MEDICAID SERVICES MANUAL
TRANSMITTAL LETTER

June 27, 2023

TO: CUSTODIANS OF MEDICAID SERVICES MANUAL

FROM: CASEY ANGRES
CHIEF OF DIVISION COMPLIANCE

SUBJECT: MEDICAID SERVICES MANUAL CHANGES
CHAPTER 1200 – PRESCRIBED DRUGS

BACKGROUND AND EXPLANATION

Revisions to Medicaid Services Manual (MSM) Chapter 1200 – Prescribed Drugs to reflect recommendations approved on April 20, 2023, by the Drug Utilization Review (DUR) Board. The proposed changes include the addition of new clinical and prior authorization (PA) criteria for Leqembi® (lecanemab-irmb) and Aduhelm® (aducanumab avwa)within the Alzheimer's Disease Agents section; updated existing clinical criteria for Epidiolex® (cannabidiol) and added new PA criteria for Ztalmy® (ganaxolone) within the Anticonvulsants section; addition of new PA criteria for Verkazia® (cyclosporine) within the newly created Ophthalmic Anti-Inflammatory Agents section.

Throughout the chapter, grammar, punctuation, and capitalization changes were made, duplications removed, acronyms used and standardized, and language reworded for clarity. Renumbering and re-arranging of sections was necessary.

These changes are effective July 3, 2023.

MATERIAL TRANSMITTED	MATERIAL SUPERSEDED
MTL N/A MSM Chapter 1200 - Prescribed Drugs	MTL N/A MSM Chapter 1200 - Prescribed Drugs

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
Appendix A Section UU	**Alzheimer's Disease Agents**	Updated existing criteria for Aduhelm® (aducanumab avwa).Added new PA criteria for Leqembi® (lecanemab-irmb).
Appendix A Section BBBB	**Anticonvulsants Section**	Updated existing clinical criteria for Epidiolex® (cannabidiol) and added new PA criteria for Ztalmy® (ganaxolone).
Appendix A Section HHHH	**Ophthalmic Anti-Inflammatory Agents**	Added new PA criteria for Verkazia® (cyclosporine).

UU. Alzheimer's Disease Agents~~Aduhelm® (aducanumab-avwa)~~

Therapeutic Class: Alzheimer's Disease Agents
Last Reviewed by DUR Board: October 26, 2021

Alzheimer's Disease Agents~~Aduhelm®~~ is subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Aduhelm® (aducanumab avwa)

a. Approval will be given if the following criteria are met and documented:

1. ~~a.~~ Submission of medical records (e.g., chart notes, laboratory values) documenting both of the following:

a. ~~1.~~ Based on the National Institute on Aging and the Alzheimer's Association (NIA-AA) criteria, one the following;

1. ~~a.~~ Diagnosis of mild cognitive impairment due to Alzheimer's disease; or

2. ~~b.~~ Diagnosis of probable Alzheimer's disease dementia; and

b. ~~2.~~ All of the following:

1. ~~a.~~ Clinical Dementia Rating-Global (CDR-G) score of 0.5 or Clinical Dementia Rating Sum of Boxes (CDR-SB) score of 0.5-4; and

2. ~~b.~~ Repeatable Battery for the Assessment of Neuropsychological (RBANS) score less than or equal to 85; and

3. ~~c.~~ Mini-Mental State Examination score of 24-30; or

4. ~~d.~~ Montreal Cognitive Assessment (MoCA) of 17 or above; and

2. ~~b.~~ Documentation of beta-amyloid protein disposition, as evidenced by one of the following:

a. ~~1.~~ Positive amyloid positron emission tomography (PET) scan; or

b. ~~2.~~ Both of the following:

1. ~~a.~~ Attestation that the patient does not have access to amyloid PET scanning; and

2. ~~b.~~ Cerebrospinal fluid (CSF) biomarker testing documents abnormalities suggestive of beta-amyloid accumulation (e.g., AB42 level, AB42:AB40 ratio); and

3. All of the following:

a. Recipient is not currently taking an anticoagulant or antiplatelet agent (unless aspirin 325 mg/day or less); and

b. Recipient has no history of transient ischemic attack (TIA) or stroke within previous year prior to initiating treatment; and

c. Recipient had no history of relevant brain hemorrhage, bleeding disorder, and cerebrovascular abnormalities in last six months; and

4. A baseline brain magnetic resonance imaging (MRI) has been completed within 12 months prior to initiating treatment to rule out other causes (e.g., stroke, small vessel disease, tumor); and

5. Counseling has been provided on the risk of amyloid-related imaging abnormalities (ARIA-E and ARIA-H) and recipient and/or caregiver are aware to monitor for headache, dizziness, visual disturbances, nausea, and vomiting; and

6. The medication is prescribed by a neurologist, geriatrician, or geriatric psychiatrist, or other expert in the disease state.

b. Recertification Request:

1. Submission of medical records (e.g., chart notes, laboratory values) documenting recipients benefitting from therapy as defined by both of the following:

a. Based on NIA-AA criteria, one of the following:

1. Recipient continues to have a diagnosis of mild cognitive impairment due to Alzheimer's disease; or

2. Recipient continues to have a diagnosis of probable disease dementia; and

b. All of the following:

1. CDR-G score of 0.5 of CDR-SB score of 0.5-4; and

2. RBANS score less than or equal to 85; and

a. Mini-Mental State Examination score of 24-30; and

c. Recipient has a follow-up brain MRI has been completed after the initiation of therapy to show one of the following:

1. Both of the following:

a. Less than ten new incident microhemorrhages; and

b. Two or less focal areas of superficial siderosis; or

2. If ten or more new incident microhemorrhages or greater than two focal areas of superficial siderosis are present then both of the following:

a. Patient has been clinically evaluated for ARIA related signs or symptoms (e.g., dizziness, visual disturbances); and

b. Follow-up MRI demonstrates radiographic stabilization (i.e., no increase in size or number of ARIA-H); and

c. The medication is prescribed by a neurologist, geriatrician, or geriatric psychiatrist.

c. PA Guidelines:

1. PA approval will be for six months.

2. Recertification requests will be approved for six months.

2. Leqembi® (lecanemab-irmb)

a. Approval will be given if the following criteria are met and documented:

1. Recipient has a diagnosis of mild cognitive impairment (MCI) due to Alzheimer's disease (AD) or mild Alzheimer's dementia as evidenced by all of the following:

a. Clinical Dementia Rating (CDR)-Global score of 0.5 to 1

b. Memory Box score greater than or equal to 0.5

c. Mini-Mental State Examination (MMSE) score 22 to 30

d. Objective evidence of cognitive impairment at screening

e. Positron emission tomography (PET) scan or cerebrospinal fluid (CSF) assessment of amyloid beta (1-42) is positive for amyloid beta plaque; and

2. Prescriber attests that other conditions causing similar symptoms have been ruled out (e.g., vascular dementia, dementia with Lewy bodies, frontotemporal dementia, normal pressure hydrocephalus); and

3. Prescribed by a neurologist, geriatrician, geriatric psychiatrist, or other expert in the treatment of Alzheimer's disease

4. Recipient does not have risk factors for intracerebral hemorrhage (e.g., prior cerebral hemorrhage greater than one centimeter in greatest diameter, more than for microhemorrhages, superficial siderosis, evidence of vasogenic edema, evidence of cerebral contusión, aneurysm, vascular malformation, infective lesions, multiple lacunar infarcts or stroke involving a major vascular territory, severe small vessel or white matter disease); and

5. Recipient has not had a stroke, transient ischemia attack (TIA), or seizure in the last 12 months; and

6. Recipient has not demonstrated clinically significant and unstable psychiatric illness in the six months; and

7. Recipient does not have a history of alcohol or substance abuse within the last 12 months; and

8. Recipient is not currently taking an anticoagulant or antiplatelet agent (with the exception of aspirin 325mg/day or less); and

9. Brain magnetic resonance imaging (MRI) has been obtained within 12 months prior to treatment initiation; and

10. Baseline disease severity has been assessed using an objective measure/tool (e.g., MMSE, Alzheimer's Disease Assessment Scale-Cognitive Subscale [ADAS-Cog-13], Alzheimer's Disease Cooperative Study-Activities of Daily Living Inventory-Mild Cognitive Impairment ~~versión~~version [ADCS-ADL-MCI], Clinical Dementia Rating-Sum of Boxes [CDR-SB].

b. Recertification Requests:

1. Recipient must continue to meet the above criteria; and

2. Scoring on an objective measure/tool (e.g., ADAS-Cog 13; ADCSADL-MCI; MMSE; CDR-SB) demonstrates improvement, stability, or slowing in cognitive and/or functional impairment; and

3. Recipient has not progressed to moderate or severe AD; and

4. Recipient has not experienced any treatment-restricting adverse effects (e.g., severe hypersensitivity reactions); and

5. Recipient has undergone MRI prior to the 5th, 7th, and 14th infusions to monitor for ARIA with edema (ARIA-E) or ARIA with hemosiderin deposition (ARIA-H).

c. PA Guidelines:

1. Initial approval will be given for six months.

2. Recertification will be given for six months.

~~c. All of the following:~~

~~1. Recipient is not currently taking an anticoagulant or antiplatelet agent (unless aspirin 325 mg/day or less); and~~

~~2. Recipient has no history of transient ischemic attack (TIA) or stroke within previous year prior to initiating treatment; and~~

~~3. Recipient had no history of relevant brain hemorrhage, bleeding disorder, and cerebrovascular abnormalities in last six months; and~~

~~d. A baseline brain magnetic resonance imaging (MRI) has been completed within 12 months prior to initiating treatment to rule out other causes (e.g., stroke, small vessel disease, tumor); and~~

~~e. Counseling has been provided on the risk of amyloid-related imaging abnormalities (ARIA-E and ARIA-H) and patient and/or caregiver are aware to monitor for headache, dizziness, visual disturbances, nausea, and vomiting; and~~

~~f. The medication is prescribed by a neurologist, geriatrician, or geriatric psychiatrist, or other expert in the disease state.~~

~~2. Recertification Request:~~

~~a. Approval will be given if the following criteria are met and documented:~~

~~1. Submission of medical records (e.g., chart notes, laboratory values) documenting recipientis benefitting from therapy as defined by both of the following:~~

a. Based on the NIA-AA criteria, one of the following:

1. Recipient continues to have a diagnosis of mild cognitive impairment due to Alzheimer's disease; or

2. Recipient continues to have a diagnosis of probable disease dementia; and

b. All of the following;

1. CDR-G score of 0.5 of CDR-SB score of 0.5-4; and

2. RBANS score less than or equal to 85; and

3. Mini-Mental State Examination score of 24-30; and

2. Recipient has a follow-up brain MRI has been completed after the initiation of therapy to show one of the following:

a. Both of the following:

1. Less than ten new incident microhemorrhages; and

2. Two or less focal areas of superficial siderosis; or

b. If ten or more new incident microhemorrhages or greater than two focal areas of superficial siderosis are present then both of the following:

1. Patient has been clinically evaluated for ARIA related signs or symptoms (e.g., dizziness, visual disturbances); and

2. Follow-up MRI demonstrates radiographic stabilization (i.e., no increase in size or number of ARIA-H); and

3. The medication is prescribed by a neurologist, geriatrician, or geriatric psychiatrist.

3. Prior Authorization Guidelines

a. Prior Authorization approval will be for six months.

b. Recertification requests will be approved for six months.

c. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

BBBB. Anticonvulsants

Therapeutic Class: Anticonvulsants
Last Reviewed by the DUR Board: April 22, 2021

Anticonvulsants are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Cannabinoid

a. Epidiolex® (cannabidiol)

1. Approval will be given if the following criteria are met and documented:

a. The recipient has a diagnosis of Lennox-Gastaut syndrome, Dravet Syndrome or Tuberous Sclerosis Complex (TSC); and

b. The recipient is one years of age or older; and

c. A recent serum transaminase (ALT and AST) and total bilirubin level has been obtained and is within normal limits; and

d. The drug is prescribed by or in consultation with a neurologist; and

e. The total dose does not exceed 20 mg/kg/day (10mg/kg twice daily) for LGS/DS or 25 mg/kg/day (12.5 mg/kg twice daily) ~~for20 mg/kg/day (10mg/kg twice daily); and~~

f. The medication will be used as adjunctive therapy in recipients with uncontrolled seizure management (the recipient has taken one or more antiepileptic drugs and has chart notes confirming persistent seizure events after titration of current anti-seizure regiment to highest tolerated doses).~~The medication will be used as adjunctive therapy (the recipient has been taking one or more antiepileptic drugs and has chart notes confirming the presence of at least four convulsive seizures per month).~~

2. Recertification Request

a. Documentation of a positive clinical response to Epidiolex® therapy; and

b. Serum transaminase (ALT and AST) and total bilirubin level has been re-checked per package insert.

3. PA Guidelines

a. Initial PA will be for three months.

b. Recertification approval will be for 12 months.

~~c. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx~~

4. For anticonvulsant criteria for children and adolescents, refer to Section N, titled Psychotropic Medications for Children and Adolescents.

2. Nayzilam® (midazolam)

a. Approval will be given if the following criteria are met and documented:

1. The recipient has a diagnosis of acute intermittent seizures; and

2. The recipient is at least 12 years of age; and

3. The medication is prescribed by or in consultation with a Neurologist; and

4. The dose must not exceed two sprays per seizure cluster, no more than one episode every three days and treat no more than five episodes per month.

b. Recertification Request

1. Documentation of positive clinical response to Nayzilam® therapy.

c. PA Guidelines

1. Initial PA will be for six months.

2. Recertification approval will be for 12 months.

~~3. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.~~

3. Valtoco® (diazepam)

a. Approval will be given if all the following criteria are met and documented:

1. The recipient has a diagnosis of epilepsy; and

2. The recipient is six years and older; and

3. The medication is prescribed for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity that are distinct from a patient's usual seizure pattern; and

4. The medication is prescribed by or in consultation with a neurologist; and

5. The quantity must not exceed five episodes per month.

b. PA Guidelines:

1. Documentation of positive clinical response to Valtoco® therapy.

c. PA Guidelines:

1. Initial authorization will be approved for six months.

2. Recertification approval will be approved for 12 months.

~~3. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx~~.

4. Fintepla® (fenfluramine)

a. Approval will be given if all the following criteria are met and documented:

1. The recipient has a documented diagnosis of seizures associated with Dravet Syndrome; and

2. The recipient is two years of age or older; and

3. The medication is prescribed by or in consultation with a neurologist.

b. Recertification Request:

1. The recipient has documentation of positive clinical response to Fintepla® therapy.

c. PA Guidelines:

1. Initial authorization will be for 12 months.

2. Recertification approval will be for 12 months.

~~3. Prior authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.~~

5. Ztalmy® (ganaxolone)

a. Approval will be given if the following criteria are met and documented:

1. Recipient is greater than or equal to two years of age; and

2. Recipient has a diagnosis of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) confirmed with genetic testing; and

3. Recipient has tried and/or is concomitantly receiving greater than or equal to two other anticonvulsant medications; and

4. Ganaxolone is prescribed by or in consultation with a neurologist.

b. Dosage Limits

1. Max Daily Dose is 1,800mg

c. Recertification Request:

1. Recipient must continue to meet the above criteria; and

2. Prescriber attests to stabilization of disease or reduction in seizure frequency from baseline; and

3. Recipient has not experienced any treatment-restricting adverse effects (e.g., somnolence, pyrexia, suicidal thoughts or behavior).

d. PA Guidelines:

1. Initial approval will be given for six months.

2. Recertification will be given for 12 months.

HHHH. Verkazia® (cyclosporine)

Therapeutic Class: Ophthalmic Anti-Inflammatory Agents
Last Reviewed by DUR Board: April 20, 2023

Verkazia® (cyclosporine) are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Approval will be given if the following criteria are met and documented

    a. Recipient is greater than or equal to four years old; and

    b. Recipient has a diagnosis of vernal keratoconjunctivitis; and

    c. Prescriber attestation that disease severity is moderate to severe; and

    d. Recipient has had a disease flare within the past one year; and

    e. Recipient is not using another immunomodulator via the ophthalmic route (e.g., other formulations of cyclosporine, tacrolimus, pimecrolimus).

2. Dosage Limits

    a. Max daily dose of four vials

3. Recertification Requests:

    a. Recipient must continue to meet the above criteria; and

    b. Prescriber attestation that recipient has had disease improvement and/or stabilization (e.g., improvement on corneal fluorescein staining [CFS], decrease in number of flares, improvement in symptoms); and

    c. Recipient has not experienced any treatment-restricting adverse effects (e.g., eye pain, infection).

4. Prior Authorization Guidelines:

    a. Initial approval will be given for 12 months.

    b. Recertification will be given for 12 months.