October 2023 DUR Board Meeting Minutes

Date: October 25, 2023

Members Present: Barnhill, Blake, Blank, Brown, McGrane, Nauts, Putsch, Stone

Members Absent: Anglim, Caldwell, Jost

Board Member Update: Nicole Turnsplenty has stepped down from her role on the Board. Mountain Pacific is actively looking for a replacement.

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

Public Comment:

1. Allyson Fonte, Nestle Health Sciences - Vowst®
2. Rochelle Yang, Teva – Austedo XR®
3. Shirley Quach, Novartis - Leqvio®
4. Erin Nowak, AbbVie - Rinvoq®, Qulipta®

Meeting Minute Review: The meeting minutes from the August 9, 2023, DUR meeting were reviewed and an amendment to the MOUD discussion was requested by Dr. Nauts. The August meeting minutes will be updated with this amendment and sent to the Board for approval. Dr. Nauts also requested the Department keep the Board updated as their concerns were addressed. This concern was responded to in the Department update below.

Department Update:
The Department had a couple of follow-ups from the last meeting as well as a new announcement.

During the last meeting, loosening of Vyvanse limits was discussed. Due to concerns expressed by the Board at that meeting, the Department has decided to leave the Vyvanse restrictions in place. The Department recommended bringing the stimulant class back to a future meeting if they would like to discuss the tightening of limits on the other products in this class.

After the MOUD discussion led by Dr. Nauts, the Board recommended removal of prior authorization criteria for buprenorphine products other than PDL requirements. As this would affect multiple other CMS requirements, the pharmacy team has been in discussions with administration on this topic. There has not been a decision made but the Department will update the Board as soon as that becomes available.

Finally, the Department informed the Board about the upcoming AMP CAP termination effective January of 2024 and the implications to the program, including, but not limited to, expected PDL changes.

Board Discussion

1. **Atypical antipsychotics –** this agenda item will be postponed until the next DUR Board meeting when the psychiatrist member will be available for this discussion.

2. **Suggested Changes to Current Criteria:**
   A. Ampyra® (dalfampridine) ER

- Recommendation: Remove all prior authorization requirements. The criteria was put in place in 2010 when the drug entered the market with a high price point. This medication is now available as a generic with a significantly lower price point.
- The Board agreed with the recommendation to remove criteria requirements.

B. Zinplava® (bezlotoxumab)

- Recommendation: Remove all prior authorization requirements. The updated IDSA/SHEA treatment guidelines now recommend Zinplava® be used for prevention of recurrent CDI.
- The Board agreed with the recommendation to remove criteria requirements.

3. Age Extensions and Language Updates:

A. Fasenra® (benralizumab)

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

1. *Changed PA and PAD criteria so both had a requirement of 150 cells/microliter.*
2. *Removed the blood level timeline.*
3. *Renewal language for member requirements changed from adherent to Fasenra® to compliant with Fasenra®.*
4. *Added requirement that Drug Prior Authorization Unit will notify provider if member is non-compliant on Fasenra® or ICS/LABA therapy.*

Initial Coverage Criteria

Member must meet all the following criteria:

- Be 12 years old or older.
- Have a diagnosis of severe uncontrolled asthma with an eosinophilic phenotype.
  - Have baseline peripheral blood eosinophil count of ≥ 150 cells/μL.
  - Have a history of severe asthma attacks despite treatment with and adherence to an optimized dose of inhaled corticosteroid in combination with a long-acting $beta_2$- agonist (ICS/LABA) for three consecutive months.

Prescriber requirements:

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

Limitations:

- Initial approval duration: 6 months.
- Maximum daily dose: 30mg SQ every 4 weeks for 3 doses, then 30mg SQ every 8 weeks.

Renewal Coverage Criteria

Member must meet all the following criteria:

- Have documentation of positive clinical response to therapy such as a reduction in frequency and/or severity of symptoms and exacerbations or medication dose reduction.

- Be compliant with Fasenra® and ICS/LABA therapy.

Prescriber must meet all of the following criteria:
- Annual specialist consult provided if prescriber not a specialist.
- Attests member **will not** use Fasenra® concomitantly with other biologics.
- Drug Prior Authorization Unit will notify provider if member has not been adherent to Fasenra ® or ICS/LABA therapy.

Limitations:
- Renewal approval duration: 1 year.
- Maximum daily dose: 30mg SQ every 8 weeks.

B. Trikafta® (tezacaftor/ivacaftor/elexacaftor)

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

1. Age expanded down to 2 years of age.

Initial Coverage Criteria

Member must meet all the following criteria:
- Be 2 years of age or older.
- Is homozygous for the F508del mutation in the Cystic Fibrosis transmembrane regulator (CFTR) gene **OR** has a mutation that is responsive based on in vitro data.
- Has history of pulmonary exacerbations within the past 12 months.

Prescriber requirements:
- Must be prescribed by a pulmonologist specializing in the treatment of Cystic Fibrosis.
- Attests the other current standard of care Cystic Fibrosis therapies have been optimized.
- Provide baseline percent predicted expiratory volume ($ppFEV_1$).

Limitations:
- Initial approval duration: 6 months.
- Maximum daily dose: Dosed per package labeling.

Renewal Coverage Criteria

Member must meet all the following criteria:
- Be compliant on Trikafta® therapy.

Prescriber requirements:
- Must be prescribed by a pulmonologist specializing in the treatment of Cystic Fibrosis.
- Attests that in comparison to baseline, the member has achieved a clinically meaningful response while on Trikafta® therapy to one or more of the following:
    - Lung function improvement as demonstrated by improvement or stability in $ppFEV_1$;
    - Decline in pulmonary exacerbations;
    - Stability or increase in body mass index (BMI).

- Drug Prior Authorization Unit will notify provider if member has not been adherent to Trikafta® and other Cystic Fibrosis maintenance medications.

Limitations:
- Renewal approval duration: 6 months.
- Maximum daily dose: 3 tablets daily.

C. Savella® (milnacipran)

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

1. *Removed contraindication with duloxetine (changed to caution with other serotonergic agents).*
2. *Added attestation for black box warning of suicidality.*

Initial Coverage Criteria

Member must meet all the following criteria:
- Be 18 years of age or older.
- Have a diagnosis of fibromyalgia.
- If 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.

Prescriber requirements:
- Attests they have reviewed the black box warning for suicidality.
- Attests that they will use with caution in combination with other serotonergic agents to avoid serotonin syndrome.

Limitations:
- Initial approval duration: 1 year.
- Maximum daily dose: 200mg daily.

Renewal Coverage Criteria

Prescriber requirements:
- Attests they have reviewed the black box warning for suicidality.
- Attests that they will use with caution in combination with other serotonergic agents to avoid serotonin syndrome.

Limitations:
- Renewal approval duration: 1 year.
- Maximum daily dose: 200mg daily.

D. Cibinqo® (abrocitinib)

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

1. *The age for atopic dermatitis (only indication) expanded down to 12 years of age.*

2. *Removed requirement for order of use of topical treatment (no order of use necessary with calcineurin inhibitors criteria removal).*

Initial Coverage Criteria

Member must meet all the following criteria:
- Be 12 years of age or older.
- Have a diagnosis of moderate-to-severe atopic dermatitis.
- Have 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.
- Had an inadequate treatment response, intolerance, or contraindication to a preferred high potency topical corticosteroid.
- Had an inadequate treatment response, intolerance, or contraindication to topical immunomodulator (i.e., tacrolimus, pimecrolimus).
- Had an inadequate treatment response, intolerance, or contraindication to other biologics with preferable safety profile (i.e., Dupixent®).

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 that they have reviewed the black box warning.
- Attests that member **will not** use Cibinqo® concomitantly with other biologics.

Limitations:
- Initial approval duration: 6 months.
- Maximum daily dose: 1 tablet daily.

Renewal Coverage Criteria

Member must meet all the following criteria:
- Has documentation of positive clinical response to therapy (e.g., 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.
- Attests that member **will not** use Cibinqo® concomitantly with other biologics.

Limitations:
- Renewal approval duration: 1 year.
- Maximum daily dose: 1 tablet daily.

4. New Indications:

A. Ingrezza® (valbenazine)

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

1. *New indication for Huntington's Chorea. The criteria created mirrors Austedo®/Austedo XR®. The Board requested that the requirement for a neurologist be removed for Austedo/Austedo XR and Ingrezza for the diagnosis of Huntington's Chorea. Initial approval in Huntington's Chorea is for 6 months.*
2. *For both indications, removal of question regarding QT prolongation.*

Initial Coverage Criteria

Huntington's Chorea

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have a functional disability resulting from chorea associated with Huntington's disease. 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.

Prescriber requirements:

- Attests they are aware of boxed warning of increased risk of depression and suicidal ideation and behavior in patients with Huntington's Disease.
- Attests member is not at significant risk of suicidal behavior.
- Attests member will be counseled on, and monitored for, depression and suicidal thoughts and behaviors.
- Attests member is not currently and will not be prescribed any MAOI or reserpine.
- Attests member **will not** use Ingrezza® concomitantly with any other vesicular monoamine transporter 2 (VMAT2) inhibitors.

Limitations:

- Initial approval duration: 6 months.
- Maximum daily dose: 1 capsule daily.

Tardive Dyskinesia

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have a diagnosis of moderate to severe tardive dyskinesia (TD).
- Have had symptoms for at least 2 months prior to prescription.
- TD interferes with functional status, including self-care and ambulation; quality of life; or creates a social stigma sufficient to cause social isolation or embarrassment.

- Have had an inadequate response to the following treatment modalities, unless all are contraindicated, not tolerated or are inappropriate to maintain stable psychiatric function:
    - Discontinuation or dose modification of the offending medication.
    - Switching from a first-generation antipsychotic to a second-generation antipsychotic.
- If 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:

- Diagnosis of moderate to severe Tardive Dyskinesia was made by or in consult with one of the following:
    - Psychiatrist
    - Neurologist
    - Psychiatric Nurse Practitioner
- Has attached the previous 6 months of chart notes.
- Provide documented baseline evaluation of the condition using the Abnormal Involuntary Movement Scale (AIMS) with a minimum score greater than 6 (six) using items 1-7 (categories I, II, III). AIMS Score (please attach).
- Has documented the specific movement(s) in the patient's medical record along with how TD is affecting the patient's function, quality of life, or socialization.
- Has determined that Tardive Dyskinesia is antipsychotic (dopamine receptor blocker) induced.
- Attests that they have ruled out other potential causes of movement disorder, including, but not limited to, stimulants, stimulant use disorder, metoclopramide, etc.
- Attests member is not currently and will not be prescribed any MAOI or reserpine.
- Attests member **will not** use Ingrezza ® concomitantly with any other vesicular monoamine transporter 2 (VMAT2) inhibitors.

Limitations:

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

Renewal Coverage Criteria

Huntington's Chorea

Member must meet all the following criteria:

- Has shown symptom improvement as evidenced by a decrease in the Total Maximal Chorea Score.
- Is not at significant risk for suicidal behavior.

Limitations:

- Renewal approval duration: 6 months.
- Maximum daily dose: 1 capsule daily.

Tardive Dyskinesia

Member must meet all of the following criteria:

- Has shown symptom improvement as evidenced by improved AIMS score.
- Has increased function, quality of life, or socialization.

Prescriber requirements:
- Provide current documented evaluation of the condition using the Abnormal Involuntary Movement Scale (AIMS), using items 1-7 (categories I, II, III).
- Has attached chart notes from the last 6 months.

Limitations:
- Renewal approval duration: 6 months.
- Maximum daily dose: 1 capsule daily.

B. Rinvoq® (upadacitinib)

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

1. *New indication for moderately to severely active Crohn's Disease in adults.*
2. *New indication for Active non-radiographic Axial Spondyloarthritis (nr-axSpA) with objective signs of inflammation in adults.*
3. *Remove "adherent to Rinvoq® therapy" renewal language.*

Initial Coverage Criteria

Atopic Dermatitis

Member must meet all of the following criteria:
- Be 12 years of age or older.
- Have a diagnosis of refractory, moderately-to-severely active atopic dermatitis.
- Have 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.
- Had an inadequate treatment response, intolerance, or contraindication to a preferred high potency topical corticosteroid.
- Had an inadequate treatment response, intolerance, or contraindication to topical immunomodulator (ie. tacrolimus, pimecrolimus).
- Had an inadequate treatment response, intolerance, or contraindication to other biologics with preferable safety profile (i.e. Dupixent®).

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 they have reviewed the black box warning.
- Attests that member will not use Rinvoq® in combination with other JAK inhibitors, biologic immunomodulators, or with other immunosuppressants.

Limitations:

- Initial approval duration: 6 months.
- Maximum daily dose: 1 tablet daily.

Rheumatoid Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis, and Non-radiographic Axial Spondyloarthritis

Member must meet all the following criteria:
- Be 18 years of age or older.
- Have a diagnosis of:
  - moderately to severely active rheumatoid arthritis
  - active psoriatic arthritis
  - active ankylosing spondylitis
  - active non-radiographic axial spondyloarthritis with objective signs of inflammation.
- Have tried and had an inadequate response, intolerance, or contraindication to a preferred TNF blocker with the same indication.

Prescriber requirements:
- Must be prescribed by, or in consult with, a rheumatology or dermatology specialist.
- If not prescribed by appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Attests that member **will not** use Rinvoq® concomitantly with other JAK inhibitors, biologic therapies, or potent immunosuppressants.

Limitations:
- Initial approval duration: 6 months.
- Maximum daily dose: 1 tablet daily.

Moderately-to-Severely Active Ulcerative Colitis and Moderately-to-Severely Active Crohn's Disease

Member must meet all the following criteria:
- Be 18 years of age or older.
- Have a diagnosis of moderately-to severely active ulcerative colitis or moderately-to severely active Crohn's disease.
- Have tried and had an inadequate response, intolerance, or contraindication to a preferred TNF blocker with the same indication.

Prescriber requirements:
- Must be prescribed by, or in consult with, a rheumatology or gastroenterology specialist.
- If not prescribed by appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Attests that member **will not** use Rinvoq® concomitantly with other JAK inhibitors, biologic therapies, or potent immunosuppressants.

Limitations:
- Initial approval duration: 6 months.
- Maximum daily dose: 1 tablet daily.

Renewal Coverage Criteria

Atopic Dermatitis

Member must meet all the following criteria:
- Has documentation of positive clinical response to therapy (e.g. 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.
- Attests that member will not use Rinvoq® in combination with other JAK inhibitors, biologic immunomodulators, or with other immunosuppressants.

Limitations:
- Renewal approval duration: 1 year.
- Maximum daily dose: 1 capsule daily.

Rheumatoid Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis, and Non-radiographic Axial Spondyloarthritis

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

Prescriber requirements:
- Annual specialist consult provided if prescriber not a specialist.
- Attests that member will not use Rinvoq® in combination with other JAK inhibitors, biologic immunomodulators, or with other immunosuppressants.

Limitations:
- Renewal approval duration: 1 year.
- Maximum daily dose: 1 capsule daily.

Moderately-to-Severely Active Ulcerative Colitis and Moderately-to-Severely Active Crohn's Disease

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

Prescriber requirements:
- Annual specialist consult provided if prescriber not a specialist.
- Attests that member will not use Rinvoq® in combination with other JAK inhibitors, biologic immunomodulators, or with other immunosuppressants.

Limitations:
- Renewal approval duration: 1 year.

- Maximum daily dose: 1 capsule daily.

C. Leqvio® (inclisiran)

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

1. *Expanded the indication to primary hyperlipidemia. The criteria was previously approved only for Heterozygous familial hypercholesterolemia (HeFH) and Atherosclerotic cardiovascular disease (ASCVD).*
2. *Amended "**will not** use Leqvio® concomitantly with Juxtapid®, Repatha®, Praluent®" to include "or other PCSK9 medications".*

Initial Coverage Criteria

Member must meet all the following criteria:

- Must be 18 years of age or older.
- Must have a diagnosis of either:
    - Heterozygous familial hypercholesterolemia (HeFH) and has an LDL-cholesterol equal to or greater than 70mg/dl **OR**
    - Primary hyperlipidemia and has an LDL-cholesterol equal to or greater than 100mg/dl.
- Must have had a trial and inadequate response, or contraindication to at least TWO high-intensity statins for at least 12-weeks AND will continue receiving maximally tolerated high-intensity statin therapy.
- Must have trialed ezetimibe for at least 12-weeks and has been ineffective or contraindicated.

Prescriber requirements:

- Must be prescribed by, or in consult with, a cardiologist, endocrinologist, or lipidologist.
- 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 Leqvio® in combination with Juxtapid®, Repatha®, Praluent® or other PCSK9 medications.

Limitations:

- Initial approval duration: 9 months.
- Maximum daily dose: 284mcg SQ initially, again at 3-months, then every 6-months.

Renewal Coverage Criteria

Member must meet the following criteria:

- Has been adherent to Leqvio®.
- Has been adherent to statin at maximally tolerated dose.
- Has documentation of positive clinical response as defined by a reduction in LDL-C.

Prescriber requirements:

- Annual specialist consult provided if prescriber not a specialist**.**
- Attests that member **will not** use Leqvio® concomitantly with Juxtapid®, Repatha®, Praluent® or other PCSK9 medications.

Limitations:

- Renewal approval duration: 1 year.
- Maximum daily dose: 284mcg SQ every 6-months.

D. Linzess® (linaclotide)

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

1. New indication for functional constipation in patients 6 to 17 years of age.

Irritable bowel syndrome with constipation (IBS-C) OR Chronic idiopathic constipation (CIC) in adults

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have had a trial and inadequate response, or contraindication to at least ONE (1) osmotic laxative (i.e., polyethylene glycol, lactulose, etc.) for at least 14 days.
- If non-preferred, has 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).

Functional constipation (FC) in pediatric patients 6 to 17 years of age

Member must meet all of the following criteria:

- Be 6 to 17 years of age.
- Have had a trial and inadequate response, or contraindication to at least ONE (1) osmotic laxative (i.e., polyethylene glycol, lactulose, etc.) for at least 14 days.
- If non-preferred, has 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).

Limitations:

- Initial and renewal approval duration: 1 year.
- Maximum daily dose: 1 capsule daily.

E. Qulipta® (atogepant)

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

1. New indication for chronic migraine. Previously, it was episodic migraine.

Initial Coverage Criteria

Member must meet all the following criteria:

- Be 18 years old or older.
- Have a diagnosis of episodic or chronic migraine.
- Have a history of inadequate response (trial of at least 2 months duration), contraindication, or intolerance to 2 prophylactic conventional therapies **that include at least 2 separate therapeutic classes** from the following below:
  - Amitriptyline or venlafaxine

- Atenolol, metoprolol, nadolol, or propranolol
- Topiramate or divalproex

- Approval for a non-preferred drug requires a trial and inadequate response, or contraindication to a preferred oral or injectable drug with the same indication from the Montana Healthcare Programs Preferred Drug List 19 (mt.gov).

Prescriber must meet all of the following criteria:
- Document number of baseline headaches
- Attests that this therapy is being used as a preventative therapy, not for treatment of acute migraine attack.
- Attests member will not be concomitantly using with other CGRP therapies.

Limitations:
- Initial approval duration: 1 year.
- Maximum daily dose: 1 tablet daily.

Renewal Coverage Criteria

Member must meet the following criteria:
- Have documentation of positive clinical response to therapy as demonstrated by reduction in migraine frequency compared to number of migraine days at baseline.

Prescriber must meet all of the following criteria:
- Have documentation of member's positive clinical response to therapy as demonstrated by reduction in migraine frequency compared to number of migraine days at baseline.
- Attests that this therapy is being used as a preventative therapy, not for treatment of acute migraine attack.
- Attests member will not be concomitantly using with other CGRP therapy.

Limitations:
- Renewal approval duration: 1 year.
- Maximum daily dose: 1 tablet daily.

5. New Drug Criteria:

A. Austedo XR® (deutetrabenazine)

New Criteria for Austedo XR® and Criteria Changes for Austedo® – criteria documented below is the updated and current criteria approved by the Board. The updates are as follows:

1. *The Board requested that the requirement for a neurologist be removed for Austedo/Austedo XR and Ingrezza for the diagnosis of Huntington's Chorea. Initial approval in Huntington's Chorea is for 6 months for Austedo and Austedo XR instead of 12 weeks as previously required for Austedo.*
2. *For both indications, removal of question regarding QT prolongation.*

Initial Coverage Criteria

Huntington's Chorea

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have a functional disability resulting from chorea associated with Huntington's disease.

Prescriber requirements:

- Attests they are aware of boxed warning of increased risk of depression and suicidal ideation and behavior in patients with Huntington's Disease.
- Attests member is not at significant risk of suicidal behavior.
- Attests member will be counseled on, and monitored for, depression and suicidal thoughts and behaviors.
- Attests member is not currently and will not be prescribed any MAOI or reserpine.
- Attests member **will not** use Austedo® or Austedo XR® concomitantly with any other vesicular monoamine transporter 2 (VMAT2) inhibitors.

Limitations:

- Initial approval duration: 6 months.
- Maximum daily dose: 48mg once daily.

Tardive Dyskinesia

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have a diagnosis of moderate to severe tardive dyskinesia (TD).
- Have had symptoms for at least 2 months prior to prescription.
- TD interferes with functional status, including self-care and ambulation; quality of life; or creates a social stigma sufficient to cause social isolation or embarrassment.
- Have had an inadequate response to the following treatment modalities, unless all are contraindicated, not tolerated or are inappropriate to maintain stable psychiatric function:
    - Discontinuation or dose modification of the offending medication.
    - Switching from a first-generation antipsychotic to a second-generation antipsychotic.
- If 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:

- Diagnosis of moderate to severe Tardive Dyskinesia was made by or in consult with one of the following:
    - Psychiatrist
    - Neurologist
    - Psychiatric Nurse Practitioner
- Has attached the previous 6 months of chart notes.
- Provide documented baseline evaluation of the condition using the Abnormal Involuntary Movement Scale (AIMS) with a minimum score greater than 6 (six) using items 1-7 (categories I, II, III). AIMS Score (please attach).
- Has documented the specific movement(s) in the patient's medical record along with how TD is affecting the patient's function, quality of life, or socialization.

- Has determined that Tardive Dyskinesia is antipsychotic (dopamine receptor blocker) induced.
- Attests that they have ruled out other potential causes of movement disorder, including, but not limited to, stimulants, stimulant use disorder, metoclopramide, etc.
- Attests member is not currently and will not be prescribed any MAOI or reserpine.
- Attests member **will not** use Austedo® or Austedo XR® concomitantly with any other vesicular monoamine transporter 2 (VMAT2) inhibitors.

Limitations:
- Initial approval duration: 12 weeks.
- Maximum daily dose: 48mg once daily.

Renewal Coverage Criteria

Huntington's Chorea

Member must meet all the following criteria:
- Has shown symptom improvement as evidenced by a decrease in the Total Maximal Chorea Score.
- Is not at significant risk for suicidal behavior.

Limitations:
- Renewal approval duration: 6 months.
- Maximum daily dose: 48mg once daily.

Tardive Dyskinesia

Member must meet all of the following criteria:
- Has shown symptom improvement as evidenced by improved AIMS score.
- Has increased function, quality of life, or socialization.

Prescriber requirements:
- Provide current documented evaluation of the condition using the Abnormal Involuntary Movement Scale (AIMS), using items 1-7 (categories I, II, III).
- Has attached chart notes from the last 6 months.

Limitations:
- Renewal approval duration: 6 months.
- Maximum daily dose: 48mg once daily.

A. Zavzpret® (zavegepant nasal spray)

Initial Coverage Criteria

Member must meet all of the following criteria:
- Be 18 years of age or older.
- Have a diagnosis of acute migraine with or without aura.

- Currently using a prophylactic medication unless contraindicated, not tolerated, or ineffective.
- Have had a trial and inadequate response, or contraindication to **TWO** triptan 5-HT1 receptor agonists, **ONE** of which is a nasal formulation.
- If non-preferred, have had a trial and inadequate response, or contraindication to a preferred drug with the same indication and the same mechanism of action (CGRP receptor antagonist) from the Montana Healthcare Programs Preferred Drug List 19 (mt.gov).

Prescriber requirements:
- Attests Zavzpret® is **not** being used for the preventative treatment of migraine.
- Attests Zavzpret® is **not** being used in combination with other CGRP agents.

Limitations:
- Initial approval duration: 1 year.
- Maximum daily dose: 1 spray daily.
- Maximum monthly quantity: 1 box (6 sprays) per month.

Renewal Coverage Criteria

Member must meet all of the following criteria:
- Has documentation of positive clinical response to therapy.
- Currently using a prophylactic medication unless contraindicated, not tolerated, or ineffective.

Prescriber requirements:
- Attests Zavzpret ® is **not** being used in combination with other CGRP agents.

Limitations:
- Initial approval duration: 1 year.
- Maximum daily dose: 1 spray daily.
- Maximum monthly quantity: 1 box (6 sprays) per month.

C. Vowst® (fecal microbiota spores, live-brpk)

Initial Coverage Criteria

Member must meet all the following criteria:
- Be 18 years of age or older.
- Have a confirmed diagnosis of a **second recurrent** CDI with a positive stool test for toxigenic Clostridioides difficile (C. difficile).
- Has been treated with standard of care antibiotics (fidaxomicin, vancomycin, metronidazole) for initial CDI and 2 recurrences (3 total episodes).
- Has had a recurrent CDI episode within the last 6 months **OR** is at a high risk for CDI recurrence, defined as any of the following:
  - Age of 65 years or older
  - Immunocompromised state
  - Hypervirulent strain of C. difficile (i.e., ribotypes 027, 078, 244)
  - Clinically severe CDI at presentation

- Has completed antibacterial treatment for recurrent CDI 2 to 4 days before initiating treatment with Vowst®.
- Has been instructed on pretreatment instructions for appropriate use of Vowst®.

Prescriber requirements:
- Must be prescribed by, or in consult with, a gastroenterologist or infectious disease specialist.
- If not prescribed by appropriate specialist, a copy of the specialty consult is required.
- Attests that antibacterials will not be administered **concurrently** with Vowst®.
- Attests patient has been informed of appropriate pre-treatment protocol:
  - If kidney function is unimpaired, drink 296 mL (10 oz) magnesium citrate on the day before and at least 8 hours prior to taking the first dose of Vowst®.
  - Do not eat or drink, except for small amount of water, for at least 8 hours prior to taking the first dose.
  - Attests in patient with decreased kidney function, provider has reviewed packaging information.

Limitations:
- Approval duration: approved for 3-day therapy.
- Maximum daily dose: 4 capsules daily.

Renewal Coverage Criteria

Member must meet all the following criteria:
- Has a laboratory confirmed recurrence of CDI within 8 weeks of an initial fecal microbiota treatment (FMT).
- Has completed antibacterial treatment for recurrent CDI 2 to 4 days before initiating treatment with Vowst®.

Prescriber requirements:
- Must be prescribed by, or in consult with, a gastroenterologist or infectious disease specialist.
- If not prescribed by appropriate specialist, a copy of the specialty consult is required.
- Attests patient has been informed of appropriate pre-treatment protocol per packaging.

Limitations:
- Approval duration: approved for 3-day therapy.
- Maximum daily dose: 4 capsules daily.

Stimulant Discussion

The Board discussed concerns raised at the August meeting about stimulant use. Their primary issues were regarding multiple daily doses of long-acting agents especially when more than one long-acting drug is involved. There is also some concern about total daily dose and a variety of combinations of multiple long-acting and short acting doses.

Case Management will gather more detailed information on the current patterns of use within our population and return with more data for the Board to review at a later meeting.

Scheduled Upcoming Meeting Dates

DUR Meeting:
February 14, 2024

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

The next meeting will be February 14, 2024, in this same format. The meeting adjourned at 2:48 p.m.