

Aduhelm™ (aducanumab-avwa)



When requesting Aduhelm™ (aducanumab-avwa), the individual requiring treatment must be diagnosed with a FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indications

Aduhelm™ is 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.

Coverage Guidelines

Due to the lack of clinical efficacy data and safety concerns, approval is not recommended for Aduhelm. The current Aduhelm efficacy information is insufficient to determine if the medication demonstrates any clinically meaningful benefits; whereas, safety concerns have been demonstrated in clinical trials. In the absence of additional clinical trials, there is not enough information to support approval.

References

1. Aduhelm™ intravenous infusion [prescribing information]. Cambridge, MA: Biogen; June 2021.
2. Alzheimer's Association. Alzheimer's disease facts and figures-2021. Available at: <https://www.alz.org/media/Documents/alzheimers-facts-and-figures.pdf>. Accessed on June 7, 2021.
3. Data on file. Unapproved Product Formulary Submission Dossier: Aducanumab in Mild Cognitive Impairment due to Alzheimer's Disease and Alzheimer's Disease Dementia. Biogen. Received April 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.
5. Alexander GC, Emerson S, Kesselhelm AS. Evaluation of aducanumab for Alzheimer Disease scientific evidence and regulatory review involving efficacy, safety, and futility. *JAMA*. 2021;325(17):1717-1718.