December 2024 DUR Board Meeting Minutes

Date: December 4, 2024

Members Present: Barnhill, Anglim, Blake, Brown, Caldwell, Jost, McGrane, Oley, Stone

Members Absent: Blank, Nauts, Putsch

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

Public Comment:
1. Bobbi Bentz, Eli Lilly – Ebglyss®
2. Siera Boyd, Billings Clinic – Eohilia®
3. Maria Herrera, Billings Clinic – Eohilia® in pediatric patients
4. Robert Konop, Novartis – Zolgensma®
5. Melinda Turkington, UCB – Bimzelx®
6. Brian Hocum, Bayer Healthcare – Kerendia® guideline update
7. Bobby White, Eisai – Monoclonal antibodies for the treatment of Alzheimer's Disease
8. Domenic Mantella, Ascendis Pharma – Yorvipath®

Written public comment was submitted to the Board before the meeting. It consisted of 4 letters from Montana providers/advocacy groups and 4 manufacturer documents. The criteria for Bimzelx®, Ebglyss®, Kerendia®, and Zolgensma were already on the agenda and the criteria was reviewed by the DUR Board (see below for finalized criteria). Brief discussions for Spravato® and atypical antipsychotics in children were had at the end of the meeting.

Meeting Minute Review: The September 25, 2024, DUR minutes were approved as written.

Department Update: None

Board Discussion

1. Age Extensions and Language Updates

A. Kerendia® (finerenone)

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

1. *Specialist requirement has been removed.*
2. A_1C *requirement has been changed from 8% to 10%.*
3. *Urine albumin-to-creatinine has been changed from greater than or equal to 30, to 30 to 300mg/g.*
4. *Removed the max GFR.*

Note: Discussion was had on removing the SGLT-2 in the criteria prior to Kerendia® being approved. Ultimately, this criteria point was retained.

Initial Coverage Criteria

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have a diagnosis of chronic kidney disease (CKD) associated with type 2 diabetes (T2D).
- Have an A_1C of less than 10% and potassium level less than 5.0mEq/L.
- Has undergone a recent trial (within the past 90 days) of an SGLT2 preferred drug from the Montana Healthcare Programs Preferred Drug List 19
- Have a urine albumin-to-creatinine of 30 to 300mg/g creatinine and eGFR greater than or equal to 25ml/min/1.73m^2.
- Is currently receiving a maximally tolerated ACE or ARB, unless contraindicated.

Prescriber requirements:

- Attests to the following:
    - Member does not have severe hepatic impairment (Child Pugh C).

Limitations:
Dosed per package labeling

Renewal Coverage Criteria

Member must meet all of the following criteria:

- Has positive clinical response to therapy (i.e., slowing of the decline of eGFR and other measures of CKD, or reduction in ASCVD events such as non-fatal heart attack, non-fatal stroke, heart failure hospitalization).

Prescriber requirements:

- Has documented response of member positive clinical response to therapy (i.e., slowing of the decline of eGFR and other measures of CKD, or reduction in ASCVD events such as non-fatal heart attack, non-fatal stroke, heart failure hospitalization).

Quantity Limits
Maximum Daily Dose = 20 mg

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

2. New Indication/Formulation:

A. Nexletol® (bempedoic acid) and Nexlizet® (bempedoic acid/ezetimibe)
Criteria Updates – the criteria documented below is the updated and current criteria approved by the Board. The updates are as follows:

1. *Indication expansion. Previously: LDL-C lowering failure in primary hyperlipidemia including heterozygous familial hypercholesterolemia. Updated to include: reducing the risk of myocardial infarction and coronary revascularization in adults who are unable to take recommended statin therapy (including those not taking a statin) with:*
    1. *Established cardiovascular disease (CVD), or*
    2. *At high risk for a CVD event but without established CVD (i.e., HBP, diabetes, metabolic syndrome, high BMI, chronic inflammation, etc.)*

Initial Coverage Criteria

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have a diagnosis of:
    - Established CVD OR high risk for a CVD event but without established CVD
    - Primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH).
- Have an LDL-cholesterol equal to or greater than 70mg/dl.
- Have a trial and inadequate response, or contraindication to at least two high intensity statins (i.e. atorvastatin/rosuvastatin) for at least 12 weeks.
- Have a trial and inadequate response, or contraindication to ezetimibe for at least 12 weeks.
- Have a trial on a PCSK-9 (Praluent/Repatha) for at least 12 weeks and has been ineffective or contraindicated.

Prescriber requirements:

- Must be prescribed by, or in consult with, a cardiology, endocrinology or lipidology 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 should be monitored for hyperuricemia.
    - Member should not use simvastatin >20 mg or pravastatin >40 mg concurrently with bempedoic acid products.

Limitations:
Dosed per package labeling

Renewal Coverage Criteria

Member must meet all of the following criteria:

- Has documentation of positive clinical response to therapy (i.e., reduction in LDL-C or reduction in incidence of CVD events)

Prescriber requirements:

- Annual specialist consult provided if prescriber not a specialist.
- Attests that member will have labs monitored.

Quantity Limits
Maximum Daily Dose = 180 mg

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

B. Bimzelx® (bimekizumab-bkzx)

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

1. *New indications for active PsA, active non-radiographic axial spondyloarthritis with objective signs of inflammation (nr-axSpA), active ankylosing spondylitis (AS), and moderate to severe hidradenitis suppurativa (HS).*

Note: Discussion was had about the updated warning for suicidal ideation that Bimzelx® has for specific indications only. The Board decided that this warning should only be added to the indications where it was seen in the clinical trials or post-marketing reports since there has been no causal link to Bimzelx® according to the FDA notification.

Initial Coverage Criteria

Plaque Psoriasis, Psoriatic Arthritis

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have a diagnosis of moderate to severe plaque psoriasis **OR** psoriatic arthritis.
- 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 or rheumatology 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®.
    - All age-appropriate vaccines and lab work have been completed prior to Bimzelx® initiation and liver enzymes will be monitored.
    - Prescriber is aware Bimzelx® in treatment of plaque psoriasis and psoriatic arthritis may increase suicidal ideation and behavior.
- Attests that member will not use Bimzelx® concomitantly with other biologics.

Limitations:
Dosed per package labeling

Non-Radiographic Axial Spondyloarthritis, Ankylosing Spondylitis

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have a diagnosis of non-radiographic axial spondyloarthritis OR ankylosing spondylitis.
- 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 rheumatology 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®.
    - All age-appropriate vaccines and lab work have been completed prior to Bimzelx® initiation and liver enzymes will be monitored.
- Attests that member will not use Bimzelx® concomitantly with other biologics.

Limitations:
Dosed per package labeling

Hidradenitis Suppurativa

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have a diagnosis of moderate to severe hidradenitis suppurativa.
    - Diagnosis, based on clinical history and physical examination, must have been present for at least 6 months.
- Lesions requirements:
    - Present in at least 2 distinct anatomic areas.
    - Presence of 5 or more inflammatory lesions (i.e. Number of abscesses plus number of inflammatory nodules).
    - Recurrent nodules with sinus tract formation or scarring (tunneling).
- Have a trial and inadequate response, or contraindication to at least one oral antibiotic for HS.
- 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®.
    - All age-appropriate vaccines and lab work have been completed prior to Bimzelx® initiation and liver enzymes will be monitored.

    - Prescriber is aware Bimzelx® in treatment of hidradenitis suppurativa may increase suicidal ideation and behavior.
- Attests that member will not use Bimzelx® concomitantly with other biologics.

Limitations:
Dosed per package labeling

Renewal Coverage Criteria

Member must meet all of the following criteria:

- Has evidence of positive clinical response to therapy (i.e., reduction in the frequency and/or severity of symptoms and exacerbations).

Prescriber requirements:

- Annual specialist consult provided if prescriber not a specialist.
- Has documentation of positive clinical response to therapy (i.e., reduction in the frequency and/or severity of symptoms and exacerbations).
- Provider attests that member **will not** use Bimzelx® concomitantly with other biologics.

Quantity Limits
Maximum Daily Dose (subcutaneous injection):
PsO:320 mg at weeks 0, 4, 8, 12, and 16, then every 8 weeks. If ≥120kg, 320mg every 4 weeks after week 16.
PsA, nr-axSpA, AS:160 mg every 4 weeks.
HS: 320 mg at weeks 0, 2, 4, 6, 8, 10, 12, 14, and 16, then every 4 weeks.

Coverage Duration
Initial approval: 16 weeks
Renewal approval duration: 12 months

C. Dupixent® (dupilumab)
Criteria Updates – the criteria documented below is the updated and current criteria approved by the Board specific to the listed indication below. For all other previously reviewed indications, the criteria remain the same:

1. *Age expansion to 12 years of age for chronic rhinosinusitis w/nasal polyps.*
2. *New indication for Chronic Obstructive Pulmonary Disease as an add-on maintenance treatment of adult patients with inadequately controlled COPD and an eosinophilic phenotype.*
3. *The Board requested a provider attestation be added stating that the provider has offered smoking cessation options to the member if they are currently smoking.*
   Note: This add is a Board request and wasn't part of the interim criteria.

Chronic Obstructive Pulmonary Disease (COPD)

Initial Coverage Criteria

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have a diagnosis of chronic obstructive pulmonary disease with 2 or more exacerbations OR one exacerbation requiring hospitalization within the past twelve months.
- Have a blood eosinophil count greater than or equal to 300 cells/mcL
- Currently be receiving standard treatment with triple inhalation therapy (LABA/LAMA/ICS) unless intolerance, or contraindication. Exacerbations indicating uncontrolled disease must have occurred while member was adherent to LABA/LAMA/ICS. Claims history will be used to verify adherence at time of exacerbation.

Prescriber requirements:

- Must be prescribed by, or in consult with a pulmonology specialist.
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- If member is an active smoker, attests that member has been offered nicotine cessation support.
- Attests that member **will not** use Dupixent® concomitantly with other biologics.

Limitations:
Not for relief of acute bronchospasm.

Renewal Coverage Criteria

Member must meet all of the following criteria:

- Has evidence of positive clinical response to therapy (i.e., reduction in the frequency and/or severity of symptoms and exacerbations and/or improved FEV_1).
- Member must currently be receiving standard treatment with triple inhalation therapy (LABA/LAMA/ICS) unless intolerance, or contraindication.
- 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 (i.e., reduction in the frequency and/or severity of symptoms and exacerbations and/or improved FEV_1).

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

Quantity Limits
Maximum Daily Dose:
300mg SQ every 2 weeks

Coverage Duration

Initial approval: 6 months
Renewal approval duration: 12 months

D. Leqembi® (lecanemab-irmb)
Criteria Updates – the criteria documented below is the updated and current criteria approved by the Board specific to the listed indication below:
1. Updated to mirror Kisunla® criteria where appropriate.

Note: Board discussion about removing a trial on cholinesterase inhibitors resulted in a decision of no change to criteria and the required trial in criteria was upheld.

Initial Coverage Criteria

Member must meet all of 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 of 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 1 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 an adequate trial of at least 3 months with a Montana Healthcare Programs preferred Alzheimer's therapy (cholinesterase inhibitor) and the preferred drug was ineffective or caused intolerable side effects. 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® and

dosages will not be adjusted during Leqembi® therapy. Additional therapies may not be initiated during Leqembi® treatment.

- Have a recent baseline brain magnetic resonance imaging (MRI) within 3-6 months prior to initiating treatment with Leqembi®.
    - Obtain an MRI prior to the 5th, 7th, and 14th infusions.
    - If a patient experiences symptoms suggestive of ARIA, clinical evaluation should be performed, including an MRI if indicated.

Prescriber requirements:

- Must be a neurology specialist.
- Must discuss genetic testing for ApoE ε4 status prior to treatment.
- 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 Beer's List).
- Agree to obtain an MRI prior to the 5th, 7th and 14th infusions. If a patient experiences symptoms suggestive of ARIA, clinical evaluation will be performed, including an MRI if indicated.
    - 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 (ARIA).
    - 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.
    - The prescriber has considered the risk of concomitant use of Leqembi® with any medication with platelet anti-aggregate or anti-coagulant properties (unless aspirin ≤ 325 mg daily.
    - Dose adjustments to medications currently being used to treat symptoms related to Alzheimer's Disease will not be allowed during Leqembi® treatment.
    - Additional Alzheimer's Disease therapies will not be initiated during Leqembi® treatment.

Limitations:
Dosed per package labeling every two weeks based on weight.

Renewal Coverage Criteria

Member must meet all of the following criteria:

- Will discontinue treatment when reduction of amyloid plaques are reduced to minimal levels on amyloid PET imaging, defined as either of the following:
    - Level is < 11 Centiloids on a single PET scan **OR**
    - Level is 11 to < 25 Centiloids on 2 consecutive PET scans.
- Has not progressed to moderate or severe AD.

Prescriber requirements:

- Be a neurology specialist.
- Obtain follow-up MRI prior to the 5th, 7th and 14th infusions.
- Monitor appropriately for ARIA. If imaging shows ARIA, manage treatment per labeling.

Quantity Limits
Maximum Dose = 10 mg/kg administered IV over approximately one hour every 2 weeks.

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

E. Zolgensma® (onasemnogene adeparvovec-xioi)
Criteria Updates – the criteria documented below is the updated and current criteria approved by the Board specific to the listed indication below:

1. *Changed language from less than or equal to 3 copies of the SMN2 gene to less than or equal to 4 copies of the SMN2 gene.*

Initial Coverage Criteria

Member must meet all of the following criteria:

- Be less than 2 years of age.
- Has reached full gestational age (if neonate was born prematurely)
- Diagnosis based on genetic testing:
    - Has confirmed bi-allelic SMN1 gene deletions or dysfunctional point mutations confirming a diagnosis of SMA.
    - Has confirmed less than or equal to 4 copies of the SMN2 gene.
- Has baseline anti-AAV9 antibody titer of less than or equal to 1:50.
- Does not have complete limb paralysis or permanent ventilator dependence.
- Has not previously received Zolgensma.

Prescriber requirements:

- Must be prescribed by, or in consult with, a neurology specialist.

- If not prescribed by an appropriate specialist, a copy of the specialty consult is required.
- Provider must submit documentation of a baseline motor function milestone evaluation test using an age-appropriate screening tool (e.g., CHOP-INTEND).
- Baseline liver function tests, platelet counts, and troponin-1 have been performed and will continue to be assessed after treatment for at least 3 months until they return to baseline.
- Attests to knowledge of boxed warning of serious liver injury and acute liver failure with Zolgensma®.
- Attests that member will not use Zolgensma® concomitantly with Spinraza® or Evrysdi™.

Limitations:
Dosed per package labeling

Renewal Coverage Criteria

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

Quantity Limitations
Max of one 1.1 x 10^{14} vector genomes/kg IV as a single weight-appropriate dose per lifetime.

Coverage Duration
Initial approval duration: one single infusion
Renewal approval duration: N/A

Tremfya® (guselkumab)
Criteria Updates – the criteria documented below is the updated and current criteria approved by the Board specific to the listed indication below. For all other previously reviewed indications, the criteria remain the same:
1. New indication for moderately to severely active ulcerative colitis in adults.

Initial Coverage Criteria

Active psoriatic arthritis

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have a diagnosis of active psoriatic arthritis.
- Have a trial and inadequate response, intolerance or contraindication to a preferred drug with the same indication from the Montana Healthcare Programs Preferred Drug List 19 (mt.gov)

Prescriber requirements:

- Must be prescribed by, or in consult with, a rheumatology specialist.
- 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:
    - Member has been screened for tuberculosis (TB) prior to initiating treatment.
- Provider will monitor for active infection.
- Provider attests member will not use Tremfya® concomitantly with other biologics.

Moderate-to-severe plaque psoriasis

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, intolerance or contraindication to a preferred drug with the same indication from the Montana Healthcare Programs Preferred Drug List 19 (mt.gov)

Prescriber requirements:

- Must be prescribed by, or in consult with, a rheumatology or dermatology specialist.
- 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:
    - Member has been screened for tuberculosis (TB) prior to initiating treatment.
    - Provider will monitor for active infection.
- Provider attests member will not use Tremfya® concomitantly with other biologics.

Moderate to severely active ulcerative colitis

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have a diagnosis of moderate to severely active ulcerative colitis.
- Have a trial and inadequate response, intolerance or contraindication to a preferred drug with the same indication from the Montana Healthcare Programs Preferred Drug List19 (mt.gov)

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.
- Prescriber attests to the following:

    - Member has been screened for tuberculosis (TB) prior to initiating treatment.
    - Provider will monitor for active infection.
- Provider attests member will not use Tremfya® concomitantly with other biologics.

Limitations:
Dosed per package labeling

Renewal Coverage Criteria

Member must meet all of the following criteria:

- Has positive clinical response to therapy (i.e., reduction in the frequency and/or severity of symptoms and exacerbations).

Prescriber requirements:

- Has documentation of positive clinical response to therapy (i.e., reduction in the frequency and/or severity of symptoms and exacerbations).
- Annual specialist consult provided if prescriber not a specialist.
- Attests that member **will not** use Tremfya® concomitantly with other biologics.

Quantity Limits

Moderate to severe plaque psoriasis and active psoriatic arthritis
Maximum Dose =100 mg subcutaneous injection at Week 0, Week 4, and every 8 weeks thereafter.

Moderate to severely active ulcerative colitis
Maximum Dose:

- Induction dosage: 200 mg by intravenous infusion at Week 0, Week 4, and Week 8.
- Maintenance: 100 mg subcutaneous injection at Week 16, and every 8 weeks thereafter **OR** 200 mg subcutaneous injection at Week 12, and every 4 weeks thereafter.

Coverage Duration

Moderate to severe plaque psoriasis and active psoriatic arthritis:
Initial approval: 28 weeks (required update from provider prior to dose at 28 weeks)
Renewal approval duration: 12 months

Moderate to severely active ulcerative colitis:
Initial approval: 24 weeks (requires update from provider prior to dose at 24 weeks)

200mg IV x 3 doses (weeks 0, 4, 8) approved through Physicians Administered Drug Program THEN 100 mg SQ at week 16 through Drug Prior Authorization (then dosed 100mg every 8 weeks).

- Prior Authorization with clinical justification required for alternate dosing of **200mg SQ every 4 weeks for approval of week 12, 16, and 20.**
- Update will be required for both dosing regimens prior to dose at week 24.
- 100mg SQ will be dosed q8 weeks and 200mg will be dosed every 4 weeks.

Renewal approval duration: 12 months through Drug Prior Authorization.

- Requests to change dosing regimen will require Prior Authorization.

4. New Drug Criteria:

A. Ohtuvayre® (ensifentrine)

Initial Coverage Criteria

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have a diagnosis of chronic obstructive pulmonary disease with 2 or more exacerbations OR one exacerbation requiring hospitalization within the past twelve months.
- Currently be receiving standard treatment with dual (LABA/LAMA) or triple (LABA/LAMA/ICS) inhalation therapy unless intolerance, or contraindication. Exacerbations indicating uncontrolled disease must have occurred while member was adherent to LABA/LAMA/ICS. Claims history will be used to verify adherence at time of exacerbation.
- Have had a trial and inadequate response, intolerance or contraindication to oral roflumilast.

Prescriber requirements:

- Must be prescribed by, or in consult with, a pulmonary specialist.
- 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:
    - Attests the provider is aware Ohtuvayre® should not be used for acute bronchospasm.
    - If member is an active smoker, attests that member has been offered nicotine cessation support.
      Note: This add is a Board request and wasn't part of the interim criteria.
- Attests the provider is aware Ohtuvayre® is associated with an increase in psychiatric adverse reactions.

Limitations:
Dosed per package labeling

Renewal Coverage Criteria

Member must meet all of the following criteria:

- Has positive clinical response to therapy (i.e., reduction in the frequency and/or severity of symptoms and exacerbations and/or improved FEV_1).
- Must currently be receiving standard treatment with dual (LABA/LAMA) or triple (LABA/LAMA/ICS) inhalation therapy unless intolerance, or contraindication.

Prescriber requirements:

- Must be prescribed by, or in consult with, a pulmonary specialist.
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Has documentation of positive clinical response to therapy (i.e., reduction in the frequency and/or severity of symptoms and exacerbations, and/or improved FEV_1).
- Member must currently be receiving standard treatment with dual (LABA/LAMA) or triple (LABA/LAMA/ICS) inhalation therapy unless intolerance, or contraindication.
- 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.

Quantity Limits
Maximum Daily Dose = Two 3mg/2.5ml nebules daily

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

B. Ebglyss® (lebrikizumab-ibkz)

Initial Coverage Criteria

Member must meet all of the following criteria:

- Be 12 years of age or older AND weigh at least 40 kg.
- 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:

- 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 Ebglyss® concomitantly with other biologics.

Limitations:
Dosed per package labeling.

Renewal Coverage Criteria

Member must meet all of the following criteria:

- Has a positive clinical response to therapy (i.e., reduction in the frequency and/or severity of symptoms and exacerbations).

Prescriber requirements:

- Annual specialist consult provided if prescriber not a specialist.
- Has documentation of a positive clinical response to therapy (i.e., reduction in the frequency and/or severity of symptoms and exacerbations).
- Attests that member **will not** use Ebglyss® concomitantly with other biologics.

Quantity Limits

- Maximum loading dose for adults and members 12 to 17 years of age weighing at least 40 kg is 500mg at week 0 and week 2 followed by 250mg every two weeks until week 16 or later, when adequate clinical response is achieved.
- Maximum maintenance dose is 250mg every four weeks.

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

C. Yorvipath® (palopegteriparatide)

Initial Coverage Criteria

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have a diagnosis of hypoparathyroidism.
    - Not indicated for acute post-surgical hypoparathyroidism.
- Have tried and been unable to meet albumin-corrected serum calcium taking calcium and active Vitamin D at recommended doses.
- Have a trial and inadequate response, or contraindication to Forteo® (teriparatide injection).
- Must have achieved an albumin-corrected serum calcium of at least 7.8mg/dL prior to trial on Yorvipath®.

Prescriber requirements:

- Must be prescribed by, or in consult with, an endocrinology specialist.
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Attests patient will be monitored for signs and symptoms of hypocalcemia or hypercalcemia and once stable, they will continue to have serum calcium levels done at least every 4 to 6 weeks.

Limitations:
Titrated and adjusted per package labeling

Renewal Coverage Criteria

Prescriber requirements:

- Annual specialist consult provided if prescriber not a specialist.
- Has clinical documentation that member has responded to Yorvipath therapy (achieving and maintaining serum calcium levels of 8.3 to 10.6 mg/dL).
- Attests continued serum calcium monitoring will be done every 4 to 6 weeks.

Quantity Limits
Maximum Daily Dose = 30mcg SQ once daily

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

4. PA Criteria Removal or Changes

a) Jynarque® (tolvaptan)

Removal of criteria request was presented to the Board. Jynarque® has an extensive REMS program so it's duplicative for providers to do the prior authorization that is currently required. The Board agreed with this request.

b) Eohilia™ (budesonide oral suspension)
The Board has requested that clinical criteria be developed. Criteria will be presented to the Board at the February 2025 DUR Board meeting for discussion and approval.

c) Emflaza® (deflazacort)
The Board will review the information provided and will notify Mountain Pacific if they'd like the criteria to be brought back for discussion at a future meeting.

d) Spravato® (esketamine)
Three letters were submitted requesting a review of the current Spravato® criteria. After discussion, the Board concluded that no changes to the existing criteria are necessary and requested that the criteria not be brought back for review at a future meeting.

e) Atypical antipsychotics for pediatric patients
A provider letter was submitted requesting an adjustment to the existing criteria to allow a grace period for initial lab work for children. This request prompted a broader discussion about the program's overall relevance and appropriateness. The Support Act requires states to have in place a program to monitor and manage the appropriate use of antipsychotic medications by children enrolled in Medicaid. The monitoring program is individualized for each State, which allows updates to the existing criteria when deemed appropriate. The Board has requested that a review of the program's outcomes and existing criteria be brought back for discussion at a future meeting.

f) Follow-up to DUR Board's query request regarding multiple sclerosis diagnoses and treatment in members 20 years of age and younger was presented to the Board. Data in this population indicates diagnosis and disease modifying medication use is appropriate. No further action.

The next Drug Utilization Review meeting will be on February 12, 2025, in this same format. The meeting was adjourned at 3:54 p.m.