

**Protocol for Aduhelm® (aducanumab)  
Approved October 2021**

**Background:**

*Alzheimer's is the most common cause of dementia, a general term for memory loss and other cognitive abilities serious enough to interfere with daily life. Alzheimer's disease accounts for 60-80% of dementia cases.*

**Aduhelm** is an amyloid beta-derived antibody indicated for the treatment of Alzheimer's disease (AD).

**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).**

**Criteria for approval:**

Patient meets **ALL** of the following with documentation:

1. Diagnosis of mild cognitive impairment or mild dementia stage Alzheimer's disease
2. Patient is  $\geq 50$  years of age
3. Patient meets all the following testing requirements:
  - a. Mini Mental State Examination (MMSE) scores between 24-29
  - b. Clinical Dementia Rating (CDR) global score of 0.5
  - c. Positive amyloid Positron Emission Tomography (PET) scan
  - d. Recent (within one year) brain MRI prior to initiating treatment
4. Absence of significant levels of impairment in other cognitive domains
5. Medication is prescribed by or in consultation with a neurologist, geropsychiatrist, geriatrician, or a physician who specializes in the treatment of Alzheimer's disease
6. Provider attests to have an MRI completed prior to the 7th and 12th dose to evaluate for the presence of asymptomatic Amyloid Related Imaging Abnormalities (ARIA)
7. Current patient's weight should be measured
8. Medication is prescribed in accordance with Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with medically appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence

**Initial Approval: 6 months**

**Continuation of therapy:**

1. Improvement or stabilization in ONE of the following compared to baseline at week 78:
  - a. MMSE score
  - b. CDR score

2. MRI is done prior to the 7th and 12th dose to evaluate for the presence of asymptomatic Amyloid Related Imaging Abnormalities (ARIA)
  - a. If radiographic presence of severe ARIA-H is observed, (10 or more new incident microhemorrhages or more than 2 focal areas of superficial siderosis, a clinical evaluation and a follow-up MRI demonstrating radiographic stabilization is submitted (i.e., no increase in size or number of ARIA-H)
3. Medication is prescribed in accordance with Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with medically appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence
4. Current patient's weight should be measured

**Renewal Approval: 6 months**

**References:**

1. Aduhelm® injection [prescribing information]. Biogen Inc. Cambridge, MA 02142
2. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2019. Updated periodically
3. CDR® Dementia Staging Instrument. Knight Alzheimer Disease Research Center. 4488 Forest Park, Suite 101, St. Louis, Missouri 63108. Accessed July 1, 2021 at: <https://knighadrc.wustledu/cdr/cdr.htm>
4. Creavin ST, Wisniewski S, Noel-Storr AH et al. Mini-Mental State Examination (MMSE) for the detection of dementia in people aged over 65. Cochrane, January 2016
5. ClinicalTrials.gov. 221AD301 Phase 3 Study of Aducanumab (BIIB037) in Early Alzheimer's Disease (ENGAGE). Available at: <https://clinicaltrials.gov/ct2/show/NCT02477800>
6. ClinicalTrials.gov. 221AD302 Phase 3 Study of Aducanumab (BIIB037) in Early Alzheimer's Disease (EMERGE). Available at: <https://clinicaltrials.gov/ct2/show/NCT02484547>
7. D. Press, M. Alexander; (2021). Treatment of Alzheimer disease. In J. Wiltedink (Ed.) *UpToDate*. Retrieved July 8, 2021, from [https://www.uptodate.com/contents/treatment-of-alzheimer-disease?search=Aduhelm&source=search\\_result&selectedTitle=2~7&usage\\_type=default&display\\_rank=1#H2549013834](https://www.uptodate.com/contents/treatment-of-alzheimer-disease?search=Aduhelm&source=search_result&selectedTitle=2~7&usage_type=default&display_rank=1#H2549013834)