February 2024 DUR Board Meeting Minutes

Date: February 14, 2024

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

Members Absent: Stone

Board Member Update: None

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

Public Comment:

1. Rochelle Yang, Teva - Uzedy® (risperidone)
2. Lynda Finch, Biogen - Zurzuvae® (zuranolone)
    - Dr. Caldwell requested additional information on the persistence of benefit after 14 days of therapy. Mountain Pacific requested that the manufacturer send the additional information to the DUR Coordinator (mbarnhill@mpqhf.org) to distribute to the Board.
3. Erin Nowak, AbbVie - Vraylar® (cariprazine)
4. Nina Banerjee, Axsome Therapeutics Inc - Sunosi® (solriamfetol)
5. Jessica Jay, Indivior - Perseris®

Written public comment was submitted to the Board prior to the meeting. It consisted of two letters from Montana providers and three manufacturer documents. The manufacturer documents were regarding Secuado®, Xelstrym®, and Sunosi®. The Board had no comments on these medications. The first letter was regarding the criteria for use of atypical antipsychotics in children. The second letter was regarding the Lybalvi® criteria**.**

Meeting Minute Review: The revised minutes from the August 9, 2023, meeting were approved as written. The meeting minutes from the October 25, 2023, meeting were reviewed and approved as written.

Dr. Nauts commented on the updated MOUD (Medications for Opioid Use Disorder) policy that was sent to all DUR board members before the meeting. While he appreciates the changes being made to the program, he still has concerns with the remaining prior authorization requirements. He has requested that the enrolled Montana Medicaid provider requirement be removed until the program requires all providers to be an enrolled provider, regardless of medication ordered or provider specialty. Also, he requested the attestation requirements be removed unless an attestation accompanies all medications covered under Montana Medicaid. Lastly, he requested the overdose risk assessment be removed, as this is still part of treatment guidelines and shouldn't be something that providers must attest to.

The Department acknowledges these concerns but this process, as reviewed and written, has been approved by the Montana Medicaid Director and is final. The requirements for all providers prescribing Suboxone® films are as follows:

- Provider is a Montana Healthcare Programs enrolled Provider. **AND**
- Patient assessment/screening supports a diagnosis of **Opioid Use Disorder** (DSM-V Criteria). Suboxone® films are not FDA approved for pain management alone and are NOT COVERED for that indication. **AND**

- Provider has performed an overdose risk assessment and recommended naloxone if appropriate.

Department Update: None

Board Discussion

1. **Atypical antipsychotics**

   During the 2023 Preferred drug list meeting reviewing atypical antipsychotics, the Board requested a review of the current prior authorization criteria for non-preferred oral atypical antipsychotics. The reason for this request was due to concern about these medications having inconsistent criteria for drugs in the same class. In response to that request, Mountain Pacific and Montana DPHHS developed several sample criteria to prompt discussion among the Board. These were distributed to all board members before the meeting. After board discussion, the criteria listed below was agreed upon as the approved criteria for non-preferred oral therapies:

   - Member must have a diagnosis that matches the FDA (Food and Drug Administration) approved indication for the requested medication **AND**
   - Member must try and fail two separate preferred oral atypical antipsychotics that have the same FDA approved indication for the diagnosis being requested.
   - For off label indication requests, providers must submit clinical literature that supports safety and efficacy of the requested therapy off-label.

   Drug specific criteria changes/updates:

   - Abilify Mycite® and Lybalvi® criteria have no changes. The Board requested that the criteria for Lybalvi be brought back for review at a future DUR meeting.
   - Rexulti® for the treatment of agitation from Alzheimer's will not require a failure of a preferred agent.
   - Nuplazid® for the treatment of Parkinson's psychosis will not require a failure of a preferred agent.
   - Secuado® will be included in the specialty dosage form rules.
   - Symbyax® will continue to require a trial of olanzapine and fluoxetine, dispensed as separate prescriptions, but dosed together.

   The Board verified that diagnosis would not be required if the requested medication is for a preferred oral product. At this time, diagnosis is not required for preferred oral atypical antipsychotics. Atypical antipsychotic requests for children 8 years of age and younger are individually reviewed by Case Management based on a process established to meet the CMS requirements for the SUPPORT Act.

   Note: All atypical antipsychotics are grandfathered unless samples, patient assistance, or cash pay have been used to bypass criteria. Special dosage forms such as patches, dose-packs, dissolvable tablets, and liquids require rationale for bypassing oral tablets/capsules.

2. **Age Extensions and Language Updates**

   A. Adbry® (tralokinumab-ldrm)

Criteria Updates – the criteria documented below is the updated and current criteria approved by the Board. The updates are as follows:

1. *Age expanded down to 12 years of age.*
2. *Add specialty consult requirement if member is less than 18 years of age.*

Initial Coverage Criteria

Member must meet all of the following criteria:

- Be 12 years of age or older.
- Have a diagnosis of moderate-to-severe atopic dermatitis.
- 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.
- Have an inadequate treatment response, intolerance, or contraindication to an age-appropriate topical steroid and a topical immunomodulator (i.e., pimecrolimus, or tacrolimus).
- Have 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:

- If member is 12 to 17 years of age, Adbry® must be prescribed by, or in consult with, a dermatology specialist. If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Attests to the following:
    - Baseline assessment has been made to allow for documentation of positive clinical response.
    - Attests that member **will not** use Adbry® concomitantly with other biologics.

Limitations:

- Initial approval duration: 6 months.
- Maximum dose:
    - Loading dose: 600mg for adults and 300mg for members 12 to 17 years of age.
    - Maintenance dose: 300mg every other week for adults and 150mg every other week for members 12 to 17 years of age.

Renewal Coverage Criteria

Member must meet all of the following criteria:

- Has 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 **AND** member is 12 to 17 years of age.
- Attests that member **will not** use Adbry® concomitantly with other biologics.

Limitations:

- Renewal approval duration: 12 months.
- Maximum dose: 300mg every other week for adults and 150mg every other week for members 12 to 17 years of age.

3. New Indication/Formulation:

A. Entyvio® (vedolizumab) Pen and Syringe

Criteria Updates – the criteria documented below is the updated and current criteria approved by the Board. The updates are as follows:

1. *Indication for subcutaneous Entyvio® Pen and Syringe is only for moderately to severely active ulcerative colitis.*
2. *Entyvio® IV infusion criteria did not change.*

Initial Coverage Criteria

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have a diagnosis of moderately to severely active ulcerative colitis.
- Has shown clinical benefit from IV Entyvio® by at least 6 weeks.

Prescriber requirements:

- Must be prescribed by, or in consult with, a gastroenterology specialist.
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Attests to the following:
    - Member has shown a clinical response to treatment at week 6 and has been evaluated for transition from intravenous to subcutaneous treatment.
    - Members who have not shown a response by week 6 may continue to week 14 on intravenous Entyvio® at which time they will need to demonstrate clinical response for authorization to either transition to subcutaneous or continue intravenous treatment.
- Attests that member **will not** use Entyvio® concomitantly with other biologics.

Limitations:

- Initial approval duration for subcutaneous dosing: After meeting criteria to switch from IV to subcutaneous dosing at week 6, approval will be granted for 5 total subcutaneous injections (to week 14).
- Maximum dose: 108mg every 2 weeks subcutaneous starting at week 6.

Renewal Coverage Criteria

Member must meet all of the following criteria:

- Has documentation of positive clinical response to therapy (reduction in the frequency and/or severity of symptoms and exacerbations). Member must continue to demonstrate improvement over baseline at week 14.

Prescriber requirements:

- Annual specialist consult provided if prescriber not a specialist.
- Attests that member **will not** use Entyvio® concomitantly with other biologics.

Limitations:

- Renewal approval duration for subcutaneous dosing: 12 months.
- Maximum dose: 108mg every 2 weeks subcutaneous.

B. Zoryve® (roflumilast 0.3%) Topical Cream and Foam

Criteria Updates – the criteria documented below is the updated and current criteria approved by the Board. The updates are as follows:

Cream

1. Criteria change due to age expansion to 6 years of age or older.

Foam

1. *New FDA product approved. Separate FDA approved age and indication than the cream formulation, so separate criteria was developed.*

Initial Coverage Criteria

Member must meet all of the following criteria:

Zoryve® Cream:

- Be 6 years of age or older.
- Have a diagnosis of plaque psoriasis.
- Have a trial and inadequate response or contraindication to a high potency topical steroid.
- Have a trial and inadequate response or contraindication to a calcipotriene agent.
- Have 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).

Zoryve® Foam:

- Be 9 years of age or older.
- Have a diagnosis of seborrheic dermatitis.
- Have a trial and inadequate response or contraindication to a topical antifungal agent.
- Have a trial and inadequate response or contraindication to a topical steroid.
- Have a trial and inadequate response or contraindication to a calcineurin inhibitor.
- Have 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:

- For Zoryve Foam, have clinical documentation of functional impairment due to seborrheic dermatitis, which may include, but is not limited to, limitations to activities of daily living (ADLs), such as skin infections or sleep disturbances.
- For both products, attests to the following:
    - The member does not have moderate to severe liver impairment (Child-Pugh B or C).

- Baseline assessment has been made to allow for documentation of positive clinical response.

Limitations for both products:

- Initial approval duration: 2 months.
- Maximum quantity: 60gm (1 tube or cannister) every 28 days.

Renewal Coverage Criteria (for both products)

Member must meet all of the following criteria:

- Has documentation of positive clinical response to therapy (reduction in the frequency and/or severity of symptoms and exacerbations) over baseline.

Limitations:

- Renewal approval duration: 12 months.
- Maximum quantity: 60gm (1 tube or cannister) every 28 days.

New Drug Criteria:

A. Abilify Asimtufii® (aripiprazole)

Initial Coverage Criteria

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have a diagnosis of Bipolar I or Schizophrenia.
- Have a clinical rationale that oral therapy cannot be used.
- Have had a trial of the molecule's oral form before requesting approval for injectable therapy.
- If medication is non-preferred, must have had a trial and inadequate response, or contraindication to a preferred drug with the same indication and dosage form from the Montana Healthcare Programs Preferred Drug List 19 (mt.gov).

Limitations:

- Initial approval duration: 12 months.
- Maximum dose:
  - Abilify Asimtufii® - 960mg every 2 months

Renewal Coverage Criteria

Member must meet all the following criteria:

- Has documentation of positive clinical response to therapy.

Limitations:

- Renewal approval duration: 12 months.
- Maximum dose:
  - Abilify Asimtufii® - 960mg every 2 months

B. Agamree® (vamorolone) Suspension

Initial Coverage Criteria

Member must meet all of the following criteria:

- Be 2 years of age or older.
- Have a diagnosis of DMD.
- Have a trial of prednisone for ≥ 6 months and has had at least one of the following significant intolerable adverse effects this is unable to be managed.
    - Cushingoid appearance.
    - Central (truncal) obesity.
    - Weight gain of at least 10% of body weight over a 6-month period.
    - Diabetes and/or hypertension that is difficult to manage.
    - Bone fracture in spite of preventive measures (i.e., weight bearing exercises, fall prevention, vitamin D and calcium supplementation, etc.) for bone loss.
    - Has experienced a severe behavioral adverse effect while on prednisone therapy that has or would require a prednisone dose reduction. Chart notes must be provided that positively document the adverse effect.

Prescriber requirements:

- Must be prescribed by, or in consult with, a provider who specializes in the treatment of DMD.
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Must submit chart notes positively documenting adverse effects resulting in requested change.

Limitations:

- Initial approval duration: 6 months.
- Maximum daily dose: 6mg/kg up to a maximum of 300mg per day.

Renewal Coverage Criteria

Member must meet all of the following criteria:

- Has documentation of positive clinical response to therapy compared to other corticosteroids.

Prescriber requirements:

- Annual specialist consult provided if prescriber not a specialist.
- Chart notes showing objective benefit have been submitted with renewal request.

Limitations:

- Renewal approval duration: 12 months.
- Maximum daily dose: 6mg/kg up to a maximum of 300mg per day.

C. Bimzelx® (bimekizumab-bkzx) Injection

Initial Coverage Criteria

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have a diagnosis of moderate to severe plaque psoriasis.
- Have 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 dermatology specialist.
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Attests to the following:
  - Member has been informed of the possible increased risk of infection while using Bimzelx®.
  - Member has been advised of increased suicidal ideation and behavior risk reported with Bimzelx® and need to monitor.
  - All age-appropriate vaccines and lab work have been completed prior to Bimzelx® initiation.
- Attests that member **will not** use Bimzelx® concomitantly with other biologics.

Limitations:

- Initial approval duration: 16 weeks (5 doses).
- Maximum dose: 320mg every 4 weeks (week 0, 4, 8, 12, and 16) for 5 doses, then every 8 weeks.

Renewal Coverage Criteria

Member must meet all of the following criteria:

- Member has 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 that member **will not** use Bimzelx® concomitantly with other biologics.

Limitations:

- Renewal approval duration: 12 months.
- Maximum dose: 320mg every 8 weeks.

D. Motpoly® XR (lacosamide)

Initial Coverage Criteria

Member must meet all of the following criteria:

- Have a weight of 50 kg or greater.
- Have a diagnosis of partial-onset seizures.
- Have tried lacosamide immediate release and have a clinically compelling reason the extended-release product is necessary.

Prescriber requirements:

- Has documented baseline seizure activity to show improvement upon transition from IR to XR lacosamide.
- Attests to the following:
  - If discontinuation of Motpoly® XR is appropriate, there will be a gradual dose reduction over at least a week.

Limitations:

- Initial approval duration: 6 months.
- Maximum daily dose: 400mg daily.

Renewal Coverage Criteria

Member must meet the following criteria:

- Has documentation of positive clinical response to therapy compared to lacosamide IR (reduction in the frequency and/or severity of symptoms and exacerbations).

Limitations:

- Renewal approval duration: 12 months.
- Maximum daily dose: 400mg daily.

E. Omvoh® (mirikizumab-mrkz)

Initial Coverage Criteria

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have a diagnosis of moderately to severely active ulcerative colitis (UC).
- Have 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 gastroenterology specialist.
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Attests to the following:
  - Member has been screened for tuberculosis (TB) prior to initiating treatment.
  - All age-appropriate vaccines and lab work have been completed prior to Omvoh® initiation.
- Attests that member **will not** use Omvoh® concomitantly with other biologics.

Limitations:

- Initial approval duration (Physician Administered Drug Program): Three IV infusions (week 0, 4, and 8). Positive clinical response required to enter maintenance treatment at week 12 with subcutaneous dosing.
- Maximum dose:
  - Induction: 300mg per IV infusion at weeks 0, 4, and 8.

- Maintenance: 200mg per subcutaneous dose (two-100mg injections) starting at week 12 and every 4 weeks thereafter.

Renewal Coverage Criteria (only for maintenance treatment)

Member must meet the following criteria:

- Have completed the induction phase of three IV infusions of Omvoh® (Physician Administered Drug Program).
- Has documentation of positive clinical response to therapy (reduction in the frequency and/or severity of symptoms and exacerbations) before moving to maintenance treatment at Week 12.

Prescriber requirements:

- Annual specialist consult provided if prescriber not a specialist.
- Attests that member **will not** use Omvoh® concomitantly with other biologics.

Limitations:

- Renewal approval duration: 12 months.
- Maximum dose: 200mg per subcutaneous dose (two-100mg injections) every 4 weeks.

F. Uzedy® (risperidone) Subcutaneous Injection

Initial Coverage Criteria

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have an indicated diagnosis.
- Have a clinical rationale that oral therapy cannot be used.
- Have had a trial of the molecule's oral form before requesting approval for injectable therapy.
- If medication is non-preferred, must have had a trial and inadequate response, or contraindication to a preferred drug with the same indication and dosage form from the Montana Healthcare Programs Preferred Drug List 19 (mt.gov)

Limitations:

- Initial approval duration: 12 months.
- Maximum dose: 125mg once monthly or 250mg every 2 months.

Renewal Coverage Criteria

Member must meet the following criteria:

- Has documentation of positive clinical response to therapy.
- Drug Prior Authorization Unit will notify the provider if member has not been adherent to injections.

Limitations:

- Renewal approval duration: 12 months.
- Maximum dose: 125mg once monthly or 250mg every 2 months.

Perseris® Subcutaneous Injection

- *The Board requested that the physician specialist requirement be removed from the current criteria.*

The Board is agreeable to allowing any psychiatric specialist (APRN with psychiatric training, PMHNP, etc), regardless of credentialing, to prescribe long-acting injectable antipsychotics. The concern is that limiting providers based on credentials will limit access to therapy.

G. Velsipity® (etrasimod)

Initial Coverage Criteria

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have a diagnosis of moderately to severely active ulcerative colitis (UC).
- Have 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).
- Have **NOT** experienced a myocardial infarction, unstable angina pectoris, stroke, transient ischemic attack (TIA), decompensated heart failure requiring hospitalization, or Class III or IV heart failure in the last 6 months.
- Have **NO** history or presence of Mobitz type II second-degree or third-degree AV block, sick sinus syndrome, or sino-atrial block, unless the patient has a functioning pacemaker.

Prescriber requirements:

- Must be prescribed by, or in consult with, a gastroenterology specialist.
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Attests to the following:
  - Vaccines and lab work should be updated prior to Velsipity® initiation.
  - Member has had an EKG and eye exam prior to initiation of Velsipity® .
  - Pertinent drug-drug interactions have been reviewed.
- Attests that member **will not** use Velsipity® concomitantly with other biologics.

Limitations:

- Initial approval duration: 12 weeks.
- Maximum daily dose: 1 tablet daily.

Renewal Coverage Criteria

Member must meet the following criteria:

- Has 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.
- Attests that member **will not** use Velsipity® concomitantly with other biologics.

Limitations:

- Renewal approval duration: 12 months.
- Maximum daily dose: 1 tablet daily.

H. Zurzuvae® (zuranolone)

Initial Coverage Criteria

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have a diagnosis of severe postpartum depression with onset of symptoms in the third trimester or within 4 weeks of delivery.
- Be within the period up to 12 months postpartum.

Prescriber requirements:

- Attests to the following:
    - Has reviewed boxed warning of impaired ability to drive or engage in other potentially hazardous activities.

Limitations:

- Initial approval duration: 14 days.
- Maximum daily dose: Two 25mg (50mg) capsules daily.

Renewal Coverage Criteria

- Zurzuvae® is indicated for 14 days of treatment only. No renewal will be approved.

Stimulant Discussion – only applies to ADHD/ADD diagnosis.

Marcella Barnhill, Mountain Pacific DUR Coordinator, presented initial data on a sampling of the approximately 500 members who were identified as taking two or more long-acting stimulants (same or different molecule) with or without a concomitant short-acting stimulant. Marcella reviewed a sample of approximately 20% of these members' prescriptions. She asked the Board if their concern for twice daily dosing is dose related or frequency only. Several Board members are interested in the frequency, but also would like information on dose. With input from the Board, the direction of this research will be to proceed with looking at all 500 members and bring a synopsis of her findings to a later DUR board meeting for further review and planning.

Scheduled Upcoming Meeting Dates

PDL Meetings:
March 13, 2024
April 17, 2024
May 22, 2024

The next meeting will be the Preferred Drug List (PDL) meeting March 13, 2024, in this same format. The meeting adjourned at 3:33 p.m.