December 2020 DUR Board Meeting Minutes

Date: December 9, 2020

Members Present: King, Blake, Blank, Caldwell, McGrane, Jost, Brown, Putsch

Members Absent: Anglim, Maxwell, Nauts, Stone

Others Present: Shannon Sexauer, Dani Feist, Dan Peterson (DPHHS); Artis, Bahny, Barnhill, Doppler, Opitz, Woodmansey (MPQH); representatives of the pharmaceutical industry.

Introductions:
Tony King opened the meeting and asked the Board and members of the audience to introduce themselves. Dr. Michael Blake, Pediatrician, was introduced as the newest member of the Montana Healthcare Programs' Drug Utilization Review (DUR) Board.

Public Comment:
The Board was sent two letters from a provider requesting formulary changes. Board members reviewed the submitted information prior to today's meeting and agreed to add it to the agenda for an upcoming Preferred Drug List (PDL) meeting.

Meeting Minute Review:
The meeting minutes from October 21, 2020 DUR were approved as written.

Department Update:
No Department updates.

Board Discussion

1. **Existing Drug Criteria Updates**

   A. Namenda (memantine) – MPQH and the Department requested Board discussion to determine if current criteria is still appropriate or if it can be removed completely. After discussion, Board Members agreed to remove the existing criteria completely.

   B. Modafinil/armodafinil – MPQH and the Department requested Board discussion regarding removal of the diagnosis requirement in the existing criteria. The Board agreed to remove the criteria requirement but to keep the age limit (≥ 18 years of age or older) and the quantity limit of 1 per day.
   ****Board requested to review utilization in 1 year after implementation****

2. **Review of New Drug Criteria**

   The following clinical criteria were reviewed and the Board recommended approval and implementation as follows:

A. Xywav™ (calcium, magnesium, potassium, and sodium oxybates)

Member must meet ***all of the following criteria***:

- Member must be ≥ 7 years of age
- Diagnosis of narcolepsy with excessive daytime somnolence **AND** cataplexy (weak or paralyzed muscles) **– Both components must be present.**
- Diagnosis made using ICSD-3 or DSM-5 diagnostic criteria. The Board requested this criteria be added to Xyrem as well.
- Approval duration: 1 year
- Quantity limitations: Max dose is 9 gm per night.

Physician Administered Drugs (PAD):

B. Spravato™ (esketamine)

Initial Coverage Criteria (member must meet *all of the following criteria*):

- Member is 18 years of age or older.
- Must be prescribed by a psychiatric specialist.
- Member has a Diagnostic and Statistical Manual of Mental Disorders (DSM-5) diagnosis of major depressive disorder (MDD).
- Member must have a baseline depression assessment using a validated depression rating scale (e.g., MADRS, PHQ-9, HAM-D, etc.) within the last 2 weeks.
- Member is currently taking an oral antidepressant and will continue to take the oral antidepressant in conjunction with Spravato®.
- Member must have **one** of the following diagnoses:
    1. **Treatment-resistant depression (TRD)**, along with **all** of the following:
        a. Inadequate treatment response after at least 6 weeks duration at a generally accepted dose, intolerance, or contraindication to at least three antidepressants with different mechanisms of action in the current depressive episode.
        b. Inadequate treatment response, intolerance, or contraindication to augmented antidepressant therapy (with concomitant atypical antipsychotic, lithium, or other appropriate therapy) in the current depressive episode.
        c. Actively involved in psychotherapy or inadequate response to psychotherapy.

    OR

    2. **Major Depressive Disorder (MDD) with acute suicidal ideation or behavior.**
        a. Must provide documentation of psychiatric assessment of suicidal ideation or behavior.
- Member does not have aneurysmal vascular disease (including thoracic and abdominal aorta, intracranial and peripheral arterial vessels), arteriovenous malformation, or history of intracerebral hemorrhage.
- Provider attests to the following:

- Member's risk for abuse or misuse is assessed prior to initiating treatment and will be assessed periodically while on therapy.
- Member and facility are enrolled in the Spravato® REMS program.
- Treatment sessions will include post-treatment observation until clinically stable for a minimum of 2 hours.

- **Initial Coverage Duration and Quantity Limitations (first four weeks):**
  - Diagnosis of treatment-resistant depression (TRD):
    - Initial approval duration: 4 weeks
    - Initial quantity limitations: 56mg intranasally on day 1, and then 56mg or 84mg intranasally twice per week for an initial duration of four weeks.

  - Diagnosis of MDD in adults with acute suicidal ideation or behavior:
    - Initial approval duration: 4 weeks
    - Initial quantity limitations: 84mg intranasally twice per week (but dosage may be decreased to 54mg twice per week based on tolerability) for an initial duration of four weeks.

Renewal Coverage Criteria:

- Treatment-resistant depression (TRD):
  - Member has been compliant with an oral antidepressant and continues to meet the initial criteria.
  - Member has been compliant with Spravato® therapy.
  - Member is receiving a benefit from Spravato® therapy, as demonstrated by a reduction in symptom severity compared to the baseline depression assessment utilizing the same rating scale.

- MDD in adults with acute suicidal ideation or behavior:
  - Not renewable, as has not been clinically studied beyond first 4 weeks.

- **Renewal Coverage Duration and Quantity Limitations (after first four weeks):**
  - Diagnosis of treatment-resistant depression (TRD)
    - Renewal approval duration: 6 months
    - Renewal quantity limitations: If treatment is still needed after initial 4-week induction phase: 56mg or 84mg intranasally once weekly for weeks 5 to 8, and then 56mg or 84mg intranasally every 2 weeks or once weekly from week 9 and after (dosing frequency should be individualized to the least frequent dosing to maintain remission/response).

  - Diagnosis of MDD in adults with acute suicidal ideation or behavior:
    - Renewal approval duration and quantity limits: None – this has not been clinically studied beyond the first 4 weeks of therapy.

C. Supprelin LA™ (histrelin acetate)

Initial Coverage Criteria (member must meet *all of the following criteria*):

- Must be prescribed by a pediatric endocrinology specialist.
- Member is ≥ 2 years of age and has not yet reached the appropriate time point for the onset of puberty (approximately 11 years for females and 12 years for males), as determined at the discretion of the prescriber.
- Member has had early onset of secondary sexual characteristics (onset earlier than 8 years of age in females and 9 years of age in males).
- Member has a diagnosis of Central Precocious Puberty (CPP) that has been confirmed by a pediatric endocrinology specialist.
- The prescriber agrees to document and monitor LH, FSH, and estradiol or testosterone at baseline, 1-month post-implantation, then every 6 months thereafter, in addition to height (for calculation of height velocity) and bone age at baseline and every 6-12 months.
- Member is not pregnant.
- Member must have had an inadequate response, intolerance, or contraindication to Lupron Depo Ped (1 month) or Lupron Depo Ped (3 month).

- **Initial Coverage Duration and Quantity Limitations:**
  - Initial approval duration: 1 year
  - Initial quantity limitations: One Supprelin LA® 50mg implant which is inserted as a subcutaneous implant in the inner aspect of the upper arm, and it gets removed and replaced every 12 months until member reaches the appropriate time point for the onset of puberty (approximately 11 years for females and 12 years for males), as determined at the discretion of the prescriber.

Renewal Coverage Criteria:

- Member's use of Supprelin LA® is being monitored by pediatric endocrinology specialist.
- Member has been compliant with Supprelin LA® treatment.
- Member has not yet reached the appropriate time point for the onset of puberty (approximately 11 years for females and 12 years for males), as determined at the discretion of the prescriber.
- Prescriber attests that member has had a positive clinical response to Supprelin LA®.
- Prescriber attests that the following is being monitored:
  - LH, FSH, and estradiol or testosterone at 1-month post-implantation, then every 6 months thereafter.
  - Height (for calculation of height velocity) and bone age every 6-12 months.

- **Renewal Coverage Duration and Quantity Limitations:**
  - Renewal approval duration: 1 year
  - Renewal quantity limitations: One Supprelin LA® 50mg implant which is inserted as a subcutaneous implant in the inner aspect of the upper arm, and it gets removed and replaced every 12 months until member reaches the appropriate time point for the

onset of puberty (approximately 11 years for females and 12 years for males), as determined at the discretion of the prescriber.

D. Zinplava™ (bezlotoxumab)

Initial Coverage Criteria (member must meet *all of the following criteria*):

- Must be prescribed by a gastroenterology or infectious disease specialist.
- Member is 18 years of age or older.
- Member has a confirmed diagnosis of *Clostridium difficile* infection (CDI) defined as diarrhea (passage of 3 or more loose bowel movements in 24 or fewer hours) and a positive stool test for toxigenic *C. difficile* from a stool sample collected within the past 7 days.
- Member is receiving concomitant standard of care antibacterial drugs for treatment of CDI (metronidazole, vancomycin, or fidaxomicin).
- Member has no history of congestive heart failure (CHF) or provider states that benefit outweighs the risk.
- Member is at a high risk for CDI recurrence, defined as **any** of the following:
    - age of 65 years or older
    - history of CDI in the past 6 months
    - immunocompromised state
    - hypervirulent strain of *C. difficile* (ribotypes 027, 078, or 244)
    - clinically severe CDI at presentation (Zar score $\geq$ 2)
        - Zar score $\geq$ 2 points:
            - Age > 60 years old (1 point)
            - Body temperature > 38.3^{o}C (>100^{o}F) (1 point)
            - Albumin level < 2.5 mg/dl (1 point)
            - Peripheral WBC count > 15,000 cells/mm^{3} (1 point)
            - Endoscopic evidence of pseudomembranous colitis (2 points)
            - Treatment in Intensive Care Unit (2 points)

- **Coverage Duration and Quantity Limitations:**
    - Approval Duration: Zinplava™ is only indicated as a single infusion. **Subsequent doses *will not* be approved.**
    - Quantity Limitations: Max of 10mg/kg IV over 60 minutes as a single infusion.

Renewal Coverage Criteria:

- Zinplava™ is only indicated as a single infusion. Subsequent doses will not be approved.

E. Zolgensma™ (onasemnogene abeparvocec-xioi)

Initial Coverage Criteria (member must meet *all of the following criteria*):

- Member is less than 2 years of age.
- Member has reached full-term gestational age.
- Member experienced onset of clinical symptoms consistent with Spinal Muscular Atrophy (SMA) before 6 months of age.
- Member has SMA Type 1 (SMA-1).
- Genetic testing has confirmed bi-allelic SMN1 gene deletions or dysfunctional point mutations and $\leq$ 2 copies of the SMN2 gene.

- Provider must submit documentation of a baseline motor function milestone evaluation test using an age-appropriate screening tool (e.g., CHOP-INTEND).
- Member does not have complete limb paralysis or permanent ventilator dependence.
- Must be prescribed by a neurology specialist.
- Member has baseline anti-AAV9 antibody titer of ≤ 1:50.
- Member does not have an active viral infection.
- Baseline liver function tests, platelet counts, and troponin-1 have been performed and will continue to be assessed after treatment for at least 3 months until they return to baseline.
- Member has not previously received Zolgensma®**.**
- Therapy with Spinraza® or Evrysdi™, if applicable, will be discontinued.

- **Coverage Duration and Quantity Limitations:**
  - Approval Duration: one infusion only
  - Quantity Limitations: Max of 1.1×10^{14} vector genomes/kg IV as a single weight-appropriate dose per lifetime.

Renewal Coverage Criteria:

- Zolgensma® is only indicated for one infusion per lifetime. The safety and effectiveness of repeat administration of Zolgensma® has not been evaluated.

F. Zulresso™ (brexanolone)

Initial coverage criteria (member must meet *all of the following criteria*):

- Member must be 18 years of age or older.
- Must be prescribed by a psychiatric specialist.
- Member is ≤ 6 months postpartum.
- Member meets Diagnostic and Statistical Manual of Mental Disorders (DSM-5) criteria for major depressive disorder **and** onset of symptoms began in the third trimester or within 4 weeks of delivery.
- Member must have moderate or severe postpartum depression consistent with a qualifying score using a standardized screening tool for depression (e.g., HAM-D Rating Scale, MADRS, PHQ-9).
- Must meet at least one of the following criteria based on severity:
  - If moderate postpartum depression:
    - must have had an inadequate response, intolerance to, or contraindication to at least 2 oral antidepressants (each trialed for at least 6 weeks).
  - If severe postpartum depression:
    - must have had an inadequate response, intolerance to, or contraindication to at least 1 oral antidepressant (trialed for at least 6 weeks)

      OR
    - due to safety concerns for the member or the member's ability to care for the infant, the member's condition is too time sensitive to trial oral antidepressants or other treatments.
- Member has not previously received Zulresso™ for current postpartum depressive episode from the most recent pregnancy.
- Provider attests to the following:

- The member and healthcare facility administering treatment are enrolled in the Zulresso™ REMS program.
- A healthcare provider will be available on site to continuously monitor the member during the infusion.

- **Coverage Duration and Quantity Limitations:**
  - Initial Approval Duration: One infusion per delivery
  - Quantity Limitations: Zulresso is only indicated for one infusion at weight-appropriate dose per delivery. It will be administered as a continuous IV infusion over 60 hours (2.5 days) in accordance with weight-based dosage regimen listed in the FDA approved labeling.

Renewal Coverage Criteria:

- Zulresso™ is only indicated for one infusion per delivery. Subsequent infusions for the same delivery will not be granted.

3. **PDL/DUR Board meeting follow-up items:**
   - Add previously mentioned formulary change requests (see public comment section) to upcoming Preferred Drug List (PDL) agenda(s).

Closed Session:
No cases to present.

The meeting adjourned at 2:30pm.