February 2025 DUR Board Meeting Minutes

Date: February 12, 2025

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

Members Absent: Brown, Nauts, Oley

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

Public Comment:
1. Carla McSpadden, Galderma – Nemluvio®
2. Ronnie DePue, Axsome Therapeutics, Inc – Auvelity®
3. Paul Miner, Ascendis Pharma – Yorvipath® (for use in hypoparathyroidism – step through Forteo®)
4. Nirmal Ghuman, Johnson & Johnson – Invega® Hafyera
5. Michele Rayes, Hypoparathyroidism Association – Yorvipath®

Written public comment was submitted to the Board before the meeting. It consisted of 1 letter from a manufacturer representative and 1 manufacturer document. Auvelity® was already on the agenda but the clinical criteria were not reviewed. The Board did not feel that the criteria needed to be brought back to a future meeting at this time. At the end of the meeting, the Board requested that the Yorvipath® criteria be brought back to a future meeting for review and discussion.

Meeting Minute Review: The December 4, 2024, DUR minutes were approved as written.

Department Update: Dani Feist introduced the new Pharmacy Program Officer, Josh Surginer. His first day was January 27, 2025.

Board Discussion

1. Language/Criteria update:

A. Auvelity® (dextromethorphan/bupropion ER)

Note: The Board did not review the clinical criteria and only discussed the change request for the initial approval duration timeframe. The Board previously approved the criteria documented below during the November 9, 2022 meeting.
Criteria Updates – the criteria documented below is the updated and current criteria approved by the Board. The updates are as follows:
1. Initial approval duration changed from 6 weeks to 60 days based on labeling.

Initial Coverage Criteria

Member must meet all of the following criteria:

- Be 18 years of age or older
- Have a diagnosis of major depressive disorder
- Have a trial and had an inadequate response, or contraindication to **two** preferred drugs with different mechanisms of action in the Novel Antidepressant category on the

Montana Healthcare Programs Preferred Drug List 19 (mt.gov) for at least 8 weeks duration.

Prescriber requirements:

- Attests to the following:
  - Discussed with the member the boxed warning regarding risk of suicidal thoughts and behaviors with this medication.
  - Member will not take a Monoamine Oxidase Inhibitor within 14 days of Auvelity®.
  - Member does not have:
    - a seizure disorder **OR**
    - a diagnosis of bulimia or anorexia nervosa **OR**
    - a diagnosis of severe hepatic or severe renal impairment **AND**
  - Member has not abruptly discontinued alcohol, benzodiazepines, barbiturates, or antiepileptic medications.
  - Member's risk for abuse or misuse is assessed prior to initiating treatment and will be assessed periodically while on therapy (Auvelity® is not a scheduled medication and in clinical studies did not indicate drug seeking behavior, however, the active drugs in Auvelity® independently have reports of misuse).

Limitations:
Dosed per package labeling

Renewal Coverage Criteria

Member must meet all of the following criteria:

- Has positive clinical response to therapy as demonstrated by a reduction in symptom severity compared to the baseline depression assessment utilizing the same rating scale.

Prescriber requirements:

- Has documentation of positive clinical response to therapy as demonstrated by a reduction in symptom severity compared to baseline depression assessment utilizing the same rating scale.

Quantity Limits
Maximum Daily Dose = Two (2) tablets daily

Coverage Duration
Initial approval: 60 days
Renewal approval duration: 12 months

B. Qelbree® (viloxazine)

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

1. *Criteria has been adjusted to reflect different requirements for members 6 to 17 years of age and members 18 years of age and older.*

Initial Coverage Criteria

All members must meet all of the following criteria:

- Be 6 years of age or older.
- Have a diagnosis of ADHD.

Pediatric members 6 years of age to less than 18 years of age:

- Has had an appropriate trial (minimum of 8 weeks of therapy at maximum tolerated dose) on, and had an inadequate response or contraindication to:
  - atomoxetine (preferred SNRI for ADHD) **AND**
  - either clonidine ER or guanfacine ER

Adult members 18 years of age and older:

- Has had an appropriate trial (minimum of 8 weeks of therapy at maximum tolerated dose) on, and had an inadequate response or contraindication to:
  - a preferred stimulant with the same indication from the Montana Healthcare Programs Preferred Drug List 19 (mt.gov) AND
  - atomoxetine (preferred SNRI for ADHD)

Limitations:
Dosed per package labeling

Renewal Coverage Criteria

Prescriber requirements:

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

Quantity Limits
Maximum Daily Dose:

- Pediatric patients 6 to 17 years of age – 400mg once daily
- Adult patients – 600mg daily

Coverage Duration
Initial approval: 2 months
Renewal approval duration: 12 months

C. Eohilia™ (budesonide oral suspension)

After Board discussion, it was agreed that clinical criteria are not required for this medication. The Preferred Drug List will manage this medication and will be approved for FDA-approved age and diagnoses.

2. New Indication/Formulation:

A. Cimzia® (certolizumab pegol)

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 indication for active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older.*

Initial Coverage Criteria

Polyarticular Juvenile Idiopathic Arthritis

Member must meet all of the following criteria:

- Be 2 years of age or older.
- Have a diagnosis of active polyarticular juvenile idiopathic arthritis (pJIA).
- 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.

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 they have reviewed the black box warning for infection risk.
- Prescriber attests member **will not** use Cimzia® concomitantly with other biologics.

Crohn's Disease, **Rheumatoid Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis, Non-radiographic Axial Spondylarthritis, Plaque Psoriasis**

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have a diagnosis of:
    - Crohn's Disease with moderately to severely active disease who have had an inadequate response to conventional therapy.
    - Rheumatoid arthritis with moderately to severely active disease.
    - Active psoriatic arthritis.
    - Active ankylosing spondylitis.
    - Active non-radiographic axial spondyloarthritis with objective signs of inflammation.
    - Moderate-to-severe plaque psoriasis AND is a candidate for systemic therapy or phototherapy.
- 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.

Prescriber requirements:

- Must be prescribed by, or in consult with, an appropriate gastroenterology, rheumatology or dermatology specialist depending on diagnosis.
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Prescriber attests they have reviewed the black box warning for infection risk.
- Prescriber attests member **will not** use Cimzia® 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/or exacerbations).

Prescriber requirements:

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

Quantity Limits
Maximum Dose:

Polyarticular Juvenile Idiopathic Arthritis
- 10 kg to less than 20 kg: 100 mg weeks 0, 2 and 4, followed by 50 mg every other week.
- 20 kg to less than 40 kg: 200 mg weeks 0, 2 and 4, followed by 100 mg every other week.
- Greater than or equal to 40 kg: 400 mg weeks 0, 2 and 4, followed by 200 mg every other week.

Crohn's Disease
- 400 mg initially and at weeks 2 and 4. If response occurs, follow with 400 mg every four weeks.

Rheumatoid Arthritis, Ankylosing Spondylitis, Psoriatic Arthritis, Non-radiographic Axial Spondyloarthritis
- 400mg initially and at weeks 2 and 4, followed by 200mg every other week or 400mg every 4 weeks.

Plaque Psoriasis
- 400 mg every other week. For some patients with body weight less than or equal to 90 kg, a dose of 400 mg initially and at weeks 2 and 4, followed by 200 mg every other week may be considered.

Coverage Duration
Initial approval: 12 months

Renewal approval duration: 12 months

B. Otezla® (apremilast)

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. Age expansion for moderate to severe plaque psoriasis in pediatrics 6 years of age and older.

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

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.

Moderate to Severe Plaque Psoriasis

Member must meet all of the following criteria:

- Be 6 years of age or older AND weigh at least 20 kg.
- 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.

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.
- Must provide pediatric member's current weight for dosing.

Oral Ulcers Associated with Behcet's Disease

Member must meet all of the following criteria.

- Be 18 years of age or older.
- Have a diagnosis of oral ulcers associated with Behcet's Disease.

- 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 (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.

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.

Quantity Limits
Maximum Daily Dose = Two (2) tablets daily

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

C. Skyrizi® (risankizumab-rzaa)

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.*
2. *The Board requested that the attestations for TB screening, provider monitoring for active infection, and avoiding the use of live vaccines be removed from all diagnosis criteria for all drugs in this therapeutic class as this is the standard of care that the provider should already be doing.*

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 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.

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.
- Provider attests that member **will not** use Skyrizi® 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, or contraindication to a preferred drug with the same indication from the Montana Healthcare Programs Preferred Drug List 19

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.
- Provider attests that member **will not** use Skyrizi® concomitantly with other biologics.

Moderately to Severely Active Crohn's disease

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have a diagnosis of moderately to severely active Crohn's disease.
- 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.

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:
    - Provider will monitor liver enzymes and bilirubin levels at baseline, during induction, and up to at least 12 weeks of treatment.
- Provider attests that member **will not** use Skyrizi® concomitantly with other biologics.

Moderately to Severely Active Ulcerative Colitis

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.
- 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.

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:
    - Provider will monitor liver enzymes and bilirubin levels at baseline, during induction, and up to at least 12 weeks of treatment.
- Provider attests that member **will not** use Skyrizi® concomitantly with other biologics.

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.
- Provider attests that member **will not** use Skyrizi concomitantly with other biologics.

Quantity Limits

Active Psoriatic Arthritis:

- Subcutaneous injection of 150 mg given at week 0, week 4, and every 12 weeks thereafter

Moderate to Severe Plaque Psoriasis:

- Subcutaneous injection of 150 mg given at week 0, week 4, and every 12 weeks thereafter

Crohn's Disease:

- Initial intravenous infusion for induction is 600 mg IV at week 0, week 4, and week 8.
- Maintenance dosage is 180 mg or 360 mg by subcutaneous injection at week 12, then every 8 weeks thereafter

Ulcerative Colitis:

- Initial intravenous infusion for induction is 1,200 mg IV at week 0, week 4, and week 8.

- Maintenance dosage is 180 mg or 360 mg by subcutaneous injection at week 12, then every 8 weeks thereafter.

Coverage Duration

Initial approval duration:

- Adults with psoriatic arthritis: 3 doses (weeks 0, 4, and 16). Update required prior to dose at 28 weeks.
- Adults with plaque psoriasis: 3 doses (weeks 0, 4, and 16). Update required prior to dose at 28 weeks.
- Adults with Crohn's disease: 4 doses (infusion weeks 0, 4, and 8. Injection week 12). Update required prior to dose at 20 weeks.
- Adults with ulcerative colitis: 4 doses (infusion weeks 0, 4, and 8. Injection week 12). Update required prior to dose at 20 weeks.

Renewal approval duration (for all diagnoses): 12 months

D. Vtama® (tapinarof)

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 atopic dermatitis in adults and pediatric patients 2 years of age and older.*

Initial Coverage Criteria

Plaque Psoriasis

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have a diagnosis of plaque psoriasis.
- Have a trial and inadequate response, or contraindication to a preferred high potency steroid from the Montana Healthcare Programs Preferred Drug List 19 (mt.gov).
- Have a trial and inadequate response, or contraindication to a preferred calcipotriene agent from the Montana Healthcare Programs Preferred Drug List 19 (mt.gov)

Prescriber requirements:

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

Atopic Dermatitis

Member must meet all of the following criteria:

- Be 2 years of age or older.
- Have a diagnosis of atopic dermatitis.

- Have a trial and inadequate response, or contraindication to a preferred topical steroid from the Montana Healthcare Programs Preferred Drug List 19 (mt.gov).
    - 2 to 17 years of age will have an adequate trial on a preferred **low to mid-potency** topical steroid.
    - 18 years of age and older will have an adequate trial on a preferred **high-potency** topical steroid.
- Have a trial and inadequate response, or contraindication to a preferred calcineurin agent from the Montana Healthcare Programs Preferred Drug List 19 (mt.gov).
- If non-preferred, 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 (unless preferred product(s) do not have the appropriate indication).

Prescriber requirements:

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

Limitations:
Dosed per package labeling

Renewal Coverage Criteria

Member must meet all of the following criteria:

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

Prescriber requirements:

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

Quantity Limits
Maximum Quantity = One (1) 60 g tube monthly

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

3. New Drug Criteria:

A. Erzofri® (paliperidone palmitate) IM Injection
Existing criteria reviewed for Invega Sustenna®, Invega Trinza®, and Invega Hafyera® and the board verified that missed doses should require reinitiation per dosing of label. For all other previously reviewed indications, the criteria remain the same.

Initial Coverage Criteria

Erzofri® and Invega Sustenna®

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have a diagnosis of
  - Schizophrenia **OR**
  - Schizoaffective disorder
- If non-preferred, must 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.
- Have tried oral paliperidone or oral or injectable risperidone.
  - Initial trial of oral paliperidone, oral risperidone or injectable risperidone will require the use of a preferred agent from the Montana Healthcare Programs Preferred Drug List 19.
  - Tolerability to oral paliperidone or oral risperidone is **required** prior to initiating treatment.

Prescriber requirements:

- Must have clinical rationale that oral therapy cannot be used.

Invega Trinza®

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have a diagnosis of schizophrenia.
- If non-preferred, must 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.
- Have been treated with a once-monthly paliperidone palmitate extended-release injection (i.e., Invega Sustenna®) for at least four consecutive months prior to approval.

Prescriber requirements:

- Must have clinical rationale that oral therapy cannot be used.

Invega Hafyera®

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have a diagnosis of schizophrenia.
- If non-preferred, must 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.
- Have been treated with:
  - At least four consecutive months of once-monthly paliperidone palmitate extended-release injection (i.e., Invega Sustenna®) **OR**
  - a single injection of an every three-month paliperidone palmitate extended-release injection (i.e., Invega Trinza®) prior to approval.

Prescriber requirements:

- Must have clinical rationale that oral therapy cannot be used.
- Must be prescribed by, or in consult 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.

Limitations:
Dosed per package labeling

Renewal Coverage Criteria

Erzofri® and Invega Sustenna®

Member must meet all of the following criteria:

- Has experienced a positive clinical response (i.e., stabilization or decrease in symptoms).

Prescriber requirements:

- Has documentation of a positive clinical response (i.e., stabilization or decrease in symptoms).

Invega Trinza®

Member must meet all of the following criteria:

- Has experienced a positive clinical response (i.e., stabilization or decrease in symptoms).

Prescriber requirements:

- Has documentation of a positive clinical response (i.e., stabilization or decrease in symptoms).
- If non-compliance is determined, the reauthorization time frame may be reduced to allow time for the provider to address member compliance. Verification of compliance will be made via Medicaid paid claims data.

Invega Hafyera®

Member must meet all of the following criteria:

- Has experienced a positive clinical response (i.e., stabilization or decrease in symptoms).

Prescriber requirements:

- Must be prescribed by, or in consult with, a psychiatry 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 a positive clinical response (i.e., stabilization or decrease in symptoms).
- If non-compliance is determined, the reauthorization time frame may be reduced to allow time for the provider to address member compliance. Verification of compliance will be made via Medicaid paid claims data.

Quantity Limits
Maximum Dose:
Erzofri®- Initiation per labeling. Maintenance dose every 4 weeks per labeling up to 234 mg.
Invega Sustenna®- Initiation per labeling**.** Maintenance dose every 4 weeks per labeling up to 234 mg.
Invega Trinza®- Maintenance dose every 3 months per labeling up to 819 mg.
Invega Hafyera ®- Maintenance dose every 6 months per labeling up to 1,560 mg.

- Re-initiation Regimen for Missed Dose (more than 6 months and 3 weeks, but less than 8 months since last dose):
  - Last dose was 1,092 mg – administer 156 mg PP1M on Day 1 then 1,092 mg 1 month after Day 1.
  - Last dose was 1,560 mg – administer 234 mg PP1M on Day 1 then 1,560 mg 1 month after Day 1.
- Reinitiation Regimen for Missed Dose (8 months up to and including 11 months since last dose):
  - Last dose was 1,092 mg – administer 156 mg PP1M on Day 1 and Day 8 then 1,092 mg 1 month after Day 8.
  - Last dose was 1,560 mg – administer 156 mg PP1M on Day 1 and Day 8 then 1,560 mg 1 month after Day 8.
- More than 11 months since last dose – re-initiate treatment with a PP1M product as described in the prescribing information for that product. (PP1M: Once monthly paliperidone palmitate)

Coverage Duration

- Initial approval: 12 months
- Renewal approval duration: 12 months

B. Nemluvio® (nemolizumab-ilto)

Initial Coverage Criteria

Atopic Dermatitis

Member must meet all of the following criteria

- Be 12 years of age or older.
- Have a diagnosis of moderate-to-severe atopic dermatitis.
- 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, and a baseline assessment has been made to allow for documentation of positive clinical response.
- 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.
- Topical corticosteroids **AND/OR** calcineurin inhibitors are concurrently being used. When the disease has sufficiently improved, discontinue use of topical therapies.

Prescriber requirements:

- Must be prescribed by, or in consult with, a dermatology 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 Nemluvio® concomitantly with other biologics.

Prurigo nodularis

Member must meet all of the following criteria

- Be 18 years of age or older.
- Has a diagnosis of prurigo nodularis.
- Has 20 or more nodular lesions.
- Has score of 7 or more on the peak pruritic numeric rating scale (PP-NRS) or worst itch numerical rating scale (WI-NRS).
- 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.

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.
- Diagnosis of prurigo nodularis confirmed by microscopic examination of lesion or biopsy.
- Must have baseline evaluation of:
    - number and severity of lesions AND
    - itching evaluation on a validated numerical rating scale of itching from 0-10 (WI-NRS or PR-NRS)
- Must obtain a current member weight for dosing.
- Attests that member **will not** use Nemluvio® concomitantly with other biologics.

Limitations:
Dosed per package labeling based on weight and diagnosis.

Renewal Coverage Criteria

Member must meet all of the following criteria:

- Has positive clinical response to therapy over baseline (i.e., decrease in number and/or severity of nodules **OR** reduction in PR-NRS or WI-NRS score by at least 4 points).

Prescriber requirements:

- Annual specialist consult provided if prescriber not a specialist.
- Has documentation over baseline of positive clinical response to therapy:
    - Reduction in number and/or severity of nodules **OR**
    - Reduction from baseline on PR-NRS or WI-NRS score by at least 4 points
- Attests that member **will not** use Nemluvio® concomitantly with other biologics.

Quantity Limits

Maximum Dose:

60mg for initiation, then 30mg every 4 weeks.
60mg for initiation, then 30mg (60mg for adults weighing 90 kg or more) every 4 weeks.

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

C. Zepbound® (tirzepatide)

Initial Coverage Criteria

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have a diagnosis of obstructive sleep apnea (OSA) with an apnea-hypopnea index (AHI) greater than or equal to 15. Sleep study must be current within the last 12 months **AND BMI at time of sleep study** must have been greater than or equal to 30 kg/m^2.
- Be currently using **AND** will continue to use positive airway pressure treatment (PAP) unless a contraindication to PAP exists.
- Have obesity with a body mass index (BMI) of greater than or equal to 30 kg/m^2 at time of Zepbound® initiation.
- Does not have type 2 diabetes. These members must be managed with an FDA approved drug for that indication from the Diabetes: GLP-1/GIP and Combos category on the Montana Healthcare Programs preferred drug list 19 (mt.gov).
- Agree to adhere to a reduced calorie diet and increased physical activity plan.

Prescriber requirements:

- Diagnosis and evaluation of obstructive sleep apnea must be made by a sleep specialist or clinic that reviews and assesses sleep study results.
- Attests to the following:
    - Does not have type 2 diabetes. These members must be managed with an FDA approved drug for that indication from the Diabetes: GLP-1/GIP and Combos category on the Montana Healthcare Programs preferred drug list 19 (mt.gov).
    - The provider attests member will continue use of PAP (unless contraindicated) and will adhere to a reduced-calorie diet and increased physical exercise.
    - The provider is aware Zepbound® 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 Zepbound® may increase the risk of suicidal behavior and ideation.

Limitations:
Dosed per package labeling

Renewal Coverage Criteria

Initial 6 months renewal criteria:

Member must meet all of the following criteria:

- Has positive clinical response to therapy by a reduction greater than or equal to 5% of body weight from baseline.
- Has continued PAP therapy (unless contraindicated).

Prescriber requirements:

- Has documentation of positive clinical response to therapy by a reduction of at least 5% of body weight from baseline.
- Attests that member has maintained a reduced calorie diet and increased physical activity plan.
- Attests member has continued PAP therapy unless contraindicated.

First year renewal criteria:

Member must meet all of the following criteria:

- Has positive clinical response to therapy by a reduction in AHI.
- Has continued PAP therapy (unless contraindicated).

Prescriber requirements:

- Has documentation of positive clinical response to therapy by a reduction in AHI.
- Attests that member has maintained a reduced calorie diet and increased physical activity plan.
- Attests member has continued PAP therapy unless contraindicated.
- Documentation of current BMI.

Subsequent renewal criteria:

Member requirements:

- Has positive clinical response to therapy by maintenance of **OR** a reduction in BMI over one year renewal.
- Has continued PAP therapy (unless contraindicated).

Prescriber requirements:

- Has documentation of positive clinical response to therapy by maintenance of **OR** a reduction in BMI over one-year renewal.
- Attests that member has maintained a reduced calorie diet and increased physical activity plan.
- Attests member has continued PAP therapy unless contraindicated.

Quantity Limits
Maximum Dose = 15 mg injected subcutaneously once weekly.

Coverage Duration
Initial approval: 6 months.
First renewal: 6 months. Weight check is required for first renewal.
Subsequent renewals: 12 months

4. The Board requested that the PDL pathway for Mounjaro® be brought back to a future meeting for review and discussion.

5. The Board requested that the Yorvipath® criteria be brought back to a future meeting to discuss the appropriateness of requiring Forteo® as a step through to Yorvipath®.

6. **PA Criteria Removal or Changes**

Vyndamax™ and Vyndaqel® category removal request:
The Board agreed to remove criteria from these medications due to low utilization.

7. **Atypical antipsychotic use in pediatrics program discussion**
Mountain Pacific requested Board direction on the PA and monitoring processes for use of atypical antipsychotics in pediatrics. After discussion, the Board requested that the program be updated with the following:
    - Guardian consent – continue to require the guardian signature and add more language on safety concerns while using these medications.
    - Metabolic labs – remove the PA requirement requiring labs be drawn before initiating therapy and put it back on the provider that they are aware of the guidelines for lab monitoring.
    - Provider consent – Update the existing consent language by creating stronger language on the risks associated with using these medications in pediatrics and that the guardian has been counseled on these risks. Continue to require provider signature.
    - Provider attestation – Create new provider attestation stating that they are aware that metabolic monitoring is recommended. Require provider signature.
    - Continue with RDUR letters.
    - As these medications are often recommended in guidelines for non-FDA approved indications and dosages for children, the Board recommended not including these components in the standard PA review process for these medications. If there is concern about a dose, Pharmacy Case Management has the option to reach out to the provider to discuss.

Mountain Pacific and MT DPHHS will consider the above requests and update the current program to reflect these requests. The final plan will be presented to the Board at a future meeting.

8. **Review of Emflaza® place in therapy**
   Continue with existing criteria and do not remove the prednisone step-through requirement.

The next meeting will be the Preferred Drug List (PDL) meeting on March 19, 2025, in this same format. The Board will receive options for dates of future DUR Board meetings after the PDL season. The meeting was adjourned at 4:20 p.m.