

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; August 2023.
2. Alzheimer's Association. Alzheimer's disease facts and figures-2023. Available at: <https://www.alz.org/media/Documents/alzheimers-facts-and-figures.pdf>. Accessed on September 21, 2023.
3. Budd Haeberlein S, Aisen PS, Barkhof F, et al. Two Randomized Phase 3 Studies of Aducanumab in Early Alzheimer's Disease. *J Prev Alzheimers Dis.* 2022;2(9):197-210.
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.