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 8, 2023
Open Session
1:00 pm – 5:00 pm

1. Call to Order

Today's meeting was held virtually via Zoom. The meeting was called to order at 1:00 pm by L Claus, Board Chair.

2. Roll Call and Introductions

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

Members Present: Liza Claus, PharmD (Chair); Brian Jackson, MD, MA (Vice Chair); Todd Brubaker, DO; Shilpa Klocke, PharmD; Patricia Lanius, BSPharm, MHA; Ken MacIntyre, DO; Ingrid Pan, PharmD; Melissa Polvi, RN
Members Absent: None
HCPF Pharmacy Office Staff: Jim Leonard, PharmD; Jeffrey Taylor, PharmD, Veronia Guirguis-Garcia, PharmD, Rachele Poissant, PharmD
CO-DUR Team: Robert Page, PharmD, MSPH; Julia Rawlings, PharmD

3. Virtual Meeting Information and General Announcements

J Rawlings shared several announcements:

- This meeting is being recorded for internal use by the Department.
- Speakers providing testimony and other meeting guests are asked to keep video and microphones turned off throughout the meeting so that Board members' votes can be easily seen and tracked. Stakeholders who have signed up in advance to provide testimony will be called upon at the appropriate times in the meeting agenda. Video and microphones for Board members will remain on throughout the meeting. Vice Chair Jackson will manage the voting process.
- If you experience technical difficulties or your connection interrupted during the meeting, please leave the meeting and use the same Zoom meeting link to be readmitted.
- Welcome to our six new Population Health interns who joined the team in June. Interns Jordan Hahn, Melina Harris, Diane Lee and Nicole DeLeon will be presenting reports and/or assisting with our Zoom technology this afternoon.

4. Colorado Department of Health Care Policy and Financing Updates

V Garcia provided updates from the Department:

- DUR Board membership updates
  - The Department wants to sincerely thank Dr. Brian Jackson and Dr. Shilpa Klocke for renewing their appointments to the DUR Board. Their new terms will expire in April 2025.

  - The DUR Board recruits for new physician and pharmacist members on a rolling basis. There is currently an opening for a physician. If you are interested in serving in this capacity, send an email, along with your current CV, to SSPPS.co-dur@cuanschutz.edu
  - This is Melissa Polvi's final DUR board meeting as the Industry Representative. Many thanks to Melissa for her service to the DUR Board since October 2022. With that in mind, The Board currently has an opening for an Industry Representative. The Industry Representative serves for one year in a non-voting role and does not need to be a physician or pharmacist by training. Please send an email with your CV to jeffrey.taylor@state.co.us if you are interested in applying for this position.
- Colorado Medicaid now prefers generic prescription suboxone to be dispensed in all available forms (ex. sublingual tablets and film, etc.)
- Effective 8/6/23, pharmacies registered with the Vaccines for Children (VFC) program may bill the pharmacy benefit and receive reimbursement for the administration fee only when the claim is for a VFC acquired vaccine. For administration fee reimbursement that is not submitted as a pharmacy claim, providers may bill for reimbursement through medical. Please refer to CDHP for enrollment questions at https://cdphe.colorado.gov/immunization/vaccines-for-children.
- On 10/01/2023, CO Medicaid will no longer be managing oral contraceptives. The Oral Contraceptives class will be removed from the PDL and it will no longer be reviewed by the P&T Committee or the DUR Board.
- As a reminder, only proposed changes to the currently posted criteria will be read aloud during today's meeting for products and drug classes currently managed with prior authorization criteria

5. Final Approval of Minutes from the May 9, 2023 Meeting

- Chair L Claus asked the Board to review minutes from the May 9, 2023 meeting.
- B Jackson moved to approve the minutes as written. Seconded by T Brubaker. 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.

Melissa Polvi, RN, Industry Representative, disclosed her conflicts of interest related to employment by Swedish Orphan Biovitrum (Sobi), a rare disease company.

7. Clinical Updates and General Orders

- **FDA New Product & Safety Updates**
  D Lee, DUR Intern, presented updates from the FDA Drug Approvals report, prepared with assistance from Andrew Rukavina, DUR Intern.
  This quarter's Safety Update, prepared by Renee Sapasap, DUR Intern, and presented by Melina Harris, DUR intern, included an FDA Communication from 05/11/2023 regarding updated warnings to improve safe use of prescription stimulants used to treat ADHD and other conditions. The FDA full safety communication is available in the meeting binder and on the FDA website.

- **Quarterly Clinical Modules**
  R Page presented an update on last quarter's Quarterly Clinical Module, *Rx Review Consultations among Health First Colorado Members with Heart Failure*. The Colorado Rx Review Program helps identify Medicaid members with significant chronic medical conditions and provide them with the opportunity to participate in a free and comprehensive medication review. Clinically significant drug related problems were identified, whether or not they were connected to the primary disease state of heart failure. An increase in members' post-consult comfort level with proper use of their medications, compared to pre-consult levels, was found to be statistically significant ($p<0.001$).
  The Colorado Evidence-based Drug Utilization Review team is currently working on clinical modules to evaluate (1) non-oral antipsychotic utilization among Health First Colorado Members (particularly long-acting injectables), and (2) medication use within certain metabolic drug classes, including medications used for weight loss.

- **Retrospective DUR Report**
  R Page presented the RDUR summary and referred Board members to today's meeting binder for more details.

- **Quarterly Drug Utilization Reports**
  R Page presented highlights from this quarter's drug utilization reports. Ventolin, gabapentin, amoxicillin, sertraline, cetirizine and omeprazole were the top drug products by claim count during the 2nd quarter of 2023. Humira, Trulicity, Biktarvy, Trikafta, Dupixent and Taltz were among the top product claims by cost. Board members were referred to utilization reports in the meeting binder for more details.

8. New Business

The New Business section of today's agenda covers the review of proposed criteria for the PDL Drug Classes scheduled for August along with several products being reviewed for addition to Appendix P (and/or Appendix Y).

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.
- There will be an opportunity for Board discussion.
- 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

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

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

Red indicates proposed deleted text
Yellow indicates proposed new text

1. Bone Resorption Suppression and Related Agents

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.

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 for 12 months (failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction) **OR**
- Member cannot swallow 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:
  - Osteoporosis, (BMD T-scores of -2.5 or less) primary or
  - Male hypogonadismal in men
  - 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 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: 20mcg 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 preferred bisphosphonate for 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

- T Brubaker moved to accept the criteria as written. Seconded by B Jackson. Motion passed unanimously.

2. Diabetes Management Classes – Insulins

a. Insulins - Long-acting

Preferred Agents
LANTUS (insulin glargine) vial, Solostar
LEVEMIR (insulin detemir) vial, FlexTouch

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

b. Insulins – 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).

Discussion

- Concentrated Insulin was moved this quarter from Short-Acting Insulins into a new subclass.
- J Taylor explained that PA criteria for non-preferred products in the Concentrated Insulins subclass were added, even though there is currently only one product in the subclass, in order to cover any new concentrated insulin products that might come to market in the future.
- L Claus moved to change the failure definition in the Short-Acting insulin subclass to "lack of efficacy, allergy or intolerable side effects" and to accept the proposed criteria as amended. Seconded by S Klocke. Motion passed unanimously.

3. Diabetes Management Classes – Non-insulins

a. Glucagon-like Peptide-1 Receptor Agonists (GLP-1 Analogues)

Preferred Agents

***Must meet eligibility criteria**

*BYETTA (exenatide)
*TRULICITY (dulaglutide)
*VICTOZA (liraglutide)

*Preferred products may be approved for members with a diagnosis of type 2 diabetes. following a 3-month trial of (or documented contraindication to) metformin prior to initiation of therapy.

Non-preferred products may be approved for members with a diagnosis of type 2 diabetes following trial and failure of a 3-month trial of metformin AND a 3-month trial 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

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

Discussion

- A question was raised about periodic drug shortages affecting the GLP-1 inhibitors. J Taylor explained that the Pharmacy Call Center has a process in place through which their team confirms the shortage and evaluates if members are able to receive an alternative product through approval of a non-preferred product.
- P Lanius moved to accept the proposed criteria as written. Seconded by T Brubaker. Motion passed unanimously.

b. Sodium-Glucose Cotransporter 2 inhibitors (SGLT-2is)

Preferred Agents
FARXIGA (dapagliflozin)
INVOKANA (canagliflozin)
JARDIANCE (empagliflozin)

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.

Use of FARXIGA (dapagliflozin), INVOKANA (canagliflozin) and JARDIANCE (empagliflozin) are for glycemic control in patients without established CV disease or CV risk factors is not recommended when eGFR is <45 mL/min/1.73 m^2 contraindicated in members on dialysis. Use of FARXIGA (dapagliflozin) for chronic kidney disease or heart failure is not recommended when eGFR is < 20 mL/min/1.73 m^2.

Use of INVOKANA (canagliflozin) or JARDIANCE (empagliflozin) for glycemic control in patients without established cardiovascular disease or cardiovascular risk factors is not recommended when eGFR is <30 mL/min/1.73 m^2. Use of JARDIANCE (empagliflozin) for chronic kidney disease or heart failure is not recommended when eGFR is < 20 mL/min/1.73 m^2. JARDIANCE (empagliflozin) is contraindicated in members on dialysis.

STEGLATRO (ertugliflozin) therapy is not recommended in patients with an eGFR <45 mL/min/1.73 m^2 and it is contraindicated in patients on dialysis. it is contraindicated in patients on dialysis.

INPEFA (sotagliflozin) is not indicated for glycemic control. The safety and efficacy of INPEFA in patients with an eGFR less than 25 mL/min/1.73 m^2 or on dialysis has not been established.

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

Discussion

- B Jackson moved to convert the renal dosing limitations safety information in this section to a table format in order to improve readability as a reference for prescribers. Seconded by L Claus. Motion passed with six votes in favor. T Brubaker abstained due to not being available for this vote.
- K MacIntyre moved to accept the proposed criteria as amended. Seconded by B Jackson. Motion passed with six votes in favor. T Brubaker abstained due to not being available for this vote.

c. Sodium-Glucose Cotransporter 2 inhibitors (SGLT-2is) Combination with Metformin

Preferred Agents
INVOKAMET (canagliflozin/metformin)
INVOKAMET XR (canagliflozin/metformin)
SYNJARDY (empagliflozin/metformin) tablet
SYNJARDY XR (empagliflozin/metformin ER) tablet
XIGDUO XR (dapagliflozin/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.

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.

SEGLUROMET therapy is not recommended when eGFR is less than 45 mL/min/1.73 m^2 and it is contraindicated in patients with an eGFR less than 30 mL/min/1.73 m^2 or on dialysis.

Discussion

- I Pan moved to accept the proposed criteria as written. Seconded by S Klocke. Motion passed with six votes in favor. T Brubaker abstained due to not being available for this vote.

4. 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.

SEGLUROMET therapy is not recommended when eGFR is less than 45 mL/min/1.73 m^2 and it is contraindicated in patients with an eGFR less than 30 mL/min/1.73 m^2 or on dialysis.

Discussion

- P Lanius moved to accept the proposed criteria as written. Seconded by B Jackson. I Pan moved to accept the proposed criteria as written. Seconded by S Klocke. Motion passed with six votes in favor. T Brubaker abstained due to not being available for this vote.

5. Overactive Bladder Agents

Preferred Agents
GELNIQUE (oxybutynin) gel packets
MYRBETRIQ (mirabegron) tablet
Oxybutynin IR, ER tablets, syrup
Oxybutynin ER tablets
Solifenacin tablet
TOVIAZ[BNR] (Fesoterodine ER) tablet

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

- S Klocke moved to accept the proposed criteria as written. Seconded by P Lanius. Motion passed with six votes in favor. T Brubaker abstained due to not being available for this vote.

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.*

12. Androgenic Agents – Topical, Injectable, Oral

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

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).

7. Contraceptives – Topical

Preferred Agents
ANNOVERA (segesterone acetate/EE) vaginal ring
NUVARING[BNR] (etonorgestrel/EE) vaginal ring
PHEXXI (lactic acid/citric acid/potassium) vaginal gel
TWIRLA (levonorgestrel/EE) 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 acid/potassium) vaginal gel may be approved for members who meet the following criteria:
- Medication is being prescribed for the prevention of pregnancy **AND**
- Member is unable to use any of the following methods of contraception due to failure, contraindication, intolerance, or preference:
  - Injection (such as medroxyprogesterone acetate)
  - Oral Contraceptive
  - Transdermal Patch
  - Vaginal Contraceptive Ring
  - Diaphragm
  - Cervical Cap

  AND
- PHEXXI (lactic acid/citric acid/potassium) is not being prescribed concomitantly with a vaginal ring product, **AND**

- Provider attests that member has been counseled regarding a higher rate of pregnancy prevention with the use of other methods of contraception (such as injection, oral contraception, transdermal patch, vaginal ring) as compared to PHEXXI.

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.

8. Diabetes Management Classes - Insulins

a. Insulin – Rapid-acting

Preferred Agents
HUMALOG (insulin lispro) 100U/mL pen [BNR],
HUMALOG (insulin lispro) KwikPen, cartridge, vial
HUMALOG Jr. (insulin lispro) KwikPen[BNR]
Insulin aspart cartridge, pen, vial
Insulin lispro vial
NOVOLOG (insulin aspart) cartridge, vial, FlexTouch pen

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. (fFailure 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. Insulin – 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. Insulin – 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. Insulin – 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).

9. Diabetes Management Classes – Non-Insulins

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

c. Dipeptidyl Peptidase-4 Enzyme Inhibitors (DPP-4is) and Combinations

Preferred Agents
***Must meet eligibility criteria**
*JANUMET (sitagliptin/metformin)
*JANUMET XR (sitagliptin/metformin)
*JANUVIA (sitagliptin) tablet
*JENTADUETO (linagliptin/metformin)
*JENTADUETO XR (linagliptin/metformin)
*TRADJENTA (linagliptin) tablet

*Approval for preferred products require a 3-month trial of (or documented contraindication to) metformin prior to initiation of therapy.

Non-preferred DPP-4 inhibitors may be approved after a member has failed a 3-month trial of metformin AND a 3-month trials 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, 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	FDA Approved Maximum Daily Dose
Alogliptin (generic Nesina)	25 mg/day
Alogliptin/metformin tablet	25 mg alogliptin/ 2,000 mg metformin
Janumet and Janumet XR (sitagliptin/metformin)	100 mg sitagliptin/ 2,000 mg of metformin
Januvia (sitagliptin)	100 mg/day
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
Nesina (alogliptin)	25 mg/day
Onglyza (saxagliptin)	5 mg/day
Tradjenta (linagliptin)	5 mg/day

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.

d. 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.

e. Thiazolidinediones (TZDs) and Combinations

Preferred Agents
Pioglitazone

Non-preferred agents may be approved following trail and failure of metformin AND 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.

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

f. Other Hypoglycemic 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).

10. Estrogen Agents

a. Oral/Transdermal

Preferred Agents
CLIMARA[BNR] (estradiol) patch
Estradiol oral tablet
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.

11. Glucagon, Self-administered

Preferred Agents
BAQSIMI (glucagon) nasal spray
GLUCAGEN HYPOKIT (glucagon)
Glucagon Emergency Kit *(Eli Lilly and Amphastar only)*
ZEGALOGUE (dasiglucagon) autoinjector

Non-preferred products may be approved if the member has failed treatment with BAQSIMI (glucagon) or ZEGALOGUE (dasiglucagon) autoinjector AND one other 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 second-line preferred and non-preferred all products: 2 doses per year unless used/damaged/lost.

12. 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).
- Member has a qualifying diagnosis:
  - 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)
- Prescription does not exceed limitations for FDA-labeled maximum dosing for prescribed indication based on prescriber submission/verification of patient weight from most recent clinical documentation

Table 1: Growth Hormone Product Maximum Dosing*		
Medication	**Pediatric Maximum Dosing (age < 18 years)**	**Adult Maximum Dosing (age ≥ 18 years)**
Genotropin	0.4833 mg/kg/week	0.08 mg/kg/week
Humatrope	0.47 mg/kg/week	0.0875 mg/kg/week
Norditropin Flexpro	0.47 mg/kg/week	0. 112 mg/kg/week
Nutropin AQ Nuspin	0.375 mg/kg/week	0..175 mg/kg/week for ≤35 years of age 0. 875 mg/kg/week for >35 years of age
Omnitrope	0.48 mg/kg/week	N/A 0.08 mg/kg/week
Saizen	0.18 mg/kg/week	N/A 0.01 mg/kg/day
Serostim	Not Indicated	42 mg/week for cachexia with HIV only (in combination with antiretroviral therapy)
Skytrofa	0.24 mg/kg/week	N/A 0.24 mg/kg/week
Zomacton	0.47 mg/kg/week	N/A 0.0125 mg/kg/day
Zorbtive	Not Indicated	8 mg/28 days for short bowel syndrome only
*Based on FDA labeled indications and dosing		

13. Phosphate Binders

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

Prior authorization for non-preferred products in this class may be approved if member meets all the following criteria:
- Member has diagnosis of end stage renal disease AND
- Member has elevated serum phosphorus [> 4.5 mg/dL or > 1.46 mmol/L] AND
- Provider attests to member avoidance of high phosphate containing foods from diet AND
- Member has trialed and failed‡ one preferred agent (lanthanum products require trial and failure‡ of a preferred sevelamer product).

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

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

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

Maximum Dose: Velphoro 3,000mg 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.

14. 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.

15. Antihyperuricemics

Preferred Agents
Allopurinol tablet
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 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

Discussion of Mass Review Section
- The Board discussed the recent removal of Androderm, a preferred product, from the U.S. market. J Taylor clarified that the Department chose to leave Androderm listed as preferred drug, for now, in case pharmacies still have the product in stock. This will allow any claims for the product to continue to pay.
- The Department was asked to review the proposed pediatric maximum dose for Skytrofa (growth hormone) of 0.24 mg/kg/week. For example, members weighing 11.5 kg would likely receive a dose of Skytrofa of 3 mg/week, which is a weight-based dose of 0.26 mg/kg/week. This situation may apply to other FDA-approved weight-based dosing levels for Skytrofa.
- It was noted that Boolean Operators (AND, OR) are missing from the criteria for non-preferred Growth Hormone products. This will be corrected for the final version of criteria posted on the PDL.
- K MacIntyre moved to accept criteria in the Mass Review section of the agenda as written. Seconded by I Pan. Motion passed unanimously.

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

R Poissant proceeded with the review process of proposed criteria for Non-PDL Products and asked if any Board members had conflicts of interest related to the seven products on today's agenda. No Board members reported a conflict of interest.

1. **Elevidys (delandistrogene moxeparvovec-rokl) single-dose intravenous infusion**

Elevidys (delandistrogene moxeparvovec-rokl) 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 aged 4 through 5 years **AND**
3. Member has a diagnosis of Duchenne Muscular Dystrophy (DMD) with a confirmed mutation in the *DMD* gene **AND**

4. Member is ambulatory and provider has performed and documented a functional level determination of baseline assessment of ambulatory function **AND**
5. Member does not have either of these conditions:
    a. elevated anti-AAVrh74 total binding antibody titers (≥1:400) based on ELISA testing
    b. any deletion in exon 8 and/or exon 9 in the *DMD* gene
6. Requested medication is being prescribed by or in consultation with a neurologist or a provider who specializes in treatment of DMD (such as a pediatric neurologist, cardiologist, or pulmonary specialist) **AND**
7. Provider attests that baseline liver function (clinical exam, GGT, total bilirubin), platelet count, and troponin-I will be assessed prior to Elevidys infusion and also monitored following the infusion according to product labeling **AND**
8. The member must be on corticosteroids at baseline or prescriber provides clinical rationale for not using corticosteroids AND
9. Provider has evaluated, and member has received, all age-appropriate vaccinations as recommended by current immunization guidelines prior to initiation of the corticosteroid regimen **AND**
10. Provider and patient or caregiver are aware that continued US FDA approval of Elevidys (delandistrogene moxeparvovec) for Duchenne muscular dystrophy (DMD) may be contingent upon verification and description of clinical benefit in confirmatory trial(s).
11. Above coverage standards will continue to be reviewed and evaluated for any applicable changes due to the evolving nature of factors including disease course, available treatment options, and available peer-reviewed medical literature and clinical evidence.

Maximum dose: one kit containing 70 single-dose 10 mL vials

Approval will be placed to allow for one treatment course

Scheduled Speaker Testimony
Stephanie Kennedy – Sarepta
Brian Denger – Community Engagement; Parent Project Muscular Dystrophy; Washington, D.C.
Susan Apkon, MD – Chief, Department of Rehabilitation, Children's Hospital Colorado
Anne Stratton, MD – Pediatric Physical Medicine and Rehabilitation, Children's Hospital Colorado
Amy Aikins – Director, Government and Social programs, Little Hercules Foundation
Erica Hill – Member of the public; Medicaid member/patient advocate

Submitted Written Testimony
Susan Apkon, MD – Chief, Department of Rehabilitation, Children's Hospital Colorado
Lauren Stanford – Director of Advocacy, Parent Project Muscular Dystrophy, Washington, D.C.

Discussion
- There was some discussion about whether this product should always be administered in a clinic or hospital setting rather than in a member's home or a long-term care (LTC) facility. J Taylor explained that the statement regarding administration in a member's home or long-term care facility is related to a standard policy that allows physician administered drugs to be covered under the pharmacy benefit, should such a situation arise. This language is frequently included in DUR criteria for medications that must be administered by a health care professional.
- The Board also discussed the possibility of members "aging out" past the 5-year-old maximum age for Elevidys administration. The Department clarified that as long as the prior authorization is submitted prior to the child's 6th birthday, there could be a window for dose administration delays due to illness, etc.
- K MacIntyre moved to add *physical medicine and rehabilitation specialist* to the provider types listed in bullet point 6. Seconded by I Pan. Motion passed unanimously.
- B Jackson moved to accept criteria as amended. Seconded by K MacIntyre. Motion passed unanimously.

2. Daybue (trofinetide) oral solution

Daybue (trofinetide) may be approved if the following criteria are met:
1. Member is ≥ 2 years of age **AND**
2. Member has been diagnosed with Rett syndrome with a documented mutation in the *MECP2* gene **AND**
3. Member does not have moderate to severe renal impairment **AND**
4. Requested medication is being prescribed by or in consultation with a neurologist or developmental pediatrician **AND**
5. Member or parent/caregiver has been counseled regarding the potential risks of diarrhea and dehydration associated with Daybue (trofinetide) therapy and to avoid pre-treatment laxative use, **AND**
6. Prescriber has performed baseline symptom assessment **AND**
7. Based on limited available clinical evidence for the use of trofinetide, the prescriber has engaged in shared decision making with the member/parent/caregiver prior to prescribing this medication.

Initial Approval: 3 months

Reauthorization: Daybue (trofinetide) may be approved for 1 year with provider attestation that:
- a follow-up symptom assessment has been performed, **AND**
- the member's clinical status is stable or improved and also free of persistent severe diarrhea, episodes of severe dehydration, or significant weight loss.

Dosing limitations:

Patient Weight	Daybue Dosage	Daybue Volume
9 kg to less than 12 kg	5,000 mg twice daily	25 mL twice daily
12 kg to less than 20 kg	6,000 mg twice daily	30 mL twice daily
20 kg to less than 35 kg	8,000 mg twice daily	40 mL twice daily
35 kg to less than 50 kg	10,000 mg twice daily	50 mL twice daily
50 kg or more	12,000 mg twice daily	60 mL twice daily

Quantity limit: four 450 mL bottles/14 days (1,800 mL/14 days)

Scheduled Speaker Testimony
Stacey Repotski — Acadia Pharmaceuticals Inc.
Heidi Hedges-Greenall – Member of the public; patient advocate

Discussion
- B Jackson moved to accept criteria as written. Seconded by S Klocke. Motion passed unanimously.

3. Joenja (leniolisib) oral tablet

Joenja (leniolisib) may be approved if the following criteria are met:

1. Member is ≥ 12 years of age and weighs at least 45 kg, **AND**
2. Member has been diagnosed with activated phosphoinositide 3-kinase delta (PI3K-delta) syndrome (APDS) with a documented variant in either *PIK3CD* or *PIK3R1* **AND**
3. Requested product is being prescribed by or in consultation with an immunologist **AND**

4. Member does not have moderate to severe hepatic impairment **AND**
5. Member is not pregnant **AND**
6. Member has not received a B-cell depleting medication within 6 months of starting leniolisib therapy **AND**
7. Member has not received an immunosuppressive medication or another PI3K-delta inhibitor within 6 weeks of starting leniolisib therapy **AND**
8. Members of reproductive potential have been advised to avoid breastfeeding and to use effective contraception during and after treatment with Joenja (leniolisib), according to FDA product labeling.

Approval: 1 year

Maximum dose: 140 mg/day

Quantity limit: 60 tablets/30 days

Scheduled Speaker Testimony
Jordan Abbott, MD, MA – Division of Allergy and Immunology, University of Colorado School of Medicine and Children's Hospital Colorado

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

4. Furoscix (furosemide) on-body infusor

Furoscix (furosemide on-body infusor) may be approved if the following criteria are met:

1. Member is ≥ 18 years of age, **AND**
2. Member has a documented diagnosis of NYHA Class II/III chronic heart failure **AND**
3. Member has tried and failed† at least one of the following oral therapies:
    a. furosemide ≥ 160 mg daily
    b. torsemide 40 mg daily
    c. bumetanide 4 mg daily

    AND
4. Member has tried and failed† the addition of oral metolazone to oral loop diuretic therapy **AND**
5. Prescriber confirms that the member has a history of at least one prior hospitalization or emergency department visit due to heart failure exacerbation and/or fluid overload **AND**
6. The requested medication is being prescribed by or in consultation with a cardiologist **AND**
7. Prescriber understands that the Furoscix (furosemide) is intended for short-term use in the outpatient setting **AND**
8. Provider attests that member will be educated on proper infusor placement on the body, instructions for starting the infusion, and safe disposal of the used infusor device.

Quantity limit: 7 pre-filled 80 mg/10 mL cartridges plus infusors per 30 days

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

Discussion
- B Jackson moved to accept criteria as written. Seconded by S Klocke. Motion passed unanimously.

5. Cuvrior (trientine tetrahydrochloride) oral tablet

Cuvrior (trientine tetrahydrochloride) may be approved if the following criteria are met:

1. Member is ≥ 18 years of age **AND**
2. Member has a diagnosis of stable Wilson's Disease meeting at least one of the following criteria:
    - Hepatic parenchymal copper content of ≥250 mcg/g dry weight
    - Presence of Kayser-Fleischer ring in cornea
    - Serum ceruloplasmin level <50 mg/L
    - Basal 24-hour urinary excretion of copper > 100 mcg (1.6 micromoles)
    - Genetic testing results indicating mutation in *ATP7B* gene
3. Requested product is being prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant specialist **AND**
4. Member has failed a three-month trial or is intolerant to penicillamine. Failure is defined as a lack of efficacy, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions **AND**
5. Member has failed a three-month trial of trientine. Failure is defined as a lack of efficacy, allergy, intolerable side effect or significant drug-drug interaction.

Approval: 1 year

Maximum dose: 3,000 mg/day

Quantity limit: 300 tablets/30 days

Discussion

- There was discussion about the FDA product labeling, "*treatment of adult patients with stable Wilson's disease who are de-coppered and tolerant to penicillamine*" and the language in bullet point 4 that member must have "*failed a three-month trial or is intolerant to penicillamine*" prior to approval of Cuvrior (trientine). This point will be taken back to the Department for further review and appropriate editing.
- S Klocke moved to accept criteria as written. K MacIntyre seconded. Motion passed unanimously.

6. Vowst (fecal microbiota spore, live-brpk) oral capsule

Vowst (fecal microbiota spore, live-brpk) may be approved if the following criteria are met:

1. Member is ≥ 18 years of age **AND**
2. Member has had a recent, positive *C. difficile* stool sample using a toxin assay **AND**
3. Member has a history of three or more *C. difficile* infection (CDI) episodes within the past 12 months (initial episode plus two recurrences) and has presented with a third or subsequent CDI episode **AND**
4. Treatment with the requested medication is following treatment of recurrent CDI with appropriate antibiotic therapy **AND**
5. Requested product is being prescribed by or in consultation with a gastroenterologist or infectious disease specialist **AND**
6. Antibacterial therapy for CDI has been discontinued 2 to 4 days prior to initiating Vowst therapy and concurrent antibacterial therapy will not be initiated during the 3-day course of Vowst therapy **AND**

7. Member has been evaluated to rule out dysphagia, known esophageal stricture, Zenker's diverticulum, gastroparesis, prior history of small bowel obstruction, prior colectomy or colostomy **AND**

8. Provider attests that member has (1) received instructions regarding the magnesium citrate (or polyethylene glycol electrolyte solution) pre-treatment regimen, and (2) has been advised to take nothing by mouth except water for at least 8 hours prior to taking the first dose of Vowst.

Approval will be placed to allow for one treatment course

Quantity limit: 12 capsules

Scheduled Speaker Testimony
Allyson Fonte, PharmD – Aimmune Therapeutics

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

7. Veozah (fezolinetant) oral tablet

Veozah (fezolinetant) may be approved if the following criteria are met:

1. Member is ≥ 18 years of age **AND**
2. Member has been diagnosed with moderate to severe vasomotor symptoms (such as hot flashes and sweating) associated with menopause **AND**
3. Member has tried and failed two alternate oral or transdermal estrogen-containing products. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction **OR** member has moderate to high risk for complications related to estrogen therapy **AND**
4. Member does not have known cirrhosis **AND**
5. Member does not have severe renal impairment (eGFR 15 to less than 30 mL/min/1.73 m^2) or end-stage renal disease (ESRD) **AND**
6. Member's baseline hepatic transaminases prior to starting fezolinetant therapy have been documented and are less than two times the upper limit of normal **AND**
7. Provider attests that hepatic transaminases will be closely monitored during fezolinetant therapy as described in the FDA product labeling **AND**
8. Member is not taking a medication that is a CYP1a2 inhibitor (fluvoxamine, mexiletine, cimetidine, omeprazole, and others)

Approval: 1 year
Maximum dose: one 45 mg tablet/day
Quantity limit: 30 tablets/30 days

Discussion
- The Board discussed possibly including cigarette smoking as an additional example of a CYP1A2 inhibitor. However, according to product labeling, there were no clinically significant differences in fezolinetant exposure in smokers during clinical trials.
- A request was made to remove omeprazole from the list of medications in bullet point 8, as it is a CYP1A2 inducer, not a CYP1A2 inhibitor.
- K MacIntyre moved to accept criteria as written. Seconded by B Jackson. Motion passed unanimously.

C. PDL Coverage Change for Generic Product Strength

- Diclofenac potassium 25 mg tablet

Diclofenac potassium 25 mg immediate-release tablets may be approved if the following criteria are met:

1. Member is ≥ 18 years of age **AND**
2. Member does not have a history any of the following medical conditions:
    a. history of recent coronary artery bypass graft (CABG) surgery
    b. history of myocardial infarction
    c. severe heart failure
    d. advanced renal disease
    e. history of gastrointestinal bleeding

    AND
3. Member has trial and failure† of four preferred oral NSAIDs at maximally tolerated doses

†Failure is defined as lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interactions.

Discussion

- J Taylor commented that today's review of diclofenac potassium 25 mg tablets is related to fraud, waste and abuse and cost utilization reviews that are monitored by the Department on a regular basis. Recent reports showed that diclofenac potassium 25 mg tablets were associated with a significant price increase. Based on this price increase, the 25 mg strength (only) of diclofenac potassium was moved to non-preferred status on the PDL on July 31, 2023.
- S Klocke mentioned that diclofenac is used to treat trigeminal autonomic cephalgia and asked if 50 mg diclofenac potassium tablets may be cut in half to obtain a 25 mg dose for use in certain patients. This question will be researched further by the Department.
- S Klocke moved to accept the criteria as written. Seconded by T Brubaker. Motion passed unanimously.

C. Adjournment

J Taylor expressed his thanks to the DUR Board members. Dr. Taylor also expressed his thanks and appreciation to the individuals who presented special testimony during today's meeting and noted that verbal testimony is integral to the public process.

Board Chair Claus reminded attendees that the next Board meeting is tentatively scheduled for Tuesday, November 14, 2023, 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 S Klocke. Motion passed unanimously.

The meeting was adjourned at 3:34 pm.

Minutes respectfully submitted by Julia Rawlings, PharmD