

Leqembi™ (lecanemab-irmb)

When requesting Leqembi™ (lecanemab-irmb), the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indication

Leqembi™ is indicated for the treatment of Alzheimer's disease. Treatment with Leqembi 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 Leqembi. The current Leqembi 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. Leqembi™ intravenous infusion [prescribing information]. Nutley, NJ: Eisai; January 2025.
2. Alzheimer's Association. Alzheimer's disease facts and figures-2022. Available at: <https://www.alz.org/media/Documents/alzheimers-facts-and-figures.pdf>. Accessed on January 19, 2024.
3. Swanson CJ, Zhang Y, Dhadda S, et al. A randomized, double-blind, phase 2b proof-of-concept clinical trial in early Alzheimer's disease with lecanemab, an anti-Aβ protofibril antibody. *Alzheimers Res Ther.* 2021;13(1):80.
4. van Dyck CH, Swanson CJ, Aisen P, et al. Lecanemab in early Alzheimer's disease. *N Engl J Med.* 2023;388(1):9-21.
5. Andrews JS, Desai U, Kirson NY, et al. Disease severity and minimal clinically important differences in clinical outcome assessments for Alzheimer's disease clinical trials. *Alzheimers Dement.* 2019;5:354-363.