



Medical Policy: ADUHELM® (aducanumab) MEDICAID ONLY

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

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

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