Mountain-Pacific Quality Health

Montana Healthcare Programs
Physician Administered Drug Coverage Criteria

ADUHELM™ (aducanumab-avwa)

I. Medication Description

Aduhelm™ is an amyloid beta-directed antibody indicated for the treatment of Alzheimer's disease.

Treatment with Aduhelm™ should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in clinical trials. There are no safety or effectiveness data on initiating treatment at earlier or later stages of the disease than were studied. This indication is approved under accelerated approval based on reduction in amyloid beta plaques observed in patients treated with Aduhelm™. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trial(s).

II. Position Statement

Coverage is determined through a prior authorization process **that must include** supporting clinical documentation for each request.

III. Initial Coverage Criteria

Member must meet all the following criteria:

- Must be 50 years of age or older
- Must be prescribed by a neurology specialist
- Has 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
    - Repeatable Battery for Assessment of Neuropsychological Status (RBANS) delayed memory index score ≤85
    - Mini-Mental Status Exam (MMSE) score between 24 and 30
    - Objective evidence of cognitive impairment at screening
- Provider has 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).
- Must have had a positive amyloid Positron Emission Tomography (PET) scan
- Must not have had a stroke or TIA within past year
- Must not be currently taking any medication with platelet anti-aggregate or anti-coagulant properties (unless aspirin ≤325mg daily)
- Must have had an adequate trial (at least 6 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 Health Care Programs preferred drugs can be found at https://medicaidprovider.mt.gov/19.

- If member is taking medications to treat symptoms related to Alzheimer's disease, dosages must be stable for at least 8 weeks prior to starting Aduhelm™. Additional therapies may not be initiated during Aduhelm™ treatment.
- Must have recent brain magnetic resonance imaging (MRI) (within one year) prior to initiating treatment
- Must have follow-up MRIs prior to the 7th and 12th infusions.
    - If radiographic severe ARIA-H is observed, treatment may be continued with caution only after a clinical evaluation and follow-up MRI demonstrates radiographic stabilization (i.e., no increase in size or number of ARIA-H).

IV. Renewal Coverage Criteria

Member must meet all the following criteria:

- Has been adherent to Aduhelm™
- Must be prescribed by a neurology specialist
- Obtained follow-up MRI prior to the 7th and 12th infusions and did not demonstrate radiographic severe ARIA-H
    - If radiographic severe ARIA-H observed, treatment may be continued with caution only after clinical evaluation and a follow-up MRI demonstrates radiographic stabilization (i.e., no increase in size or number of ARIA-H).
- Is receiving a benefit from Aduhelm™ therapy, as demonstrated by an improvement or stabilization from baseline on the Clinical Dementia Rating (CDR) and Mini-Mental Status Exam (MMSE)

V. Quantity Limitations

Max 10mg/kg IV every 4 weeks.

VI. Coverage Duration

- Initial approval duration: 6 months
- Renewal approval duration: 6 months