Medical Policy:
ADUHELM™ (aducanumab-avwa)

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.329	August 11, 2023	August 10, 2021

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 an amyloid beta-directed antibody indicated to treat Alzheimer's disease. Aduhelm was approved by the FDA under the FDA Accelerated Approval Pathway. This pathway intends to provide patients who have a serious disease with earlier access to drugs when there is an expectation of clinical benefit, despite uncertainty about the clinical benefit. Accelerated approval is based upon the drug's effect on a surrogate endpoint — an endpoint that reflects the effect of the drug on an important aspect of the disease — where the drug's effect on the surrogate endpoint is expected, but not proven to predict clinical benefit. In the case of Aduhelm, the surrogate endpoint is the reduction of amyloid beta plaque. The reduction of these plaques is not proven to provide clinical benefit to the patient. The accelerated approval pathway requires the company to verify clinical benefit in a post-approval trial. If the sponsor cannot verify clinical benefit, the FDA may initiate proceedings to withdraw approval of the drug.

EmblemHealth Inc. has reviewed the available Aduhelm information regarding efficacy and safety and has consulted internal and external resources in making the coverage determination. The company will monitor and evaluate new scientific information as it becomes available.

Policy Statement

EmblemHealth will not cover Aduhelm due to lack of conclusive evidence confirming clinical efficacy.

Applicable Procedure Codes

Code	Description
J0172	Injection, aducanumab-avwa, 2 mg

Applicable NDCs

Code	Description
64406-101-01	170 mg/1.7 mL (100 mg/mL) single-dose vial
64406-102-02	300 mg/3 mL (100 mg/mL) single-dose vial

ICD-10 Diagnoses

Code	Description
G30.0	Alzheimer's disease with early onset
G30.1	Alzheimer’s disease with late onset
G30.9	Alzheimer’s disease, unspecified
G31.84	Mild cognitive impairment, so stated

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	8/11/2023	Annual Review: ICD-10 Codes: Added 30.0, G31.84, removed G30.8
EmblemHealth & ConnectiCare	9/1/2022	Transferred policy to new template
EmblemHealth & ConnectiCare	8/10/2021	New Policy

References

1. Aduhelm intravenous Injection [package insert]. Cambridge, MA. Biogen. Revised June, 2021.
2. Knopman, David, et al. Failure to demonstrate efficacy of aducanumab: An analysis of the EMERGE and ENGAGE trials as reported by Biogen, December 2019. November 2020. https://doi.org/10.1002/alz.12213.
3. 5. Samtani MN, Raghavan N, Novak G, Nandy P, Narayan VA. Disease progression model for Clinical Dementia Rating-Sum of Boxes in mild cognitive impairment and Alzheimer's subjects