

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.

Coverage Guidelines

Alzheimer's Disease

The individual must meet the following criteria for an initial authorization:

1. Has mild cognitive impairment due to Alzheimer's disease or mild dementia due to Alzheimer's disease;
2. Has had one of the following baseline assessments:
 - a. Clinical Dementia Rating-Global Score (CDR-GS); OR
 - b. Mini-Mental State Examination (MMSE); OR
 - c. Montreal Cognitive Assessment (MoCA); OR
 - d. Saint Louis University Mental Status (SLUMS); OR
 - e. Rowland Universal Dementia Assessment Scale (RUDAS);
3. Meets ALL of the following:
 - a. Has had a magnetic resonance imaging (MRI) of the brain within the past 1 year; AND
 - b. The MRI showed ≤ 4 brain microhemorrhage, brain hemorrhage ≤ 1 cm, and ≤ 1 pre-treatment localized superficial siderosis; AND
 - c. Ruled out medical or neurological conditions, other than Alzheimer's disease, that may be contributing to the patient's cognitive impairment;
4. Has had a positive test for amyloid beta based on Positron Emission Tomography (PET) scan OR cerebrospinal fluid (CSF) beta-amyloid;
5. Leqembi is prescribed by or under the supervision of a neurologist.

The individual must meet the following criteria for re-authorization:

1. Has not progressed beyond mild dementia due to Alzheimer's disease;
2. Has undergone MRI monitoring for amyloid related imaging abnormalities (ARIA) and meets one of the following:
 - a. Does not have ARIA; OR

- b. Continuation of therapy is appropriate;
- 3. Leqembi is prescribed by or under the supervision of a neurologist.

Approval Duration (initial): 6 months

Approval Duration (renewal): 12 months

Dosing Recommendations

The recommended starting dosage is 10 mg/kg once every 2 weeks administered as an intravenous infusion OR 500 mg once a week administered as subcutaneous injection.

After 18 months, continue treatment with the starting dosage or transition to an intravenous or subcutaneous maintenance dosage.

The recommended maintenance dosage is 10 mg/kg once every 4 weeks administered as an intravenous infusion OR 360 mg once a week administered as subcutaneous injection.

References

1. Leqembi® intravenous infusion and Leqembi® IQLIK™ subcutaneous injection [prescribing information]. Nutley, NJ: Eisai; July 2026.
2. Alzheimer's Association. Alzheimer's disease facts and figures-2025. Available at: <https://www.alz.org/media/Documents/alzheimers-facts-and-figures.pdf>. Accessed on February 17, 2026.
3. van Dyck CH, Swanson CJ, Aisen P, et al. Lecanemab in early Alzheimer's disease. *N Engl J Med*. 2023;388(1):9-21.
4. van Dyck CH, Sperling R, Johnson K, et al. Long-term safety and efficacy of lecanemab in early Alzheimer's disease: Results from the clarity AD open-label extension study. *Alzheimer's Dement*. 2025;21(12):e70905.