Bile Salts

(Reviewed above - pulled out of mass review today)

23. GI Motility, Chronic

Preferred Agents
PA Required for all agents in this class
LINZESS (linaclotide) capsule
Lubiprostone 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), Functional Constipation (FC) or Opioid Induced Constipation (OIC) in patients with opioids prescribed for noncancer pain AND
- Member does not have a diagnosis of GI obstruction AND
- For indication of OIC, member opioid use must exceed 4 weeks of treatment
- For indications of CIC, OIC, IBS-C; member must have documentation of adequate trial of two or more over-the-counter motility agents (polyethylene glycol, docusate or bisacodyl, for example). OR If the member cannot take oral medications, then the member must fail a 7-day trial with a nonphosphate enema (docusate or bisacodyl enema). Failure is defined as a lack of efficacy for a 7-day trial, allergy, intolerable side effects, contraindication to, or significant drug-drug interaction AND
- For indication of IBS-D, must have documentation of adequate trial and failure with loperamide and trial and failure with dicyclomine or hyoscyamine. Failure is defined as a lack of efficacy for a 7-day trial, allergy, intolerable side effects, contraindication to, or significant drug-drug interaction.

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

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

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

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

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

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

Medication	FDA approved indication	FDA Max Dose
Amitiza (lubiprostone)	IBS-C (females only), CIC, OIC (not caused by methadone)	48 mcg/day
Linzess (linaclotide)	IBS-C, CIC (≥ 18 years)	290 mcg/day
	FC (6 to 17 years)	72 mcg/day
Movantik (naloxegol)	OIC	25 mg/day
Viberzi (eluxadoline)	IBS-D	200 mg/day

Relistor subcutaneous injection (methylnaltrexone)	OIC	12 mg/day
Relistor oral (methylnaltrexone)	OIC	450 mg/day
Lotronex (alosetron)	IBS-D (femaleswomen only)	2 mg/day (femaleswomen only)
Symproic (Naldemedine)	OIC	0.2 mg/day
Trulance (plecanatide)	CIC, IBS-C	3 mg/day
Motegrity (prucalopride)	CIC	2 mg/day

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

24. Hemorrhoidal, Anorectal, and Related Topical Anesthetic Agents

Preferred Agents

Hydrocortisone single agents
- ANUSOL-HC (hydrocortisone) 2.5% cream with applicator
- CORTIFOAM (hydrocortisone) 10% aerosol
- Hydrocortisone 1% cream with applicator
- Hydrocortisone 2.5% cream with applicator
- Hydrocortisone enema

Lidocaine single agents
- Lidocaine 3% cream
- Lidocaine 5% ointment

Other and Combinations
- Hydrocortisone-Pramoxine 1%-1% cream
- Lidocaine-Hydrocortisone 3-0.5% cream with applicator
- Lidocaine-Prilocaine Cream (all other manufacturers)
- 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).

Rectiv (nitroglycerin) ointment may be approved if meeting the following:
- Member has a diagnosis of anal fissure **AND**
- Prescriber attests that member has trialed and maximized use of appropriate supportive therapies including sitz bath, fiber, topical analgesics (such as lidocaine), and stool softeners/laxatives.

25. Pancreatic Enzymes

Preferred Agents
- CREON (pancrelipase) capsule
- VIOKACE (pancrelipase) tablet
- 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.)

26. Non-Biologic Ulcerative Colitis Agents

a. Non-Biologic Ulcerative Colitis Agents, Oral

Preferred Agents
APRISO (mesalamine ER) capsule
Mesalamine DR tablet (generic Lialda) (Takeda only)
Mesalamine ER capsule (generic Apriso) (Teva only)
PENTASA[BNR] (mesalamine) capsule
Sulfasalazine IR and DR tablet

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

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

b. Non-Biologic Ulcerative Colitis Agents, Rectal

Preferred Agents
Mesalamine suppository
Mesalamine 4 gm/60 mL enema (generic SF ROWASA)
sfROWASA (mesalamine) enema

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

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

27. Anticoagulants

a. Anticoagulants, Oral

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

SAVAYSA (edoxaban) may be approved if all the following criteria have been met:

- The member has failed therapy with two preferred agents. (Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction) **AND**
- Member is not on dialysis **AND**
- Member does not have CrCl > 95 mL/min **AND**

- The member has a diagnosis of deep vein thrombosis (DVT), pulmonary embolism (PE) **OR**
- The member has a diagnosis of non-valvular atrial fibrillation **AND**
- The member does not have a mechanical prosthetic heart valve

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

XARELTO (rivaroxaban) oral suspension may be approved without prior authorization for members <18 years of age who require a rivaroxaban dose of less than 10 mg **OR** with prior authorization verifying the member is unable to use the solid oral dosage form.

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.

28. Antiplatelet Agents

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

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

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

29. Colony Stimulating Factors

Preferred Agents
PA Required for all agents in this class*
FULPHILA (pegfilgrastim-jmdb) syringe
NEUPOGEN (filgrastim) vial, syringe

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

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

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

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

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

30. Erythropoiesis Stimulating Agents

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

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

- Medication is being administered in the member's home or in a long-term care facility **AND**
- Member meets one of the following:
  - A diagnosis of cancer, currently receiving chemotherapy, with chemotherapy-induced anemia, and hemoglobin† of 10g/dL or lower **OR**
  - A diagnosis of chronic renal failure, and hemoglobin† below 10g/dL **OR**
  - A diagnosis of hepatitis C, currently taking ribavirin and failed response to a reduction of ribavirin dose, and hemoglobin† less than 10g/dL (or less than 11g/dL if symptomatic) **OR**
  - A diagnosis of HIV, currently taking zidovudine, hemoglobin† less than 10g/dL, and serum erythropoietin level of 500 mU/mL or less **OR**
  - Member is undergoing elective, noncardiac, nonvascular surgery and medication is given to reduce receipt of allogenic red blood cell transfusions, hemoglobin† is greater than 10g/dL, but less than or equal to 13g/dL and high risk for perioperative blood loss. Member is not willing or unable to donate autologous blood pre-operatively

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

†Hemoglobin results must be from the last 30 days.

Mass Review Discussion

- S Cho requested to pull Oral Antipsoriatics out of Mass Review for a full review.
- No Board members reported potential conflicts of interest for the Mass Review section.
- K MacIntyre moved to accept the criteria as written. Seconded by S Klocke. Motion passed unanimously.

19. Antipsoriatics

19.a Antipsoriatics, Oral (pulled out of Mass Review)

Preferred Agents
Acitretin capsule

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

Discussion

- S Cho requested to pull Oral Antipsoriatics out of Mass Review for a full review.
- No Board members reported potential conflicts of interest for this therapeutic class.
- The Board discussed oral methoxsalen in more detail. This medication should be administered under the supervision of a healthcare provider. Dr. Cho noted that this medication is not a medication that members would take at home on their own.
- S Cho moved to add language to criteria in this subclass to specify that methoxsalen will be used under the supervision of a healthcare provider. Seconded by K MacIntyre. Motion passed unanimously.
- I Pan moved to accept the criteria as amended. Seconded by S Klocke. Motion passed unanimously.

B. Proposed Coverage Criteria for Non-PDL Products Managed Under the Pharmacy Benefit

Current coverage criteria for non-PDL products covered under the pharmacy benefit can be referenced on Appendix P at https://hcpf.colorado.gov/pharmacyresources#PDLP

No Board members reported potential conflicts of interest for the eight products included in the Non-PDL Products section of today's agenda.

1. **Kerendia** (finerenone) oral tablet

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

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

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

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

Maximum dose: 20 mg/day

Maximum quantity: 30 tablets/month

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

Scheduled Speaker Testimony
B Hocum – Bayer – *yielded time*

Discussion

- J Taylor acknowledged that
  - The second failure statement in this section that includes lack of efficacy with a 6-week trial will be deleted in the final criteria set
  - In the continuation of therapy statement, "a non-preferred product" will be replaced by "Kerendia (finerenone)"
- In bullet point 3, need to add the word "or" between "intolerance" and "contraindication."
- L Claus moved to approve the criteria as amended. Seconded by K MacIntyre. Motion passed unanimously.

2. **Crenessity** (crinecerfont) oral capsule, oral solution

Crenessity (crinecerfont) may be approved if the following criteria are met:

1. Member is ≥ 4 years of age AND
2. Member has a diagnosis of 21-hydroxylase deficiency classic congenital adrenal hyperplasia confirmed by ONE of the following:
    a. Elevated 17-hydroxyprogesterone level
    b. Confirmed *CYP21A2* genotype
    c. Positive newborn screening with confirmatory second-tier testing
    d. Diagnostic results after cosyntropin stimulation

    AND
3. The requested medication is being prescribed by or in consultation with an endocrinologist, urologist, or a physician who specializes in the treatment of adrenal hyperplasia AND
4. Crenessity (crinecerfont) will be taken in combination with adequate systemic glucocorticoid replacement therapy AND
5. Member does not have severe renal impairment or end-stage renal disease AND
6. Member has been counseled to take each dose of Crenessity (crinecerfont) with a meal AND
7. The dose of Crenessity (crinecerfont) will be adjusted appropriately according to product labeling for members who are concurrently taking a strong or moderate CYP3A4 inducer.

Maximum dose: 400 mg/day

Maximum quantity:
25 mg capsules: two capsules/day
50 mg capsules: two capsules/day
100 mg capsules: four capsules/day

Oral solution 50 mg/mL: 4 mL twice daily

Scheduled Speaker Testimony
R Kong - Neurocrine Biosciences

Discussion

- B Jackson moved to add genetics/metabolic physician to the list of subspecialists in bullet point 3. Seconded by I Pan. Motion passed unanimously.
- S Klocke moved to approve the criteria as amended. Seconded by L Claus. Motion passed unanimously.

3. **Attruby** (acoramidis hydrochloride) oral tablet

ATTRUBY (acoramidis) may be approved if the following criteria are met:

1. Member is ≥ 18 years of age AND
2. Member has a diagnosis of cardiomyopathy of wild type or hereditary transthyretin-mediated amyloid cardiomyopathy (ATTR-CM), AND
3. Requested medication is being prescribed by or in consultation with a cardiologist AND
4. Member does not have polyneuropathy associated with ATTR, AND
5. Member has a documented history of heart failure with NYHA functional class I to III

Maximum dose: 1,424 mg/day

Maximum quantity: four 356 mg tablets/day

Scheduled Speaker Testimony
T Gregorian – Bridgebio

Written Testimony
Attruby Summary Document Submission - Bridgebio

Discussion

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

4. **Onapgo** (apomorphine hydrochloride) on-body subcutaneous infusion system

Onapgo (apomorphine HCl) may be approved if the following criteria are met:

1. Member is ≥ 18 years of age AND
2. Member has a confirmed diagnosis of advanced Parkinson's Disease AND
3. Member is experiencing "off" episodes such as muscle stiffness, slow movements, or difficulty starting movements for a minimum of 3 hours per day AND
4. The requested medication is being used as an adjunct therapy with other medications for acute, intermittent treatment of hypomobility, "off" episodes ("end-of-dose wearing off" and unpredictable "on/off" episodes) in patients with advanced Parkinson's disease AND
5. The medication is being prescribed by or in consultation a neurologist AND
6. Member has tried and failed treatment (lack of efficacy or intolerable side effects) with Apokyn (apomorphine HCl) Pen, AND
7. Due to the risk of severe nausea, member will be pre-treated with an antiemetic other than ondansetron, granisetron or palonosetron (see bullet point 8) AND
8. Due to the risk of profound hypotension and loss of consciousness, member is not concomitantly using a 5HT3 antagonist such as ondansetron, granisetron, palonosetron or alosetron, AND
9. Onapgo (apomorphine HCl) will be administered only as a subcutaneous infusion AND
10. For members with mild-to-moderate renal impairment, the recommended initial extra dose Onapgo (apomorphine HCl) is 0.5 mg to 1 mg and should not exceed 1 mg AND
11. Member has been counseled to avoid operating a motor vehicle or performing hazardous work while taking Onapgo due to unpredictable episodes of drowsiness AND
12. The member's concurrent medications have been reviewed to avoid or minimize the use of medications with overlapping sedative effects AND
13. Prescriber acknowledges that to avoid increasing the severity of motor symptoms, Onapgo (apomorphine HCl) must be tapered and not abruptly discontinued, AND
14. Member has been counseled about the risk of falls due to decreases in blood pressure and to avoid concurrent use of sublingual nitroglycerin while taking Onapgo (apomorphine HCl) AND
15. Prescriber attests that member is capable of understanding and using the delivery system themselves or by a caregiver AND
16. Provider attests that member will be educated on proper infusion device placement on the body, instructions for starting the infusion, and safe disposal of the used infusion device.

Maximum Dose: 98 mg/day

Maximum Quantity: one 98 mg single-dose prefilled cartridge/day

Initial Approval: 6 months

Reauthorization: Onapgo (apomorphine hydrochloride) may be reauthorized for one year with provider attestation that the member has demonstrated response to treatment by showing significant clinical improvement or reduction in "off" time.

Discussion

- S Klocke moved to (1) include antidopaminergic antiemetics (such as promethazine and prochlorperazine) in the bullet points involving antiemetic drug-drug interactions with Onapgo, and (2) request that the Department examine other antiemetics that could be appropriately used with Onapgo. Seconded by I Pan. Motion passed unanimously.
- The Board discussed antiemetics that may and may not be used as pre-treatment medications to prevent nausea. The only antiemetic currently mentioned in Onapgo product labeling as having been studied and determined safe for concomitant use is trimethobenzamide (generic Tigan®); however, trimethobenzamide is currently a non-preferred agent on the PDL and its availability is sometimes impacted by drug shortages.
- J Taylor offered that the Department can consider creating a prior authorization approval pathway to trimethobenzamide specifically for its use as an antiemetic prior to Onapgo administration.
- The Board also discussed the possibility of aprepitant as a safe pre-treatment antiemetic option; however, aprepitant is also associated with some level of increased risk for QTc prolongation it has not yet been studied as a pre-treatment antiemetic for Onapgo.
- The Board discussed whether the intention of bullet point 11 is to state that members taking Onapgo should never drive, or if the intent is to ensure that the member has been counseled to not drive if drowsiness occurs. The Board did not offer any alternative language for this bullet.
- The word "with" needs to be added before "a neurologist" in bullet point 5.
- A failure definition needs to be created for bullet point 6.
- "Provider" needs to be edited to "prescriber" in bullet point 16 and the reauthorization section in order to align with the other bullet points.
- S Klocke moved to approve the criteria as amended above. Seconded by B Jackson. Motion passed unanimously.

5. **Tryngolza** (olezarsen sodium) subcutaneous injection single-dose autoinjector

Tryngolza (olezarsen sodium) may be approved if the following criteria are met:

1. Member is ≥ 18 years of age AND
2. Member has a diagnosis of familial chylomicronemia syndrome AND
3. Member's diagnosis has been confirmed by genetic testing AND
4. Tryngolza (olezarsen sodium) is being prescribed as adjunct therapy with lifestyle interventions including a low-fat diet and abstaining from alcohol consumption, AND
5. Provider attests that member will be educated on proper injection technique and safe storage and disposal of autoinjectors.

Maximum Dose: 80 mg subcutaneously once monthly

Maximum Quantity: one 80 mg/0.8 mL single-dose autoinjector/month

Discussion

- K MacIntyre moved to approve the criteria as written. Seconded by B Jackson. Motion passed unanimously.

6. **Ctexli** (chenodiol) 250 mg oral tablet

Ctexli (chenodiol) may be approved if the following criteria are met:

1. Member is ≥ 18 years of age AND
2. Member has a confirmed diagnosis of cerebrotendinous xanthomatosis (CTX) confirmed by genetic tests showing pathogenic variants in the *CYP27A1* gene, AND
3. The request medication is being prescribed by a gastroenterologist, hepatologist, neurologist, or cardiologist AND
4. Baseline ALT, AST, and total bilirubin levels have been assessed prior to initiation of therapy AND
5. Member has trial and failure with a generic chenodiol 250 mg product. Failure is defined as lack of efficacy, allergy, or intolerable side effects

AND

6. Member will be monitored for signs and symptoms of hepatotoxicity during therapy and if signs and symptoms consistent with hepatotoxicity occur, Ctexli (chenodiol) will be immediately discontinued AND
7. If member is concurrently taking a bile acid sequestering agent (such as cholestyramine and colestipol) or aluminum-based antacids, the member has been counseled to take Ctexli (chenodiol) doses at least 4 hours prior to taking those interacting drugs AND
3. If member is concurrently taking anticoagulant therapy (such as warfarin), the member has been counseled about the increased risk of bleeding while taking Ctexli (chenodiol).

Maximum Dose: 750 mg/day

Quantity Limit: 90 tablets/30 days

Discussion

- I Pan moved to delete (CTX) in bullet point 2 as extraneous since there are no subsequent references to it, and also to avoid any confusion with the same abbreviation commonly used to refer to ceftriaxone in hospital practice. Seconded by M Ash. Motion passed unanimously.
- S Klocke moved to approve the criteria as amended. Seconded by I Pan. Motion passed unanimously.

7. **Inzirqo** (hydrochlorothiazide) powder for oral suspension

INZIRQO (hydrochlorothiazide powder for oral suspension) may be approved if the following criteria are met:

1. Member is ≥ 6 months of age AND
2. Member has a feeding tube or has difficulty swallowing solid dosage forms

Maximum dose:

<2 years of age	37.5 mg/day
2 years of age and older	100 mg/day

Maximum quantity: 4 bottles of 800 mg oral powder for reconstitution/ month

Discussion

- I Pan moved to approve the criteria as written. Seconded by T Brubaker. Motion passed unanimously.

8. **Metronidazole 125 mg** oral tablet

Approval of metronidazole 125 mg tablets may be granted if the prescriber provides clinical rationale supporting the necessity of this specific dosage form, along with clinical justification demonstrating that no alternative tablet strength of metronidazole can be used.

Discussion

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

C. Adjournment

Board Chair Claus reminded attendees that the next Board meeting is scheduled for Tuesday, August 12, 2025, from 1:00 to 5:00 pm. She also reminded Board members to delete their meeting binders and associated emails at the conclusion of today's meeting.

Tentative dates for 2026 DUR Board meetings will be determined in the coming weeks. Details will be distributed to Board members when they are available.

L Claus moved to adjourn the meeting. Seconded by I Pan. Motion passed unanimously and the meeting was adjourned at 3:41 pm.

Minutes prepared by Julia Rawlings, PharmD, Secretary