June 2024 DUR Board Meeting Minutes

Date: June 19, 2024

Members Present: Barnhill, Blank (absent from 3 p.m.– 3:30 p.m.), Brown, Caldwell, Jost, McGrane, Nauts, Oley, Stone

Members Absent: Anglim, Blake, Putsch

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

Public Comment:

1. Erin Nowak, AbbVie - Qulipta®
2. Katherine Khachatourian, Novo Nordisk - Wegovy®
3. Christine Dube, AstraZeneca - Fasenra®
4. Paul Thompson, Alkermes - Lybalvi®
5. Jennifer Melbourne, Braeburn - Brixadi®

Written public comment was submitted to the Board before the meeting. It consisted of four letters from Montana providers and two manufacturer documents. The manufacturer documents were regarding Fasenra® and Xolair®. The Board had no comments on these medications. Of the received provider letters, one was regarding the Lybalvi® criteria and the other three were regarding Wegovy®. The criteria for both drugs were reviewed during this meeting and the modified and approved criteria are documented below.

Meeting Minute Review: The minutes from the May 22, 2024, PDL meeting will be reviewed at the next DUR Board meeting.

Department Update: None

Board Discussion

1. **Alvaiz™ (eltrombopag choline), Promacta® (eltrombopag olamine), Doptelet® (avatrombopag)**

   -TPO-RAs

   A. Alvaiz™ (eltrombopag choline)

   Initial Coverage Criteria

   Treatment of thrombocytopenia in patients with persistent or chronic immune thrombocytopenia (ITP)

   Member must meet all of the following criteria:

   - Be 6 years of age or older.
   - Have a diagnosis of persistent or chronic ITP.
   - Have a platelet count of $<30x10^9$/L OR a platelet count of $30x10^9$/L to $50x10^9$/L with symptomatic bleeding or risk factors for bleeding.
   - Have a trial and inadequate response to corticosteroids, OR immunoglobulins, OR splenectomy, OR rituximab.

Prescriber requirements:

- Must be prescribed by a hematologist.
- Attests to the following:
    - Clinical hematology and liver function tests will be measured at least monthly throughout course of treatment. Current labs from within the last 30 days will be attached to prior authorization forms.
    - Member **will not** use Alvaiz™ concomitantly with other thrombopoietin receptor agonists (e.g., Nplate®, Doptelet®, Mulpleta®, Promacta®) or with spleen tyrosine kinase inhibitors (e.g., Tavalisse®).

Treatment of thrombocytopenia in patients with chronic Hepatitis C whose degree of thrombocytopenia prevents or limits interferon-based therapy

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have a diagnosis of chronic Hepatitis C whose degree of thrombocytopenia prevents the initiation or limits the ability for maintenance of interferon-based therapy.
- Have a platelet count of $<75x10^9/L$.
- Be starting or maintaining interferon-based therapy for chronic Hepatitis C.

Prescriber requirements:

- Must be prescribed by a hematologist.
- Attests to the following:
    - During antiviral therapy CBCs with differentials, including platelet counts, will be monitored weekly until a stable platelet count is achieved.
    - Clinical hematology and liver function tests will be measured at least monthly throughout course of treatment. Current labs from within the last 30 days will be attached to prior authorization forms.
    - Member **will not** use Alvaiz™ concomitantly with other thrombopoietin receptor agonists (e.g., Nplate®, Doptelet®, Mulpleta®, Promacta®) or with spleen tyrosine kinase inhibitors (e.g., Tavalisse®).
    - Alvaiz™ will be discontinued when interferon-based therapy is discontinued.

Refractory severe aplastic anemia (monotherapy)

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have a diagnosis of severe Aplastic Anemia.
- Has had an insufficient response to at least one prior immunosuppressive therapy.

Prescriber requirements:

- Must be prescribed by a hematologist.
- Attests to the following:
    - Clinical hematology and liver function tests will be measured at least monthly throughout course of treatment. Current labs from within the last 30 days will be attached to prior authorization forms.
    - Member **will not** use Alvaiz™ concomitantly with other thrombopoietin receptor agonists (e.g., Nplate®, Doptelet®, Mulpleta®, Promacta®) or with spleen tyrosine kinase inhibitors (e.g., Tavalisse®).

Limitations:

Dosed per package labeling according to diagnosis.

Renewal Coverage Criteria

Treatment of thrombocytopenia in patients with persistent or chronic immune thrombocytopenia (ITP)

Member must meet all of the following criteria:

- Platelet count is greater than 50 x 10^9/L OR
- Number of clinically significant bleeding events has declined.

Prescriber requirements:

- Must be prescribed by a hematologist.
- Attests clinical hematology and liver function tests will be measured at least monthly throughout course of treatment. Current labs from within the last 30 days will be attached to prior authorization forms.
- Verification of compliance will be made via Medicaid paid claims data. If non-compliance is determined, the reauthorization time frame may be reduced to allow time for the provider to address member compliance.
- Attests that member **will not** use Alvaiz™ concomitantly with other thrombopoietin receptor agonists (e.g., Nplate®, Doptelet®, Mulpleta®, Promacta®) or with spleen tyrosine kinase inhibitors (e.g., Tavalisse®).

Treatment of thrombocytopenia in patients with chronic Hepatitis C whose degree of thrombocytopenia prevents or limits interferon-based therapy

Member must meet all of the following:

- Has ongoing treatment with interferon-based therapy.

Prescriber requirements:

- Must be prescribed by a hematologist.
- Attests clinical hematology and liver function tests will be measured at least monthly throughout course of treatment. Current labs from within the last 30 days will be attached to prior authorization forms.
- Verification of compliance will be made via Medicaid paid claims data. If non-compliance is determined, the reauthorization time frame may be reduced to allow time for the provider to address member compliance.
- Attests that member **will not** use Alvaiz™ concomitantly with other thrombopoietin receptor agonists (e.g., Nplate®, Doptelet®, Mulpleta®, Promacta®) or with spleen tyrosine kinase inhibitors (e.g., Tavalisse®).

Treatment of refractory severe aplastic anemia (monotherapy)

Member must meet the following:

- Has documentation of positive clinical response to therapy (i.e., increased platelet count, reduction in number or severity of bleeding events, etc.)

Prescriber requirements:

- Must be prescribed by a hematologist.
- Attests clinical hematology and liver function tests will be measured at least monthly throughout course of treatment. Current labs from within the last 30 days will be attached to prior authorization forms.
- Verification of compliance will be made via Medicaid paid claims data. If non-compliance is determined, the reauthorization time frame may be reduced to allow time for the provider to address member compliance.

- Attests that member **will not** use Alvaiz™ concomitantly with other thrombopoietin receptor agonists (e.g., Nplate®, Doptelet®, Mulpleta®, Promacta®) or with spleen tyrosine kinase inhibitors (e.g., Tavalisse®).

Quantity Limits

Maximum Daily Dose: dose optimization is required

- ITP: 54 mg daily
- Chronic Hepatitis C-associated thrombocytopenia: 72 mg daily
- Refractory severe aplastic anemia: 108 mg daily

Coverage Duration

Initial approval: 6 months
Renewal approval duration: 6 months

B. Promacta® (eltrombopag olamine)

Initial Coverage Criteria

Treatment of thrombocytopenia in patients with persistent or chronic immune thrombocytopenia (ITP)

Member must meet all of the following criteria:

- Be 1 year of age or older.
- Have a diagnosis of persistent or chronic ITP.
- Have a platelet count of $<30x10^9$/L OR a platelet count of $30x10^9$/L to $50x10^9$/L with symptomatic bleeding or risk factors for bleeding.
- Have a trial and inadequate response to corticosteroids, OR immunoglobulins, OR splenectomy, OR rituximab.

Prescriber requirements:

- Must be prescribed by a hematologist.
- Attests to the following:
  - Clinical hematology and liver function tests will be measured at least monthly throughout course of treatment. Current labs from within the last 30 days will be attached to prior authorization forms.
  - Member **will not** use Promacta® concomitantly with other thrombopoietin receptor agonists (e.g., Nplate®, Doptelet®, Mulpleta®, Alvaiz™) or with spleen tyrosine kinase inhibitors (e.g., Tavalisse®).

Treatment of thrombocytopenia in patients with chronic Hepatitis C whose degree of thrombocytopenia prevents or limits interferon-based therapy

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have a diagnosis of chronic Hepatitis C whose degree of thrombocytopenia prevents the initiation or limits the ability for maintenance of interferon-based therapy.
- Have a platelet count of $<75x10^9$/L.
- Be starting or maintaining interferon-based therapy for chronic Hepatitis C.

Prescriber requirements:

- Must be prescribed by a hematologist.
- Attests to the following:

- During antiviral therapy CBCs with differentials, including platelet counts, will be monitored weekly until a stable platelet count is achieved
- Clinical hematology and liver function tests will be measured at least monthly throughout course of treatment. Current labs from within the last 30 days will be attached to prior authorization forms.
- Member **will not** use Promacta® concomitantly with other thrombopoietin receptor agonists (e.g., Nplate®, Doptelet®, Mulpleta®, Alvaiz™) or with spleen tyrosine kinase inhibitors (e.g., Tavalisse®).
- Promacta® will be discontinued when interferon-based therapy is discontinued.

First-line treatment of severe aplastic anemia

Member must meet all of the following criteria:

- Be 2 years of age or older.
- Have a diagnosis of severe Aplastic Anemia
- Is currently being treated in combination with standard immunosuppressive therapy (ATG and cyclosporine).

Prescriber requirements:

- Must be prescribed by a hematologist.
- Attests to the following:
  - Clinical hematology and liver function tests will be measured at least monthly throughout course of treatment. Current labs from within the last 30 days will be attached to prior authorization forms.
  - Member **will not** use Promacta® concomitantly with other thrombopoietin receptor agonists (e.g., Nplate®, Doptelet®, Mulpleta®, Alvaiz™) or with spleen tyrosine kinase inhibitors (e.g., Tavalisse®).

Refractory severe aplastic anemia (monotherapy)

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have a diagnosis of severe Aplastic Anemia.
- Has had an insufficient response to at least one prior immunosuppressive therapy.

Prescriber requirements:

- Must be prescribed by a hematologist.
- Attests to the following:
  - Clinical hematology and liver function tests will be measured at least monthly throughout course of treatment. Current labs from within the last 30 days will be attached to prior authorization forms.
  - Member **will not** use Promacta® concomitantly with other thrombopoietin receptor agonists (e.g., Nplate®, Doptelet®, Mulpleta®, Alvaiz™) or with spleen tyrosine kinase inhibitors (e.g., Tavalisse®).

Limitations:

Dosed per package labeling according to diagnosis.

Renewal Coverage Criteria

Treatment of thrombocytopenia in patients with persistent or chronic immune thrombocytopenia (ITP)

Member must meet all of the following criteria:

- Platelet count is greater than 50 x 10^9/L OR
- Number of clinically significant bleeding events has declined.

Prescriber requirements:
- Must be prescribed by a hematologist.
- Attests clinical hematology and liver function tests will be measured at least monthly throughout course of treatment. Current labs from within the last 30 days will be attached to prior authorization forms.
- Verification of compliance will be made via Medicaid paid claims data. If non-compliance is determined, the reauthorization time frame may be reduced to allow time for the provider to address member compliance.
- Attests that member **will not** use Promacta® concomitantly with other thrombopoietin receptor agonists (e.g., Nplate®, Doptelet®, Mulpleta®, Alvaiz™) or with spleen tyrosine kinase inhibitors (e.g., Tavalisse®).

Treatment of thrombocytopenia in patients with chronic Hepatitis C whose degree of thrombocytopenia prevents or limits interferon-based therapy

Member must meet all of the following:
- Has ongoing treatment with interferon-based therapy.

Prescriber requirements:
- Must be prescribed by a hematologist.
- Attests clinical hematology and liver function tests will be measured at least monthly throughout course of treatment. Current labs from within the last 30 days will be attached to prior authorization forms.
- Verification of compliance and ongoing interferon-based therapy will be made via Medicaid paid claims data. If non-compliance is determined, the reauthorization time frame may be reduced to allow time for the provider to address member compliance.
- Attests that member **will not** use Promacta® concomitantly with other thrombopoietin receptor agonists (e.g., Nplate®, Doptelet®, Mulpleta®, Alvaiz™) or with spleen tyrosine kinase inhibitors (e.g., Tavalisse®).

Treatment of severe aplastic anemia (first line and refractory)

Member must meet the following:
- Has documentation of positive clinical response to therapy (i.e., increased platelet count, reduction in number or severity of bleeding events, etc).

Prescriber requirements:
- Must be prescribed by a hematologist.
- Attests clinical hematology and liver function tests will be measured at least monthly throughout course of treatment. Current labs from within the last 30 days will be attached to prior authorization forms.
- Verification of compliance will be made via Medicaid paid claims data. If non-compliance is determined, the reauthorization time frame may be reduced to allow time for the provider to address member compliance.
- Attests that member **will not** use Promacta® concomitantly with other thrombopoietin receptor agonists (e.g., Nplate®, Doptelet®, Mulpleta®, Alvaiz™) or with spleen tyrosine kinase inhibitors (e.g., Tavalisse®).

Quantity Limits
Maximum Daily Dose: dose optimization is required

- ITP:75 mg daily
- Chronic Hepatitis C-associated thrombocytopenia: 100 mg daily
- Severe aplastic anemia: 150 mg daily

Coverage Duration
Initial approval: 6 months
Renewal approval duration: 6 months

C. Doptelet® (avatrombopag)

Initial Coverage Criteria

Treatment of thrombocytopenia in patients with chronic immune thrombocytopenia (ITP)

Member must meet all of the following criteria:
- Be 18 years of age or older.
- Have a diagnosis of chronic ITP.
- Have a platelet count of $<30x10^9$/L OR a platelet count of $30x10^9$/L to $50x10^9$/L with symptomatic bleeding or risk factors for bleeding.
- Have a trial and inadequate response to corticosteroids, OR immunoglobulins, OR splenectomy, OR rituximab.

Prescriber requirements:
- Must be prescribed by a hematologist.
- Attests to the following:
  - Platelet count will be measured at least monthly throughout course of treatment. Current labs from within the last 30 days will be attached to prior authorization forms.
  - Member **will not** use Doptelet® concomitantly with other thrombopoietin receptor agonists (e.g., Nplate®, Promacta®, Mulpleta®, Alvaiz™) or with spleen tyrosine kinase inhibitors (e.g., Tavalisse®).

Treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure.

Member must meet all of the following criteria:
- Be 18 years of age or older.
- Have a diagnosis of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure.

Prescriber requirements:
- Must be prescribed by a hematologist.
- Have a platelet count of $<50x10^9$/L. Current labs from within the last 30 days will be attached to prior authorization forms.
- Attests to the following:
  - Platelet count will be measured on the day prior to initiation of treatment to determine Doptelet® dose.
  - Member **will not** use Doptelet® concomitantly with other thrombopoietin receptor agonists (e.g., Nplate®, Promacta®, Mulpleta®, Alvaiz™ or with spleen tyrosine kinase inhibitors (e.g., Tavalisse®).

Limitations:
Dosed per package labeling according to diagnosis.

Renewal Coverage Criteria

Treatment of thrombocytopenia in patients with chronic immune thrombocytopenia (ITP).

Member must meet all of the following criteria:

- Platelet count is greater than or equal to 50 x 10^9/L, but less than 400 x 10^9/L OR
- Number of clinically significant bleeding events has declined.

Prescriber requirements:

- Must be prescribed by a hematologist.
- Platelet count will be measured at least monthly throughout course of treatment. Current labs from within the last 30 days will be attached to prior authorization forms.
- Verification of compliance will be made via Medicaid paid claims data. If non-compliance is determined, the reauthorization time frame may be reduced to allow time for the provider to address member compliance.
- Attests that member **will not** use Doptelet® concomitantly with other thrombopoietin receptor agonists (e.g., Nplate®, Promacta®, Mulpleta®, Alvaiz™) or with spleen tyrosine kinase inhibitors (e.g., Tavalisse®).

Treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure.

No renewal of Doptelet® is allowed for this diagnosis. Prior authorization is required for each scheduled procedure.

Quantity Limits

Maximum Daily Dose: dose optimization is required

- ITP:40 mg daily
- Thrombocytopenia in Chronic Liver Disease Patient Undergoing Scheduled Procedure: 60 mg daily for 5 days ONLY.

Coverage Duration

Treatment of thrombocytopenia in patients with chronic immune thrombocytopenia (ITP)
Initial approval: 6 months
Renewal approval duration: 6 months

Treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure
Initial approval: 5 days
Renewal approval duration: A new prior authorization request is required for each scheduled procedure.

2. CGRP Agents

The Board reviewed a potential change of criteria based on the updated Headache Society recommendations. After discussion, the Board voted 5 to 3 to keep the current criteria of 2 prior trials of prophylactic medications before approval of a CGRP for chronic or episodic migraine.

3. Age Extensions and Language Updates

A. Dupixent® (dupilumab)

Criteria Updates – the criteria documented below is the updated and current criteria approved by the Board specific to the listed indications below. For all other previously reviewed indications, the criteria remain the same. The updates are as follows:

1. *Asthma (corticosteroid dependent)*
    - *Prior Criteria:*

Member has a history of moderate to severe asthma attacks despite treatment with the following medications <u>at optimized doses in combination for 3 consecutive months:</u>

- *An inhaled corticosteroid (ICS)*
- *A long-acting beta2-agonist (LABA)*
- *An oral corticosteroid (OCS)*

- *Changed to:*
  - *A 30-day period of daily oral corticosteroids within the last year while taking an ICS/LABA **OR***
  - *2 bursts of oral corticosteroids during a 3-month period in the last year while taking an ICS/LABA.*

2. *Eosinophilic Esophagitis (EoE) – updated age and dosage indications for pediatric patients aged 1 year and older and weighing at least 15 kg.*

Initial Coverage Criteria

Asthma (corticosteroid dependent)

Member must meet all of the following criteria:

- Be 6 years of age or older.
- Have a diagnosis of moderate to severe asthma despite the following treatment:
  - A 30-day period of daily oral corticosteroids within the last year while taking an ICS/LABA **OR**
  - 2 bursts of oral corticosteroids during a 3-month period in the last year while taking an ICS/LABA.

Prescriber requirements:

- Must be prescribed by, or in consult with a pulmonology, immunology or allergy specialist.
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Attests that member **will not** use Dupixent® concomitantly with other biologics.

Eosinophilic Esophagitis (EoE)

Member must meet all of the following criteria:

- Be 1 year of age or older and weigh at least 15 kg.
- Have a diagnosis of eosinophilic esophagitis with documentation of ≥15 intraepithelial eosinophils per high-power field (eos/hpf) AND symptoms of dysphagia as measured by the Dysphagia Symptom Questionnaire (DSQ).
- Has a documented trial and an inadequate treatment response, intolerance or contraindication within the last 6 months to swallowed topical corticosteroid (budesonide, fluticasone) for a minimum of 4 weeks.

Prescriber requirements:

- Must be prescribed by, or in consult with a gastroenterology, or allergy specialist.
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Attests that member **will not** use Dupixent® concomitantly with other biologics.

Limitations:

Dosed according to weight per package labeling

Renewal Coverage Criteria

Asthma (corticosteroid dependent)

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 and/or decrease in corticosteroid dosing).
- Has been adherent to therapy.
- Verification of adherence will be made via Medicaid paid claims data. If non-compliance is determined, the reauthorization time frame may be reduced to allow time for the provider to address member compliance.

Prescriber requirements:

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

Eosinophilic Esophagitis (EoE)

Member must meet all of the following criteria:

- Has been adherent to therapy.
- Verification of adherence will be made via Medicaid paid claims data. If non-compliance is determined, the reauthorization time frame may be reduced to allow time for the provider to address member compliance.

Prescriber requirements:

- Annual specialist consult provided if prescriber not a specialist.
- Has documentation of positive clinical response to therapy by reduction in peak esophageal intraepithelial eosinophil count (<6=remission) after the initial 6 months of treatment..
- Has documentation of positive clinical response to therapy by reduction in DSQ score (Dysphagia Symptom Questionnaire).
- Attests that member **will not** use Dupixent® concomitantly with other biologics.

Quantity Limits

Maximum Daily Dose:
Asthma (corticosteroid dependent): Age dependent dosing
EoE: Age dependent dosing

Coverage Duration

Initial approval: 6 months
Renewal approval duration: 12 months

4. 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. *Subcutaneous Entyvio® Pen and Syringe is now indicated for both moderately to severely active ulcerative colitis and moderately to severely active Crohn's disease.*
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 **OR** moderately to severely active Crohn's disease.
- Have shown clinical benefit from IV Entyvio after 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:
Dosed per package labeling after intravenous infusions at week 0 and 2, then subcutaneously every 2 weeks 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). After initial approval to switch to subcutaneous injection at week 6, patient 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.

Quantity Limits
Maximum Daily Dose = 108mg every 2 weeks subcutaneously starting at week 6.

Coverage Duration
Initial approval for subcutaneously dosing: After meeting criteria to switch at week 6, approval will be granted for 5 total subcutaneous injections (to week 14) at which time an update will be required.
Renewal approval duration: 12 months

B. Fasenra® (benralizumab)

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

1. *Age indication changed from 12 years of age to 6 years of age.*

Initial Coverage Criteria

Member must meet all of the following criteria:

- Be 6 years of age or older.
- Have a diagnosis of severe uncontrolled asthma with an eosinophilic phenotype.
    - Have baseline peripheral blood eosinophil count of ≥150 cells/μL.
    - Have a history of severe asthma attacks despite treatment with, and adherence to, an optimized dose of inhaled corticosteroid in combination with a long-acting beta2-agonist (ICS/LABA) for three consecutive months.

Prescriber requirements:

- Must be prescribed by, or in consult with, a pulmonology, allergy, or immunology specialist.
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Attests that member **will not** use Fasenra® concomitantly with other biologics.

Limitations:
Dosed per package labeling.

Fasenra® is not indicated for treatment of other eosinophilic conditions or for the relief of acute bronchospasm or status asthmaticus.

Renewal Coverage Criteria

Member must meet all of the following criteria:

- Have documentation of positive clinical response to therapy such as a reduction in frequency and/or severity of symptoms and exacerbations or medication dose reduction.
- Be compliant with Fasenra® and ICS/LABA therapy.

Prescriber requirements:

- Annual specialist consult provided if prescriber not a specialist.
- Verification of compliance will be made via Medicaid paid claims data. If non-compliance is determined, the reauthorization time frame may be reduced to allow time for the provider to address member compliance.
- Attests that member **will not** use Fasenra® concomitantly with other biologics.

Quantity Limits
Maximum Dose:
Adults and adolescents 12 years of age and older: 30mg SQ every 4 weeks for 3 doses, then 30mg SQ every 8 weeks.

Children 6 to 11 years of age and older:

- Weighing less than 35 kg:10 mg SQ every 4 weeks for the first 3 doses, then 10 mg SQ once every 8 weeks.
- Weighing 35 kg or more:30 mg SQ every 4 weeks for the first 3 doses, then 30 mg SQ once every 8 weeks.

Coverage Duration
Initial approval: 6 months
Renewal approval duration: 12 months

C. Xolair® (omalizumab)

Criteria Updates – the criteria documented below is the updated and current criteria approved by the Board specific to the listed indications below. For all other previously reviewed indications, the criteria remain the same.

1. *New indication for IgE-Mediated Food Allergy.*

2. *Changed language from Chronic Idiopathic Urticaria (CIU) to Chronic Spontaneous Urticaria (CSU) to be consistent with labeling.*

Initial Coverage Criteria

IgE-Mediated Food Allergy

Member must meet all of the following criteria:

- Be 1 year of age or older.
- Have a diagnosis IgE-mediated food allergy (Type I) to one or more foods.

Prescriber requirements:

- Must be prescribed by, or in consult with, an allergy or immunology specialty clinic.
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Has placed member on a food allergen avoidance program.
- Must submit pretreatment serum total IgE level and current body weight for dose verification.
- Attests to the following:
    - Due to the boxed warning risk of anaphylaxis, Xolair® will be initiated in a healthcare setting and only appropriate patients will be allowed to self-administer.
    - Concomitant use of Xolair® and allergen immunotherapy has not been evaluated and will not be prescribed.

Limitations: Dosed per labeling based on IgE and weight.

Chronic Spontaneous Urticaria (CSU):

Member must meet all of the following criteria:

- Be 12 years of age or older.
- Have a diagnosis of chronic spontaneous urticaria (also called chronic idiopathic urticaria).
- Must have had an inadequate response to 2 different H1 antihistamine trials of 4 weeks each.

Prescriber requirements:

- Must be prescribed by, or in consult with an allergy, dermatology, or immunology specialty clinic.
- 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:
    - Due to the boxed warning risk of anaphylaxis, Xolair® will be initiated in a healthcare setting and only appropriate patients will be allowed to self-administer.
    - Concomitant use of Xolair® with immunosuppressive therapy has not been evaluated and will not be prescribed.

Renewal Coverage Criteria

IgE-Mediated Food Allergy

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).
- Has been adherent to therapy.

Prescriber requirements:

- Annual specialist consult provided if prescriber not a specialist.
- Attests that concomitant use of Xolair® and allergen immunotherapy has not been evaluated and will not be prescribed.
- Verification of compliance will be made via Medicaid paid claims data. If non-compliance is determined, the reauthorization time frame may be reduced to allow time for the provider to address member compliance.

Chronic Spontaneous Urticaria (CSU)

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).
- Has been adherent to therapy.

Prescriber requirements:

- Annual specialist consult provided if prescriber not a specialist.
- Attests that concomitant use of Xolair® with immunosuppressive therapy has not been evaluated and will not be prescribed.
- Verification of compliance will be made via Medicaid paid claims data. If non-compliance is determined, the reauthorization time frame may be reduced to allow time for the provider to address member compliance.

Quantity Limits
Maximum Daily Dose:
IgE-Mediated Food Allergy: 600 mg every 2 weeks
CSU: 300 mg every 4 weeks

Coverage Duration
Initial approval:
IgE-Mediated Food Allergy: 6 months
CSU: 3 months

Renewal approval duration:
IgE-Mediated Food Allergy: 12 months
CSU: 6 months

5. New Drug Criteria:

A. Brixadi® (buprenorphine extended-release injection)

Initial Coverage Criteria

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Assessment/screening supports a diagnosis of opioid use disorder (DSM-V).

Prescriber requirements:

- Must be a Montana Healthcare Programs enrolled provider.

- Must provide clinical rationale documenting necessity to switch to injectable product.
- Must perform an overdose risk assessment and recommend naloxone if appropriate.
- Attests to the following:
    - For injection of Brixadi® weekly:
        - Members **NOT currently receiving** buprenorphine treatment:
            - Have tolerated at least one sublingual 4 mg dose of buprenorphine prior to injection AND
            - Will NOT receive injection in the **upper arm** until steady state has been achieved (4 consecutive doses). Buttock, thigh or abdomen are the appropriate sites of injection for those not previously maintained on buprenorphine until steady state.

        - Member **currently receiving** buprenorphine treatment:
            - Will be transitioned from another buprenorphine product according to labeling.
    - For injection of Brixadi® monthly:
        - Member is currently being treated with a transmucosal buprenorphine-containing product of at least 8 mg per day. OR
        - Member is currently transitioning from Brixadi® weekly of at least a dose of 16mg per week.

Limitations:
Dosed subcutaneously by a healthcare provider and titrated per package labeling.

To avoid missed doses, the weekly dose may be administered up to 2 days before or after the weekly time point, and the monthly dose may be administered up to 1 week before or after the monthly time point.

Renewal Coverage Criteria

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

Prescriber requirements:
- Must be a Montana Healthcare Programs enrolled provider.

Quantity Limits
Maximum Allowed Dose
Brixadi® weekly: 32 mg every 7 days.
Brixadi® monthly: 128 mg every 28days.

Coverage Duration
Initial approval: Weekly and Monthly Brixadi® will be approved each month for 3 total months, then approval for an additional 3 months. Dose changes will require a new PA.
Renewal approval duration: Approvals after 6 months at the same dose will be approved for 12 months.

Note: use in pregnancy discussed and while this is not indicated, but not contraindicated, in pregnancy, these requests would be approved if the benefit outweighed the risk of the mother not being on MOUD therapy.

B. Odactra™ (Dermatophagoides farinae and Dermatophagoides pteronyssinus) Allergen Extract

Initial Coverage Criteria

Member must meet all of the following criteria:
- Be 12-65 years of age.

- Have a diagnosis of house dust mite (HDM) induced allergic rhinitis, with or without conjunctivitis.
- Have a trial and inadequate response, or contraindication to an oral antihistamine AND nasal steroid.

Prescriber requirements:

- Must be prescribed by, or in consult with, an allergy specialist.
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Must confirm specific allergy (by positive skin-prick test specific for IgE antibodies to Dermatophagoides farinae and Dermatophagoides pteronyssinus house dust mites, or by positive skin testing to licensed house dust mite allergen extracts).
- Attests to the following:
    - Odactra™ **will not** be used concomitantly with other allergen immunotherapy.

Limitations:
Dosed per package labeling

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.
- Attests that member **will not** use Odactra™ concomitantly with other allergen immunotherapy

Quantity Limits
Maximum Daily Dose = 1.0 tablet

Coverage Duration
Initial approval: 12 months
Renewal approval duration: 12 months

C. Rykindo® (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:
Dose: Rykindo® is dosed intramuscularly per package labeling every two weeks.

Renewal Coverage Criteria

Member must meet all of the following criteria:

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

Quantity Limits
Maximum Dose = 50 mg every two weeks.

Coverage Duration
Initial approval: 12 months
Renewal approval duration: 12 months

D. Tryvio® (aprocitentan)

Initial Coverage Criteria

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have a diagnosis of hypertension with a mean sitting systolic blood pressure (SiSBP) greater than or equal to 140 mmHg while taking at least 3 antihypertensive therapies at maximized tolerated doses.
- Have tried at least 4 antihypertensive therapies of different pharmacological classes, and currently taking 3 antihypertensive therapies at maximized tolerated doses including a diuretic, at a stable dose for at least 12 weeks prior to PA request and will remain on this treatment while on Tryvio®.

Prescriber requirements:

- Mean sitting systolic blood pressure measurement is documented prior to treatment with Tryvio®.
- Must be prescribed by, or in consultation with a cardiology, nephrology, or endocrinology 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:
    - The member, if a female of childbearing age, has confirmation of a negative pregnancy test.
    - The provider is aware of the boxed warning of **Embryo-Fetal toxicity** AND the REMS requirements.
    - Other causes of hypertension have been ruled out or treated. This will be verified against claims and diagnosis history.
    - The member **will continue all** baseline antihypertensives while taking Tryvio®.

Limitations:
Dosed per package labeling.

Renewal Coverage Criteria

Member must meet all of the following criteria:

- Must have a confirmed reduction in sitting systolic blood pressure.
- Must maintain all baseline antihypertensive medications.

Prescriber requirements:

- Has documented a reduction in systolic blood pressure.
- Annual specialist consult provided if prescriber not a specialist.
- Drug Prior Authorization Unit will notify provider if member has not been adherent to baseline antihypertensive medications.

Quantity Limits
Maximum Daily Dose = 1 tablet daily

Coverage Duration
Initial approval: 4 weeks (Most of the BP-lowering effect occurred within the first two weeks of treatment with Tryvio®)
Note: Due to Board recommendations that Tryvio® is prescribed by, or in consultation with a cardiac specialist and initial prior authorization review must include verification that other causes of hypertension have been ruled out or treated, it was agreed that Mountain Pacific Pharmacy Case Management pharmacists would do the initial review for these requests. Cases will be tracked, and once sufficient data is collected to assess if this is being prescribed appropriately, the results will be presented to the DUR Board, at which time, discussion will be had to determine if this will continue to remain with Pharmacy Case Management or if it can be handed off to the Drug Prior Authorization team.

Renewal approval duration: 12 months

E. Wegovy® (semaglutide injection)

Initial Coverage Criteria

Member must meet all of the following criteria:
- Be 18 years of age or older.
- Have established cardiovascular disease with a history of prior myocardial infarction, prior stroke, or peripheral arterial disease.
- A BMI of greater than 27 kg/m^2.
- Does NOT have type 2 diabetes (These members must be managed with a GLP-1 agonist FDA approved for that indication from the Montana Healthcare Programs preferred drug list.)
- Agreed to adhere to a reduced calorie diet and increased physical activity plan.

Prescriber requirements:
- Must be prescribed by, or in consult with, an appropriate cardiac 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:
    - The provider is aware Wegovy® is contraindicated in members with a personal or family history of medullary thyroid cancer or multiple endocrine neoplasia 2.
    - The provider is aware of boxed warning about the risk of thyroid C-cell tumors.
    - The provider is aware of the risk of pancreatitis, gallbladder disease, hypoglycemia, acute kidney injury and diabetic retinopathy complications.
    - The provider is aware Wegovy® may increase the risk of suicidal behavior and ideation.
- Attests that member will be placed on a reduced calorie diet and increased physical activity plan.

Limitations:
Dosed per package labeling

Renewal Coverage Criteria

Member must meet all of the following criteria:

- Has documentation of positive clinical measures of cardiovascular disease risk reduction (i.e., weight reduction, reduced waist circumference, blood pressure improvement, improved cholesterol profile, etc.).

Prescriber requirements:

- Annual specialist consult provided if prescriber not a specialist.
- Attests that member has maintained a reduced calorie diet and increased physical activity plan.

Quantity Limits
Maximum Dose = 2.4 mg weekly

Coverage Duration
Initial approval: 12 months
Renewal approval duration:12 months

F. Winrevair™ (sotatercept-csrk)

Initial Coverage Criteria

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have documented diagnostic right heart catheterization (RHC) at any time prior to screening confirming the diagnosis of **WHO pulmonary arterial hypertension (PAH) Group 1** in any of the following subtypes:
  - Idiopathic PAH
  - Heritable PAH
  - Drug/toxin-induced PAH
  - PAH associated with connective tissue disease
  - PAH associated with simple, congenital systemic-to-pulmonary shunts at least 1 year following repair
- Currently taking and will continue to take background PAH therapy prescribed by or in consultation with a PH specialist. Therapy consists of an endothelin-receptor antagonist (ERA), a phosphodiesterase 5 (PDE5) inhibitor, a soluble guanylate cyclase stimulator, a prostacyclin analog or receptor agonist.

Prescriber requirements:

- Must be prescribed by, or in consult with, an appropriate specialist for pulmonary arterial hypertension (i.e., cardiologist, pulmonologist, primary care center at a large hospital, etc.).
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Provider will monitor hemoglobin and platelets for drug induced changes.
- Provider will submit the baseline distance of member's 6-minute walk test with initial PA request.

Limitations:
Dosed per package labeling

Renewal Coverage Criteria

Member must meet all of the following criteria:

- Has documentation of improvement in 6-minute walk distance.
- Has continued to take background PAH Therapy.

Prescriber requirements:

- Annual specialist consult provided if prescriber not a specialist.
- Provider will attach current 6-minute walk test results.
- Drug Prior Authorization Unit will notify provider if member has not been compliant with baseline PAH therapy. Verification of compliance will be made via Medicaid paid claims data. If non-compliance is determined, the reauthorization time frame may be reduced to allow time for the provider to address member compliance.

Quantity Limits
Maximum Daily Dose = 0.7mg/kg every 3 weeks

Coverage Duration
Initial approval: 6 months
Renewal approval duration: 12 months

6. Medications for Opioid Use Disorder (OUD) Discussion

A. Sublingual buprenorphine criteria discussion:

The Board discussed their preferences for sublingual buprenorphine therapy for OUD, agreeing that both Suboxone® Film and generic buprenorphine monotherapy SL tablets specifically, should be preferred on the Preferred Drug List, and opting to remove **all clinical criteria** requirements for sublingual therapy, including the OB/GYN notification for members who are pregnant and being actively treated for OUD. The existing provider requirement, which requires all providers treating OUD to be a Montana Healthcare Programs enrolled provider, will continue to be enforced. Additionally, all enrolled providers are strongly encouraged to fill out the MOUD Provider Attestation Form and fax it back to Montana Allied Health Services Pharmacy Program Officer to be added to the electronic list that will allow electronic prior authorization for preferred oral buprenorphine products. These decisions aim to streamline access and enhance treatment options for Montana Healthcare Programs members.

For requests to exceed the allowed quantity and/or dose limits (see below), prescriptions for multiple strengths, refill-to-soon requests, or coverage for non-preferred products will continue to require manual prior authorization and the providers office and/or pharmacy will need to contact the Drug Prior Authorization Unit to discuss.

B. Dose limits for sublingual buprenorphine therapy:

The Board discussed the appropriateness of the current dose limits of 24 mg per day for sublingual therapy. After considering updated studies and recommendations, the maximum daily dose limit was increased to 32 mg of buprenorphine per day for both buprenorphine monotherapy and Suboxone® (buprenorphine/naloxone) SL. Doses exceeding 32 mg per day will be reviewed on a case-by-case basis.

7. Lybalvi® (olanzapine and samidorphan) Criteria Discussion

During previous DUR Board meetings, board members requested that the criteria for Lybalvi® be brought back for review. After discussion, the criteria was modified and is documented below:

Initial Coverage Criteria

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have a diagnosis of Schizophrenia or Bipolar I Disorder.
- Have at least a 7-day opioid-free interval from the last use of short-acting opioids, AND at least a 14-day opioid-free interval from the last use of long-acting opioids.
- Have a positive trial of olanzapine, but experiences unacceptable weight gain (5% or more) seen within 12 weeks or less of starting treatment AND have documented trials with inadequate response or contraindication to two (2) additional preferred atypical antipsychotics with the same indication at maximally tolerated doses for at least 4 weeks.
  OR
- If no trial on olanzapine but have a trial on two (2) other preferred atypical antipsychotics with the same indication at maximally tolerated doses and experiences unacceptable weight gain (5% or more) seen within 12 weeks or less of starting treatment, approval may be granted without an olanzapine trial.
  OR
- If no trial on olanzapine but have a trial on two (2) other preferred atypical antipsychotics with the same indication at maximally tolerated doses and little to no weight gain (less than 5%) seen within 12 weeks or less of starting treatment, member will have to trial olanzapine and experience 5% or more of weight gain within 12 weeks of starting treatment.

Prescriber requirements:

- Must be prescribed by, or in consultation with a psychiatric specialist.
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Attests that prior to initiating therapy, member has had at least a 7-day opioid-free interval from the last use of short-acting opioids, AND at least a 14-day opioid-free interval from the last use of long-acting opioids.

Limitations:
Dosed per package labeling.

Renewal Coverage Criteria

Member must meet all of the following criteria:

- Has documentation of positive clinical response to therapy and weight has either decreased or stabilized.

Prescriber requirements:

- Annual specialist consult provided if prescriber not a specialist.
- Verification of compliance will be made via Medicaid paid claims data. If non-compliance is determined, the reauthorization time frame may be reduced to allow time for the provider to address member compliance.

Quantity Limits

Maximum Daily Dose = 1 tablet daily

Coverage Duration
Initial approval: 6 months
Renewal approval duration: 12 months

The next Drug Utilization Review meeting will be on September 25, 2024, in this same format. The meeting adjourned at 4:23 p.m.