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

August 12, 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 1:01 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 seven voting members participating. Quorum is five voting members.

Members Present: 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: Liza Claus, PharmD (Chair)

HCPF Pharmacy Office: Veronia Garcia, 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, 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.
- Speakers who will be 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.
- We welcome five CU Skaggs School of Pharmacy Doctor of Pharmacy candidates who are new Population Health Interns, to their first DUR Board meeting.

4. Colorado Department of Health Care Policy and Financing Updates

- V Garcia provided some updates from the Department
    - This is Mary Shefchyk's final DUR board meeting as the Industry Representative. Many thanks to Mary for her service to the DUR Board during the past year.
    - The Department is transitioning components of its Pharmacy Benefit Management System (PBMS) from Prime Therapeutics (formerly Magellan) to MedImpact. Implementation is planned for October of 2025 and February of 2026. What providers should know:
        - The Opioid Risk module is not changing and will continue to be managed by OpiSafe.
        - MedImpact will implement and manage four new PBMS modules:
            - Rebate (October 2025)
            - Preferred Drug List (October 2025)
            - Real-Time Benefit Tool (February 2026)
            - The core PBMS (February 2026) – which involves the pharmacy system
    - Only proposed changes to the currently posted prior authorization criteria for products and drug classes will be read aloud during today's meeting.

5. Final Approval of Minutes from the May 6, 2025 Meeting

- Vice Chair B Jackson asked the Board to review minutes from the May 6, 2025 meeting. T Brubaker moved to approve the minutes as written. Seconded by I Pan. 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**
  Z Ghafoori, Population Health Intern, presented 3 FDA Drug Safety Communications regarding (1) severe itching after stopping long-term use of cetirizine or levocetirizine, (2) heat-related complications with Transderm Scōp (scopolamine) patches, and (3) weight loss risk in patients younger than 6 years taking extended-release stimulants for ADHD.

- **FDA New Drug Approvals Report**
  M Overlie, Population Health Intern, presented this quarter's FDA Drug Approvals summary report.

- **Quarterly Clinical Module Summary**
  R Page presented a summary of last quarter's clinical module analysis entitled *Stimulant Prescribing and Utilization among Health First Colorado Members: A 2025 Update*. The full module was delivered to the Department on June 30, 2025.

- **Retrospective DUR (RDUR) Report**
  - R Page presented the quarterly RDUR summary.
  - J Rawlings presented a new educational letter, developed in collaboration with the Department, that will be mailed to select providers in September. The letter's focus is for Health First Colorado members with atrial fibrillation plus a history of stroke, TIA, or thromboembolism, and no claims for an anticoagulant medication during the evaluation period. The goal is to promote evidence-based anticoagulation therapy for members who may be at higher risk for an adverse outcome.

- **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:

- The Department considered a motion made during the May 2025 meeting undertake an evaluation of the term "contraindication" in criteria failure definitions and to look for opportunities for consistency by adding "contraindication" to all failure definitions across the board. The DUR team determined that failure definitions are crafted on a class-by-class or case-by-case basis. Some opportunities were identified to make some changes and those were applied. However, there were some drug classes, such as the antidepressants, where there are several low-cost generic products that are preferred. In those cases, a having a contraindication to one specific product does not qualify a member to claim having a contraindication to the entire drug class (when the member may be able to use a different preferred product). As the DUR Board reviews failure definitions going forward, consideration should be given as to whether adding the term "contraindication" may or may not make sense in individual situations. The Department is open to more motions or failure definition suggestions. However, sometimes differences will exist among individual failure definitions.
- The PDL subclass that includes DPP-4 inhibitor combination products with metformin has been preemptively pulled out of Mass Review and into regular review due to a few preferred product changes and some additional criteria changes, this subclass has been moved into regular review.

J Rawlings introduced the process to evaluate proposed criteria for PDL drug classes scheduled for August Board review, along with 9 non-PDL products to be reviewed toward the end of the agenda.

- Board members present will be asked about any potential conflicts of interest to disclose prior to reviewing the therapeutic drug classes and products listed in the meeting agenda.
- Time is 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.
- Motions, seconds and voting results will be captured for the minutes, along with any abstentions and recusals.

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. Injectable Antipsychotics

Preferred agents
ABILIFY (aripiprazole) ASIMTUFII syringe, vial
ABILIFY (aripiprazole) MAINTENA ER, syringe, vial
ARISTADA (aripiprazole) ER syringe
ARISTADA INITIO syringe
Chlorpromazine ampule, vial
Fluphenazine vial
Fluphenazine decanoate vial
HALDOL (haloperidol decanoate) ampule
Haloperidol decanoate ampule, vial
Haloperidol lactate syringe, vial
INVEGA (paliperidone) HAFYERA syringe
INVEGA (paliperidone) SUSTENNA syringe
INVEGA (paliperidone) TRINZA syringe
Olanzapine vial
PERSERIS ER (risperidone) syringe, syringe kit
RISPERDAL CONSTA[BNR] (risperidone microspheres) syringe, vial
UZEDY ER (risperidone) syringe
Ziprasidone vial
ZYPREXA RELPREVV vial kit

Non-preferred brand name medications do not require a prior authorization when the equivalent generic is preferred and "dispense as written" is indicated on the prescription.

*Preferred long-acting injectable products are subject to meeting the FDA-labeled dosing summarized in Table 1.

Table 1

Long-acting injectable	Route	Quantity Limit
ABILIFY ASIMTUFII (aripiprazole)	IM	1 pack/2 months (56 days)
ABILIFY MAINTENA (aripiprazole)	IM	1 pack/28 days
ARISTADA ER (aripiprazole)	IM	1,064 mg: 1 pack/2 months (56 days) All other strengths: 1 pack/28 days
ARISTADA INITIO (aripiprazole)	IM	1 pack/7 weeks (49 days)
INVEGA HAFYERA (paliperidone)	IM	1 pack/6 months (168 days)
INVEGA SUSTENNA (paliperidone)	IM	156 mg: 2 packs/5 weeks (35 days) All other strengths: 1 pack/28 days
INVEGA TRINZA (paliperidone)	IM	1 pack/3 months (84 days)

PERSERIS ER (risperidone)	subcutaneous (physician administered)	1 pack/28 days
RISPERDAL CONSTA (risperidone)	IM	2 packs/28 days
UZEDY ER (risperidone)	subcutaneous	150 mg, 200 mg and 250 mg: 1 pack/2 months (56 days) All other strengths: 1 pack/28 days
ZYPREXA RELPREVV (olanzapine)	IM	405 mg: 1 pack/28 days All other strengths: 1 pack/14 days

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

- Medication is being prescribed for an FDA-Approved indication AND
- Prescription meets dose limitations (Table 1) AND
- Member has history of trial and failure of one preferred product with FDA approval for use for the prescribed indication. (Failure is defined as lack of efficacy with 6-week trial, allergy, intolerable side effects, contraindication, significant drug-drug interactions, or known interacting genetic polymorphism that prevents safe preferred product dosing)

Note: Effective January 14, 2022, no place of service prior authorization is required for extended-release injectable medications (LAIs) used for the treatment of mental health or substance use disorders (SUD), when administered by a healthcare professional and billed under the pharmacy benefit. In addition, LAIs may be administered in any setting (pharmacy, clinic, medical office or member home) and billed to the pharmacy or medical benefit as most appropriate and in accordance with all Health First Colorado billing policies.

Scheduled Speaker Testimony
M John, Abilify Asimtufii – Otsuka

Written Testimony
M Sohal, Uzedy (risperidone) ER Injection - Teva Pharmaceuticals

Discussion

- No Board members reported a potential conflict of interest for this therapeutic class.
- A recommendation was made to update the drug class name on the PDL from "Long-Acting Injectable Antipsychotics" to "Injectable Antipsychotics" since this class also includes short-acting products.
- K MacIntyre moved to accept the criteria as written. Seconded by S Klocke. Motion passed unanimously.

2. Androgenic Agents, Topical, Injectable, Oral

Preferred agents
PA Required for all agents in this class
ANDRODERM (testosterone) patch
Testosterone cypionate vial
Testosterone gel packet (generic Androgel)
Testosterone 1% (5 g) gel packet *(Upsher Smith only)*
Testosterone 1.62% gel pump (generic Androgel)

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

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

Preferred products may be approved for members meeting the following:

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

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

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

Gender Transition/Affirming Hormone Therapy:

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

1. Female sex assigned at birth and has reached Tanner stage 2 of puberty AND
2. Is undergoing female to male transition AND
3. Has a negative pregnancy test prior to initiation AND
4. Hematocrit (or hemoglobin) is being monitored.

Non-Preferred Products:

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

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

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

‡Failure is defined as lack of efficacy with 8-week trial, allergy, intolerable side effects, contraindication to, or significant drug-drug interaction.
For all agents and diagnoses, members < 16 years of age will require a manual prior authorization review by a pharmacist (with exception of members ≥ 12 years of age with a diagnosis of hypogonadotropic or hypogonadism secondary to Klinefelter Syndrome).

Discussion

- No Board members reported a potential conflict of interest for this therapeutic class.
- A suggestion was offered to potentially delete the first bullet point under Reauthorization that begins "Member is a male patient > 16 years of age…" since it is a duplicate bullet from the Hypogonadotropic or Primary Hypogonadism in the section immediately above. Dr. Taylor explained that the duplicative bullet may have been put in place for situations in which an initial authorization was approved under another health plan, in order to apply the current Colorado Medicaid criteria at the time reauthorization is requested.
- A comment was offered that the Androderm (testosterone) patch was discontinued by the manufacturer some time ago and it is still included on the preferred list for this class. Dr. Taylor explained that management of the preferred product list falls under the purview of the PDL Pharmacist and the P&T Committee; however, the Department does keep discontinued products on the PDL for a period of time in case a pharmacy has unexpired product remaining on the shelf that might be dispensed.
- S Klocke moved to accept the criteria as written. Seconded by I Pan. Motion passed unanimously.

3. Contraceptives, Topical

Effective 01/14/22, topical contraceptive patch products are eligible for coverage with a written prescription by an enrolled pharmacist. Additional information regarding pharmacist enrollment can be found at https://hcpf.colorado.gov/pharm-serv.

Preferred agents
- ANNOVERA (segesterone acetate/EE) vaginal ring
- Etonogestrel/EE vaginal ring *(Pasco only)*
- Norelgestromin/EE TD patch (generic Xulane)
- NUVARING[BNR] (etonorgestrel/EE) vaginal ring
- PHEXXI (lactic acid/citric/potassium) vaginal gel*
- TWIRLA (levonorgestrel/EE) TD patch
- XULANE (norelgestromin/EE) TD patch

*EE = Ethinyl estradiol

Non-preferred topical contraceptive products may be approved following a trial and failure of one preferred topical contraceptive product. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.

*__PHEXXI__ (lactic acid/citric/potassium) vaginal gel quantity limit: 120 grams per 30 days

Continuation of therapy: Members who are currently using Annovera (segesterone/ethinyl estradiol) vaginal ring may receive approval to continue use of the product.

Effective 7/1/2022: Prescriptions are eligible to be filled for up to a twelve-month supply.

Note: IUD and select depot product formulations are billed through the medical benefit

Discussion

- No Board members reported a potential conflict of interest for this therapeutic class.
- G Miller, PDL Pharmacist, explained that the Nuvaring brand name product is still manufactured; however, it is no longer a participating product in the Medicaid Drug Rebate Program (MDRP) and therefore Health First Colorado cannot cover it. Etonogestrel/ethinyl estradiol vaginal ring *(Pasco only)* has been added as a preferred product.
- T Brubaker moved to accept the criteria as written. Seconded by S Cho. Motion passed unanimously.

4. Bone Resorption Suppression and Related Agents

a. Bisphosphonates

Preferred agents
Alendronate tablet, solution
Ibandronate tablet
Risedronate tablet

Non-preferred bisphosphonates may be approved for members who have failed treatment with one preferred product at treatment dose. Failure is defined as lack of efficacy with a 12-month trial, allergy, intolerable side effects, or significant drug-drug interaction.

For members who have a low risk of fracture, discontinuation of bisphosphonate therapy and drug holiday should be considered following 5 years of treatment. Low risk is defined as having a bone mineral density, based on the most recent T-score, of greater than (better than) -2.5 AND no history of low trauma or fragility fracture.

b. Non-Bisphosphonates

Preferred agents
***No PA Required (Must meet eligibility criteria)**
*FORTEO (teriparatide) pen injector
Raloxifene tablet

***FORTEO** (teriparatide) or generic teriparatide may be approved if the following criteria are met:

- Member has one of the following diagnoses:
  - Male primary or hypogonadal osteoporosis (BMD T-score of -2.5 or less)
  - Osteoporosis due to corticosteroid use
  - Postmenopausal osteoporosis

AND

5. Member is at very high risk for fracture† **OR** member has history of trial and failure of one preferred bisphosphonate for 12 months. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.

CALCITONIN SALMON (nasal) may be approved if the member meets the following criteria:

- Member has a diagnosis of post-menopausal osteoporosis (BMD T-scores of -2.5 or less)

AND

- Has trial and failure of preferred bisphosphonate or non-bisphosphonate for 12 months (failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction) **OR**
- Member is unable to use a solid oral dosage form.

Quantity limit: One spray daily

FORTEO (teriparatide) or generic teriparatide may be approved if the member meets the following criteria:

- Member has one of the following diagnoses:
- Male primary or hypogonadal osteoporosis (BMD T-scores of -2.5 or less).
- Osteoporosis due to corticosteroid use
- Postmenopausal osteoporosis

AND

- Member is at very high risk for fracture* **OR** member has history of trial and failure of one preferred bisphosphonate or non-bisphosphonate product for 12 months. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction **AND**
- Prior authorization will be given for one year and total exposure of parathyroid hormone analogs (Forteo and Tymlos) shall not exceed two years

Maximum dose: 20 mcg daily

TYMLOS (abaloparatide) may be approved if the member meets the following criteria:

- Member has a diagnosis of postmenopausal osteoporosis (BMD T-scores of -2.5 or less) **AND**
- Member is post-menopausal with very high risk for fracture*† **OR** member has history of trial and failure of Forteo (teriparatide) one preferred bisphosphonate or non-bisphosphonate product for 12 months. (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction) **AND**
- Prior authorization will be given for one year and total exposure of parathyroid hormone analogs (Forteo and Tymlos) shall not exceed two years.

Maximum dose: 80 mcg daily

All other non-preferred non-bisphosphonates may be approved for FDA-labeled indications for members who have failed treatment with one preferred bisphosphonate product at treatment dose. Failure is defined as lack of efficacy with a 12-month trial, allergy, unable to use oral therapy, intolerable side effects, or significant drug-drug interaction.

*Members at very high risk for fracture: †Members will be considered at very high risk for fracture if they meet one of the following:

- A history of fracture within the past 12 months **OR**
- Fractures experienced while receiving guideline-supported osteoporosis therapy **OR**
- A history of multiple fractures **OR**
- A history of fractures experienced while receiving medications that cause skeletal harm (such as long-term glucocorticoids) **OR**
- A very low T-score (less than -3.0) **OR**
- A high risk for falls or a history of injurious falls **OR**
- A very high fracture probability by FRAX (> 30% for a major osteoporosis fracture or > 4.5% for hip fracture)

Raloxifene maximum dose: 60 mg daily

Non-Bisphosphonate Product	FDA-approved Maximum Dose
Calcitonin salmon nasal spray	1 metered dose spray (200 units) daily
Evista (raloxifene) oral tablet	60 mg daily
Forteo (teriparatide) subcutaneous injection	20 mcg daily
Tymlos (abaloparatide) subcutaneous injection	80 mcg daily

Note: Prior authorization criteria for Prolia (denosumab) and other injectable bone resorption and related agents are listed on Appendix P.

Discussion

- No Board members reported a potential conflict of interest for this therapeutic class.
- S Klocke moved to add this statement back to the updated criteria for Forteo (teriparatide): "Prior authorization will be given for one year and total exposure of parathyroid hormone analogs (Forteo and Tymlos) shall not exceed two years." Seconded by I Pan. Motion passed unanimously.
- S Cho moved to edit the failure statement "…member has history of trial and failure of one preferred bisphosphonate for 12 months. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction" to "…member has history of trial and failure of one preferred bisphosphonate. Failure is defined as lack of efficacy with a 12-month trial, allergy, intolerable side effects, or significant drug-drug interaction" in order to avoid the implication that allergy, side effects, or drug-drug interactions would need to be tolerated for 12 months. This motion applies to all places this wording appears within the osteoporosis section. Seconded by B Jackson. Motion passed unanimously.
- K MacIntyre moved to accept the criteria as amended. Seconded by M Ash. Motion passed unanimously.

5. Diabetes Management Classes, Non-Insulin

a. Dipeptidyl Peptidase-4 Enzyme inhibitors (DPP-4is)

Preferred agents
JANUVIA (sitagliptin) tablet
TRADJENTA (linagliptin) tablet

Non-preferred DPP-4 inhibitors may be approved after a member has failed a 3-month trial of two one preferred products. Failure is defined as lack of efficacy (such as not meeting hemoglobin A1C goal despite adherence to regimen), allergy, intolerable side effects, or a significant drug-drug interaction.

Continuation of therapy: Members currently stabilized on Januvia (sitagliptin) may receive approval for continuation of therapy with that agent.

Maximum Dose:
Prior authorization will be required for doses exceeding the FDA-approved maximum dosing listed in the following table:

DPP-4 Inhibitor	FDA-Approved Maximum Daily Dose
Alogliptin (generic Nesina)	25 mg/day
Januvia (sitagliptin)	100 mg/day
Nesina (alogliptin)	25 mg/day
Onglyza (saxagliptin)	5 mg/day
Tradjenta (linagliptin)	5 mg/day
Zituvio (sitagliptin)	100 mg/day

Discussion

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

b. Glucagon-like Peptide-1 Receptor Agonists (GLP-1 analogues)

Preferred agents

***Must meet eligibility criteria**

*BYETTA[BNR] (exenatide) pen

***BYDUREON BCise (exenatide ER) autoinjector

*Liraglutide pen

*OZEMPIC (semaglutide) pen

*TRULICITY (dulaglutide) pen

*VICTOZA (liraglutide) pen

**WEGOVY (semaglutide) pen *(for cardiovascular disease indication only)*

*Preferred products may be approved for members with a diagnosis of type 2 diabetes.

****BYDUREON BCise** (exenatide ER): may be approved for members with a diagnosis of Type 2 diabetes following a 3-month trial and failure‡ of ONE other preferred product.

****WEGOVY (semaglutide)** may be approved if meeting the following criteria:

- Member is 18 years of age or older AND
- Member has established cardiovascular disease (history of myocardial infarction, stroke, or symptomatic peripheral arterial disease) and either obesity or overweight (defined as a BMI ≥25 kg/m^2) AND
- Member does not have a diagnosis of Type 1 or Type 2 diabetes AND
- Wegovy (semaglutide) is being prescribed to decrease the risk of adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) AND
- Member has been counseled regarding implementation of lifestyle interventions (diet modification and exercise) to promote weight loss.

Zepbound (tirzepatide) may be approved if meeting the following criteria:

- Member is 18 years of age or older AND
- Member has a documented diagnosis of moderate to severe obstructive sleep apnea (OSA) AND
- Member has a BMI ≥30 kg/m^2 indicating obesity documented in medical chart notes AND
- A polysomnogram has been performed at baseline with a documented result of Apnea-Hypopnea Index (AHI) ≥15 events/hour AND
- Patient Member is not pregnant or planning to become pregnant AND
- Member has been counseled regarding the risk of medullary thyroid cancer (MTC) with the use of Zepbound (tirzepatide) and does not have a personal or family history of MTC or Multiple Endocrine Neoplasia syndrome type 2 (MEN 2) AND
- The requested medication is being prescribed by or in consultation with a neurologist, pulmonologist, otolaryngologist, or other sleep medicine specialist
  AND
- Member has been counseled regarding and is engaged in implementation of lifestyle interventions (diet modification and exercise) to promote weight loss AND
- Member has failed a 6-month trial of continuous positive airway pressure (CPAP) or has a contraindication to the use of PAP therapy.

Maximum dose for OSA in adults with obesity: 15 mg subcutaneously once a week

Maximum quantity:

Zepbound injection strength	Pre-filled Pens (4 pack)	Vials (4 pack)
2.5 mg/0.5 mL	One pack of 4 single-dose pens/28 days	One pack of 4 single-dose vials/28 days
5 mg/0.5 mL		
7.5 mg/0.5 mL		
10 mg/0.5 mL		
12.5 mg/0.5 mL		
15 mg/0.5 mL		

Initial approval: 1 year

Reauthorization: Reauthorization may be approved for 1 year if the following criteria are met:

- Member has demonstrated a favorable clinical response to Zepbound, demonstrated by at least one of the following:
  - A ≥20% decrease from baseline in AHI value determined by polysomnogram OR
  - A change in OSA severity status from baseline, determined by polysomnogram, to Remission/Normal (AHI value < 5) or Mild Non-Symptomatic (AHI value 5-14) AND an Epworth Sleepiness Scale (ESS) score of ≤ 10.

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

Requests for GLP-1 analogues that are FDA-indicated for the treatment of metabolic dysfunction-associated steatohepatitis (MASH) may be approved if meeting the following:

- A diagnosis of MASH 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 MASH 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 AND
- Non-preferred agents will be subject to meeting non-preferred criteria below.

All other non-preferred products may be approved for members with an FDA-labeled diagnosis following trial and failure‡ of three preferred agents that are FDA-labeled for the prescribed indication.
All other non-preferred products may be approved for members with a diagnosis of type 2 diabetes following a 3-month trial and failure‡ of two preferred products.

Maximum Dose:
Prior authorization is required for all products exceeding maximum dose listed in product package labeling.

Table 1: GLP-1 Analogue Maximum Dose	
Bydureon Bcise (exenatide ER)	2 mg weekly
Byetta (exenatide)	20 mcg daily
Mounjaro (tirzepatide)	15 mg weekly
Ozempic (semaglutide)	2 mg weekly
Rybelsus (semaglutide)	14 mg daily
Trulicity (dulaglutide)	4.5 mg weekly
Victoza (liraglutide)	1.8 mg daily
Wegovy (semaglutide)	2.4 mg weekly

‡Failure is defined as lack of efficacy (such as not meeting hemoglobin A1C goal despite adherence to regimen), allergy, intolerable side effects, limited dexterity resulting in the inability to administer doses of a preferred product, or a significant drug-drug interaction.

Note: Prior Authorization for GLP-1 analogues prescribed solely for weight loss will not be approved.

Scheduled Speaker Testimony
S Bellefeuille, Ozempic, Rybelsus and Wegovy – Novo Nordisk *(yielded time)*

Discussion

- No Board members reported a potential conflict of interest for this therapeutic class.
- B Jackson moved to request that the Department reevaluate the proposed authorization criteria to allow for the off-label use of GLP-1 analogues in the pediatric population, such as including criteria to allow prescribing of these agents in pediatric members in consultation with a pediatric endocrinologist or a pediatric nutrition medicine physician. Seconded by T Brubaker. Motion passed unanimously.
- J Taylor noted that criteria presented on the PDL is based on FDA labeling. The Department receives case-by-case exception requests for off-label medical necessity scenarios through the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit that includes children and adolescents under age 21 years. Dr. Taylor clarified that while there have been cases in which coverage was opened up to the pediatric population for off-label indications, a substantial amount of evidence is necessary—by Medicaid rule—to support those case-by-case requests.
- T Brubaker moved to accept the criteria as amended. Seconded by I Pan. Motion passed unanimously.

c. Sodium-Glucose Cotransporter (SGLT) Inhibitors

Preferred agents
FARXIGA[BNR] (dapagliflozin) tablet
JARDIANCE (empagliflozin) tablet

Non-preferred products may receive approval following trial and failure with two one preferred products. Failure is defined as lack of efficacy with 3-month trial (such as not meeting hemoglobin A1C goal despite adherence to regimen), allergy, intolerable side effects, or a significant drug-drug interaction.

Maximum Dose:
Prior authorization is required for all products exceeding maximum dose listed in product package labeling.

Discussion

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

6. Growth Hormones

Preferred agents

No PA Required (If diagnosis and dose met)

GENOTROPIN (somatropin) cartridge, Miniquick pen
NGENLA (somatrogon-ghla) pen*2nd Line*
NORDITROPIN (somatropin) Flexpro pen
SKYTROFA (lonapegsomatropin-tcgd) cartridge*2nd Line*

All preferred products may be approved if the member has one of the qualifying diagnoses listed below (diagnosis may be verified through AutoPA) AND if prescription does not exceed limitations for maximum dosing (Table 1). Second line preferred products require trial and failure of Genotropin (somatropin) OR Norditropin (somatropin).

Non-preferred Growth Hormone products may be approved if the following criteria are met:

- Member failed treatment with one preferred growth hormone product (failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions) AND
- Member has a qualifying diagnosis that includes any of the following conditions:
  - Prader-Willi Syndrome (PWS)
  - Chronic renal insufficiency/failure requiring transplantation (defined as Creatinine Clearance < 30mL/min)
  - Turner's Syndrome
  - Hypopituitarism: as a result of pituitary disease, hypothalamic disease, surgery, radiation therapy or trauma verified by one of the following:
    - Has failed at least one GH stimulation test (peak GH level < 10 ng/mL)
    - Has at least one documented low IGF-1 level (below normal range for patient's age – refer to range on submitted lab document)
    - Has deficiencies in ≥ 3 pituitary axes (such as TSH, LH, FSH, ACTH, ADH)
    - Cachexia associated with AIDS
    - Noonan Syndrome
    - Short bowel syndrome
    - Neonatal symptomatic growth hormone deficiency (limited to 3-month PA approval)AN

  AND

  - Prescription does not exceed limitations for FDA-labeled maximum dosing for prescribed indication (Table 1) based on prescriber submission/verification of patient weight from most recent clinical documentation

Table 1: Growth Hormone Product Maximum Dosing*		
Medication	Pediatric Maximum Dosing per week (age < 18 years)	Adult Maximum Dosing per week (age ≥ 18 years)
Genotropin	0.48 mg/kg/week	0.08 mg/kg/week
Humatrope	0.47 mg/kg/week	0.0875 mg/kg/week
Ngenla	0.66 mg/kg/week	Not Indicated
Norditropin Flexpro	0.47 mg/kg/week	0.112 mg/kg/week
Nutropin AQ Nuspin	0.7 mg/kg/week	0.175 mg/kg/week for ≤35 years of age 0.0875 mg/kg/week for >35 years of age
Omnitrope	0.48 mg/kg/week	0.08 mg/kg/week
Saizen	0.18 mg/kg/week	0.07 mg/kg/week
Serostim	Not Indicated	42 mg/week for HIV wasting or cachexia (in combination with antiretroviral therapy)
Skytrofa	1.68 mg/kg/week	Not Indicated
Sogroya	Dose Individualized for each patient, based on growth response	8 mg/week
Zomacton	0.47 mg/kg/week	0.0875 mg/kg/week
Zorbtive	Not Indicated	56 mg/week for up to 4 weeks for short bowel syndrome only

*Based on FDA labeled indications and dosing

Scheduled Speaker Testimony
K Packard, Ngenla – Pfizer

Discussion

- No Board members reported a potential conflict of interest for this therapeutic class.
- Observations were offered that there has been an injector device shortage for Genotropin and a prolonged product shortage for Norditropin. Both of these growth hormone products are dosed daily.
- K Packard clarified that the manufacturer of Genotropin is continuing to provide product and injection devices to members with certain diagnoses who require growth hormone therapy; however, new starts of Genotropin are affected.
- S Klocke moved to accept the criteria as written. Seconded by S Cho. Motion passed with six votes in favor. Dr. Pan abstained.

7. Benign Prostatic Hyperplasia (BPH) Agents

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

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

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

‡Failure is defined as lack of efficacy with 8-week trial, allergy, intolerable side effects, contraindication to, or significant drug-drug interaction.
***CIALIS** (tadalafil) may be approved for members with a documented diagnosis of BPH who have failed a trial of finasteride (at least 3 months in duration) AND either a trial of a nonselective alpha blocker (therapeutic dose for at least two months) OR a trial of tamsulosin (therapeutic dose for at least one month).

Documentation of BPH diagnosis will require BOTH of the following:

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

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

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

Discussion

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

9.f DPP-4 Inhibitors – Combination with Metformin (pulled out of Mass Review)

Preferred agents
JANUMET (sitagliptin/metformin) tablet
JANUMET XR (sitagliptin/metformin) tablet
JENTADUETO (linagliptin/metformin) tablet
JENTADUETO XR (linagliptin/metformin) tablet

Non-preferred combination products may be approved for members who have been stable on the two individual ingredients of the requested combination for three months AND have had adequate three-month trial and failure of a preferred combination agent. Failure is defined as lack of efficacy (such as not meeting hemoglobin A1C goal despite adherence to regimen), allergy, intolerable side effects, or a significant drug-drug interaction.

Maximum Dose:
Prior authorization will be required for doses exceeding the FDA-approved maximum dosing listed in the following table:

Continuation of therapy: Members currently stabilized on Janumet (sitagliptin/metformin) or Janumet XR (sitagliptin ER/metformin ER) may receive approval for continuation of therapy with those agents.

DPP-4 Inhibitor Combination	FDA Approved Maximum Daily Dose
Alogliptin/metformin tablet	25 mg alogliptin/ 2,000 mg metformin
Janumet and Janumet XR (sitagliptin/metformin)	100 mg sitagliptin/ 2,000 mg of metformin
Jentadueto and Jentadueto XR (linagliptin/metformin)	5 mg linagliptin/ 2,000 mg metformin
Kazano (alogliptin/metformin)	25 mg alogliptin/ 2,000 mg metformin
Kombiglyze XR (saxagliptin ER/metformin ER) tablet	5 mg saxagliptin/ 2,000 mg metformin

Discussion
- No Board members reported a potential conflict of interest for this therapeutic class.
- S Klocke moved to accept the criteria as written. Seconded by M Ash. 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.*

8. Diabetes Management Classes, Insulins

a. Rapid acting

Preferred agents

HUMALOG (insulin lispro) cartridge
Insulin aspart cartridge, pen, vial
Insulin lispro Kwikpen, Jr. Kwikpen, vial (*Eli Lilly only*)
NOVOLOG (insulin aspart) cartridge, FlexPen, vial

All non-preferred products may be approved following trial and failure of treatment with two preferred products, one of which is the same rapid-acting insulin analog (lispro or aspart) as the non-preferred product being requested. (Failure is defined as allergy [hives, maculopapular rash, erythema multiforme, pustular rash, severe hypotension, bronchospasm, and angioedema] or intolerable side effects).

Afrezza (human insulin) may be approved if meeting the following criteria:
- Member is 18 years or older AND
- Member has trialed and failed treatment with two preferred products (failure is defined as allergy [hives, maculopapular rash, erythema multiforme, pustular rash, severe hypotension, bronchospasm, or angioedema] or intolerable side effects) AND
- Member must not have chronic lung disease such as COPD or asthma AND
- If member has type 1 diabetes, must use in conjunction with long-acting insulin AND

- Prescriber acknowledges that Afrezza is not recommended in patients who smoke or have recently stopped smoking.

b. Short acting

Preferred agents

HUMULIN R U-100 (insulin regular) vial (OTC)
NOVOLIN R U-100 (insulin regular) FlexPen (OTC)

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

c. Intermediate acting

Preferred agents

HUMULIN N U-100 (insulin NPH) vial, Kwikpen (OTC)
NOVOLIN N U-100 (insulin NPH) FlexPen (OTC)

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

d. Long acting

Preferred agents

*Insulin degludec, vial
LANTUS[BNR] (insulin glargine) vial, Solostar
*TRESIBA[BNR] (insulin degludec) FlexTouch, vial

*Preferred Tresiba pen and insulin degludec vial formulations may be approved for members who have trialed and failed‡ Lantus.

Non-preferred products may be approved if the member has tried and failed‡ treatment with Lantus **AND** a preferred insulin degludec product.

‡Failure is defined as lack of efficacy, allergy, or intolerable side effects

e. Mixtures

Preferred agents

HUMALOG [BNR] MIX (insulin lispro prot/insulin lispro) 50/50 Kwikpen
HUMULIN MIX 70/30 (OTC) Kwikpen, vial
Insulin aspart protamine/insulin aspart 70/30 FlexPen, vial (generic Novolog Mix)
Insulin lispro protamine/insulin lispro 75/25 Kwikpen (generic Humalog Mix)
NOVOLOG MIX (insulin lispro prot/insulin lispro) 70/30 Flexpen, vial

Non-preferred products may be approved if the member has failed treatment with two of the preferred products (failure is defined as: allergy or intolerable side effects).

f. Concentrated

Preferred agents

HUMULIN R U-500 (insulin regular) concentrated vial, Kwikpen

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

9. Diabetes Management Classes, Non-insulin

a. Amylin

Preferred agents
NONE

SYMLIN (pramlintide) may be approved following trial and failure of metformin AND trial and failure of a DPP4-inhibitor or GLP-1 analogue. Failure is defined as lack of efficacy (such as not meeting hemoglobin A1C goal despite adherence to regimen) following 3-month trial, allergy, intolerable side effects, or a significant drug-drug interaction. Prior authorization may be approved for Symlin (pramlintide) products for members with a diagnosis of Type 1 diabetes without requiring trial and failure of other products.

Maximum Dose: Prior authorization will be required for doses exceeding FDA-approved dosing listed in product package labeling.

b. Biguanides

Preferred agents
Metformin IR tablets
Metformin ER 500mg, 750mg tablets (generic Glucophage XR)

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

Liquid metformin may be approved for members that are unable to use a solid oral dosage form.

c. Meglitinides

Preferred agents
Repaglinide tablet

Non-preferred products may be approved for members who have failed treatment with one preferred product sulfonylurea. Failure is defined as: lack of efficacy (such as not meeting hemoglobin A1C goal despite adherence to regimen), allergy, intolerable side effects, or significant drug-drug interaction.

d. Thiazolidinediones (TZDs)

Preferred agents
Pioglitazone tablet

Non-preferred agents may be approved following trial and failure of one preferred product. Failure is defined as lack of efficacy (such as not meeting hemoglobin A1C goal despite adherence to regimen) with a 3-month trial, allergy, intolerable side effects, or a significant drug-drug interaction.

e. Meglitinides Combination with Metformin

Preferred agents
NONE

Non-preferred products may be approved for members who have been stable on the two individual ingredients of the requested combination for 3 months.

9.f DPP-4 Inhibitors – Combination with Metformin
(Reviewed above - pulled out of mass review)

g. SGLT Inhibitor Combinations with Metformin

Preferred agents

SYNJARDY (empagliflozin/metformin) tablet
SYNJARDY XR (empagliflozin/metformin) tablet
XIGDUO XR[BNR] (dapagliflozin/metformin) tablet

Non-preferred products may be approved for members who have been stable on the two individual ingredients of the requested combination for 3 months.

INVOKAMET, INVOKAMET XR, SEGLUROMET, SYNJARDY, SYNJARDY XR and XIGDUO XR are contraindicated in patients with an eGFR less than 30 mL/min/1.73 m^2 or on dialysis.

h. Thiazolidinediones Combination with Metformin

Preferred agents

Pioglitazone/metformin

Non-preferred products may be approved for members who have been stable on the two individual ingredients of the requested combination for 3 months.

i. Other Combinations

Preferred agents

NONE

Non-preferred products may be approved for members who have been stable on each of the individual ingredients in the requested combination for 3 months (including cases where the ingredients are taken as two separate 3-month trials or when taken in combination for at least 3 months).

SOLIQUA (insulin glargine/lixisenatide) may be approved if member has had a trial and failure with one preferred GLP-1 **AND** one preferred insulin glargine product (Failure is defined as lack of efficacy (such as not meeting hemoglobin A1C goal despite adherence to regimen), allergy, intolerable side effects, or significant drug-drug interaction.)

10. Estrogen Agents

Oral/Transdermal

Preferred agents

Estradiol oral tablet
Estradiol (generic Climara) weekly patch
MINIVELLE[BNR] (estradiol) patch
VIVELLE-DOT[BNR] (estradiol) patch

Injectable

Preferred agents

DELESTROGEN[BNR] (estradiol valerate) vial
DEPO-ESTRODIOL (estradiol cypionate) vial
Estradiol valerate 40 mg/mL vial

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

Non-preferred oral estrogen agents may be approved with trial and failure of one preferred oral agent. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.

Non-preferred transdermal estrogen agents may be approved with trial and failure of two preferred transdermal agents. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.

Table 1: Transdermal Estrogen FDA-Labeled Dosing	
ALORA (estradiol) patch	2/week
CLIMARA (estradiol) patch	1/week
DOTTI (estradiol) patch	2/week
Estradiol patch (once weekly)	1/week
Estradiol patch (twice weekly)	2/week
LYLLANA (estradiol) patch	2/week
MENOSTAR (estradiol) patch	1/week
MINIVELLE (estradiol) patch	2/week
VIVELLE-DOT (estradiol) patch	2/week

Note: Estrogen agents are a covered benefit for gender affirming hormone therapy and treating clinicians and mental health providers should be knowledgeable about the diagnostic criteria for gender-affirming hormone treatment and have sufficient training and experience in assessing related mental health conditions

11. Glucagon, self-administered

Preferred agents
- BAQSIMI (glucagon) nasal spray
- Glucagon Emergency Kit *(Amphastar, Eli Lilly, Fresenius only)*
- ZEGALOGUE (dasiglucagon) autoinjector

Non-preferred products may be approved if the member has failed treatment with two preferred products (failure is defined as allergy to ingredients in product, intolerable side effects, contraindication, or inability to administer dosage form).

Quantity limit for all products: 2 doses per year unless used/damaged/lost

12. Phosphate Binders

Preferred agents
- Calcium acetate capsule
- PHOSLYRA (calcium acetate) solution
- Sevelamer carbonate tablet, powder pack

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

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

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

- Member is diagnosed with end-stage renal disease, receiving dialysis, and has elevated serum phosphate (> 4.5 mg/dL or > 1.46 mmol/L). AND
- Provider attests to counseling member regarding avoiding high phosphate containing foods from diet AND
- Member has trialed and failed‡ three preferred agents with different mechanisms of action prescribed for hyperphosphatemia in end stage renal disease

  OR
- Member is diagnosed with chronic kidney disease with iron deficiency anemia and is not receiving dialysis AND
- Member has tried and failed‡ at least two different iron supplement product formulations (OTC or RX)

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

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

Maximum Dose: Velphoro 3000mg daily

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

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

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

13. Prenatal Vitamins/Minerals

Preferred agents

***Must meet eligibility criteria**

COMPLETE NATAL DHA pack
M-NATAL PLUS tablet
NESTABS tablets
PRENATAL VITAMIN PLUS LOW IRON tablet (*Patrin Pharma only)*
SE-NATAL 19 chewable tablet[BNR]
TARON-C DHA capsule
THRIVITE RX tablet

TRINATAL RX 1 tablet
VITAFOL gummies
WESNATAL DHA COMPLETE tablet
WESTAB PLUS tablet

*Preferred and non-preferred prenatal vitamin products are a benefit for members from 11-60 years of age who are pregnant, lactating, or trying to become pregnant.

Prior authorization for non-preferred agents may be approved if member fails 7-day trial with four preferred agents. Failure is defined as: allergy, intolerable side effects, or significant drug-drug interaction.

14. Antihyperuricemics

Preferred agents
Allopurinol 100 mg, 300 mg tablets
Colchicine tablet
Febuxostat tablet
Probenecid tablet
Probenecid/colchicine tablet

Non-preferred xanthine oxidase inhibitor products (allopurinol or febuxostat formulations) may be approved following trial and failure of preferred allopurinol. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. If member has tested positive for the HLA-B*58:01 allele, it is not recommended that they trial allopurinol. A positive result on this genetic test will count as a failure of allopurinol.

Prior authorization for all other non-preferred agents (non-xanthine oxidase inhibitors) may be approved after trial and failure of two preferred products. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.

GLOPERBA (colchicine) oral solution may be approved for members who require individual doses <0.6 mg **OR** for members who are unable to use a solid oral dosage form.

Colchicine tablet quantity limits:
- Chronic hyperuricemia/gout prophylaxis: 60 tablets per 30 days
- Familial Mediterranean Fever: 120 tablets per 30 days

15. Overactive Bladder Agents

Preferred agents
Fesoterodine ER tablet
GELNIQUE (oxybutynin) gel packet
MYRBETRIQ^{BNR} (mirabegron) tablet
Oxybutynin IR, ER tablets, syrup
Solifenacin tablet
Tolterodine IR tablet, ER capsule
Trospium tablet, ER capsule

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

Members with hepatic failure can receive approval for trospium (Sanctura) or trospium extended release (Sanctura XR) products without a trial on a Preferred product.

Discussion

- No Board members reported a potential conflict of interest within the Mass Review section.
- K MacIntyre moved to accept the criteria as written. Seconded by M Ash. Motion passed unanimously.

Proposed Coverage Criteria for Non-PDL Products

1. Vykat XR (diazoxide choline)

Vykat XR (diazoxide choline) may be approved if the following criteria are met:

1. Member is ≥ 4 years of age AND
2. Member has a diagnosis of Prader-Willi syndrome (PWS) confirmed by genetic testing indicating mutation on chromosome 15 AND
3. Member is being treated for hyperphagia associated with PWS AND
4. Vykat XR (diazoxide choline) is being prescribed by or in consultation with an endocrinologist, gastroenterologist, genetics/metabolic physician, or developmental pediatrician AND
5. Prior to initiation of therapy, baseline fasting glucose and HbA1c labs have been drawn and blood glucose has been optimized in members who have hyperglycemia AND
6. Prescriber acknowledges that Vykat XR (diazoxide choline) may precipitate congestive heart failure in patients with compromised cardiac reserve and it should be used with caution in these patients AND
7. Prescriber acknowledges of important Vykat XR (diazoxide choline) dose adjustment considerations for members who are taking concomitant strong CYP1A2 inhibitors, per product labeling AND
8. After initiation of treatment, fasting glucose, HbA1c, and signs or symptoms of edema or fluid overload will be monitored according to product labeling.

Note: Do not substitute diazoxide oral suspension for Vykat XR (diazoxide choline) tablets because the pharmacokinetic profiles are different.

Maximum Dose: 525 mg/day

Maximum Quantities:

25 mg tablets: 4 tablets/day
75 mg tablets: 2 tablets/day
150 mg tablets: 3 tablets/day

Scheduled Speaker Testimony
M Kwong – Soleno Therapeutics

Discussion

- No Board members reported a potential conflict of interest for this product.
- K MacIntyre recommended removing the word “of” from bullet point 7.
- There was some discussion about possibly including cigarette smoking in bullet point 7 regarding interactions; however, the Board determined that cigarette smoke is a CYP1A2 inducer, not an inhibitor, so ultimately no changes to the proposed criteria were recommended.
- M Ash moved to add nutrition physician to the list of subspecialists in bullet point 4. Seconded by B Jackson. Motion passed unanimously.
- M Ash moved to accept the criteria as amended. Seconded by T Brubaker. Motion passed unanimously.

2. Khindivi (hydrocortisone)

Khindivi (hydrocortisone) oral solution may be approved if the following criteria are met:

1. Member is ≥ 5 years of age AND
2. Member has a diagnosis of adrenocortical insufficiency AND
3. Prescriber confirms that member is unable to use an alternative generic glucocorticoid
    a. therapy AND
4. Prescriber confirms that member cannot take a solid oral dosage form AND
5. Member will be counseled that Khindivi (hydrocortisone) oral solution must be stored in a refrigerator and protected from light.

Maximum Quantity: Two 16-ounce bottles/30 days

Discussion

- No Board members reported a potential conflict of interest for this product.
- S Klocke moved to accept the criteria as written. Seconded by I Pan. Motion passed unanimously.

3. Alkindi Sprinkle (hydrocortisone)

Alkindi Sprinkle (hydrocortisone) oral granules may be approved if the following criteria are met:

1. Member is ≤ 17 years of age AND
2. Member has a diagnosis of adrenocortical insufficiency AND
3. Prescriber confirms that member is unable to use an alternative generic glucocorticoid therapy AND
4. Prescriber confirms that member cannot take a solid oral dosage form AND
5. Member does not have a nasogastric or gastric tube AND
6. Counseling has been provided that capsules cannot be swallowed whole and that the oral granules within each capsule cannot be crushed or chewed and should be given and swallowed within 5 minutes by:
    a. Pouring them directly onto the back of the member's tongue
    OR
    b. Pouring the granules onto a spoon and placing in the member's mouth
    OR
    c. Sprinkling onto a spoonful of cold or room temperature soft food (such as yogurt or fruit puree) and placing in the member's mouth
    AND
7. Counseling has been provided to immediately follow each dose of granules with fluids such as water, milk, breast milk or formula to ensure that all granules are swallowed.

Maximum Quantity: Three 50 capsule packages/30 days

Discussion

- No Board members reported a potential conflict of interest for this product.
- B Jackson moved to ask the Department to summarize bullet points 6 and 7 into to a more concise paragraph or "counseling has been provided that the medication be administered according to package labeling." Seconded by S Klocke. Motion passed unanimously.
- B Jackson moved to eliminate the upper limit of age 17 years in bullet point 1 so that members will not age out of these criteria when they are 18 years old. Seconded by M Ash. Motion passed with 6 votes in favor. S Klocke abstained.
- I Pan moved to accept the criteria as amended. Seconded by M Ash. Motion passed with 6 votes in favor. S Klocke abstained.

4. Vanrafia (atrasentan)

VANRAFIA (atrasentan) may be approved if the following criteria are met:

1. Member is ≥ 18 years of age AND
2. Member has a diagnosis of primary immunoglobulin A nephropathy (IgAN) confirmed by kidney biopsy and is at risk of rapid disease progression AND
3. Member has a baseline urine protein-to-creatinine ratio of ≥1.5 g/g or proteinuria ≥ 1 g/day AND
4. Member has an eGFR ≥ 30 mL/min/1.73 m^2 AND
5. Member is not pregnant or breastfeeding AND
6. Member has tried and failed† maximally tolerated dose of an immunosuppressant AND
7. Member has not achieved desired clinical outcomes with maximally tolerated ACE inhibitor or ARB therapy for three months and will continue on ACE inhibitor or ARB therapy unless the member has an allergy, intolerance, or contraindication to ACE inhibitor or ARB therapy AND
8. Member will continue to receive concomitant ACE inhibitor or ARB therapy unless the member has an allergy, intolerance, or contraindication to ACE inhibitor or ARB therapy AND
9. Provider attests that member's medication profile has been reviewed for drug interactions between Vanrafia (atrasentan) and strong/moderate CYP3A inhibitors, strong CYP3A inducers, OATP1B1/1Be inhibitors and other agents that may result in clinically significant interactions, according to product labeling AND
10. Member is not concurrently taking another endothelin receptor antagonist (such as ambrisentan, bosentan or sparsentan) AND
11. Prior to initiation of Vanrafia (atrasentan) therapy, the member's hepatic aminotransferases (ALT, AST) are not greater than 3 times the upper limit of normal AND
12. Requested medication is being prescribed by or in consultation with a nephrologist or immunologist AND
13. Prescriber acknowledges that continued FDA approval of Vanrafia (atrasentan) to slow kidney function decline in patients with IgAN may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

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

Maximum dose: 0.75 mg daily

Maximum quantity: one tablet/day

Initial approval: 1 year

Reauthorization: Reauthorization may be approved for 1 year if meeting the following:

- Member has experienced disease improvement and/or stabilization as indicted by:
  - Decrease of urine protein-to-creatinine ratio (UPCR) or decrease in proteinuria from baseline **AND**
  - Member has not experienced any treatment-restricting adverse effects such as clinically relevant liver transaminase elevations, increase in bilirubin greater than 2 times upper limit of normal, or clinical symptoms of hepatotoxicity.

Scheduled Speaker Testimony
S Quach - Novartis

Discussion

- No Board members reported a potential conflict of interest for this product.
- S Klocke moved to accept the criteria as written. Seconded by S Cho. Motion passed unanimously.

5. Imaavy (nipocalimab)

Imaavy (nipocalimab) may be approved if the following criteria are met:

1. For billing under the pharmacy benefit, medication is being administered in the member's home or in a long-term care facility (LTCF) by a healthcare professional AND
2. Prescriber acknowledges that doses administered by a healthcare provider in the doctor's office or clinic are to be billed through the Health First Colorado medical benefit through the standard buy-and-bill process AND
3. Member is ≥ 12 years of age AND
4. Member has a diagnosis of generalized myasthenia gravis that falls within Myasthenia Gravis Foundation of America (MGFA) Class II to IV disease AND
5. Member has a positive serologic test for anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibodies AND
6. Member has not experienced myocardial infarction, unstable ischemic heart disease, or stroke within the 12 weeks prior to initiating Imaavy (nipocalimab) therapy AND
7. Requested product is being prescribed by or in consultation with a neurologist AND
8. A baseline Quantitative Myasthenia Gravis (QMG) assessment has been documented AND
9. Patient has a MG-Activities of Daily Living (MG-ADL) total score of ≥6 AND
10. Member has failed† treatment with one of the following:
    a. Two concomitant immunosuppressive therapies for at least 1 year
    OR
    b. At least one year of immunosuppressive therapy in combination with acute or chronic therapeutic treatment with plasmapheresis or plasma exchange or intravenous immunoglobulin (IVIG)

    AND
11. As a precaution, consider discontinuing Imaavy (nipocalimab) and using alternative therapies in members receiving long term therapy with medications that bind to the human Fc receptor (such as IVIG, other immunoglobulins, or other C5 complement inhibitors).

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

Initial approval: 6 months

Reauthorization: Reauthorization for one year may be approved if meeting all of the following:

- Member has increase from baseline in MG-Activities of Daily Living (MG-ADL) assessment and/or MG-Activities of Daily Living (MG-ADL) score AND
- Member has demonstrated improvement in muscle strength with fatigue maneuvers from baseline AND
- Member has not experienced any treatment restricting adverse effects

Scheduled Speaker Testimony
A Hale – Johnson & Johnson

Discussion

- No Board members reported a potential conflict of interest for this product.
- S Klocke moved to ask the Department further review bullet point 6 regarding cardiovascular risk factors to ensure its clinical appropriateness for Imaavy (nipocalimab), and potentially for Rystiggo (rozanolixizumab) and Vyvgart (efgartigimod alfa), as well, since those agents are in the same therapeutic class. Seconded by T Brubaker. Motion passed unanimously.
- S Klocke moved to ask the Department to rewrite bullet point 10.b, particularly the language around acute vs chronic therapy with plasmapheresis, plasma exchange or IVIG, to be clearer as to the role of these other inventions within the prior authorization criteria for nipocalimab. Seconded by S Cho. Motion passed unanimously
- S Klocke moved to accept the criteria as amended. Seconded by S Cho. Motion passed unanimously.

6. Zelsuvmi (berdazimer)

Zelsuvmi (berdazimer) may be approved if the following criteria are met:

1. Member is ≥ 1 year of age AND
2. Member has a diagnosis of molluscum contagiosum AND
3. Prior to treatment, a full skin examination has been performed to identify all lesions AND
4. The member does not have lesions involving the ocular mucosa or eyelids AND
5. Requested product is being prescribed by or in consultation with a dermatologist AND
6. Member has failed a 4-week trial with topical podofilox. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction AND
7. Member has undergone a surgical intervention (such as cryotherapy, surgical scraping, laser therapy) with inadequate resolution OR provider has determined that member is not a good candidate for any of these procedures AND
8. Counseling has been provided about how to properly prepare and apply Zelsuvmi (berdazimer) AND
9. Counseling has been provided to use Zelsuvmi (berdazimer) only as directed by the prescriber AND
10. Member has been informed that molluscum contagiosum is usually self-limiting in immunocompetent individuals, and that a decision to forgo treatment may be appropriate for some cases and should be weighed against the severity of disease progression and the potential for adverse effects associated with therapeutic interventions.

Quantity limit: 1 kit/30 days

Approval will be limited to one 12-week treatment course per year

Discussion

- No Board members reported a potential conflict of interest for this product.
- S Cho moved to (1) remove bullet point 9, and (2) to clarify that the 4-week trial in the failure definition in bullet point 6 only applies to lack of efficacy. Seconded by S Klocke. Motion passed unanimously.
- I Pan moved to request that the Department further evaluate whether topical podofilox is an appropriate trial and failure requirement for pediatric patients. Seconded by T Brubaker. Motion passed unanimously.
- I Pan suggested that any edits made regarding podofilox use in the Zelsuvmi (berdazimer) criteria also be applied to the criteria for Ycanth (cantharidin) currently posted on Appendix P, as those criteria also contain a podofilox trial and failure requirement. J Taylor noted that this request will be taken into consideration by the Department, even though Ycanth is not currently undergoing review.
- I Pan moved to accept the criteria as amended. Seconded by S Cho. Motion passed unanimously.

7. LDL-C Lowering Agents

a. Evkeeza (evinacumab)

Evkeeza (evinacumab) may be approved if the following criteria are met:

1. For billing under the pharmacy benefit, medication is being administered in the member's home or in a long-term care facility (LTCF) by a healthcare professional AND
2. Member is ≥ 5 years of age AND
3. Member has a diagnosis of homozygous familial hypercholesterolemia (HoFH) AND
4. The requested drug is being prescribed by, or in consultation with a cardiologist, Certified Lipid Specialist (CLS) or an endocrinologist AND
5. Member has failed to achieve desired LDL-C with three months of maximally tolerated therapy with one high-potency statin (atorvastatin or rosuvastatin) in combination with ezetimibe. Failure is defined as lack of efficacy (member with ASCVD and LDL-C >55 mg/dL or member with HoFH and LDL-C >100 mg/dL), allergy, intolerable side effects,

contraindication, or significant drug-drug interaction. For members with past or current incidence of rhabdomyolysis, trial and failure of statin therapy is not required AND

6. Member has trialed and failed a three-month course of therapy with a PCSK9 inhibitor (alirocumab or evolocumab). Failure is defined as lack of efficacy, allergy, intolerable side effects, contraindication, or significant drug-drug interaction AND
7. Member is not pregnant and members of reproductive potential have been counseled regarding use of effective contraception during and for 5 months following treatment.

Note: The safety and effectiveness of Evkeeza (evinacumab) have not been established in patients with other causes of hypercholesterolemia, including those with heterozygous familial hypercholesterolemia (HeFH).

Initial approval: 1 year

Reauthorization: Reauthorization may be approved for 1 year with provider attestation confirming efficacy in lowering LDL-C.

Discussion

- No Board members reported a potential conflict of interest for this product.
- S Cho moved to clarify that the 3-month trial in the failure definition in bullet points 5 and 6 only applies to a lack of efficacy. Seconded by S Klocke. Motion passed unanimously.
- S Cho moved to accept the criteria as amended. Seconded by I Pan. Motion passed unanimously.

b. Praluent (alirocumab)

Praluent (alirocumab) may be approved if the following criteria are met:

1. The requested medication is being prescribed for one of the following indications, based on the member's age
    a. Members ≥ 18 years of age:
        i. To reduce the risk of myocardial infarction, stroke, and unstable angina requiring hospitalization in a member with established cardiovascular disease
        ii. As an adjunct to diet, to reduce LDL-C (alone or in combination with other LDL-C lowering therapies) to treat primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH)
        iii. As an adjunct to other LDL-C-lowering therapies, to treat homozygous familial hypercholesterolemia (HoFH)
    b. Members 8 to 17 years of age:
        i. As an adjunct to diet and other LDL-C-lowering therapies to treat heterozygous familial hypercholesterolemia (HeFH)

AND

2. The requested drug is being prescribed by, or in consultation with a cardiologist, Certified Lipid Specialist (CLS) or an endocrinologist AND
3. Member has failed to achieve desired LDL-C with three months of maximally tolerated therapy with one high-potency statin (atorvastatin or rosuvastatin) in combination with ezetimibe. Failure is defined as lack of efficacy (member with ASCVD and LDL-C >55 mg/dL or member with HoFH and LDL-C >100 mg/dL), allergy, intolerable side effects, contraindication, or significant drug-drug interaction. For members with past or current incidence of rhabdomyolysis, trial and failure of statin therapy is not required AND
4. Hypersensitivity vasculitis, angioedema, and other hypersensitivity reactions requiring hospitalization have been reported with Praluent (alirocumab) use. If a serious hypersensitivity reaction occurs, discontinue alirocumab treatment, treat according to the standard of care, and monitor until signs and symptoms resolve AND

5. Member will be counseled that Praluent (alirocumab) pens must be stored in a refrigerator, protected from exposure to light, not shaken, and brought to room temperature prior to use.

Maximum Dose (adults): 150 mg every two weeks

Quantity Limit:
75 mg/mL single-dose prefilled pen: 2 pens/month
150 mg/mL single-dose prefilled pen: 2 pens/month
Initial approval: 1 year

Reauthorization: Reauthorization may be approved for 1 year with provider attestation confirming efficacy in lowering LDL-C

Discussion

- No Board members reported a potential conflict of interest for this product.
- J Taylor acknowledged, based on previous similar motions today, that the three month trial mentioned in bullet point 3 will be edited in the final August criteria set to apply only to lack of efficacy.
- T Brubaker moved to accept the criteria as written. Seconded by I Pan. Motion passed unanimously.

c. Repatha (evolocumab)

1. The requested medication is being prescribed for one of the following indications, based on the member's age
    a. Members ≥ 18 years of age:
        i. To reduce the risk of myocardial infarction, stroke, and unstable angina requiring hospitalization in a member with established cardiovascular disease
        ii. As an adjunct to diet, to reduce LDL-C (alone or in combination with other LDL-C lowering therapies) to treat primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH)
    b. Members ≥10 years of age:
        i. As an adjunct to diet and other LDL-C lowering therapies to treat heterozygous familial hypercholesterolemia (HeFH)
        ii. As an adjunct to other LDL-C-lowering therapies to treat homozygous familial hypercholesterolemia (HoFH)

    AND
2. The requested drug is being prescribed by, or in consultation with a cardiologist, Certified Lipid Specialist (CLS) or an endocrinologist AND
3. Member has failed to achieve desired LDL-C with three months of maximally tolerated therapy with one high-potency statin (atorvastatin or rosuvastatin) in combination with ezetimibe. Failure is defined as lack of efficacy (member with ASCVD and LDL-C >55 mg/dL or member with HoFH and LDL-C >100 mg/dL), allergy, intolerable side effects, contraindication, or significant drug-drug interaction. For members with past or current incidence of rhabdomyolysis, trial and failure of statin therapy is not required AND
4. Hypersensitivity vasculitis, angioedema, and other hypersensitivity reactions requiring hospitalization, have been reported with Repatha (evolocumab) use. If a serious hypersensitivity reaction occurs, discontinue evolocumab, treat according to the standard of care, and monitor until signs and symptoms resolve AND
5. Member will be counseled that Repatha (evolocumab) pens must be stored in a refrigerator, protected from exposure to light, not shaken, and brought to room temperature prior to use.

Maximum Dose: 420 mg subcutaneously/month

Quantity Limits:
140 mg/mL single-dose prefilled autoinjector: 6 autoinjectors/month
140 mg/mL single-dose prefilled syringe: 6 prefilled syringes/month
420 mg/3.5 mL single-dose on-body infusor: 1 infusor/month

Initial approval: 1 year

Reauthorization: Additional one year may be approved with provider attestation to efficacy in LDL-C lowering.

Discussion

- No Board members reported a potential conflict of interest for this product.
- J Taylor acknowledged, based on previous similar motions today, that the three month trial mentioned in bullet point 3 will be edited in the final August criteria set to apply only to lack of efficacy.
- S Klocke moved to accept the criteria as written. Seconded by I Pan. Motion passed unanimously.

C. Adjournment

Board Vice Chair Jackson reminded attendees that the next Board meeting is scheduled for Tuesday, November 4, 2025, from 1:00 to 5:00 pm. He also reminded Board members to delete their meeting binders and associated emails at the conclusion of today's meeting.

M Shefchyk thanked the DUR Board, Dr. Taylor, and the other providers in the HCPF Pharmacy Office for giving her the honor and privilege of serving on the Board as Industry Representative for the past year. She shared that her experience has resulted in her having a high level of respect for all the providers who serve on this Board and for those who care for Colorado Medicaid members.

S Klocke moved to adjourn the meeting. Motion passed unanimously and the meeting was adjourned at 3:53 pm.

Minutes prepared by Julia Rawlings, PharmD, Secretary