September 2024 DUR Board Meeting Minutes

Date: September 25, 2024

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

Members Absent: Nauts, Putsch

Others Present: Katie Hawkins, Shannon Sexauer, Dani Feist (3 p.m.) (DPHHS); Bahny, Miranda, Opitz (1:48 p.m. for PAD discussion), and Zody (Mountain Pacific); and representatives from the pharmaceutical industry.

Public Comment:

1. Kierra Brown, UCB, Inc. - Nayzilam®
2. Alexandra Wallem, Lilly - Kisunla®

Meeting Minute Review: The minutes from the May 22, 2024, PDL meeting and the June 19, 2024, DUR meeting were approved as written.

Department Update:
The Preferred Drug List (PDL) is being updated to include Sublocade®, Brixadi®, and Vivitrol® as these medications are primarily utilized under the pharmacy benefit instead of the medical benefit. For members with opioid use disorder who require injectable therapy instead of oral medication, Sublocade® and Brixadi® will be the preferred options, while Vivitrol® will be non-preferred. Authorization for Vivitrol® will be available for members being treated for alcohol dependence, or for those with OUD who have a contraindication or intolerance to buprenorphine.

Board Discussion

1. Age Extensions and Language Updates

A. Wakix® (pitolisant)

Criteria Updates – the criteria documented below is the updated and current criteria approved by the Board specific to the listed indications:

Initial Coverage Criteria

Treatment of Excessive Daytime Sleepiness (EDS) or cataplexy in adult patients with narcolepsy.

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have a diagnosis of narcolepsy with:
  - EDS **OR**
  - cataplexy
- Diagnosis of EDS impacts activities of daily living.
- Have had an inadequate response, intolerance to, or contraindication to the following:
  - For EDS in narcolepsy:
    - a CNS stimulant (i.e., methylphenidate, dextroamphetamine, etc.) **AND**
    - Modafinil OR armodafinil **AND**
    - Xyrem® **AND**
    - Sunosi®

- For Cataplexy in narcolepsy:
  - Dextroamphetamine **AND**
  - Xyrem®

Prescriber requirements:
- Diagnosis must be made using ICSD-3 or DSM-5 diagnostic criteria.
- Diagnosis of EDS impacts activities of daily living as demonstrated by the Epworth Sleepiness Scale.

Treatment of EDS in children 6 years of age and older with narcolepsy.

Member must meet all of the following criteria:
- Be 6 years of age or older.
- Have a diagnosis of narcolepsy with EDS.
- Diagnosis of EDS impacts activities of daily living.
- Have had an inadequate response, intolerance to, or contraindication to the following:
  - If 6 years of age, modafinil.
  - If 7 years of age or older, modafinil **AND** Xyrem®.
    Note: guidelines supporting modafinil for EDS in children: Maski et al. Journal of Clinical Sleep Medicine 2021;17:1881-1893

Prescriber requirements:
- Diagnosis must be made using ICSD-3 or DSM-5 diagnostic criteria.
- Diagnosis of EDS impacts activities of daily living, as demonstrated by the Epworth Sleepiness Scale.

Limitations:
Dosed per package labeling according to titration.

Renewal Coverage Criteria

Member must meet all of the following criteria:
- Has a positive clinical response to therapy (reduction in the frequency and/or severity of symptoms and exacerbations).

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

Quantity Limits
Maximum Daily Dose = 35.6 mg daily after titration for adults or children **who weigh 40 kg or greater.**
Maximum Daily Dose = 17.8 mg for children 6 years of age or older and **who weigh less than 40 kg.**

Coverage Duration
Initial approval: 3 months
Renewal approval duration: 12 months

2. New Indication/Formulation:

A. Zoryve® (roflumilast) cream 0.15%
Criteria Updates – the criteria documented below is the updated and current criteria approved by the Board. The updates are as follows:
1. *Zoryve® cream has a new strength of 0.15% and a new indication for mild to moderate atopic dermatitis.*

2. *Zoryve® cream 0.3% and Zoryve® foam criteria did not change.*

Initial Coverage Criteria
Member must meet all of the following criteria:
- Be 6 years of age or older.
- Have a diagnosis of mild to moderate atopic dermatitis.
- Have a trial and inadequate response or contraindication to a high-potency topical steroid.
- Have a trial and inadequate response or contraindication to a calcineurin inhibitor.
- Have had 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:
- Attests to the following:
  - The member does not have moderate to severe liver impairment (Child-Pugh B or C).

Limitations:
Dosed per package labeling.

Renewal Coverage Criteria

Member must meet all of the following criteria:
- Has a positive clinical response to therapy (reduction in the frequency and/or severity of symptoms and exacerbations) compared to baseline.

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

Quantity Limits
Maximum Quantity = 60 gm (1 tube) every 28 days.

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

B. Kevzara® (sarilumab)

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 Polyarticular Juvenile Idiopathic Arthritis (pJIA).*

Initial Coverage Criteria

Member must meet all of the following criteria:
- Weigh 63 kg or greater.
- Have a diagnosis of polyarticular juvenile idiopathic arthritis.
- Have had 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 rheumatologist.

- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Prescriber attests they have reviewed the black box warning for infection risk.
- Prescriber attests that member **will not** use Kevzara® 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 (reduction in the frequency and/or severity of symptoms and exacerbations).

Prescriber requirements:
- Has documentation of member's clinical response to therapy (reduction in frequency and/or severity of symptoms and exacerbations).
- Annual specialist consult provided if prescriber not a specialist.
- Attests that member **will not** use Kevzara® concomitantly with other biologics.

Quantity Limits
Maximum Daily Dose = 200 mg subcutaneously every 2 weeks for all indications.
(The prefilled syringe, not the prefilled pen, is to be used in pediatric patients for pJIA).

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

C. Rinvoq® (upadacitinib)

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. *Age expansion to pediatric patients for active psoriatic arthritis (PsA).*
2. *New indication for active polyarticular juvenile idiopathic arthritis (pJIA) treatment in patients 2 years of age or older who have had an inadequate response or intolerance to one or more TNF blockers.*

Initial Coverage Criteria

Psoriatic Arthritis

Member must meet all the following criteria:
- Be 2 years of age or older.
- Have a diagnosis of active psoriatic arthritis.
- Have had a trial and inadequate response, intolerance, or contraindication to a preferred TNF blocker 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, an appropriate 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.

- Attests that they have reviewed the black box warning.
- Attests that member **will not** use Rinvoq® concomitantly with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants.

Polyarticular Juvenile Idiopathic Arthritis

Member must meet all the following criteria:
- Be 2 years of age or older.
- Have a diagnosis of active polyarticular juvenile idiopathic arthritis (pJIA).
- Have had a trial and inadequate response, intolerance, or contraindication to a preferred TNF blocker 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, an appropriate rheumatology specialist.
- If not prescribed by appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Attests that they have reviewed the black box warning.
- Attests that member **will not** use Rinvoq® concomitantly with other JAK inhibitors, biologic DMARDS, or potent immunosuppressants.

Limitations:
Dosing per package labeling.
Rinvoq LQ oral solution is not substitutable with Rinvoq extended-release tablets.

Renewal Coverage Criteria

Member must meet all the following criteria:
- Has a positive clinical response to therapy (e.g. for AD, reduction in body surface area involvement, reduction in pruritus severity or decrease in severity index using a scoring tool)

Prescriber requirements:
- Annual specialist consult provided if prescriber not a specialist.
- Has documentation of positive clinical response to therapy (e.g. for AD, reduction in body surface area involvement, reduction in pruritus severity or decrease in severity index using a scoring tool)
- Attests that member **will not** use Rinvoq® in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants.

Quantity Limits
Maximum Daily Dose:
Rinvoq® tablets maximum daily dose = 1 tablet daily.
Rinvoq LQ® 1 mg/ml oral solution for PsA and pJIA:
- Members 10 kg to less than 20 kg = 3 mg twice daily
- Members 20 kg to less than 30 kg = 4 mg twice daily
- Members 30 kg and greater = 6 mg twice daily

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

3. New Drug Criteria:

A. DMD Gene Therapy

The Board recommended removing criteria from DMD gene therapy drugs which currently include Amondys® 45, Exondys® 51, Viltepso®, and Vyondys® 53. Additionally, the Board recommended that criteria not be added to Duvyzat™.

B. Kisunla™ (donanemab-azbt)

Initial Coverage Criteria

Member must meet all of the following criteria:

- Be 60 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.
    - List of Montana Healthcare Programs preferred drugs can be found at: 19 (mt.gov)
    - If taking medications to treat symptoms related to Alzheimer's Disease, dosages must be stable for at least 12 weeks prior to starting Kisunla™ and dosages will not be adjusted during Kisunla™ therapy. Additional therapies may not be initiated during Kisunla™ treatment.
- Have a recent baseline brain magnetic resonance imaging (MRI) within 3-6 months prior to initiating treatment with Kisunla™.
    - Obtain an MRI prior to the 2nd, 3rd, 4th, and 7th infusions.
    - If a patient experiences symptoms suggestive of amyloid related imaging abnormalities (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 2nd, 3rd, 4th, and 7th infusions.
- Attests that 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 Kisunla™ 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 Kisunla™ treatment.

- Additional Alzheimer's Disease therapies **will not** be initiated during Kisunla™ treatment.

Limitations:
Dosed per package labeling every four weeks: IV infusion of 700 mg for infusions 1, 2, and 3, then IV infusion of 1400 mg for infusion 4 and beyond.

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 2nd, 3rd, 4th, and 7th infusions.
- Monitor appropriately for ARIA. If imaging shows ARIA, manage treatment per labeling.

Quantity Limits
Maximum Dose = 1400 mg infused over approximately 30 minutes.

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

C. Libervant™ (diazepam) Buccal Film

Initial Coverage Criteria
Member must meet all of the following criteria:
- Be 2 to 5 years of age.
- Have a diagnosis of epilepsy.
- Is taking baseline antiepileptic medication.
- If medication is non-preferred, must have had a trial and inadequate response, or contraindication to a preferred drug with the same indication from the Montana Healthcare Programs Preferred Drug List 19 (mt.gov).

Prescriber requirements:
- Member is being prescribed baseline antiepileptic medication.
- Any request for Libervant™, without the use of concurrent antiepileptic therapies, will require prior authorization based on clinical information.

Limitations:
Dosed per package labeling

Renewal Coverage Criteria

Member must meet all of the following criteria:

- Verification of baseline antiepileptic medication 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.
- Has positive clinical response to therapy.

Prescriber requirements:
- Verification of baseline antiepileptic medication 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.
- Has documentation of positive clinical response to therapy.

Quantity Limits
Maximum Quantity = 10 units each month

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

Criteria for Diastat®, Nayzilam®, and Valtoco® have been updated to match the Libervant™ format. The quantity limits for Diastat® are also updated to match the maximum quantity limit of the other medications in this class. The criteria for Diastat®, Nayzilam®, and Valtoco® are listed below:

Diastat® (diazepam) rectal gel

Initial Coverage Criteria

Member must meet all of the following criteria:
- Be 2 years of age or older.
- Have a diagnosis of epilepsy.
- Is taking baseline antiepileptic medication.
- If medication is non-preferred, must have had 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:
- Member is being prescribed baseline antiepileptic medication.
- Any request for Diastat®, without the use of concurrent antiepileptic therapies, will require prior authorization based on clinical information.

Limitations:
Dosed per package labeling.

Renewal Coverage Criteria

Member must meet all of the following criteria:
- Verification of baseline antiepileptic medication 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.
- Has positive clinical response to therapy.

Prescriber requirements:

- Verification of baseline antiepileptic medication 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.
- Has documentation of positive clinical response to therapy.

Quantity Limits
Maximum Quantity = 10 units each month.

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

Nayzilam® (midazolam) nasal spray

Initial Coverage Criteria

Member must meet all of the following criteria:
- Be 12 years of age or older.
- Have a diagnosis of epilepsy.
- Is taking baseline antiepileptic medication.
- If medication is non-preferred, must have had 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:
- Member is being prescribed baseline antiepileptic medication.
- Any request for Nayzilam®, without the use of concurrent antiepileptic therapies, will require prior authorization based on clinical information.

Limitations:
Dosed per package labeling.

Renewal Coverage Criteria

Member must meet all of the following criteria:
- Verification of baseline antiepileptic medication 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.
- Has positive clinical response to therapy.

Prescriber requirements:
- Verification of baseline antiepileptic medication 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.
- Has documentation of positive clinical response to therapy.

Quantity Limits
Maximum Quantity = 10 units each month.

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

Valtoco® (diazepam) nasal spray

Initial Coverage Criteria

Member must meet all of the following criteria:

- Be 6 years of age or older.
- Have a diagnosis of epilepsy.
- Is taking baseline antiepileptic medication.
- If medication is non-preferred, must have had 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:

- Member is being prescribed baseline antiepileptic medication.
- Any request for Valtoco®, without the use of concurrent antiepileptic therapies, will require prior authorization based on clinical information.

Limitations:
Dosed per package labeling.

Renewal Coverage Criteria

Member must meet all of the following criteria:

- Verification of baseline antiepileptic medication 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.
- Has positive clinical response to therapy.

Prescriber requirements:

- Verification of baseline antiepileptic medication 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.
- Has documentation of positive clinical response to therapy.

Quantity Limits

Maximum Quantity = 10 units each month.

Coverage Duration

Initial approval: 12 months
Renewal approval duration: 12 months

D. Rezdiffra™ (resmetirom)

Initial Coverage Criteria

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have a diagnosis of noncirrhotic nonalcoholic steatohepatitis (NASH) with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) diagnosed by one of the following:
    - Specialized ultrasound (such as FibroScan®) measuring fat, inflammation, and scarring in the liver.
    - Liver biopsy.
- Have had a trial of diet, exercise, and lifestyle modification.

- Continue with diet, exercise, and lifestyle modifications.

Prescriber requirements:
- Must be prescribed by, or in consult with, a gastroenterology or hepatology 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 will be monitored during treatment for elevations in liver tests and for the development of liver-related adverse reactions.
    - The member has not had adequate improvement in fibrosis stage with diet, exercise and lifestyle modification alone, but will continue this program.

Limitations:
Dosed per package labeling.

Renewal Coverage Criteria

Initial 12-month review:

Member must meet all of the following criteria:
- Has clinical improvement in NASH with no worsening of fibrosis **OR**
- Has clinical improvement in fibrosis with no worsening of NASH.
- Has continued with diet, exercise, and lifestyle modifications.

Prescriber requirements:
- Specialist consult provided if prescriber not a specialist.
- Has documentation of improvement in NASH with no worsening of fibrosis **OR** improvement of fibrosis with no worsening of NASH documented by one (1) of the following:
    - Specialized ultrasound (such as FibroScan®) measuring fat, inflammation, and scarring in the liver.
    - Liver biopsy.

Subsequent annual reviews:

Member must meet all of the following criteria:
- Has maintenance or improvement in fibrosis score.
- Continue with diet, exercise, and lifestyle modifications.

Prescriber requirements:
- Annual consult required for yearly reauthorization.
- Has documentation of maintenance or improvement in fibrosis score.

Quantity Limits
Maximum Daily Dose = 1 tablet daily, based on weight, up to 100 mg tablet.

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

E. Korlym® (mifepristone)

Initial Coverage Criteria

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have diagnoses of endogenous Cushing's Syndrome AND type 2 diabetes mellitus OR glucose intolerance.
- Has failed surgical resection (transsphenoidal surgery with adenomectomy) **OR** is not a candidate for surgical resection.

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 to the following:
    - The member, if a female of childbearing age, has confirmation of a negative pregnancy test.
    - Member has been made aware this medication will result in termination of pregnancy if member is a female of childbearing age.

Limitations:
Korlym® should not be used in the treatment of patients with type 2 diabetes unless it is secondary to Cushing's syndrome.
Dosed per package labeling.

Renewal Coverage Criteria

Member must meet all of the following criteria:

- Has a positive clinical response to therapy.

Prescriber requirements:

- Annual specialist consult provided if prescriber not a specialist.
- Has documentation of positive clinical response to therapy.
- The member, if a female of childbearing age, has confirmation of a negative pregnancy test.

Quantity Limits
Maximum Daily Dose = 1200 mg daily, not to exceed 20 mg/kg per day.

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

4. **PA Criteria Removal or Changes**
    A. **Vimpat® (lacosamide)** – criteria will be removed due to high approval rate.

    B. **Lidocaine Patches –** The PA process will be updated to be more automated.

5. **Board input for RDUR**
    Concerns were raised by a Board member regarding the appropriate use of medications in Multiple Sclerosis patients 20 years of age and under. Pharmacy Case Management will review the available data and provide an update to the Board at a later meeting.

The next Drug Utilization Review meeting will be on December 4, 2024, in this same format. The meeting was adjourned at 3:55 p.m.