July 2022 DUR Board Meeting Minutes

Date: July 13, 2022

Members Present: Barnhill, Blake, Blank, Brown, Caldwell, Jost, Nauts

Members Absent: Anglim, Maxwell, McGrane, Putsch, Stone

Others Present: Katie Hawkins, Shannon Sexauer, Dani Feist, (DPHHS); Bahny, Doppler, Miranda, Opitz, Woodmansey (MPQH); and representatives from the pharmaceutical industry.

Introductions: The Board was provided with an update regarding the pharmacy department staffing changes within Mountain Pacific. Marcella Barnhill was introduced as the DUR Coordinator, Jennifer Miranda as the Pharmacy Case Management Supervisor, and Courtney Bahny as the Drug Prior Authorization Supervisor, replacing Angie Opitz**.**

Public Comment:

- Mariola Vazquez - Leo Pharma - Adbry®
- Victoria Romo-LeTourneau - Pfizer - Cibinqo®
- Shirley Quach - Novartis - Leqvio®
- Charlie Lovan - AbbVie - Rinvoq®
- Mark Maneval - Boehringer Ingelheim - Jardiance®

Meeting Minute Review: The meeting minutes from the May 25, 2022 Preferred Drug List (PDL) Board Meeting were approved as written.

Department Update:

Mike Randol Introduction:

Dani Feist introduced Mike Randol, who has been selected as the Executive Director of the Health Services Branch, who will also serve as the new Medicaid Director. Mike has a comprehensive understanding of Medicaid and is an experienced leader. His most recent role was Senior Director with Cerner Corporation, leading the product development team for Medicaid technology solutions. Mike has also served as the Iowa Medicaid Director and Kansas State Medicaid Director. Prior to these roles, Mike was the Veterans Services Manager for the Kansas Department of Commerce. Before joining public service, Mike was a Vice-President with US Bank Corporate Payment Systems. Mike retired from the military where he served as a proud member of the United States Air Force. Mike holds a Master of Business Administration degree from William Woods University with an emphasis in finance, as well as a Bachelor of Science degree in accounting from the University of the State of New York. He started his position on May 31st.

Public Health Emergency (PHE) Unwind:

DPHHS has started some communication regarding unwinding of the PHE. DPHHS is asking healthcare providers for their help in ensuring they have the most accurate information for Montana Medicaid members. For example, ensuring the address Medicaid has on file is current, when they check the MATH portal. This is important because when the PHE ends, DPHHS will begin the process of redetermining eligibility for all current Medicaid members. For more information regarding this, please refer to the Provider Notice posted on the provider webpage. Additionally, there is a link and little blurb in the Summer 2022 DUR Newsletter.

Board Discussion

1. Updates:

A. DPHHS has requested approval to allow step-through requirements for new medications which are the same molecule as a medication that had previously been reviewed, without bringing them back for Board review. The Board has approved this request and has requested that if the medication is significantly different than the previously approved molecules, that it be brought back for review.

B. The Board was presented with a proposed, updated, meeting format. The proposed format is below and approved by the Board members. This format will become effective at the next DUR Board meeting.

Items that will be presented to the Board for further review (similar to the Red category for the PDL meetings):

1. **A new drug that is a novel agent or first in class.**
2. **Drugs that have criteria previously approved, but that have new indications that significantly alter the standing criteria.**
3. **Criteria change on an entire category of medications.**

The following types of criteria will be sent out in advance of the meeting. These items are to be reviewed prior to the meeting (similar to the Blue category for the PDL meetings):

1. **New drugs with criteria limited to diagnosis, age, quantity limits that come directly from FDA indications** (not studies).
2. **Non-preferred drugs that will require a step through one specific PDL preferred medication.**
3. **New FDA indication on a drug that has previous criteria that was Board approved. Criteria will not be substantially change, just updated with the new indication.**

2. SGLT2 Category Discussion

During the Preferred Drug List (PDL) process, the Board requested that the criteria for the SGLT2s be brought back for further review to determine if the criteria requirements are still appropriate. When established, the criteria included only Type 2 Diabetes Mellitus (DM). In recent years, the indications have expanded to include Heart Failure with and without reduced ejection fraction (HFrEF and HFpEF) Based on this information, and additional information provided to Board members, the Board has recommended that the clinical criteria for the SGLT2 products be removed.

3. LAMA/SAMA Therapeutic Duplication (TD) Discussion

During a COPD Academic Detailing Project, performed by a pharmacy case management pharmacist, it was discovered that the TD criteria between LAMAs and SAMAs were preventing members from getting either their COPD maintenance inhaler (LAMA) at times or preventing them from getting ipratropium containing products (SAMA containing inhaler or nebulizer solution) which was most often needed for a COPD exacerbation, while also being prescribed guideline directed maintenance COPD medications (LABA/LAMA). Originally, the criteria was put in place due to provider concerns for

increased anticholinergic side effects between LAMAs and SAMAs. After reviewing claims data and discussing with providers, it was felt the benefits of the combination exceeded the risks and the board moved to have the TD criteria removed to ensure members had access to both the LAMA and SAMA when needed.

4. Drug Criteria Review:

A. Dartisla® ODT (glycopyrrolate)

Initial Coverage Criteria

Member must meet all the following criteria:

- The member is 18 years of age or older.
- The member has a diagnosis of peptic ulcer disease.
- The member will be using Dartisla® ODT as an adjunct to treatment of peptic ulcer disease (i.e., proton pump inhibitors or histamine H2 antagonists) AND has been compliant with that treatment.
- The member has experienced therapeutic failure, contraindication, or intolerance to generic glycopyrrolate tablets.
- **Limitations:**
  - Maximum dose limit is 6.8mg per day (4 tablets daily).
  - Initial coverage authorization will be granted for 6 months.

Renewal Coverage Criteria

Member must meet all the following criteria:

- The member's peptic ulcer disease has not resolved or has recurred.
- The member will be using Dartisla ODT® as an adjunct to treatment of peptic ulcer disease AND has been compliant with that treatment.
- The prescriber attests that the member has experienced positive clinical response to therapy.
- **Limitations:**
  - Maximum dose limit is 6.8mg per day (4 tablets daily).
  - Renewal authorization will be granted for 1 year.

B. Seglentis® (celecoxib and tramadol hydrochloride)

Initial Coverage Criteria

Member must meet all the following criteria:

- Member is using Seglentis® for acute pain (not indicated for chronic pain).
- Member must be 18 years of age or older.
- Clinical rationale why the medications cannot be taken separately (not convenience) is required.
- Member will not be taking additional celecoxib or tramadol dosages.
- **Limitations:**
  - Quantity limit is 4 tablets daily.
  - Initial coverage authorization will be granted for one (1) 30-day fill.

Renewal Coverage Criteria

Member must meet all of the following criteria:

- Authorization may be renewed in 30-day increments.
- **Limitations:**
  - Quantity limit is 4 tablets daily.
  - The maximum quantity approved is three (3) 30-day fills (including the initial fill)
    - Approvals beyond three (3) consecutive months of therapy will not be approved.

C. Belbuca® (buprenorphine buccal film)

- Belbuca® is a non-preferred product in the Long-Acting Opioid PDL category which does not allow concurrent treatment with more than one agent.
- Member has had an inadequate treatment response, intolerance, or contraindication to the preferred long-acting buprenorphine pain management product on the PDL.
- **Limitations:**
  - Quantity limit is 2 buccal films daily.
  - Maximum dose limit is 900mcg every 12 hours.
  - Initial coverage authorization will be granted for 1 year.
  - Renewal authorization will be granted for 1 year

D. Vtama® (tapinarof)

Initial Coverage Criteria

Member must meet all the following criteria:

- Diagnosis of plaque psoriasis.
- Member must not be pregnant.
- Member is at least 18 years old.
- Member has tried a preferred high potency topical steroid.
- Member must have trialed a preferred calcipotriene agent, subject to the current PDL.
- **Limitations:**
  - Quantity limit is one (1) 60gm tube per 28 days.
  - Initial coverage authorization will be granted for 6 months.

Renewal Coverage Criteria

Member must meet all the following criteria:

- Provider attests that the member has shown improvement in condition over baseline.
- **Limitations:**
  - Quantity limit is one (1) 60gm tube per 28 days.
  - Renewal authorization will be granted for 1 year.

E. Ibsrela® (tenapanor)

Initial Coverage Criteria

Member must meet all the following criteria:

- Subject to PDL requirements (PDL class wide requirement).

- Member must be 18 years of age or older (Black box warning in <18y/o).
- Diagnosis of irritable bowel syndrome with constipation (IBS-C).
- Member must have been unsuccessful with documented treatment with at least one (1) osmotic laxative (i.e., polyethylene glycol, lactulose, etc). **The Board requested that other medications for IBS-C with criteria for failure of stimulant laxative and lactulose be updated to match this criteria bullet as well.**
- **Limitations:**
    - Maximum dose limit is 100mg (two 50mg tabs) per day.
    - Initial coverage authorization will be granted for 1 year.

Renewal Coverage Criteria

Member must meet all the following criteria:

- Member has experienced a positive clinical response.
- **Limitations:**
    - Maximum dose limit is 100mg (two 50mg tabs) per day.
    - Renewal authorization will be granted for 1 year.

F. Orexin Receptor Antagonists - Belsomra® (suvorexant), Dayvigo® (lemborexant), & Quviviq® (daridorexant)

Initial Coverage Criteria

Member must meet all the following criteria:

- Member must at least 18 years old.
- Member must have a diagnosis of insomnia with NO history of narcolepsy.
    - **These medications will not be approved if member has a history of narcolepsy.**
- Prescriber is aware of the increased risk of suicidal ideations with Orexin Receptor Antagonists and has discussed this with the member.
- Provider is aware of interaction of Orexin Receptor Antagonists with other CNS depressants (i.e., opioids, ethanol, etc.) and has discussed this with the member.
- Prescriber has considered or recommended clinic based, or electronically delivered, Cognitive Behavioral Therapy and Mindfulness for insomnia.
- Member must have a documented inadequate response or contraindication to **TWO** (2) of the following in the past 24 months, for a minimum trial of 14 days each: zolpidem, eszopiclone, or zaleplon.
- Member must have a documented inadequate response or contraindication to low dose doxepin in the past 24 months, for a minimum trial of 14 days.
- For Dayvigo® or Quviviq® requests, the member must have had an inadequate response or contraindication to Belsomra® first.
- **Limitations:**
    - Maximum dose is 1 tablet daily.
    - Initial approval granted for 3 months.
    - Duplication with other sedative hypnotics will not be approved.

Renewal Coverage Criteria

Member must meet all the following criteria:

- Provider attests that member has experienced a positive clinical response.
- **Limitations:**
    - Maximum dose is 1 tablet daily.
    - Renewal authorization will be granted in increments of 6 months.
    - Duplication with other sedative hypnotics will not be approved.

G. Juxtapid® (lomitapide)

Initial Coverage Criteria

Member must meet all the following criteria:

- Member must be 18 years of age or older.
- Member must have a diagnosis of homozygous familial hypercholesterolemia (HoFH).
- Must be prescribed by, or in consult with, a cardiologist, endocrinologist, or lipidologist.
- Member has an LDL-cholesterol of equal to or greater than 70mg/dl.
- Member must have trialed at least TWO high-intensity statins for at least 12 weeks each AND will continue receiving maximally tolerated high-intensity statin therapy unless ineffective or contraindicated.
- Member has trialed ezetimibe for at least 12-weeks and has been ineffective or contraindicated.
- Member has trialed a PCSK-9 Inhibitor for at least 12 weeks and has been ineffective or contraindicated.
- **Limitations:**
    - Maximum dose limit is 60mg per day.
    - Initial coverage authorization will be granted for 6 months.

Renewal Coverage Criteria

Member must meet the following criteria:

- Member has been adherent to Juxtapid®.
- Member has been adherent to statin at maximally tolerated dose.
- Member has experienced a positive clinical response as defined by a reduction in LDL-C.
- Annual specialist consult required if prescriber not a specialist**.**
- **Limitations:**
    - Maximum dose limit is 60mg per day.
    - Renewal authorization will be granted for 1 year.

H. Leqvio® (inclisiran)

Initial Coverage Criteria

Member must meet all the following criteria:

- Member must be 18 years of age or older.
- Must be prescribed by, or in consult with, a cardiologist, endocrinologist, or lipidologist.
- Member has an LDL-cholesterol equal to or greater than 70mg/dl.
- Member has diagnosis of either:
    - Heterozygous familial hypercholesterolemia (HeFH)
    - Atherosclerotic cardiovascular disease (ASCVD)

- Member must have trialed at least TWO high-intensity statins for at least 12 weeks each AND will continue receiving maximally tolerated high-intensity statin therapy unless ineffective or contraindicated.
- Member has trialed ezetimibe for at least 12-weeks and has been ineffective or contraindicated.
- Member will not be using this in combination with Juxtapid®, Repatha®, or Praluent®.
- **Limitations:**
    - Maximum dose limit is 284mcg SQ initially, again at 3-months, then every 6-months.
    - Initial coverage authorization will be granted for 9 months.

Renewal Coverage Criteria

Member must meet the following criteria:

- Member has been adherent to Leqvio®.
- Member has been adherent to statin at maximally tolerated dose.
- Member has experienced a positive clinical response as defined by a reduction in LDL-C.
- Annual specialist consult provided if prescriber not a specialist**.**
- **Limitations:**
    - Maximum dose limit is 284mcg SQ every 6-months.
    - Renewal authorization will be granted for 1 year.

I. Adbry® (tralokinumab-ldrm)

Initial Coverage Criteria

Member must meet all the following criteria:

- Member must be 18 years of age or older.
- Diagnosis of moderate-to-severe atopic dermatitis.
- Member has clinical documentation of functional impairment due to atopic dermatitis, which may include, but is not limited to, limitations to activities of daily living (ADLs), such as skin infections or sleep disturbances and a baseline assessment has been made to allow for documentation of positive clinical response.
- Member has had an inadequate treatment response*, intolerance, or contraindication to (in this order):
    - A preferred moderate to very high-potency topical corticosteroid AND
    - A topical immunomodulator (Elidel® or Protopic®).
- Member must not concurrently be receiving another biologic medication.
- **Limitations:**
    - Maximum dose limit is 600mg (4 X 150mg syringe) initially, then 300mg (2 X 150mg syringe) every 2 weeks.
    - Initial coverage authorization will be granted for 6 months.

*NOTE: Inadequate treatment response to topical therapy is defined as failure to achieve and maintain remission or a low disease activity state despite treatment with a daily regimen, applied for ≥ 28 days or for the maximum duration recommended by the product prescribing information (i.e., 14 days for high or very-high potency topical corticosteroids).

Renewal Coverage Criteria

Member must meet the following criteria:

- Member has documentation of positive clinical response to Adbry® (i.e., reduction in body surface area involvement, reduction in pruritus severity or decrease in severity index using a scoring tool).
- For yearly authorization, patient must continue to maintain improvement over baseline evaluation.
- **Limitations:**
    - Maximum dose limit is 300mg (2 X 150mg syringe) every 2 weeks.
    - Renewal authorization will be granted for 1 year.

J. Tezspire® (tezepelumab-ekko) (Physician Administered Drug)

Initial Coverage Criteria

Member must meet all the following criteria:

- Member must be 12 years of age or older.
- Member has diagnosis of severe asthma.
- Must be prescribed by, or in consult with, an appropriate specialist (Allergist/Pulmonologist/Immunologist).
- Member has a history of *severe* asthma attacks despite treatment with inhaled corticosteroid (ICS) in combination with long-acting beta$_2$-agonist (LABA) inhaler at optimized doses for three consecutive months.
- Member will continue to use ICS in combination with LABA inhaler at optimized dose.
- Provider attests that member will not use Tezspire® concomitantly with other biologics.
- **Limitations:**
    - Maximum dose limit is 210mg SQ every 4 weeks.
    - Initial coverage authorization will be granted for 1 year.

Renewal Coverage Criteria

Member must meet all the following criteria:

- Member has been adherent to Tezspire® AND ICS/LABA therapy.
- Member has experienced a positive clinical response (reduction in frequency and/or severity of symptoms and exacerbations or medication dose reduction).
- Annual specialist consult provided if prescriber not a specialist.
- **Limitations:**
    - Maximum dose limit is 210mg SQ every 4 weeks.
    - Renewal authorization will be granted for 1 year.

K. Cibinqo® (abrocitinib)

Review and discussion have been tabled for future meeting.

L. Rinvoq® (upadacitinib)

Review and discussion have been tabled for future meeting.

Closed Session:

All guests not affiliated with Mountain Pacific Staff, DPHHS, or Board members, left the meeting room (signed off) and the Board went into executive session to review one sensitive case request.

The meeting adjourned at 3:30pm