Medical Pharmacy Drug Prior Authorization Criteria

Drug Trade Name:	Aduhelm	**Drug Generic Name:**	Aducanumab-avwa
J Code:	J0172	**1 billable unit =**	2mg
Original Date of Review:	12/7/2022	**Last Reviewed:**	12/7/2022
Revision Date History			

Aduhelm (aducanumab-avwa) is an amyloid beta-directed antibody.

Criteria:

- **Length of authorization:** 6 months (initial), 6 months (renewal)
- **Age:** 50 years
- **Diagnoses [including ICD-10 codes]:**
- **Quantity Limit:**
  - Infusion 1 and 2: 1mg/kg
  - Infusion 3 and 4: 3mg/kg
  - Infusion 5 and 6: 6mg/kg
  - Infusion 7 and beyond: 10mg/kg

- **Initial Approval Criteria**
  - Patient is at least 50 years of age AND
  - Prescribed by or in consultation with a neurologist AND
  - Patient has a diagnosis of Alzheimer's disease with mild cognitive impairment or mild dementia as demonstrated by 3 validated scales, one of which must be the MMSE (Mini Mental State Exam) AND
  - Patient's Alzheimer's disease is confirmed with beta amyloid pathology as evidenced by ONE of the following:
    - A positive amyloid PET scan interpreted by a radiologist or nuclear medicine specialist OR
    - Amyloid is detected in CSF from a lumbar puncture AND
  - Patient has had a brain MRI within the past 12 months prior to initiating treatment that does NOT show ANY of the following:
    - Pre-treatment localized superficial siderosis OR
    - 10 or more brain microhemorrhages OR
    - A brain hemorrhage greater than 1 cm AND
  - Patient has undergone a complete physical and neurological exam to comprehensively rule out all other possible causes of neurocognitive decline including but not limited to:
    - Any medication potentially causing cognitive impairment must have been stopped for at least 4 weeks with continued cognitive symptoms
    - Currently uncontrolled psychiatric condition (including alcohol or substance abuse)
    - Parkinson's disease
    - Lewy body dementia
    - Vascular dementia (such as from a stroke) AND
  - Patient is not taking any blood thinners (exception: aspirin 81mg or less) AND
  - Prescriber attests that the patient and/or caregiver understands the risks and benefits of Aduhelm therapy AND
  - Prescriber attests that the patient and/or caregiver understands and is committed to receiving scheduled doses and enhanced clinical vigilance during the titration period

- The following documentation must be provided at time of requests:
  - Healthcare facility's written processes and procedures to support enhanced clinical vigilance during the titration period
  - Patient's educational materials to empower patient and caregiver during the enhanced clinical vigilance period and thereafter including ways to contact prescriber and other relevant clinical staff

- **Renewal Criteria**
  - Documentation of follow-up MRIs to evaluate for ARIA-E, ARIA-H, and other structural changes prior to the 7th and 12th infusions, then at least once annually AND
  - Documentation of current disease severity as demonstrated by current MMSE score (at least every 6 months)
    - Coverage authorization may be discontinued when Alzheimer's disease progresses rapidly into moderate to severe Alzheimer's disease unless the prescriber provides published peer-reviewed clinical research supporting its continue use
    - Rapid decline is defined as a 4-point reduction in a 6-month period on the MMSE, with an additional 1-point reduction in the following 6 months

- **Dosage/Administration**

Aduhelm	
Indication	**Dose**
Alzheimer's disease	IV Infusion every 4 weeks • Infusion 1 and 2: 1mg/kg • Infusion 3 and 4: 3mg/kg • Infusion 5 and 6: 6mg/kg • Infusion 7 and beyond: 10mg/kg

NDC: Aduhelm vial 63306-0102-XX

References:

1) Aduhelm Prescribing Information. Cambridge, MA: Biogen, Inc.; June 2021.Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761178s000lbl.pdf Accessed November 17, 2022.

2) ClinicalTrials.gov. 221AD301 Phase 3 Study of Aducanumab (BIIB037) in Early Alzheimer's Disease (ENGAGE). Available at: https://clinicaltrials.gov/ct2/show/NCT02477800 . Accessed November 17, 2022.

3) Institute for Clinical and Economic Review: Draft Evidence Report - Aducanumab for Alzheimer's disease: Effectiveness and Value. May 5, 2021. Available at: https://icer.org/wp-content/uploads/2020/10/ICER_ALZ_Draft_Evidence_Report_050521.pdf. Accessed November 17, 2022

4) Peripheral and Central Nervous System (PCNS) Drugs Advisory Committee Meeting. Combined FDA and Applicant PCNS Drugs Advisory Committee Briefing Document. November 6, 2020. Available at: https://www.fda.gov/advisory-committees/advisory-committee-calendar/november-6-2020-meeting-peripheral-and-central-nervous-system-drugs-advisory-committee-meeting#event-materials. Accessed November 17, 2022

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
G30.0	Alzheimer's disease with early onset
G30.1	Alzheimer's disease with late onset
G30.8	Other Alzheimer's disease
G30.9	Alzheimer's disease, unspecified