Clinical Policy: Aducanumab-avwa (Aduhelm)

Reference Number: IN.CP.PHAR.468
Effective Date: 02.2022
Last Review Date: 05.2022
Line of Business: IN Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Aducanumab-avwa (Aduhelm™) is a monoclonal antibody targeting amyloid beta.

FDA Approved Indication(s)

Aduhelm is indicated for the treatment of Alzheimer's disease. Treatment with Aduhelm should be initiated in paints with mild cognitive impairment or mild dementia stage of the 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).

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Aduhelm is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Alzheimer's Disease (must meet all)**:**

1. Diagnosis of Alzheimer's disease
2. Prescribed in consultation with a neurologist, geriatric psychiatrist or geriatrician.
3. Age Limit ≥ 50 years and ≤ 85 years
4. One of the following:
   a. Presence of beta-amyloid plaque levels confirmed by an amyloid positron emission tomography (PET) scan. Document of this required.
   b. Presence of amyloid proteins in Cerebral spinal fluid (CSF) obtained from a lumbar puncture. Documentation required.
5. Baseline MRI of brain has been obtained within the past year that confirm all the following amyloid related imaging abnormalities (ARIA) parameters. Demonstrating all the following (a, b, and c):
   a. No localized superficial siderosis.
   b. Less than 10 brain microhemorrhages.
   c. No brain hemorrhage > 1 cm within the past year.

6. Mild Cognitive impairment of mild dementia consistent with stages 3 or 4 Alzheimer's disease, assessed using at least one of the following:
   a. A Clinical Dementia Rating Clinical Dementia Rating-Global Score (CDR-GS) of 0.5.
   b. A Repeatable Battery for Assessment of Neuropsychological Status (RBANS) delayed memory index score of less than or equal to 85.
   c. Mini-Mental State Exam (MMSE) score greater than or equal to 24.
7. Member is currently not taking any blood thinners, except aspirin ≤ 325 mg.
8. Member has not had a stroke or transient ischemic attach TIA within the past 12 months or any relevant
   a. Brain Hemorrhage
   b. Cerebrovascular abnormalities.
9. All the following clinical conditions have been ruled out:
   a. Cardiovascular disease
   b. Bleeding disorders
   c. Clinically significant hepatic disease
   d. Clinically significant renal disease
   e. Acquired immunodeficiency syndrome (AIDS) or Huma Immunodeficiency Virus (HIV) infection.
   f. Member has not been diagnosed concurrently with another potentially contributory medical neurological or psychiatric condition.

10. Dose does not exceed the following (must meet all):
    a. Infusion 1 and 2: 1 mg/kg per 4 weeks.
    b. Infusion 3 and 4: 3 mg/kg per 4 weeks.
    c. Infusion 5 and 6: 6 mg/kg per 4 weeks.

Approval duration: 6 months (6 doses of infusion only)

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Alzheimer's Disease (must meet all)**:**

1. History of the requested agent within the past 60 days.
2. Prescriber has provided updated documentation of clinical improvement or stabilization when compared to previous Clinical Dementia Rating (CDR) global score. Repeatable Battery for Assessment of Neuropsychological Status (RBANS) delayed memory index score or mini-Mental state Examination (MMSE) score.
3. Prescriber provides updated brain MRI results (performed prior to the seventh and twelfth doses) that demonstrates the following Amyloid related imaging abnormalities (ARIA) parameters. (Documentation required) and all the following (a or b):
   a. Less than 10 new incident microhemorrhages

b. Less than 2 focal areas of superficial siderosis.
c. Prior authorization for continuation of therapy may be requested if subsequent clinical evaluation and brain MRH results demonstrate stabilization.

4. For continuation of therapy beyond the first 18 months and every 18 months thereafter, provide documentation of decreases (or at a minimum, no increases) in amyloid beta plaque levels, confirmed by either an amyloid-positron emission tomography (PET) scan or amyloid protein concentrations in Cerebral Spinal Fluid (CSF) obtained from a lumbar puncture performed after the seventh dose. The method of measuring amyloid beta plaque levels should be consistent for each re-evaluation period (comparable PET scan to PET scan measurements or CSF to CSF measurements).If request is for a dose increase, new dose does not exceed 10 mg/kg once every 4 weeks.

Approval duration:

- **Members with < 7 total infusions: up to the 6th total infusion**
- **Members with < 12 total infusions but > 7 total infusions: up to the 11th total infusion**
- **Members with > 12 total infusions: 6 infusions per PA approval**

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policies CP.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration
CDR-GS: Clinical Dementia Rating – global score
CSF: cerebrospinal fluid
DLB: Lewy body dementia
FTD: frontotemporal dementia
MMSE: Mini-Mental State Exam
MRI: magnetic resonance imaging
PET: positron emission tomography

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Alzheimer's disease	Initial dose should be titrated up as shown below: **IV infusion (every 4 weeks)** / **Aduhelm dosage (administered over approximately one hour)** Infusion 1 and 2 — 1 mg/kg Infusion 3 and 4 — 3 mg/kg Infusion 5 and 6 — 6 mg/kg Infusion 7 and beyond — 10 mg/kg After an initial titration, the recommended maintenance dose is 10 mg/kg intravenously via a 0.2 or 0.22 micron in-line filer over approximately one hour every four weeks, and at least 21 days apart.	10 mg/kg every 21 days

VI. Product Availability

Vial for injection (single dose): 170 mg/1.7 mL, 300 mg/3 mL

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
TBD	Injection, aducanumab, # mg

Reviews, Revisions, and Approvals	Date	Approval Date
New policy per IN Medicaid Moratorium.	02.01.22	02.01.22
Revisions align with IN Medicaid FFS and approved by IN Medicaid DUR board	7/01/2022	5/20/2022