# August 2023 DUR Board Meeting Minutes

**Date: August 9, 2023**

**Members Present:** Barnhill, Blake, Blank, Brown, Caldwell, Jost, McGrane, Nauts, Putsch, Stone

**Members Absent:** Anglim, Turnsplenty

**Others Present:** Katie Hawkins, Shannon Sexauer, Dani Feist, (DPHHS); Bahny, Miranda, Ulishney, Zody (Mountain Pacific); and representatives from the pharmaceutical industry.

**Introduction:** Jennifer Miranda introduced Jacki Ulishney as the new Pharmacy Case Management pharmacist who joined Mountain Pacific in July 2023.

**Public Comment**:

1. Madeline Shurtleff, Otsuka - Rexulti®
2. Charles Elroy, Sanofi - TZIELD®
3. Shirley Quach, Novartis - Entresto®
4. Paul Thompson, Alkermes - Lybalvi®
5. Erin Nowak, AbbVie - Vraylar®

Feedback from the Board was requested regarding letters sent to the State from providers. One letter expressed concerns about the atypical antipsychotics in children program and psychotropic medications in the foster care children program. The other letter was in respect to the Lybalvi® criteria.

As a result of the concerns about the psychotropic medications in the foster care program, the Board was provided the foster care provider response form and the foster program description letter to review. The Board wanted to ensure that metabolic labs could be drawn at a facility or lab outside of the psychiatry office, and the Board was assured that is allowed. The Board also wanted to ensure that an atypical antipsychotic would not be denied approval if the member is past due for a well child check or is not referred for behavioral health services. It was explained that the latter are items reviewed for the Foster Care program and provided to the prescriber for informational/educational purposes but are not part of the atypical prior authorization criteria in children aged seven years and younger. After the discussion, the Board agreed to proceed with the current foster and atypical programs and the current process in place.

Then, the Board decided to consider the Lybalvi® comments when reviewing the atypical antipsychotic criteria later in the meeting.

**Meeting Minute Review:** The meeting minutes from the May 24, 2023, Preferred Drug List (PDL) were approved as written.

**Department Update:** No Department update.

**Board Discussion**

1. **Suggested Changes to Current Criteria:**
   - **A. CGRP Inhibitors**

- Recommendation: Remove three-month initial approval and change to one-year approval, as internal research has shown members will not continue with therapy past the first few months if it is not showing effectiveness.
- The Board agreed to change the initial approval time to 1 year.

**B. Vyvanse® (lisdexamfetamine)**

- Recommendation: Change limits to allow up to two strengths each month, which is consistent with other long-acting ADHD stimulants. The Board expressed concerns over loosening restrictions on stimulant medications, especially when not consistent with FDA labeling. The PA call center detailed large call volumes related to dose changes and questioned whether the benefit of the limitations outweighed the resource cost.
- The Board agreed to this recommendation if the Department deemed necessary, but continued to express reservations. The Department will discuss the Board's concerns and staffing resources and make a determination regarding this criteria change.

**C. Sublocade® (buprenorphine extended release)**

- Informed the Board the initial approval for the first three months was changed to month-to-month in order to verify the member has a scheduled appointment and the medication was requested by the provider/office versus it being auto-shipped. This was done to mitigate the waste that was occurring.
- The Board was asked if they have any concerns with this change and the Board did not have any.

**D. Calcineurin Inhibitors**

- Recommendation: Remove all criteria and manage only through the PDL. Criteria was originally developed due to initial safety concerns for these products. Over time, these concerns have not been realized and criteria is no longer felt to be necessary.
- The Board agreed to remove the criteria for all the topical calcineurin inhibitors.

**2. Age Extensions and Language Updates:**

**A. Diacomit® (stiripentol)**

**Initial Coverage Criteria**

Member must meet all the following criteria:

- Be six months of age or older.
- Weigh at least 7kg.
- Have a diagnosis of Dravet syndrome.
- Be concurrently taking clobazam.
- Seizures have been inadequately controlled by at least two (2) oral anti-epileptic therapies indicated for Dravet syndrome.

Prescriber requirements:

- Must be prescribed by, or in consultation with, a neurologist.
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Prescriber attests to the following:
  - Baseline neutrophil and platelet count have been performed and drug interactions have been reviewed.
  - Baseline seizure activity has been documented.

Limitations:

- Initial approval duration: 1 year.
- Maximum daily dose:
  - 300mg daily in children 1 year old or older AND weighing ≥10kg.
  - 50mg/kg/day in children at least 6 months old AND weighing 7 to <10kg.

**Renewal Coverage Criteria**

Member must meet all the following criteria:

- Has documentation of positive clinical response to therapy ~~(reduction in the frequency and/or severity of seizures from baseline)~~. ***Board recommended to remove the strikethrough section of the criteria***.

Prescriber requirements:

- Annual specialist consult provided if prescriber is not a specialist.

Limitations:

- Renewal approval duration: 1 year
- Maximum daily dose:
  - 300mg daily in children 1 year old or older AND weighing ≥10kg.
  - 50mg/kg/day in children at least 6 months old AND weighing 7 to <10kg.

**B. Evkeeza® (evinacumab-dgnb)**

**Initial Coverage Criteria**

Member must meet all the following criteria:

- Be five years of age or older.
- Have a diagnosis of Homozygous Familial Hypercholesterolemia (HoFH).
- Have LDL-Cholesterol equal to or greater than 70mg/dl.
- Must have had an inadequate response (trial of at least 12-weeks duration), intolerance or contraindication to **ALL** the following medications:
  - **TWO** high-intensity statins (12-week trial each):
    - Ezetimibe
    - PCSK9 inhibitor
- Member must continue background lipid-lowering therapies in combination with Evkeeza®.

Prescriber requirements:

- Must be prescribed by, or in consult with, a cardiology or endocrinology specialist.
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Provider attests female members of childbearing age have been counseled on use of contraception while using Evkeeza® due to potential fetal harm.
- Provider attests member **will not** use Evkeeza® concomitantly with other biologics.

Limitations:

- Initial approval duration: 6 months.

- Maximum dose: 15mg/kg IV every 4 weeks.
- The safety and effectiveness of Evkeeza® have not been established in patients with other causes of hypercholesterolemia, including those with heterozygous familial hypercholesterolemia (HeFH).
- The effects of Evkeeza® on cardiovascular morbidity and mortality have not been determined.

**Renewal Coverage Criteria**

Member must meet all the following criteria:
- Has documentation of positive clinical response to therapy.
- Has been adherent to Evkeeza® and all additional lipid lowering agents the member was taking at initiation of Evkeeza® therapy.

Prescriber requirements:
- Annual specialist consult provided if prescriber not a specialist.
- Provider attests member will be prescribed and monitored for ongoing additional lipid lowering agents in addition to Evkeeza®.
- Provider attests member **will not** use Evkeeza® concomitantly with other biologics.

Limitations:
- Renewal approval duration: 1 year.
- Maximum dose: 15mg/kg IV every 4 weeks.

**C. Lucemyra® (lofexidine)**

**Initial Coverage Criteria**

Member must meet all the following criteria:
- Be 18 years of age or older.
- Have a diagnosis of opioid withdrawal symptoms after abrupt opioid discontinuation.
- Have a documented clinically significant intolerance to clonidine (no significant efficacy difference between clonidine and Lucemyra®).

Prescriber requirements:
- Prescriber attests they are aware of risk of Q-T prolongation with Lucemyra®.

Limitations:
- Initial approval duration: 7 days.
- Maximum daily dose: 16 tablets.

**Renewal Coverage Criteria**

Member must meet all the following criteria:
- Has documentation of positive clinical response to therapy but continues to have withdrawal symptoms.

Limitations:

- Renewal approval duration: 7 days.
- Maximum daily dose: 16 tablets.

**3. New Indication:**

**A. Kevzara® (sarilumab)**

**Initial Coverage Criteria**

**Rheumatoid Arthritis**
Member must meet all the following criteria:
- Be 18 years of age or older.
- Have a diagnosis of moderately to severely active rheumatoid arthritis.
- Have had an inadequate response or intolerance to one or more disease-modifying antirheumatic drugs (DMARDs).
- Have had a trial and inadequate response or contraindication to a preferred drug with the same indication from the Montana Healthcare Programs Preferred Drug List 19 (mt.gov) (unless preferred product(s) do not have the appropriate indication).

Prescriber requirements:
- Must be prescribed by, or in consult with, a rheumatologist.
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Prescriber attests they have reviewed the black box warning for infection risk.
- Prescriber attests member **will not** use Kevzara® concomitantly with other biologics.

Limitations:
- Initial approval duration: 1 year.
- Maximum daily dose: 200mg subcutaneously every 2 weeks.

**Polymyalgia Rheumatica**
Member must meet all the following criteria:
- Be 18 years of age or older.
- Have a diagnosis of polymyalgia rheumatica.
- Have had a trial and inadequate response or intolerance to corticosteroids or cannot tolerate a corticosteroid taper.
- Have had a trial and inadequate response, or contraindication to a preferred drug with the same indication from the Montana Healthcare Programs Preferred Drug List 19 (mt.gov)(unless preferred product(s) do not have the appropriate indication).

Prescriber requirements:
- Must be prescribed by, or in consult with, a rheumatologist.
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Prescriber attests they have reviewed the black box warning for infection risk.
- Prescriber attests member **will not** use Kevzara® concomitantly with other biologics.

Limitations:

- Initial approval duration: 1 year.
- Maximum daily dose: 200mg subcutaneously every 2 weeks.

**Renewal Coverage Criteria**

**Rheumatoid Arthritis and Polymyalgia Rheumatica**
Member must meet all the following criteria:
- Have documentation of positive clinical response to therapy (reduction in the frequency and/or severity of symptoms and exacerbations).

Prescriber requirements:
- Annual specialist consult provided if prescriber not a specialist.
- Provider attests member **will not** use Kevzara® concomitantly with other biologics.

Limitations:
- Renewal approval duration: 1 year.
- Maximum daily dose: 200mg subcutaneously every 2 weeks.

**4. New Criteria:**

**A. Lumryz® (sodium oxybate)**

**Initial Coverage Criteria**

Member must meet all of the following criteria:
- Be 18 years of age or older.
- Have a diagnosis of cataplexy or excessive daytime sleepiness (EDS) with narcolepsy.
- Have a trial and inadequate response to Xyrem® (immediate acting sodium oxybate) **for a minimum of three months and at the maximum tolerated dose.** ***Board recommended to add this bolded section***.

Prescriber requirements:
- Prescriber must be enrolled in the REMS program.
- Diagnosis must be made using ICSD-3 or DSM-5 diagnostic criteria using Multiple Sleep Latency Test (MSLT) and Sleep-onset rapid eye movement (SOREM).

Limitations:
- Initial approval duration: 1 year.
- Maximum daily dose: 9g per night.

**Renewal Coverage Criteria**

Member must meet all the following criteria:
- Have documentation of positive clinical response to therapy.

Limitations:
- Renewal approval duration: 1 year.
- Maximum daily dose: 9g per night.

***The Board approved the request to update the sleep latency verbiage on the existing criteria for Xyrem® and Xywav® to match the verbiage on Lumryz®.***

**B. Leqembi® (lecanemab-irmb), Aduhelm® update**

**Leqembi® (lecanemab-irmb)**

**Initial Coverage Criteria**

Member must meet all the following criteria:

- Be 50 years of age or older.
- Have a diagnosis of mild cognitive impairment due to Alzheimer's disease or has mild Alzheimer's dementia stage of disease as evidenced by all the following:
  - Clinical Dementia Rating (CDR)-Global Score of 0.5.
  - Mini-Mental Status Exam (MMSE) score between 22 and 30 and a Memory Box score of 0.5.
  - Objective evidence of cognitive impairment at screening as indicated by at least one standard deviation below age-adjusted mean in the Wechsler-Memory Scale-IV Logical Memory II.
- Have a positive amyloid Positron Emission Tomography (PET) scan confirming presence of amyloid beta pathology.
- Have not had a stroke or transient ischemic attack (TIA) within past year.
- Is not currently taking any medication with platelet anti-aggregate or anti-coagulant properties (unless aspirin ≤325mg daily).
- Have an adequate trial of at least six months with a Montana Healthcare Programs preferred Alzheimer's therapy (cholinesterase inhibitor) and the preferred drug was ineffective or caused intolerable side effects.
  - List of Montana Healthcare Programs preferred drugs can be found at: 19 (mt.gov).
  - If taking medications to treat symptoms related to Alzheimer's disease, dosages must be stable for at least 12 weeks prior to starting Leqembi®. Additional therapies may not be initiated during Leqembi® treatment.
- Have a recent brain MRI (within one year) prior to initiating treatment.
- Have follow-up MRIs prior to the fifth, seventh and 14$^{th}$ infusions to evaluate for the presence of asymptomatic amyloid related imaging abnormalities (ARIA).

Prescriber requirements:

- Must be a neurology specialist.
- Have ruled out any other medical or neurological conditions (other than Alzheimer's disease) that may be contributing to member's cognitive impairment, including any medications that can substantially contribute to cognitive impairment (see Beers List).
- Agree to MRIs done prior to the fifth, seventh and 14$^{th}$ infusions to evaluate for the presence of asymptomatic amyloid related imaging abnormalities (ARIA). Leqembi® can cause amyloid related imaging abnormalities -edema (ARIA-E) and -hemosiderin deposition (ARIA-H).
  - For patients with radiographic findings of ARIA, enhanced clinical vigilance is recommended.
  - Additional MRIs may be considered if clinically indicated.
  - Interruption of treatment may be indicated per labeling based on severity of results.
- Prescriber attests to the following:

- The prescriber is aware of the boxed warning (black box) of amyloid-related imaging abnormalities.
- The prescriber is aware of the boxed warning of increased risk to patients who are apolipoprotein E ε4 homozygotes and has discussed this with patients at risk.

Limitations:
- Initial approval duration: 6 months.
- Maximum daily dose: 10mg/kg over one hour every 2 weeks.

**Renewal Coverage Criteria**

Member must meet all the following criteria:
- Have documentation of positive clinical response to Leqembi® therapy, as demonstrated by an improvement or stabilization from baseline on the Clinical Dementia Rating (CDR) and Mini-Mental Status Exam (MMSE).

Prescriber requirements:
- Be a neurology specialist.
- Obtain follow-up MRI prior to the fifth, seventh and 14th infusions.
- Monitor appropriately for ARIA. If imaging shows ARIA, manage treatment per labeling.

Limitations:
- Renewal approval duration: 6 months.
- Maximum daily dose: 10mg/kg over one hour every 2 weeks.

**Aduhelm® (aducanumab-avwa)**

**Initial Coverage Criteria**

Member must meet all the following criteria:
- Be 50 years of age or older.
- Have a diagnosis of mild cognitive impairment due to Alzheimer's disease or has mild Alzheimer's dementia stage of disease as evidenced by all the following:
  - Clinical Dementia Rating (CDR)-Global Score of 0.5.
  - Repeatable Battery for Assessment of Neuropsychological Status (RBANS) delayed memory index score ≤85.
  - Mini-Mental Status Exam (MMSE) score between 24 and 30.
  - Objective evidence of cognitive impairment at screening.
- Have a positive amyloid Positron Emission Tomography (PET) scan confirming presence of amyloid beta pathology.
- Have not had a stroke or TIA within past year.
- Is not currently taking any medication with platelet anti-aggregate or anti-coagulant properties (unless aspirin ≤ 325mg daily).
- Have an adequate trial of at least six months with a Montana Healthcare Programs preferred Alzheimer's therapy (cholinesterase inhibitor) and the preferred drug was ineffective or caused intolerable side effects.
  - List of Montana Healthcare Programs preferred drugs can be found at: 19 (mt.gov)

- If taking medications to treat symptoms related to Alzheimer's Disease, dosages must be stable for at least ~~8 weeks~~ **12 weeks** prior to starting Aduhelm®. Additional therapies may not be initiated during Aduhelm® treatment. ***Board approved to change the time frame from eight weeks to twelve weeks.***

- Have a recent brain MRI (within one year) prior to initiating treatment.
- Have follow-up MRIs prior to the fifth, seventh, ninth and 12th infusions to evaluate for the presence of asymptomatic amyloid related imaging abnormalities (ARIA).

Prescriber requirements:

- Must be a neurology specialist.
- Have ruled out any other medical or neurological conditions (other than Alzheimer's Disease) that may be contributing to member's cognitive impairment, including any medications that can substantially contribute to cognitive impairment (see Beers List).
- Agree to MRIs done prior to the fifth, seventh, ninth and 12th infusions to evaluate for the presence of asymptomatic amyloid related imaging abnormalities (ARIA). Aduhelm® can cause amyloid related imaging abnormalities -edema (ARIA-E) and -hemosiderin deposition (ARIA-H).

- Prescriber attests to the following:
  - Prescriber is aware of Amyloid Related Imagining Abnormalities (ARIA): Enhanced clinical vigilance for ARIA is recommended during the first eight doses of treatment with Aduhelm®, particularly during titration. Risk of ARIA, including symptomatic ARIA, was increased in apolipoprotein E ε4 homozygotes compared to heterozygotes and noncarriers.

Limitations:

- Initial approval duration: 6 months.
- Maximum daily dose: 10mg/kg IV every 4 weeks.

**Renewal Coverage Criteria**

Member must meet all the following criteria:

- Have had follow-up MRIs prior to the fifth, seventh, ninth and 12th infusions and did not demonstrate radiographic evidence of severe amyloid related imaging abnormalities (ARIA)
  - For patients with radiographic findings of ARIA, enhanced clinical vigilance is recommended.
  - Additional MRIs may be considered if clinically indicated.
  - Interruption of treatment may be indicated per labeling based on severity of results.
- Have documentation of positive clinical response to Aduhelm® therapy, as demonstrated by an improvement or stabilization from baseline on the Clinical Dementia Rating (CDR) and Mini-Mental Status Exam (MMSE).

Prescriber requirements:

- Be a neurology specialist.
- Review follow-up MRIs prior to the fifth, seventh, ninth and 12th infusions and they did not demonstrate radiographic evidence of severe amyloid related imaging abnormalities (ARIA).
  - For patients with radiographic findings of ARIA, enhanced clinical vigilance is recommended.

- Additional MRIs may be considered if clinically indicated.
- Interruption of treatment may be indicated per labeling based on severity of results.

Limitations:
- Renewal approval duration: 6 months.
- Maximum daily dose: 10mg/kg IV every 4 weeks.

**C. TZIELD® (teplizumab-mzwv)**

**Initial Coverage Criteria**

Member must meet all the following criteria:
- Be eight years of age or older.
- Have confirmed Stage 2 type 1 diabetes, documented by BOTH of the following:
  - At least two (2) of the following positive pancreatic islet cell autoantibodies:
    - Glutamic acid decarboxylase 65 (GAD) autoantibodies.
    - Insulin autoantibody (IAA).
    - Insulinoma-associated antigen 2 autoantibody (IA-2A).
    - Zinc transporter 8 autoantibody (ZnT8A).
    - Islet cell autoantibody (ICA).
  - Dysglycemia without overt hyperglycemia using an oral glucose tolerance test. If an oral glucose tolerance test is not available, an alternative method for diagnosing dysglycemia without overt hyperglycemia may be appropriate. Examples are:
    - Fasting plasma glucose level of 100 to 125mg/dL.
    - Two-hour post-prandial glucose of 140 to 199mg/dL.

Prescriber requirements:
- Must be prescribed by, or in consult with, an endocrinologist.
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required.
- Must include a current patient body surface area (BSA).
- Prescriber attests to the following:
  - Member has had a complete blood count and liver enzyme tests prior to initiating Tzield®.
  - Prescriber ensures the clinical history of the patient does not suggest type 2 diabetes.
  - Prescriber is aware of the risk of cytokine release syndrome, serious infection and other risks associated with Tzield® infusion.

Limitations:
- Initial approval duration: 14-day course.
- Maximum daily dose: 14-day dosing regimen based on body surface area.

**Renewal Coverage Criteria**

- No renewal is available. This treatment is for a one-time, 14-day course.

**5. Entresto® (sacubitril/valsartan) Discussion**

- After reviewing the information provided by the cardiology clinics, the Board agreed that the criteria for Entresto® should be removed. Also, the question was asked if this needed to be a "Must Add" on the PDL to ensure access. The Department voiced their intention to add as a

preferred product once criteria was removed. Further discussion regarding a "Must Add" recommendation by the Board will be had during the 2024 PDL meeting that this category falls under.

**6. MOUD Discussion**

- The Board discussed the information provided by Dr. Nauts and supported his recommended removal of clinical PA criteria for buprenorphine products. As this was a DUR meeting, PDL placement was not addressed. The Department will discuss and respond to the Board at a later date.

- October 25, 2023 Amendment

  Dr. Nauts requested the August Board meeting minutes be amended to reflect his recommendation for removal of PA criteria in regard to the preferred product of Suboxone®. He also included his discussion of the barriers to care caused by the current PA and attestation process that impacts both members and providers, such as emergency department providers and previously non-x waived providers. He indicated he was not asking for global opportunity for members to get MOUD agents without having to step through criteria. He supports the continued use of the Montana Healthcare Programs Preferred Drug List and the stipulation to use a preferred product when appropriate but requested that the current process that limits open access to MOUD medications be changed.

  Ian McGrane also requested the meeting minutes be amended to reflect the consensus of the Board to remove the barrier which would lock members out of getting opioids after initiating MOUD. The Board's recommendation is to make efforts to remove that limitation as it disincentivizes people to prescribe. Dr. Nauts indicated this was also part of his issue with the attestation and current PA criteria.

**7. Atypical Antipsychotic Discussion**

- Due to a shortage of time, the Board requested this discussion be brought back to the October 25, 2023 meeting for further discussion.

The next meeting will be October 25, 2023, and in this same format. The meeting adjourned at 4:02 p.m.