*February 2021 DUR Board Meeting Minutes*

**Date: February 3, 2021**

**Members Present:** King, Anglim, Blank, Blake, Brown, Jost, Caldwell, Maxwell, McGrane, Nauts, Putsch, Stone

**Members Absent:**

**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 provided opportunity for public comment.

**Public Comment**:
No comment(s) presented.

**Meeting Minute Review:**
The meeting minutes from December 9, 2020 DUR Board Meeting were approved as written.

**Department Update:**
No Department updates

**Board Discussion**

1. **Specialty Clinic Discussion**
   The DUR Board was asked to determine who qualifies as a specialist within a specific specialty when the prescriber is not an MD and/or there is no MD on staff. These types of clinics are becoming more common, resulting in the request for clarification from the Board.

   At this time, the Board requests that this topic continue to be added as an agenda item for ongoing discussion. The Board is requesting additional information from the Montana Board of Nursing, as well as national guidelines for nurse practitioners, be provided. They also requested to review the drug categories/individual drugs that require a specialist to determine if the specialist requirement for these medications is necessary.

2. **Naltrexone and Bupropion in Methamphetamine Use Disorder Article**
   An overview of the *Bupropion and Naltrexone in Methamphetamine Use Disorder* article from the New England Journal of Medicine (384;2 January 14, 2021) was presented and clarification was requested on how Montana Healthcare Programs was going to handle requests for extended-release injectable naltrexone for stimulant/methamphetamine use, as currently this diagnosis is not covered under Montana Healthcare Programs.

   Mountain-Pacific Quality Health (MPQH) Case Management staff explained that extended-release injectable naltrexone is only covered for alcohol use disorder or opioid use disorder. At this time, the Board reaffirms the criteria of only approving the extended-release injectable naltrexone for the FDA approved diagnoses of opioid use disorder or alcohol use disorder.

**3. Ketamine discussion**

Prior to the meeting, this topic was resolved internally. The Board had no questions or concerns regarding this and agreed to pass on this discussion.

**4. Existing Drug Criteria Updates**

**A.** Ofev **(new FDA approved indications – systemic sclerosis associated interstitial lung disease, and chronic fibrosing interstitial lung disease)**

- Member must meet all of the following criteria:
  - Must be prescribed by, or in consult with, a pulmonologist
  - Diagnosis of idiopathic pulmonary fibrosis, systemic sclerosis associated interstitial lung disease, or chronic fibrosing interstitial lung disease
  - Member must be a non-smoker OR has quit smoking
  - Initial authorization granted for 6 months
  - Continuation of therapy granted for 12 months after receiving pulmonology update documenting a positive response to therapy AND that member has remained non-smoking.
  - Limitations:
    - Max daily dose of 2 capsules daily

**5. Review of New Drug Criteria**

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

***A. Nexletol™ (bempedoic acid)***

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

- Member is 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 **2** high-intensity statins for at least 12 weeks **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 product for at least 12-weeks and has been ineffective or contraindicated
- Initial authorization granted for 6 months
- Maximum daily dose is 180mg/day

**Renewal Coverage Criteria:**

- Provider must provide documentation showing positive clinical improvement and adherence to therapy
- Renewal authorization granted for 1 year and maximum daily dose is 180mg/day

***Physician Administered Drugs (PAD):***

***B. Zolgensma™ (onasemnogene abeparvovec-xioi)***

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

- Member is less than 2 years of age with Spinal Muscular Atrophy (SMA).
- Member has reached full-term gestational age.
- Genetic testing has confirmed bi-allelic SMN1 gene deletions or dysfunctional point mutations
- Genetic testing has confirmed ≤3 copies of the SMN2 gene, or member has >3 copies of the SMN2 gene with clinical symptoms consistent with SMA before 2 years of age.
- 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 x $10^{14}$ 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.

**PDL/DURB Meeting Follow-Up Items:**

- Gabapentin discussion is still on tracker but nothing to discuss at this time. Monitoring still ongoing.
- Benzodiazepine discussion is still on tracker but nothing to discuss at this time. Monitoring still ongoing.
- Upcoming meeting dates and information:
    - No plans at this time for in-person meetings due to ongoing pandemic crisis
    - Board requesting to receive documents electronically vs mail
    - PDL meetings: March 24, 2021 / April 21, 2021 / May 26, 2021

**Closed Session:**
No cases to present.

The meeting adjourned at 2:58pm.