Medical Policy:
ADUHELM® (aducanumab) MEDICAID ONLY

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.361	August 11. 2023	August 2, 2022

Definitions

Aduhelm® is FDA approved for the treatment of Alzheimer's disease. It was approved under the FDA accelerated approval process based on the surrogate endpoint of reducing amyloid-beta (Aβ) plaques in people with MCI or mild dementia stage of Alzheimer's disease.

Aduhelm® is a recombinant human immunoglobulin G1 (IgG1) monoclonal antibody designed to promote the clearance of amyloid aggregates and insoluble forms of amyloid beta (Aβ) in the brain. Aβ plaques in the brain are a pathophysiological feature of Alzheimer's disease.

Length of Authorization 12 months

Dosing Limits [Medical Benefit]

- Initial:
  Dosing based on actual body weight:
  - 1 mg/kg once every 4 weeks for infusions 1 and 2
  - 3 mg/kg once every 4 weeks for infusions 3 and 4

- 6 mg/kg once every 4 weeks for infusions 5 and 6

- Maintenance dose:
  - 10 mg/kg once every 4 weeks starting with infusion 7.

Administer infusions at least 21 days apart.

Guideline

I. Initial

1. **Alzheimer's Disease:** (Approve if A, B, C, D, E, and F)
   A. Evidence exists of mild cognitive impairment (MCI) due to Alzheimer's disease (AD) or mild Alzheimer's dementia by a Clinical Dementia Rating (CDR)-Global Score of 0.5 to 1, MiniMental Status Exam (MMSE) score between 24 and 30, and/or a Montreal Cognitive Assessment (MoCA) score of at least 18; **AND**
   B. Apolipoprotein E ε4 carrier status has been evaluated; **AND**
   C. A positron emission tomography (PET) scan or cerebrospinal fluid (CSF) analysis was completed that was positive for amyloid beta deposits; **AND**
   D. The patient does not have evidence of any medical or neurological condition other than Alzheimer's disease that might be a contributing cause of the subject's cognitive impairment, including, but not limited to, stroke/vascular dementia, tumor, dementia with Lewy bodies, or frontotemporal dementia; **AND**
   E. The patient does not have a history of a clotting disorder or is taking any form of antiplatelet or anticoagulant medications other than aspirin ≤325 mg/ day; **AND**
   F. The use of aducanumab is consistent with the FDA-approved product information.

II. Renewal Criteria

Coverage may be renewed when **all** the following criteria are met:

1. Provider must attest that the patient's score remained stable or improved, utilizing the same baseline assessment utilized for initial approval (Clinical Dementia Rating (CDR)-Global Score, MiniMental Status Exam (MMSE) score, and/or a Montreal Cognitive Assessment (MoCA) score.

Applicable Procedure Codes

Code	Description
J0172	Injection, aducanumab-avwa, 2 mg

Applicable NDCs

Code	Description
64406-0101-01	170 mg/1.7mL (100 mg/mL) single-dose vial
64406-0102-02	300 mg/3 mL (100 mg/mL) single- dose vial

ICD-10 Diagnoses

Code	Description
G30.1	Alzheimer's disease with late onset
G30.8	Other Alzheimer's disease
G30.9	Alzheimer's disease, unspecified

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	8/11/2023	Annual Review: No criteria changes
EmblemHealth & ConnectiCare	11/17/2022	Added Renewal Criteria-Provider must attest that the patient's score remained stable or improved, utilizing the same baseline assessment utilized for initial approval (Clinical Dementia Rating (CDR)-Global Score, MiniMental Status Exam (MMSE) score, and/or a Montreal Cognitive Assessment (MoCA) score.
EmblemHealth & ConnectiCare	8/2/2022	New Policy – MEDICAID ONLY

References

1. Product Information: ADUHELM® intravenous injection, aducanumab-avwa intravenous injection. Biogen Inc (per FDA), Cambridge, MA, 2022.
2. New York State Medicaid Update- November 2022 Volume 38- Number 13. Available at: https://www.health.ny.gov/health_care/medicaid/program/update/2022/no13_2022-11.htm