ALASKA MEDICAID
Prior Authorization Criteria

Aduhelm™
(aducanumab-avwa)

FDA INDICATIONS AND USAGE[1]

Aduhelm™ is an amyloid beta-directed antibody indicated for the treatment of Alzheimer's disease. Treatment with Aduhelm™ should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in clinical trials. There are no safety or effectiveness data on initiating treatment at earlier or later stages of the disease than were studied. This indication is approved under accelerated approval based on reduction in amyloid beta plaques observed in patients treated with Aduhelm™ continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trial(s).

APPROVAL CRITERIA[1,2,3,4]

1. Patient is 50 years of age or older **AND**;
2. Prescribed by or in consultation with a neurologist **AND**;
3. Patient has the diagnosis of Alzheimer's disease **AND**;
4. Patient has the presence of beta-amyloid plaques verified by either a positron emission tomography (PET) scan or cerebrospinal fluid (CSF) testing **AND**;
5. Patient must have a documented brain magnetic resonance imaging (MRI) within the last year showing no localized superficial siderosis, has less than 10 brain microhemorrhages, and no brain hemorrhages that are greater than 1 cm in the past year **AND**;
6. Must have objective evidence of cognitive impairment at screening **AND**;
7. Patient has a Clinical Dementia Rating (CDR) global score of 0.5 **AND**;
8. Patient has a Mini-Mental State Exam (MMSE) of greater than or equal to 24 **AND**;
9. Other known causes of dementia have been ruled out (i.e. vascular dementia, Parkinson's disease dementia, etc.)

DENIAL CRITERIA[1]

1. Failure to meet approval criteria **OR**;
2. Patient is taking any blood thinners, other than aspirin 81mg or less **OR**;
3. Patient has had a brain hemorrhage , bleeding disorder, or cerebrovascular abnormalities in the last 6 months **OR**;
4. Patient has a significant systematic illness or infection in past 30 days **OR**;
5. Patient has a history of unstable angina, myocardial infarction, advanced chronic heart failure, or clinically significant conduction abnormalities within 1 year prior to Screening

CAUTIONS[1]

- Amyloid Related Imaging Abnormalities (ARIA): Enhanced clinical vigilance for ARIA is recommended during the first 8 doses of treatment with Aduhelm™, particularly during titration. If a patient experiences symptoms which could be suggestive of ARIA, clinical evaluation should be performed, including MRI testing if indicated.
- The most common adverse reactions include ARIA-Edema, headache, ARIA-H microhemorrhage, ARIA-H superficial siderosis, and falls.

DURATION OF APPROVAL

- Initial Approval: up to 3 months
- Reauthorization Approval: up to 6 months if:
  - MRI has been obtained prior to the 7th and 12th doses and shows no increase in size or number of ARIA-H. **AND**;
  - Documented evidence the patient is responding positively, has slowed the rate of cognitive decline, and evidence of no adverse reactions.

QUANTITY LIMIT

- Infusion 1 and 2 = 1 mg/kg every 4 weeks
- Infusion 3 and 4 = 3 mg/kg every 4 weeks
- Infusion 5 and 6 = 6 mg/kg every 4 weeks
- Infusion 7 and beyond = maximum of 10 mg/kg every 4 weeks

REFERENCES / FOOTNOTES:

1. Aduhelm Prescribing Information. Cambridge, MA: Biogen, Inc.; June 2021.Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761178s000lbl.pdf Accessed July 16, 2021.
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 17, 2021.
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 July 17, 2021.
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 July 19, 2021.