COLORADO
Department of Health Care Policy & Financing

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

May 7, 2024
Open Session
1:00 pm – 5:00 pm

1. Call to Order

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

2. Roll Call and Introductions

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

Members Present: Brian Jackson, MD, MA (Chair); Liza Claus, PharmD (Vice Chair); Todd Brubaker, DO; Shilpa Klocke, PharmD; Patricia Lanius, BSPharm, MHA; Ken MacIntyre, DO; Ingrid Pan, PharmD

Members Absent: None

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

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

3. Virtual Meeting Information and General Announcements

J Rawlings shared several announcements:

- This meeting is being recorded for internal use by the Department
- 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, or if your connection is interrupted 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.
- CU Skaggs School of Pharmacy Doctor of Pharmacy candidates J Hahn and R Sapasap will be starting their advanced clinical practice rotations in June, so today they are participating in their last quarterly Board meeting as Population Health Interns. Dr. Rawlings thanked them for their excellent contributions to the DUR program during the past year.

4. Colorado Department of Health Care Policy and Financing Updates

V Garcia provided updates from the Department:

- The Department recently reprocured our pharmacy benefit management system (PBMS) with a contract award being made to MedImpact. The Department is starting the transition to MedImpact's PBMS this month with an anticipated completion date of Fall 2025.
- The department of Health Care Policy and Financing has implemented a program called Centers of Excellence in Chronic Pain. This program supports members with chronic pain, to insure they have access to the treatments they need, as well as supporting their providers with educational opportunities and specialist consults.
- The Board recruits for new physician and pharmacist members on a rolling basis. There is currently an opening for a physician member of the Board. If you are interested in serving in this capacity, send an email with your current CV to the email address SSPPS.co-dur@cuanschutz.edu
- As a reminder, for products and drug classes currently managed with prior authorization criteria, only proposed changes to the currently posted criteria will be read aloud during today's meeting.

5. Final Approval of Minutes from the February 13, 2024 Meeting

- Chair B Jackson asked the Board to review minutes from the February 13, 2024 meeting.
- L Claus moved to approve the minutes as written. Seconded by S Klocke. P Lanius abstained, as she did not attend the February meeting. Motion passed with six votes in favor.

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

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

Rules for Speaker Testimony: Presentations shall be restricted to products being reviewed for prior authorization criteria. Presentations shall be limited to a maximum of three minutes per drug product. Only one presentation per product will be permitted for a manufacturer. Persons must sign up no later than 24 hours in advance with the DUR Account Manager in order to speak at the DUR Board Meeting.

Persons will be called in the order in which they signed in for each set of prior authorization criteria. Presentations must be limited to verbal comments. No visual aids, other than designated handouts are permitted. Persons giving oral presentations must verbally disclose all relationships to pharmaceutical manufacturers.

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

7. Clinical Updates and General Orders

- **FDA New Product & Safety Updates**
  J Hahn, DUR Intern, presented this quarter's FDA Drug Approvals report that was prepared by A Rukavina, DUR Intern. There have been no new FDA safety communications since the last meeting.
- **Quarterly Clinical Modules**
  R Page presented an executive summary of last quarter's clinical module analysis, *Evaluation of Specific Medication Claim Patterns Associated with Overutilization and Misuse among Health First Colorado Members,* that was delivered to the Department on March 31.

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

- **Quarterly Drug Utilization Reports**
  R Page presented highlights from this quarter's drug utilization reports. Ventolin® HFA, gabapentin, amoxicillin, trazodone, ondansetron ODT, sertraline, omeprazole, hydroxyzine HCl, cetirizine, and atorvastatin were the top drug products by claim count during the 1st quarter of 2024. Humira®, Trulicity®, Trikafta®, Biktarvy®, Dupixent®, Taltz®, and Vyvanse® were among the top product claims by cost. Board members were referred to utilization reports in the meeting binder for more details.

8. New Business

The New Business section of today's agenda covers the review of proposed criteria for the PDL Drug Classes scheduled for May review, along with several products being reviewed for addition to Appendix P.

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

- Board members will be asked if they have potential conflicts of interest to verbally disclose prior to reviewing therapeutic drug classes or individual products listed in the meeting agenda.
- Time will be permitted for stakeholder comment. All of today's speakers have registered in advance and each will be given up to 3 minutes to provide testimony.
- There will be an opportunity for Board discussion.

R Page proceeded with the review process of proposed criteria and asked if any Board members had conflicts of interest to report related to the PDL therapeutic classes included on today's agenda up to the Mass Review section. No Board members reported potential conflicts.

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

Red indicates proposed deleted text

Yellow indicates proposed new text

1. Pulmonary Arterial Hypertension (PAH) Therapies

a. Phosphodiesterase Inhibitors (PDEIs)

Preferred Agents

***Must meet eligibility criteria**

*REVATIO (sildenafil) oral suspension

*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.

REVATIO (sildenafil) **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/swallow tablet and attests 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**
*Epoprostenol vial
*FLOLAN (epoprostenol) vial
*ORENITRAM (treprostinil ER) tablet, titration pack
*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 Stimulators

Preferred Agents
NONE

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

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

  AND
- Member has a CrCl ≥ 15 mL/min and is not on dialysis **AND**
- Member does not have severe liver impairment (Child Pugh C) **AND**
- 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

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

2. Statins & Combinations

a. Statins

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

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

Age Limitations: Altoprev will not be approved for members < 18 years of age. Fluvastatin 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
Ezetimibe/Simvastatin 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
- L Claus moved to accept the criteria as written. Seconded by T Brubaker. Motion passed unanimously.

3. Movement Disorder Agents *(New therapeutic class on the PDL)*

Preferred Agents
***Must meet eligibility criteria**
*Austedo (deutetrabenazine) tablet, ER tablet
*Ingrezza (valbenazine) capsule
*Tetrabenazine tablet

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

- Member is ≥18 years of age AND
- Member has been diagnosed with tardive dyskinesia clinically or chorea associated with Huntington's disease AND
- Member does not have 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
- If the member has severe hepatic impairment, FDA labeling for use has been evaluated, AND
- Member has trialed and failed tetrabenazine; adequate trial duration is 1 month (Failure is defined as a lack of efficacy, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions) AND
- For tardive dyskinesia: Has
  - 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 evaluated
- For tardive dyskinesia, a baseline AIMS AND 12 week AIMS are required. If the 12-week AIMS does not show improvement from baseline, the prior authorization will no longer be approved

Xenazine (tetrabenazine)
Maximum dose 50mg/day
Quantity limit: 60 tablets per 30 days

Ingrezza (valbenazine)
Quantity limits:

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

Maximum dose: 80 mg/day

Austedo (deutetrabenazine)
Maximum dose: 48mg/day
Quantity limit: 120 tablets 30 days

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
J Deason, Ingrezza – Neurocrine Biosciences
M Sohal, Austedo – Teva

Discussion

- K MacIntyre moved to change "a baseline AIMS has been evaluated" to "a baseline AIMS has been performed." Seconded by P Lanius. T Brubaker abstained due to not being available for this vote. Motion passed by six votes in favor.

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

4. Acne Agents, Topical

Preferred Agents

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

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

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

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

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

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

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

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

Discussion

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

5. Anti-Psoriatics

a. Oral

Preferred Agents
Acitretin capsule

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

Discussion

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

b. Topical

Preferred Agents
Calcipotriene cream, solution
Calcipotriene/betamethasone dipropionate ointment
DOVONEX (calcipotriene) cream
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 ≥ 6 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) of 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 ≥ 9 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) 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) 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 antifungal (such as ketoconazole, ciclopirox)
    - 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.

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

6. Immunomodulators, Topical

a. Atopic Dermatitis

Preferred Agents
ELIDEL (pimecrolimus) cream
*Pimecrolimus cream (Oceanside only)
PROTOPIC (tacrolimus) ointment
Tacrolimus ointment

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

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

OPZELURA (ruxolitinib) 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
- Must be 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 have trialed and/or failed twice-daily pimecrolimus and tacrolimus. Failure is defined as a lack of efficacy, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions 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 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 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.

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

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

Written Testimony
Lisa Percy Albany, JD – American Academy of Dermatology
Various communications from patient advocates for the treatment of vitiligo

Scheduled Speaker Testimony
H Patadia, Opzelura – Incyte

Discussion
- S Klocke moved to accept the criteria as written. Seconded by K MacIntyre. Motion passed unanimously.

b. Antineoplastic Agents

Preferred Agents
(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.

Discussion
- K MacIntyre moved to accept the criteria as written. Seconded by P Lanius. Motion passed unanimously.

c. Other Agents

Preferred Agents
CONDYLOX (podofilox) gel
Imiquimod (generic Aldara) cream
Podofilox 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.

Discussion
- P Lanius moved to accept the criteria as written. Seconded by L Claus. Motion passed unanimously.

7. *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
- S Klocke moved to accept the criteria as written. Seconded T Brubaker. Motion passed unanimously.

8. Proton Pump Inhibitors (PPIs)

Preferred Agents
DEXILANT (dexlansoprazole) capsule[BNR]
Esomeprazole DR capsule (RX)
Lansoprazole DR capsules (RX)
Lansoprazole ODT (lansoprazole) *(for members under 2 years)*
NEXIUM[BNR] (esomeprazole) oral suspension packet
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 or ranitidine) be trialed in order to reduce long-term PPI use.

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

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

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

Adult members with GERD on once daily, high-dose PPI therapy who continue to experience symptoms may receive initial prior authorization approval for a 4-week trial of twice daily, high-dose PPI therapy. Continuation of the twice daily dosing regimen for GERD beyond 4 weeks will require additional prior

authorization approval verifying adequate member response to the dosing regimen and approval may be placed for one year. If a member with symptomatic GERD does not respond to twice daily, high-dose PPI therapy, this should be considered a treatment failure.

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

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

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

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

Discussion
- K MacIntyre moved to remove ranitidine as an H2-blocker step-down therapy option, as it is no longer on the market. Seconded by I Pan. Motion passed unanimously.
- T Brubaker 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.*

Dr. Taylor highlighted for the Board proposed edits within the Mass Review section. In the beta blocker single-agent subclass there are new proposed criteria for Innopran® XL, a branded propranolol ER product. Other proposed criteria additions in this subclass include continuation of therapy provisions for both Bystolic® and non-preferred carvedilol ER capsules. Dr. Taylor read these new sections aloud during the meeting. There was also a proposed deletion of the small section of current criteria for Nyvepria (pegfilgrastim-apgf) in the Colony Stimulating Factors therapeutic class since it is becoming a preferred agent.

If any Board member wants to pull a drug class from Mass Review for further review, that can be decided during the discussion regarding this section of the agenda.

Dr. Jackson asked if any Board members had conflicts of interest to report related to the PDL therapeutic classes included in today's Mass Review section. No Board members reported potential conflicts.

9. 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 has difficulty swallowing and cannot take solid oral dosage forms.

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

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

  AND
- Maximum duration of use is 14 days

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

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. Single Agent

Preferred Agents
Acebutolol capsule
Atenolol tablet
Bisoprolol tablet
BYSTOLIC (nebivolol) tablet
*Carvedilol ER capsule
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

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

***HEMANGEOL (propranolol) oral solution** may be approved for members between 5 weeks and 1 year of age with proliferating infantile hemangioma requiring systemic therapy.

Maximum dose: 1.7 mg/kg twice daily

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. Antiarrhythmics

Preferred Agents
Sotalol tablet

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

Maximum dose: 320 mg/day

c. Beta 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

b. Dihydropyridines (DHPs)

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.

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

c. Non-Dihydropyridines (Non-DHPs)

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 Inhibitors (ACEIs) and Combinations

a. Single Agent

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

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

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

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

b. ACE Inhibitor Combinations

Preferred Agents
- Benazepril Amlodipine capsule
- Benazepril/HCTZ tablet
- Enalapril/HCTZ tablet
- Lisinopril/HCTZ tablet

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

14. Angiotensin Receptor Blockers (ARBs) and Combinations

a. Single Agent

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

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

b. ARB Combinations

Preferred Agents
No PA Required (Unless indicated*)
*ENTRESTO (sacubitril/valsartan) tablet
Irbesartan/HCTZ tablet
Losartan/HCTZ tablet
lmesartan/Amlodipine tablet
Olmesartan/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 & 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
Fenofibrate capsule, tablet (generic Lofibra/Tricor)
Fenofibric acid tablet (generic Trilipix)
Gemfibrozil tablet

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

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

c. Lipotropics, Other Agents

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

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

- Member has a baseline triglyceride level > 500 mg/dl AND
- Member has failed an adequate trial of generic omega-3 ethyl esters AND an adequate trial of gemfibrozil or fenofibrate (failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions)

OR

- Medication is being prescribed to reduce CV risk for members on maximally tolerated statin therapy with triglyceride levels ≥ 150mg/dL and LDL-C levels between 41-100 mg/dL AND member meets one of the following:
    - Member is ≥ 45 years of age and has established atherosclerotic CV disease (e.g., coronary artery disease, cerebrovascular/carotid disease, peripheral arterial disease) OR
    - Member is ≥ 50 years of age with diabetes mellitus and has one or more of the following additional risk factors for CV disease:
        - Male ≥ 55 years of age or female ≥ 65 years of age
        - Cigarette smoker
        - Hypertension
        - HDL-C ≤ 40 mg/dL for men or ≤ 50 mg/dL for women
        - hsCRP >3.00 mg/L (0.3 mg/dL)
        - CrCl 30 to 59 mL/min
        - Retinopathy
        - Micro- or macroalbuminuria
        - ABI <0.9 without symptoms of intermittent claudication

Maximum Dose: 4g daily

17. Acne Agents, Oral Isotretinoins

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

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

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

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

18. Rosacea Agents

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

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

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

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

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

19. Topical Steroids

a. Low Potency

Preferred Agents
Hydrocortisone (Rx) cream, ointment, lotion
DERMA-SMOOTHE-FS (fluocinolone) oil
Desonide 0.05% cream, ointment
*Fluocinolone 0.01% body oil, 0.01% cream, 0.01% scalp oil

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

b. Medium Potency

Preferred Agents
- Betamethasone dipropionate 0.05% cream, lotion
- Betamethasone valerate 0.1% cream, ointment
- Hydrocortisone valerate 0.2% cream
- Fluocinolone 0.025% cream, 0.05% cream, 0.005% ointment
- Mometasone 0.1% cream, 0.1% ointment, 0.1% solution
- Triamcinolone acetonide 0.025% cream, 0.1% cream, 0.025% ointment, 0.05% ointment, 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. High Potency

Preferred Agents
(*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. Very High Potency

Preferred Agents
(Unless exceeds duration of therapy*)
- *Betamethasone dipropionate/propylene glycol (augmented) 0.05% ointment, lotion
- *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.

20. Antiemetics

a. Oral

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

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.

Written Testimony
Erica Scott, Bonjesta – Duchesnay USA, Inc.

b. 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.

21. GI Motility, Chronic

Preferred Agents
PA Required for all agents in this class
AMITIZA[BNR] (lubiprostone) capsule
LINZESS (linaclotide) capsule
Lubiprostone capsule (generic Amitiza)
MOVANTIK (naloxegol) tablet

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

Preferred agents may be approved if the member meets the following criteria:
- Has diagnosis of Irritable Bowel Syndrome – Constipation (IBS-C), Chronic Idiopathic Constipation (CIC), or Opioid Induced Constipation (OIC) in patients with opioids prescribed for noncancer pain AND
- Member does not have a diagnosis of GI obstruction AND
- For indication of OIC, member opioid use must exceed 4 weeks of treatment
- For indications of CIC, OIC, IBS-C; member must have documentation of adequate trial of two or more over-the-counter motility agents (polyethylene glycol, docusate or bisacodyl, for example). OR If the member cannot take oral medications, then the member must fail a 7-day trial with a 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)	48mcg/day
Linzess (linaclotide)	IBS-C, CIC	290mcg/day
Movantik (naloxegol)	OIC	25mg/day
Viberzi (eluxadoline)	IBS-D	200mg/day
Relistor subcutaneous injection (methylnaltrexone)	OIC	12mg/day
Relistor oral (methylnaltrexone)	OIC	450mg/day
Lotronex (alosetron)	IBS-D (females only)	2mg/day (females only)
Symproic (naldemedine)	OIC	0.2mg/day
Trulance (plecanatide)	CIC, IBS-C	3mg/day
Motegrity (prucalopride)	CIC	2mg/day

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

22. Hemorrhoidal, Anorectal, and Related Topical Anesthetic Agents

Preferred Agents

Hydrocortisone single agent

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
PROCTO-MED HC (hydrocortisone) 2.5% cream
PROCTO-PAK (hydrocortisone) 1% cream
PROCTOSOL-HC 2.5% (hydrocortisone) cream
PROCTOZONE-HC 2.5% (hydrocortisone) cream

Lidocaine single agent

Lidocaine 5% ointment

Other and Combinations

Hydrocortisone-Pramoxine 1%-1% cream
Hydrocortisone-Pramoxine 2.5%-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.

23. 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.)

24. Non-Biologic Ulcerative Colitis

a. Oral

Preferred Agents
- APRISO[BNR] (mesalamine ER) capsule
- LIALDA[BNR] (mesalamine DR) tablet
- PENTASA[BNR] (mesalamine) capsule
- Sulfasalazine IR and DR tablet

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

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

b. Rectal

Preferred Agents
- Mesalamine suppository
- Mesalamine 4gm/60 ml enema (generic SF ROWASA)

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

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

25. Anticoagulants

a. Oral

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

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

XARELTO 2.5mg (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. 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

26. 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.

27. Colony Stimulating Factors

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

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

- Medication is being used for one of the following indications:
  - Patient with cancer receiving myelosuppressive chemotherapy –to reduce incidence of infection (febrile neutropenia) (Either the post nadir ANC is less than 10,000 cells/mm3 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/mm3)

AND

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

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

- Medication is being used for one of the following indications:
  - Patient with cancer receiving myelosuppressive chemotherapy –to reduce incidence of infection (febrile neutropenia) (Either the post nadir ANC is less than 10,000 cells/mm3 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/mm3)

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.

28. Erythropoiesis Stimulating Agents

Preferred Agents

PA Required for all agents in this class*

EPOGEN (epoetin alfa) vial

RETACRIT (epoetin alfa-epbx) *(Pfizer only)*

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

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

AND

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

†Hemoglobin results must be from the last 30 days.

Discussion regarding Mass Review

- The Board recommended to the Department to work toward more general and standardized prior authorization language to apply to situations in which members cannot swallow solid oral dosage forms and need to take liquid dosage forms.
- K MacIntyre moved to accept criteria in the Mass Review section of the agenda as written. Seconded by T Brubaker. Motion passed unanimously.

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

R Page proceeded with the review process of proposed criteria for Non-PDL Products and asked if any Board members had conflicts of interest related to the six products on today's agenda. No Board members reported a potential conflict of interest for the ten products included in this section of the agenda.

To better accommodate today's speakers, products were reviewed in the following order: Rezdiffra®, Wegovy®, Sohonos®, Filsuvez®, Jesduvroq®, and Rivfloza®.

1. Rezdiffra (resmetirom) oral tablet

Rezdiffra (resmetirom) may be approved for members meeting the following criteria:

1. Member is ≥ 18 years of age AND
2. Member has a diagnosis of noncirrhotic nonalcoholic steatohepatitis (NASH) with stage F2 to F3 fibrosis that has been confirmed by labs, imaging or clinical presentation AND
3. The member does not have decompensated cirrhosis AND
4. The member's cardiovascular risk factors (such as hypertension, dyslipidemia, diabetes) have been evaluated and appropriately treated AND
5. Members who are overweight or have obesity have been counseled regarding implementation of lifestyle interventions (diet modification and exercise) to promote weight loss AND
6. The medication is being prescribed by or in consultation with a gastroenterologist or hepatologist AND
7. If member is concurrently taking a CYP2C8 inhibitor (such as clopidogrel), the dose of Rezdiffra will be appropriately adjusted per product labeling AND
8. Regarding concurrent statin therapy, provider attests that:
    a. If member is taking rosuvastatin or simvastatin, the dose of Rezdiffra (resmetirom) will be limited to 20 mg/day
    b. If member is concurrently taking pravastatin or atorvastatin, the dose of Rezdiffra will be limited to 40 mg/day

AND

Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Maximum Dose: 100 mg/day

Quantity Limit: 30 tablets/30 days
Approval: 1 year

Scheduled Speaker Testimony
W Lam, Madrigal Pharmaceuticals

Discussion

- L Claus moved to correct line items 8a and 8b to the following text. Seconded by K MacIntyre. Motion passed unanimously.
    - If member is taking rosuvastatin or simvastatin, the dose of the statin will be limited to 20 mg/day.
    - If member is concurrently taking pravastatin or atorvastatin, the dose of the statin will be limited to 40 mg/day.

- B Jackson moved to include subspecialists in gastroenterologist, hepatologist, endocrinologist or obesity medicine specialist among those who may prescribe Rezdiffra. Seconded by I Pan. Motion passed unanimously.
- L Claus moved to accept criteria as amended. Seconded by S Klocke. Motion passed unanimously.

2. Wegovy (semaglutide) subcutaneous injection

Wegovy (semaglutide) may be approved for members meeting the following criteria:

1. Member is 18 years of age or older AND
2. Member has established cardiovascular disease (previous myocardial infarction, previous stroke, or symptomatic peripheral arterial disease) and either obesity or overweight (defined as a BMI ≥27 kg/m^2) AND
3. Member does not have a diagnosis of Type 1 or Type 2 diabetes AND
4. Wegovy (semaglutide) is being prescribed to decrease the risk of adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) AND
5. Member has been counseled regarding implementation of lifestyle interventions (diet modification and exercise) to promote weight loss.

Note: Prior authorization requests for Wegovy (semaglutide) prescribed solely for weight loss will not be approved.

Maximum dose: 2.4 mg subcutaneously once weekly

Quantity limit: four prefilled syringes/30 days

Scheduled Speaker Testimony
C Francavilla, MD
K Wolf Khachatourian – Novo Nordisk

Discussion

- L Claus moved to change "established cardiovascular disease (previous myocardial infarction, previous stroke, or symptomatic peripheral arterial disease)" to "established atherosclerotic cardiovascular disease (ASCVD)." Seconded by S Klocke. Motion passed unanimously.
- B Jackson moved to change "four prefilled syringes/30 days" to "four prefilled syringes/28 days." Seconded by L Claus. Motion passed unanimously.
- L Claus moved to accept criteria as amended. Seconded by I Pan. Motion passed unanimously.

3. Jesduvroq (daprodustat) oral tablet

Jesduvroq (daprodustat) may be approved for members meeting the following criteria:

1. Member is 18 years of age or older AND
2. Member has chronic kidney disease (CKD) and has been receiving dialysis for at least four months AND
3. Member is not taking a strong CYP2C8 inhibitor (such as gemfibrozil) AND
4. Member does not have uncontrolled hypertension, AND
5. Laboratory tests to evaluate ALT, AST, alkaline phosphatase, total bilirubin, hemoglobin and iron status will be performed at baseline and during treatment with Jesduvroq (daprodustat), according to product labeling, AND
6. The requested medication is not being prescribed as a substitute for red blood cell transfusions in patients who require immediate correction of anemia AND

7. The requested medication is not being prescribed for treatment of anemia of chronic kidney disease in patients who are not on dialysis AND
8. For members NOT being treated with an erythropoiesis stimulating agent (ESA), initial dosing will be based on the baseline hemoglobin level (g/dL) per product labeling AND
9. For members being switched from an ESA to Jesduvroq (daprodustat) therapy, the starting dose will be based on the dose of the ESA at the time of substitution

Maximum dose: 24 mg/day

Discussion

- P Lanius recommended changing "at the time of substitution" in bullet point 9 to "at the time of the switch." This suggestion was noted by the Department. S Klocke moved to accept criteria as amended. Seconded by B Jackson. T Brubaker abstained due to his unavailability for this vote. Motion passed with six votes in favor.

4. Rivfloza (nedosiran) subcutaneous injection

Rivfloza (nedosiran) may be approved for members meeting the following criteria:

1. Member is 9 years of age or older AND
2. Member has a diagnosis of primary hyperoxaluria type 1 (PH1) confirmed by either:
    a. Genetic testing that demonstrates a mutation of the alanine glyoxylate aminotransferase (*AGXT*) gene OR
    b. Liver analysis demonstrating absent or significantly reduced AGXT enzyme

   AND
3. Member has relatively preserved kidney function (eGFR ≥ 30 mL/min/1.73 m^2) AND
4. Medication is being prescribed by, or in consultation with a nephrologist or other healthcare provider with expertise in treating PH1 AND
5. Member has documented baseline urinary oxalate excretion or plasma oxalate concentrations.

Quantity limit: one single-dose vial or prefilled syringe/month

Initial approval: one year

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

Members currently stabilized on a Rivfloza (nedosiran) regimen may receive prior authorization approval for continuation of therapy if meeting reauthorization criteria listed above.

Discussion

- S Klocke moved to accept the proposed criteria as written. Seconded by P Lanius. T Brubaker abstained, as he had to leave the meeting early and was unavailable for this vote. Motion passed with six votes in favor.

5. Sohonos (palovarotene) oral capsule

Sohonos (palovarotene) may be approved for members meeting the following criteria:

1. Member is 8 years and older if female and 10 years and older if male AND
2. Member has a confirmed diagnosis of fibrodysplasia ossificans progressiva (FOP) AND
3. For members of reproductive potential, a negative pregnancy test has been obtained within one week prior to initiating Sohonos (palovarotene) therapy AND
4. Member is not pregnant AND

5. Provider has evaluated, and member has received, all age-appropriate vaccinations as recommended by current immunization guidelines prior to initiating treatment AND
6. Member is not taking a tetracycline derivative, strong CYP3A4 inhibitor (such as ketoconazole, itraconazole, voriconazole, ritonavir) or strong CYP3A4 inducer (such as carbamazepine, rifampin) AND
7. If applicable, member has been counseled to use effective contraception starting at least one month before starting Sohonos (palovarotene) therapy, during treatment, and for at least one month after the last dose

Initial approval: 6 months

Reauthorization: Sohonos (palovarotene) may be approved for one year if volume of new heterotopic ossification as verified by imaging.

Scheduled Speaker Testimony
Phong Pham – Ipsen Biopharmaceuticals

Discussion

- B Jackson moved (1) to correct the reauthorization language to read "Sohonos (palovarotene) may be approved for one year if new heterotopic ossification is reduced in volume from baseline, as verified by imaging, and (2) at the beginning of bullet 7, change criteria to read "Members who are able to become pregnant have been counseled…", and (3) Member has been counseled about the potential for premature epiphyseal growth closure and resulting growth failure and provider attests that member will be monitored for this effect." Seconded by I Pan. Motion passed unanimously.
- B Jackson moved to accept criteria as amended. Seconded by I Pan. Motion passed unanimously.

6. Filsuvez (birch triterpenes) topical gel

Filsuvez (birch triterpenes) may be approved if the following criteria are met:

1. Member is ≥ 6 months of age, **AND**
2. Member must have undergone testing confirming one of the following diagnoses and genetic mutations:
   a. Dystrophic epidermolysis bullosa (DEB), based on mutation(s) in the collagen type VII alpha 1 chain (*COL7A1*) gene
   OR
   b. Junctional epidermolysis bullosa (JEB), based on mutation(s) in the collagen type XVII gene (*COL17A1*), laminin 332 genes (*LAMA3, LAMB3 and LAMC2*), integrin α6β4 genes (*ITGA6 and ITGB4*) or the integrin α3 subunit (*IGTA3*)
   AND
3. The requested medication is being prescribed by or in consultation with a provider who has expertise in treating dystrophic epidermolysis bullosa

Initial approval: Approval will be limited to one 90-day treatment course per one year.

Reauthorization: Reauthorization requests for an additional treatment course of Filsuvez (birch triterpenes) will undergo clinical review by a call center pharmacist on a case-by-case basis and require provider submission of clinical information (such as documentation from medical chart notes) demonstrating complete wound closure with completion of prior treatment course.

Claims limitation: 15 day supply per fill, up to one tube daily

Scheduled Speaker Testimony
Joy Sherrick – Chiesi

Discussion

- B Jackson moved to remove the word "dystrophic" from bullet point 3. Seconded by S Klocke. Motion passed unanimously.
- K MacIntyre moved to accept the criteria as amended. B Jackson seconded. Motion passed unanimously.

7. Proposed Compound Claims Cost Ceiling Policy

Effective 7/1/2024, compound claims for topical formulations exceeding $200.00 require prior authorization and are subject meeting the following:

- The prescriber attests that a reasonable effort has been made to use the more cost-effective compound product ingredient when multiple products with the same active ingredient are available, covered, and clinically appropriate for use in the compound AND
- Each active ingredient in the compounded medication is FDA-approved or national compendia supported for the condition being treated AND
- The compound ingredient therapeutic amounts and combinations are supported by national compendia or peer-reviewed literature for the condition being treated in the requested route of delivery AND
- Any compound product ingredient requiring drug specific prior authorization will be subject to meeting criteria listed on the Health First Colorado Preferred Drug List or Appendix P.

Discussion

- After Dr. Taylor responded to a few clarifying questions from Board members, I Pan moved that the Department communicate this upcoming policy change to applicable compounding pharmacies in advance of the effective date through a bulletin or similar method. B Jackson seconded. Motion passed unanimously.
- B Jackson moved to accept the proposed policy language as written. Seconded by S Klocke. Motion passed unanimously.

8. Proposed Changes to OTC Product Coverage Criteria for Acetaminophen and Pediatric Iron Formulations

The following non-PDL OTC products are covered without prior authorization:

- Children's liquid and chewable acetaminophen for ages 2-11 years members < 12 years of age

The following non-PDL OTC products may be covered with prior authorization if meeting criteria listed below:

- Ferrous sulfate and ferrous gluconate may be approved with a diagnosis of iron deficient anemia OR iron deficiency verified by low serum ferritin. OR "at risk" members < 2 years of age (such as preterm infants)

Written Testimony
D Keller – University of Colorado School of Medicine and Children's Hospital Colorado

Discussion

- The Board discussed the potential implications of the minimum age for acetaminophen being set at age 0.

- B Jackson moved to include to a current recommendation for babies who are at least 4 months old, exclusively breast fed, and not yet on iron-enriched solid food to receive iron supplementation (even if full term) as another example of "at-risk members" above. I Pan seconded. Motion passed unanimously.
- B Jackson initially moved to edit the age range for acetaminophen from "< 12 years of age" to 42 days to 12 years of age. J Leonard offered additional input that in the prior authorization system ages less than 1 year are considered "0 years" of age and a 42-day minimum age probably could not be detected and implemented without creating a new prior authorization. The Board instead considered adding a statement that "acetaminophen use in members younger than 42 days is not recommended." The Department noted this suggestion and Dr. Jackson withdrew his original motion.
- I Pan moved to accept the proposed policy language as amended. Seconded by B Jackson. Motion passed unanimously.

9. Maximum Dose for Buprenorphine-Containing Products Used to Treat OUD

Prior authorization requests for buprenorphine/naloxone SL film doses exceeding 24mg buprenorphine/day will be eligible to undergo clinical review by a call center pharmacist on a case-by-case basis with provider submission of clinical information (such as documentation from medical chart notes) may be approved with provider attestation to clinical rationale supporting the need for doses exceeding the 24 mg/day maximum (eligible for 6-month one year approval for up to 32 mg buprenorphine/day dosing). Prior authorization requests for buprenorphine SL tablet for members that are pregnant or unable to tolerate naloxone due to allergy or intolerable side effects will also be eligible for submission and review. one year approval.

Discussion

- B Jackson moved to accept the criteria as amended. S Klocke seconded. Motion passed unanimously.

C. Adjournment

Board Vice Chair Claus reminded attendees that the next Board meeting is scheduled for Tuesday, August 13, 2024, 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.

L Claus moved to adjourn the meeting, Seconded by I Pan. Motion passed unanimously and the meeting was adjourned at 3:57 pm.

Minutes respectfully submitted by Julia Rawlings, PharmD