

Aducanumab

(Aduhelm®) J0172 (2 mg)

Formulary Exclusion (Eligible for a Medical Necessity Review)

Aducanumab (Aduhelm®) may be authorized via a medical necessity review. Otherwise, it is currently excluded from the formulary due to insufficient clinical efficacy data. The risk versus benefit is still uncertain for Aduhelm®.

U.S. Food and Drug Administration:

This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.

Aduhelm® is an amyloid beta-directed antibody indicated for the treatment of Alzheimer’s disease. It works via reduction in amyloid beta plaques. Treatment with Aduhelm is intended for patients with mild cognitive impairment or mild dementia stage of disease.

References:

1. *Aduhelm® (Aducanumab) Label*. (2021, June). [Accessdata.fda.gov](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761178s000lbl.pdf). Retrieved January 24, 2023, from https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761178s000lbl.pdf
2. Haddad HW, Malone GW, Comardelle NJ, et al. Aduhelm, a novel anti-amyloid monoclonal antibody, for the treatment of Alzheimer’s Disease: A comprehensive review. *Health Psychology Research*. 2022;10(2). doi:10.52965/001c.37023

Criteria History/ Revision Information:

Date	Summary of Changes
September 2021	Criteria for use summary developed by the Ascension Ambulatory Care Expert Review Panel.
January 2023	Criteria for use summary revised by the Ascension Medical Specialty Prior Authorization Team.
January 2023	Criteria for use summary approved by the Ascension Ambulatory Care Expert Review Panel.
March 2023	Criteria for use revision summary approved by the Ascension Therapeutic Affinity Group.

If you have questions, call [833-980-2352](tel:833-980-2352) to speak to a member of the Ascension Rx prior authorization team or email your questions to smarthealthspecialty@ascension.org.