CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Aduhelm (aducanumab-avwa)
BILLING CODE	J0172
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Home/Office/Outpatient
STATUS	Prior Authorization Required

Aduhelm, a monoclonal antibody that targets amyloid plaque buildup in the brain, was initially approved by the FDA in June 2021. It is indicated for Alzheimer's disease patients with mild cognitive impairment or mild dementia stage of disease. Aduhelm is the first drug approved to slow the progression of Alzheimer's. There has been significant controversy surrounding the accelerated approval of this product, including conflicting results from the phase 3 clinical trials EMERGE and ENGAGE, and concerns regarding safety outcomes.

Aduhelm (aducanumab) will be considered for coverage when the following criteria are met:

Alzheimer's Disease

For **initial** authorization:

1. Member is at least 50 years of age; AND
2. Medication must be prescribed by or in consultation with a neurologist or geriatrician; AND
3. Member has a diagnosis of Alzheimer's disease with mild cognitive impairment or mild dementia as evidenced by ALL of the following assessments:
   a) MMSE score[10] of at least 21, and
   b) CDR-GS score equal to 0.5, and
   c) At least one of the following:
      i) MoCA score of at least 18,
      ii) QDRS score between 2 and 5,
      iii) RBANS score of 85 or less; AND
4. Member's Alzheimer's disease is of confirmed beta amyloid pathology as evidenced by ONE of the following:
   a) A positive amyloid PET scan interpreted by a radiologist or nuclear medicine specialist, or
   b) Amyloid is detected in CSF from a lumbar puncture; AND
5. Member has had a brain MRI within the past 12 months that does NOT show ANY of the following:
   a) Pre-treatment localized superficial siderosis,
   b) 10 or more brain microhemorrhages,
   c) A brain hemorrhage greater than 1 cm; AND
6. Member has undergone a complete physical and neurological exam to comprehensively rule out all other possible causes of neurocognitive decline including but not limited to:
   a) Any medication potentially causing cognitive impairment must have been stopped for at least 4 weeks with continued cognitive symptoms,
   b) Currently uncontrolled psychiatric condition (including alcohol or substance abuse),
   c) Parkinson's disease,
   d) Lewy body dementia,
   e) Vascular dementia (such as from a stroke); AND

7. Member is not taking any blood thinners (exception: low dose aspirin).
8. **Dosage allowed/Quantity limit:** After initial titration (see below), the recommended maintenance dose is 10 mg/kg every 4 weeks as an IV infusion.

IV Infusion (every 4 weeks)	ADUHELM Dosage (administered over approximately one hour)
Infusion 1 and 2	1 mg/kg
Infusion 3 and 4	3 mg/kg
Infusion 5 and 6	6 mg/kg
Infusion 7 and beyond	10 mg/kg

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Member has had a follow up assessment to determine that they have not progressed to moderate/severe dementia, as concluded by at least two of the following cognitive tests:
   a) MMSE score of at least 19,
   b) CDR-GS score of 1.0 or less,
   c) CDR-SB score of 9.0 or less,
   d) MoCA score of at least 18,
   e) QDRS score of 12 or less; AND
2. Prior to the 7th infusion (first dose of 10 mg/kg) and 12th infusion (sixth dose of 10 mg/kg), repeat MRI must be completed to evaluate for amyloid related imaging abnormalities-edema (ARIA-E), which can be observed on MRI as brain edema, and amyloid related imaging abnormalities-hemosiderin deposition (ARIA-H), which includes microhemorrhage. Discontinuation is warranted in those with severe symptomatic ARIA[10], radiographically severe ARIA-H, and as otherwise outlined in the prescribing information.

If all the above requirements are met, the medication will be approved for an additional 6 months.

CareSource considers Aduhelm (aducanumab) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
07/13/2021	New policy for Aduhelm created.
02/03/2022	Updated J code.

References:

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7. Sevigny J, Chiao P, Bussière T, et al. The antibody aducanumab reduces Aβ plaques in Alzheimer's disease. *Nature*. 2016;537(7618):50-56. doi:10.1038/nature19323
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9. Ackley SF, Zimmerman SC, Brenowitz WD, et al. Effect of reductions in amyloid levels on cognitive change in randomized trials: instrumental variable meta-analysis. *BMJ*. 2021;372:n156. Published 2021 Feb 25. doi:10.1136/bmj.n156
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