

lecanemab-irmb (Leqembi)

Commercial Medical Benefit Drug Policy

Place of Service

Home Infusion Administration
Infusion Center Administration
Office Administration
Outpatient Facility Infusion Administration

Drug Details

USP Category: CENTRAL NERVOUS SYSTEM AGENTS

Mechanism of Action: Amyloid beta-directed antibody

HCPCS:

J0174:Injection, lecanemab-irmb, 1 mg

How Supplied:

- 200 mg/2 mL (100 mg/mL) solution in a single-dose vial
- 500 mg/5 mL (100 mg/mL) solution in a single-dose vial

Condition(s) listed in policy *(see coverage criteria for details)*

- Alzheimer's Disease (AD)

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Coverage Criteria

The following condition(s) require Prior Authorization/Preservice.

Alzheimer's Disease (AD)

Meets medical necessity if all the following are met:

Initial

1. Being prescribed by or in consultation with a neurologist, geriatrician, or relevant specialist
2. Patient is 50 years of age or older
3. Meets ONE of the following:
 - a. Positive for beta amyloid pathology based on PET scan
 - b. Lumbar puncture results confirming the presence of elevated P-tau, and/or T-tau protein and reduced beta amyloid-42, or a low AB42/AB40 ratio as determined by lab assay detected in cerebral spinal fluid (CSF)

4. Diagnosis of mild cognitive impairment (MCI) or mild dementia due to AD as determined by one of the following:
 - a. Clinical Dementia Rating Global Score (CDR-GS) of 0.5 to 1
 - b. Montreal Cognitive Assessment (MoCA) score greater than or equal to 16
 - c. Mini Mental State Exam (MMSE) score of 22-30
5. Patient does not have a history of transient ischemic attack, stroke, or seizures within the past 12 months
6. No significant pathological findings on pre-treatment magnetic resonance imaging (MRI) scan within the last 12 months to rule out pre-existing amyloid related imaging abnormalities (ARIA) or other irregular findings (e.g., cerebral contusions, encephalomalacia, aneurysms, vascular malformations, infective lesions, multiple lacunar infarcts or stroke involving a major vascular territory, etc.) that may increase the likelihood of significant adverse events
7. Patient is not currently receiving anticoagulant therapy except for aspirin at a prophylactic dose or less (i.e., less than or equal to 325 mg)

Reauthorization

1. Prescribed by or in consultation with a neurologist, geriatrician, or relevant specialist
2. Patient has not progressed beyond MCI or mild dementia related to AD as determined by ONE of the following:
 - a. CDR-GS greater than 1
 - b. MoCA less than 16
 - c. MMSE less than or equal to 21
3. Patient does not have any of the following based upon the results of monitoring MRI scans:
 - a. Moderate-to-severe ARIA-E symptoms or any ARIA-H symptoms
 - b. Asymptomatic but moderate to severe radiographic findings of ARIA-E and/or ARIA-H
 - c. Presence of intracerebral hemorrhage greater than 1 cm in diameter

Covered Doses:

Not to exceed 10 mg/kg given intravenously once every 2-4 weeks

Coverage Period:

Initial: 6 months

Reauthorization: one year

References

1. AHFS. Available by subscription at <http://www.lexi.com>
2. DrugDex. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
3. Leqembi (lecanemab-irmb) Prescribing Information. Eisai Inc., Nutley, NJ: 1/2026.
4. Wolk DA and Dickerson BC. Clinical features and diagnosis of Alzheimer disease. www.uptodate.com. Literature review current through December 2025. Topic last updated September 30, 2024. Accessed on January 25, 2026.
5. Mendez MF. Mental status scales to evaluate cognition. www.uptodate.com. Literature review current through December 2025. Topic Last updated February 27, 2025. Accessed on January 25, 2026.

Review History

Date of Last Annual Review: 1Q2026

Changes from previous policy version:

- No clinical changes following annual review

*Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee*