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

August 13, 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 L Claus, Board Vice Chair.

2. Roll Call and Introductions

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: Liza Claus, PharmD (Vice Chair); Todd Brubaker, DO; Shilpa Klocke, PharmD; Patricia Lanius, BSPharm, MHA; Ken MacIntyre, DO; Ingrid Pan, PharmD, Marshal Ash, DO

Members Absent: Brian Jackson, MD, MA (Chair)

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

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

Dr. Taylor welcomed Dr. Lisa Rothgery to HCPF as the new Chief Medical Officer.

3. Virtual Meeting Information and General Announcements

J Rawlings shared several announcements:

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

4. Colorado Department of Health Care Policy and Financing Updates

V Garcia provided updates from the Department:

- DUR Board membership updates:
  - With her term expiring on October 31, this is the final DUR board meeting for Patte Lanius as an invaluable pharmacist member. We sincerely thank Patte for her dedicated service during the past 4 years.
  - Congratulations to new physician member Dr. Marshal Ash on his appointment to the DUR board for a 2-year term.
  - The Department would like to thank Shilpa Klocke, Brian Jackson, Liza Claus, Ingrid Pan, and Kenneth MacIntyre for renewing their terms at various times in recent months to generously continue their service to the Board and to the State of Colorado.
  - Thank you to all members of the Board and the larger DUR team for promptly submitting annual conflict of interest disclosure forms to the Department in July.
  - The Board recruits for new Board members on a rolling basis. There will be an opening for a pharmacist member on the Board in early November 2024.
  - The Board also currently has an opening for an Industry Representative. The Industry Representative serves for one year in a non-voting role and does not need to be a physician or pharmacist by training.
  - If you are interested in serving on the DUR Board, send an email along with your current CV to SSPPS.co-dur@cuanschutz.edu
- The Department recently reprocured its pharmacy benefit management system (PBMS) with a contract award being made to MedImpact. The Department is continuing to transition to MedImpact's PBMS with an anticipated completion date of Fall 2025.
- 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.

• Final Approval of Minutes from the May 7, 2024 Meeting

- Vice Chair L Claus asked the Board to review minutes from the May 7, 2024 meeting.
- T Brubaker moved to approve the minutes as written. Seconded by S Klocke. Motion passed unanimously.

• 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 Update**
  D Lee, Population Health/DUR Intern, presented this quarter's FDA Drug Approvals report that was prepared by intern N Gyasi. There have been no new FDA safety communications since the last Board meeting.
- **Quarterly Clinical Modules**
  R Page presented an executive summary of last quarter's clinical module analysis, *Pharmacotherapy for Secondary Prevention (Lipids) Drug Utilization Among Health First Colorado Members*, that was delivered to the Department on June 30.
- **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. 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 August review, along with several products being reviewed for addition to Appendix P.

J Taylor provided a brief overview of today's new business section of the agenda.

- A couple of today's therapeutic classes are <u>not</u> included in Mass Review also have no proposed criteria changes to be presented by the Department. These include Androgens and Phosphate Binders.
- The Androgen therapeutic class was listed by mistake on the agenda under both full review and Mass Review; however, you will find the proposed criteria for Androgens in the <u>full</u> review section of the meeting binder.
- Long-acting insulins have been pulled out of the Mass Review section of the meeting binder and placed at the end of the full review section to allow for registered speaker testimony.
- To increase efficiency toward the end of the agenda, Non-PDL section may be slightly rearranged to better accommodate today's pre-registered speakers.

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 this quarter's proposed criteria.

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

Red indicates proposed deleted text

Yellow indicates proposed new text

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

Preferred agents

***No PA Required (if FDA-labeled dosing is met)**

ABILIFY (aripiprazole) ASIMTUFII syringe
ABILIFY (aripiprazole) MAINTENA ER, syringe, vial
ARISTADA (aripiprazole) ER
ARISTADA INITIO syringe
Fluphenazine decanoate vial
HALDOL (haloperidol decanoate) ampule
Haloperidol decanoate ampule, 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) vial
UZEDY ER (risperidone) syringe
Ziprasidone vial
ZYPREXA (olanzapine)
ZYPREXA RELPREVV (olanzapine)

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. 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.

*Preferred 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 (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)

Scheduled Speaker Testimony
M John, Abilify Maintena – Otsuka - *yielded time*
M John, Abilify Asimtufii – Otsuka - *yielded time*
A Hale, Invega – Johnson & Johnson
M Sohal, Uzedy – Teva - *yielded time*

Discussion

- No Board members reported potential conflicts of interest for this therapeutic class.
- K MacIntyre moved to accept the criteria as written. Seconded by I Pan. Motion passed with six votes in favor. S Klocke abstained, as she was unavailable for this vote.

2. Androgenic Agents, Topical, Injectable, Oral

Preferred agents

PA Required for all agents in this class
ANDRODERM (testosterone) patch
Testosterone cypionate IM injection
Testosterone gel packet
Testosterone 1.62% gel pump

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 meeting the above criteria with trial and failed‡ therapy with two preferred topical androgen formulations.

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

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

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

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

Discussion

- No Board members reported potential conflicts of interest for this therapeutic class.
- T Brubaker moved to accept the criteria as written. Seconded by P Lanius. Motion passed with six votes in favor. S Klocke abstained, as she was unavailable for this vote.

3. 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

Raloxifene tablet

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 cannot swallow is unable to use a solid oral dosage forms or has a feeding tube.
- Quantity limit: One spray daily

RALOXIFENE may be approved if the member meets the following criteria:

- Diagnosis of postmenopausal osteoporosis (BMD T-scores of -2.5 or less)
  AND
- Has trial and failure of preferred bisphosphonate for one year (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction)

  Maximum dose: 60mg 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 a preferred bisphosphonate for one year. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction AND
- For brand FORTEO, member has trialed and failed one preferred bisphosphonate or non-bisphosphonate for 12 months generic teriparatide. 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 a one preferred bisphosphonate or non-bisphosphonate for 12 months one year (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 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)

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 potential conflicts of interest for this therapeutic class.
- S Klocke moved to accept the criteria as written. Seconded by P Lanius. Motion passed unanimously.

4. Diabetes Management Classes, Non-Insulin

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

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

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

Preferred agents
***Must meet eligibility criteria**
******BYDUREON BCISE (exenatide) autoinjector
*BYETTA (exenatide) pen
*TRULICITY (dulaglutide) pen
*VICTOZA[BNR] (liraglutide) pen

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

**BYDUREON BCISE (exenatide) 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 ≥27 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.

  Maximum dose: 2.4 mg subcutaneously once weekly

  Quantity limit: four prefilled syringes/28 days

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

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.

‡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.

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

Table 1: GLP-1 Analogue Maximum Dose	
Adlyxin (lixisenatide)	20 mcg per day
Bydureon Bcise (exenatide)	2 mg weekly
Byetta (exenatide)	20 mcg per day
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 per day
Wegovy (semaglutide)	2.4 mg weekly

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

c. Sodium-Glucose Cotransporter (SGLT-2) Inhibitors

Preferred agents

FARXIGA[BNR] (dapagliflozin) tablet
INVOKANA (canagliflozin) tablet
JARDIANCE (empagliflozin) tablet

Non-preferred products may receive approval following trial and failure with two 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.

SGLT Inhibitor	Clinical Setting	Renal Dosing Recommendations (FDA labeling)
FARXIGA (dapagliflozin)	Glycemic control in patients without established CV disease or CV risk factors	Initiation of therapy Nnot recommended when eGFR is <less than 45 mL/min/1.73 m^2
	Reduce risk of CV death; Chronic kidney disease (CKD); Reduce risk of CV death, hospitalization or urgent visit for heart failure (HF)	Initiation of therapy not recommended when eGFR is < less than 25 mL/min/1.73 m^2 (safety and efficacy in members on dialysis has not been established)
INPEFA (sotagliflozin)	Reduce risk of CV death, HF hospitalization and urgent HF visit in adults with HF or Type 2 DM, chronic kidney disease CKD and other CV risk factors	Safety and efficacy of initiating therapy in members with when eGFR is less than 25 mL/min/1.73 m^2 or on dialysis has not been established
INVOKANA (canagliflozin)	Glycemic control in adults with Type 2 DM patients without established CV disease or CV risk factors	Safety and efficacy of initiatingon of therapy not recommended when eGFR is <less than 30 mL/min/1.73 m^2 or on dialysis has not been established

	Reduce risk of major CV events in adults with Type 2 DM and established CVD; Reduce risk of ESKD, doubling of serum creatinine, CV death, and hospitalization for HF in adults with Type 2 DM and diabetic nephropathy (albuminuria > 300 mg/day)	Initiation of therapy not recommended when eGFR is <less than 30 mL/min/1.73 m^2
JARDIANCE (empagliflozin)	Glycemic control in patients 10 years and older with Type 2 DM without established CV disease or CV risk factors	Not recommended when eGFR is < less than 30 mL/min/1.73 m^2 (contraindicated in members on dialysis)
	Reduce risk of CV death and hospitalization for HF; Chronic kidney disease (CKD); Reduce risk of CV death in adults with Type 2 DM and established CVD or heart failure (HF)	Initiation of therapy Nnot recommended when eGFR is < less than 20 mL/min/1.73 m^2 (contraindicated in members or on dialysis)
STEGLATRO (ertugliflozin)	Adjunct to diet and exercise in members patients with Type 2 DM	Not recommended when eGFR is < less than 45 mL/min/1.73 m^2 (contraindicated in members on dialysis)

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

Scheduled Speaker Testimony
KW Khachatourian, Ozempic – Novo Nordisk
KW Khachatourian, Rybelsus – Novo Nordisk
KW Khachatourian, Wegovy – Novo Nordisk
C Francavilla, CVD risk and Wegovy – Family Physician, Lakewood, CO *(time yielded - did not attend)*

Discussion

- No Board members reported potential conflicts of interest for this therapeutic class. The Board reviewed DPP4is, GLP-1 analogues and SGLT inhibitors as a single section.
- The Board discussed aligning prior authorization for Wegovy® (semaglutide) with a March 1, 2024 FDA labeling update that removed the specific BMI of ≥27 kg/m^2 that was an inclusion criterion in the SELECT trial (2023). L Claus moved to change "defined as a BMI ≥27 kg/m^2" in the current criteria for Wegovy to "defined as a BMI ≥25 kg/m^2." Seconded by I Pan. Motion passed unanimously.
- I Pan moved to accept the criteria for this therapeutic class as amended. Seconded by T Brubaker. Motion passed unanimously.

5. Growth Hormones

Preferred agents
No PA Required (If diagnosis and dose met)
GENOTROPIN (somatropin) cartridge, Miniquick pen
NORDITROPIN (somatropin) Flexpro pen

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).

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 at least one 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)

  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	0.375 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	0.017 mg/kg/dayweek
Serostim	Not Indicated	42 mg/week for HIV wasting or with cachexia only (in combination with antiretroviral therapy)
Skytrofa	0.2625 1.68 mg/kg/week	N/A Not Indicated
Sogroya	Dose Individualized for each patient, based on growth response	8 mg/week

Zomacton	0.47 mg/kg/week	0.0125 0.0875 mg/kg/dayweek
Zorbtive	Not Indicated	8 56 mg/week28 days for up to 4 weeks for short bowel syndrome only

*Based on FDA labeled indications and dosing

Discussion

- No Board members reported potential conflicts of interest for this therapeutic class.
- To clarify the intended meaning, T Brubaker recommended that the words "any of" be added to this statement: "Non-preferred Growth Hormone products may be approved if any of the following criteria are met."
- J Taylor confirmed that the Department allows overrides in cases of growth hormone product shortages. Overrides do require a phone call from either the provider or the pharmacy to verify that the requested product is unavailable. The Department also monitors drug shortages on an ongoing basis.
- S Klocke moved to accept the criteria as written. Seconded by T Brubaker. Motion passed unanimously.

6. Phosphate Binders

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

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

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

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

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

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

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

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

Maximum Dose: Velphoro 3000 mg daily

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

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

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

Discussion

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

7. Insulin, Long-acting

Preferred agents
No PA Required*
*Insulin degludec, vial
LANTUS[BNR] (insulin glargine) vial, Solostar
LEVEMIR (insulin detemir) vial, FlexTouch
*TRESIBA[BNR] (insulin degludec) FlexTouch

***Insulin degludec vial** or **Tresiba** (insulin degludec FlexTouch pen) may be approved for members who have trialed and failed‡ Lantus (insulin glargine).

All other non-preferred products may be approved if the member has tried and failed‡ treatment with Lantus **AND** Tresiba.

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

Scheduled Speaker Testimony
KW Khachatourian, Tresiba – Novo Nordisk - *yielded time*

Discussion

- No Board members reported potential conflicts of interest for this therapeutic class.
- **J Taylor mentioned that product shortages involving the long-acting insulins are also monitored by the Department on an ongoing basis.**
- T Brubaker moved to accept the criteria as written. Seconded by S Klocke. Motion passed unanimously.

Dr. Taylor introduced the next section of the agenda and acknowledged a few minor proposed changes that are included within today's Mass Review.

- In the Topical Contraceptive subclass: a proposed edit to allow for continuation of therapy for members currently using Annovera (segesterone/ethinyl estradiol)vaginal ring, since that product is moving to non-preferred status.
- In the Biguanide and Antihyperuricemic subclasses: proposed edits to simplify the language to allow approval of metformin oral liquid or Gloperba (colchicine) oral solution, respectively, for members who are unable to use a solid oral dosage form.

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. 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
Norelgestromin/EE TD patch (generic Xulane)
ANNOVERA (segesterone acetate/EE) vaginal ring
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.

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

***PHEXXI** (lactic acid/citric/potassium) vaginal gel

- Quantity Limit: 120 grams per 30 days

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

9. Diabetes Management Classes, Insulins

a. Rapid acting

Preferred agents

HUMALOG[BNR] 100U/mL KwikPen, vial
HUMALOG (insulin lispro) cartridge

HUMALOG Jr[BNR] (insulin lispro) KwikPen
Insulin aspart cartridge, pen, vial
NOVOLOG (insulin aspart) cartridge, FlexTouch pen, vial

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).
bone

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 (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 - *(pulled from Mass Review due to registered speaker)*

e. Mixtures

Preferred agents

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

10. 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 who meet one of the following:

- Member is under the age of 12 with a feeding tube **OR** prescriber confirms that member has difficulty swallowing unable to use a solid oral dosage form.

c. Meglitinides

Preferred agents

NONE

Non-preferred products may be approved for members who have failed treatment with one 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. 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.

e. DPP-4 Inhibitors – Combination with Metformin

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:

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

f. SGLT Inhibitor Combinations with Metformin

Preferred agents

INVOKAMET (canagliflozin/metformin)tablet
INVOKAMET XR (canagliflozin/metformin) tablet
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.

g. 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.

h. 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).

11. Estrogen Agents

a. Parenteral

Preferred agents

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

b. Oral/Transdermal

Preferred agents

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

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

12. Glucagon, self-administered

Preferred agents
- BAQSIMI (glucagon) nasal spray
- GLUCAGEN HYPOKIT (glucagon)
- Glucagon Emergency Kit *(Eli Lilly)*
- Glucagon Emergency Kit *(Amphastar)*
- 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

13. Prenatal Vitamins/Minerals

Preferred agents
***Must meet eligibility criteria**
- COMPLETE NATAL DHA tablet
- M-NATAL PLUS tablet
- NESTABS tablets
- PNV 29-1 tablet
- PRENATAL VITAMIN PLUS LOW IRON tablet *(Patrin Pharma only)*
- PREPLUS CA-FE 27 mg – FA 1 mg tablet
- SE-NATAL 19 chewable tablet
- TARON-C DHA capsule
- THRIVITE RX tablet
- TRINATAL RX 1 tablet
- Virt C DHA softgel
- VITAFOL gummies
- VP-PNV-DHA softgel
- 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 have documented swallowing difficulty due to young age and/or a medical condition (preventing use of 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. 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.

16. Overactive Bladder Agents

Preferred agents
Fesoterodine ER tablet
GELNIQUE (oxybutynin) gel
MYRBETRIQ[BNR] (mirabegron) tablet
Oxybutynin IR, ER tablets, syrup
Solifenacin tablet
Tolterodine IR tablet
Tolterodine 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 potential conflicts of interest for the PDL therapeutic classes or products included in today's Mass Review section.
- K MacIntyre moved to accept the criteria in Mass Review as written. Seconded by P Lanius. 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. No Board members reported a potential conflict of interest for the eight products included in this section of the agenda.

To better accommodate today's speakers, products were reviewed in the following order: Tryvio®, OTC Choline, Winrevair®, Libervant®, Eohilia®, Adzynma®, Alvaiz® and Voydeya®.

1. OTC Choline

Over-the-counter (OTC) oral choline may be approved for members meeting the following criteria:

1. Choline supplementation is directly related to one of the following conditions:
   a. Member is pregnant or planning to become pregnant
   b. Member is currently breastfeeding
2. Quantity limitation is met

Prior authorization approvals are limited to the following OTC products (product list may be subject to change):
- choline citrate 650 mg tablet, *mfr. Endurance* NDC 29135-0187-20
- choline SR 300 mg tablet, *mfr. Freeda Health* NDC 58487-0021-81

Quantity limit: Limited to quantity sufficient to achieve 550 mg daily

Written Stakeholder Testimony
Robert Freeman, MD – Dept of Psychiatry, University of Colorado Anschutz Medical Campus

Discussion

- J Taylor provided additional context that Health First Colorado coverage of certain OTC products is optional. State of Colorado leadership has made a decision for CO Medicaid to cover OTC choline when meeting the clinical circumstances described in the set of criteria above. Coverage of OTC choline is expected to go into effect earlier than what is required in the related State statute.
- K MacIntyre moved to accept the criteria as written. Seconded by T Brubaker. Motion passed unanimously.

2. Winrevair (sotatercept-csrk)

Winrevair (sotatercept-csrk) may be approved if the following criteria are met:

1. Member is an adult > 18 years of age AND
2. Member has a diagnosis of pulmonary arterial hypertension (PAH), WHO group 1, AND
3. Member is not currently experiencing serious bleeding and has not experienced serious bleeding events in the past, AND
4. Member's pre-treatment platelet count is >50,000/mm^3 AND
5. Member is not pregnant or planning to become pregnant, AND
6. Member will not be breastfeeding during and within 4 months after last dose AND
7. Initial prescription for the requested product is being prescribed by or in consultation with a pulmonologist or cardiologist AND
8. Member has tried and failed‡ a preferred medication from one of the following categories:
    1. Phosphodiesterase Inhibitors
    2. Endothelin Receptor Antagonists
    3. Prostacyclin Analogues and Receptor Agonists

    AND
9. Since Winrevair is intended for use under the guidance of a healthcare professional, prescriber attests that the member self-administering the drug will be permitted to do so only when (1) it is considered appropriate, and (2) after they have received adequate initial training and administration technique assessment from a healthcare professional, AND
10. Prescriber attests that hemoglobin (Hgb) and platelet counts will be assessed before each dose for the first 5 doses of Winrevair (or longer if lab values are unstable), and also monitored periodically thereafter to assess the need for dose adjustments.

Maximum dose: 0.7 mg/kg every 3 weeks

Continuation of therapy: Members who are currently stabilized on Winrevair (sotatercept-csrk) may receive authorization to continue use of the product.

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

Discussion

- No Board members reported potential conflicts of interest for this product.
- The Board briefly discussed bullet point 3 regarding serious bleeding events and which clinical situations these events might be related to (such as bleeding disorders, thrombocytopenia, trauma, etc.). The Department will take the question into consideration as the criteria are finalized. However, no specific edits to the proposed criteria were recommended by the Board during today's discussion.
- S Klocke moved to accept the criteria as written. Seconded by I Pan. Motion passed unanimously.

3. Libervant (diazepam)

Libervant (diazepam buccal film) may be approved if the following criteria are met:

1. Member is 2 to 5 years of age AND
2. Member has a diagnosis of epilepsy with intermittent, stereotypic episodes of frequent seizure activity (such as seizure clusters, acute repetitive seizures) that are distinct from their usual seizure pattern, AND
3. Member does not have acute-narrow angle glaucoma AND
4. Due to increased risk of additive effects, prescriber attests that members on concomitant CNS depressants will be closely monitored for central nervous system and respiratory depression after administration of Libervant AND
5. Based on the member's concurrent medication profile, prescriber has evaluated potential interactions that may occur between diazepam and:
   a. Inhibitors of CYP2C19 (such as cimetidine, quinidine, tranylcypromine) and CYP3A4 (such as ketoconazole, clotrimazole) that could increase adverse reactions with diazepam
   AND
   b. Inducers of CYP2C19 (such as rifampin) and CYP3A4 (such as carbamazepine, phenytoin, dexamethasone, phenobarbital) that could decrease the efficacy of diazepam
   AND
6. Initial prescription for the requested product is ordered by or in consultation with a pediatric neurologist AND
7. Parent/caregiver has been educated about appropriate identification of seizure cluster signs and symptoms, and proper Libervant buccal film administration.

Quantity limit: 4 films per year unless used / damaged / lost

Members are limited to one prior authorization approval on file for Libervant (diazepam), Nayzilam (midazolam) or Valtoco (diazepam).

Continuation of therapy: Members who are currently stabilized on Libervant (diazepam) buccal films as part of their epilepsy treatment plan may receive authorization to continue use of the product.

Discussion

- No Board members reported potential conflicts of interest for this product.
- The Board discussed the point that FDA approval for Libervant films is currently limited to children between 2 to 5 years of age, as well as the possibility of expanding the upper age limit in these criteria so that members in older age groups could have access to a buccal film dosage form. FDA labeling should generally be followed; however, the Board recommended that utilization of Libervant be monitored by the Department once these initial criteria have been finalized and that consideration be given to expanding the age range as new information becomes available in evidence-based compendia and/or the FDA product labeling is updated in the future.
- The Board also discussed the bullet point describing a limitation to one prior authorization (PA) on file among the benzodiazepine nasal sprays and buccal films used for seizure management. J Taylor explained that, despite the differences in FDA-labeling regarding age ranges for the products included in that bullet point, the statement is intended to be a general one that applies to Libervant (diazepam) as well as other products in the category that not being reviewed today.
- T Brubaker moved to approve the criteria as written. Seconded by I Pan. Motion passed unanimously.

4. Eohilia (budesonide)

Eohilia (budesonide) oral suspension may be approved if the following criteria are met:

1. Member is ≥ 11 years of age AND
2. Member has a documented diagnosis of eosinophilic esophagitis (EoE), AND
3. Member is following appropriate dietary therapy interventions AND
4. Medication is being prescribed by or in consultation with a gastroenterologist, allergist or immunologist AND
5. Because the use of corticosteroids may cause a reduction of growth velocity, the growth of pediatric patients who are taking Eohilia (budesonide) will be monitored, AND
6. Member (or parent/caregiver) has been counseled:
   a. That Eohilia (budesonide) should not be given along with food or liquid
   b. That the member should not eat or drink for at least 30 minutes after each dose
   c. After each dose, to rinse mouth with water and spit out contents without swallowing
   d. To avoid consumption of grapefruit juice for the duration of therapy

Maximum dose: 4 mg (20 mL)/day

Maximum quantity: 60 unit-dose packets/30 days

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

Discussion

- No Board members reported potential conflicts of interest for this product.
- Similar to today's previous discussion, the Board noted that FDA approval for Eohilia is currently limited to members 11 years of age and older. Board members suggested that Eohilia is another potential candidate for additional monitoring by the Department and that consideration be given to revising the age range for approval of Eohilia as new information becomes available in evidence-based compendia and/or the FDA product labeling is updated in the future.
- S Klocke moved to accept the proposed criteria as written. Seconded by K MacIntyre. 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. Adzynma (apadamtase alfa)

Adzynma (apadamtase alfa) may be approved if the following criteria are met:

1. For claims billed through the pharmacy benefit, prescriber verifies that the medication is being administered by a healthcare professional in the member's home or in a long-term care facility AND
2. Member is ≥ 2 years of age AND
3. Member has a diagnosis of congenital thrombotic thrombocytopenic purpura (cTTP) confirmed by genetic testing indicating severe deficiency of ADAMTS13 protease and/or based on clinical judgment, AND
4. Requested product is being prescribed by or in consultation with a hematologist

Maximum dose
Prophylactic therapy: 40 IU/kg weekly
On-demand therapy: 40 IU/kg/day

Discussion

- No Board members reported potential conflicts of interest for this product.
- K MacIntyre moved to accept criteria as written. Seconded by I Pan. Motion passed with six votes in favor.

6. Alvaiz (eltrombopag choline)

Alvaiz (eltrombopag choline) may be approved if the following criteria are met:

For ALL indications:

1. Eltrombopag choline is not substitutable with other eltrombopag products on a mg-per-mg basis AND
2. Prescriber is aware that eltrombopag choline may increase the risk of severe and potentially life-threatening hepatotoxicity and that hepatic function must be monitored before and during therapy AND
3. Prescriber is aware that member will undergo ocular exams prior to initiation of therapy, during therapy, and will be regularly monitored for signs and symptoms of cataracts AND
4. Member has been counseled to take eltrombopag choline at least 2 hours before or 4 hours after any products containing polyvalent cations (such as iron, calcium, aluminum, magnesium, selenium, zinc, dairy products, and supplements containing minerals) to avoid a significant reduction in eltrombopag absorption, AND
5. Member is not breastfeeding AND
6. Alvaiz tablets should not be split, chewed, or crushed. Pediatric patients must be able to swallow tablets whole.

For persistent or chronic immune thrombocytopenia:

1. Member is ≥ 6 years of age AND
2. Member has a confirmed diagnosis of persistent or chronic (> 3 months) immune thrombocytopenia AND
3. Member's degree of thrombocytopenia and clinical condition increase the risk (documented) of bleeding as demonstrated by the following lab values:
   a. Platelet count less than 20,000/mm^3 or
   b. Platelet count less than 30,000/mm^3 accompanied by signs and symptoms of bleeding

   AND
4. Requested medication is being prescribed by a hematologist AND
5. Within the past 6 months, member has tried and failed (failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions) systemic corticosteroids (such as prednisone 1-2 mg/kg for 2 to 4 weeks, or pulsed dexamethasone 40 mg daily for 4 days), immunoglobulin replacement, or splenectomy

For thrombocytopenia associated with hepatitis C:

1. Member has a confirmed diagnosis of chronic hepatitis C associated thrombocytopenia AND
2. Member is ≥ 18 years of age AND
3. Requested medication is being prescribed by a gastroenterologist, infectious disease specialist, transplant specialist, or hematologist AND
4. Member has clinically documented thrombocytopenia (defined as platelets < 60,000 microL), AND
5. Prescriber is aware that safety and efficacy have not been established for the use of Alvaiz (eltrombopag choline) in combination with direct-acting antiviral agents used without interferon for the treatment of chronic hepatitis C infection, AND
6. Prescriber is aware that in patients with chronic hepatitis C, Alvaiz (eltrombopag choline) used in combination with interferon and ribavirin may increase the risk of hepatic decompensation.

For severe aplastic anemia:
1. Member has a confirmed diagnosis of severe aplastic anemia AND
2. Member is ≥ 18 years of age AND
3. Requested medication is being prescribed by a hematologist AND
4. Member must have had a documented insufficient response to immunosuppressive therapy [antithymocyte globulin (ATG)], alone or in combination with cyclosporine and/or a corticosteroid.

Maximum dose:
- Persistent or chronic immune thrombocytopenia: 54 mg/day
- Thrombocytopenia associated with hepatitis C: 72 mg/day
- Severe aplastic anemia: 108 mg/day

Initial approval: All initial prior authorization approvals will be granted for 12 months.

Reauthorization:
Reauthorization approvals for a maximum of 6 months will require documentation both of lab results and efficacy of treatment with Alvaiz (eltrombopag choline).

Discussion
- No Board members reported potential conflicts of interest for this product.
- The Board requested that this product be consistently referred to using both the brand and generic product names throughout the PA criteria.
- S Klocke moved to accept the proposed criteria as written. Seconded by K MacIntyre. Motion passed with six votes in favor.

7. Voydeya (danicopan)

Voydeya (danicopan) may be approved as add-on therapy to ravulizumab or eculizumab if the following criteria are met:

1. Member is ≥18 years of age AND
2. Member has a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) confirmed by high sensitivity flow cytometry AND
3. Member does not have severe hepatic disease (Child-Pugh Class C) AND
4. Member does not have any active infections caused by an encapsulated bacteria (such as *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae* type b) AND
5. Member has received vaccination against encapsulated bacteria (such as *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae* type b) at least 2 weeks prior to initiation of Voydeya (danicopan) therapy AND
6. Member has residual anemia (hemoglobin < 9.5 g/dL) at baseline, with absolute reticulocyte count ≥ 120×10^9/L with or without transfusion support, and has been stable on ravulizumab or eculizumab therapy for at least 6 months, AND
7. If urgent danicopan therapy is indicated in a patient who is not up to date with vaccines, or the vaccines were administered within the last 2 weeks, prescriber attests that the member will receive appropriate antibacterial drug prophylaxis and the vaccines will be administered as soon as possible AND

8. Requested product is being prescribed by or in consultation with a hematologist, immunologist or nephrologist AND
9. Member's medication profile does not indicate any clinically significant drug interactions with BCRP substrates: Monitor patients more frequently for adverse reactions and consider dose reduction of the BCRP substrate drug. For rosuvastatin, the dose should not exceed 10 mg once daily. P-gp substrates: Dose adjustment might be necessary for P-gp substrates where minimal concentration changes may lead to serious adverse reactions, AND
10. Prescriber is enrolled in the Voydeya Risk Evaluation and Mitigation Strategy (REMS) program.

Quantity limit: 120 tablets/30 days

Maximum dose: 600 mg/day

Initial Approval: 6 months

Reauthorization: Approval for 1 year may be given with prescriber attestation that member's hemoglobin has increased by ≥2 g/dL from baseline while on Voydeya (danicopan) therapy.

Discussion

- The Board had a broader discussion regarding the inclusion or exclusion of references to Risk Evaluation and Mitigation Strategy (REMS) programs in DUR criteria in general (rather than specifically concerning REMS programs associated with specific products). The general recommendation from the Board today was to exclude references to REMS programs for PA criteria drafted in the future when the REMS program enrollment in the program is required in order to procure the drug product. The Board noted that checkpoints for prescribers, pharmacies and sometimes patients are inherently built into more stringent REMS, while other types of REMS may be more educational in nature. For REMS that do not require enrollment in order to procure the requested drug product, DUR criteria could potentially include provider attestations that they are aware of significant safety warnings in the REMS associated with the requested product.
- A recommendation was made to rearrange and clarify the content of bullet point 9 so that it begins with, "Review for clinically significant drug interactions…" and has separate sub-categories for BCRP substrate and P-gp substrate interacting drugs.
- S Klocke moved to remove bullet point 10 related to the Voydeya REMS program. Seconded by M Ash. Motion passed with six votes in favor.
- I Pan moved to accept the criteria as amended. Seconded by M Ash. Motion passed with six votes in favor.

8. Tryvio (aprocitentan)

Tryvio (aprocitentan) may be approved for members meeting the following criteria:

1. Member is 18 years of age or older AND
2. Member has a diagnosis of hypertension AND
3. Member has a blood pressure > 140/90 mmHg and meets both of the following:
   a. The requested product is being prescribed concurrently with a regimen containing at least three preferred antihypertensive agents from different drug classes **AND**
   b. Member has trialed and failed a trial of an antihypertensive regimen containing three preferred antihypertensive agents from different drug classes at maximally tolerated doses. (Failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects, or significant drug-drug interaction) AND
4. Member is not receiving a concurrent endothelin receptor antagonist, AND
5. Member does not have NYHA class III-IV heart failure AND

6. Member does not have moderate to severe hepatic impairment AND
7. Prescriber attests that member's liver function tests are less than 3 times the upper limit of normal (ULN) prior to initiating Tryvio (aprocitentan) therapy, AND the member does not have moderate to severe hepatic impairment, AND that liver function tests, complete blood count (CBC) and hemoglobin will be monitored during therapy AND
8. Prescriber attests that members who can become pregnant have been counseled regarding the potential for major birth defects and to use acceptable contraception prior to initiation of treatment, during treatment, and for one month after stopping TRYVIO therapy.

Dose Limit: 12.5 mg/day

Initial approval: 3 months

Reauthorization: TRYVIO (aprocitentan) may be approved for one year if, after 3 months of therapy, the member's blood pressure is within the goals established by national guidelines

Scheduled Speaker Testimony
H Bullard – Idorsia Pharmaceuticals

Discussion

- No Board members reported potential conflicts of interest for this product.
- It was noted that bullet #6 is duplicative with the content of bullet #7 and can be deleted.
- S Klocke moved to approve the proposed criteria as written. T Brubaker seconded. Motion passed unanimously.

C. Adjournment

Vice Chair Claus reminded attendees that the next Board meeting is scheduled for Tuesday, November 12, 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.

I Pan moved to adjourn the meeting, Seconded by K MacIntyre. Motion passed unanimously and the meeting was adjourned at 3:45 pm.

Minutes respectfully submitted by Julia Rawlings, PharmD