

## 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.

#### **Coverage Criteria**

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

#### Alzheimer's Disease (AD)

**Meets medical necessity if all the following are met:**

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  $\geq 16$

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- 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.,  $\leq 325\text{mg}$ )

**Covered Doses:**

Up to 10 mg/kg given intravenously once every 2-4 weeks

**Coverage Period:**

Initial: 6 months

Reauthorization: 12 months if meets ALL the below criteria

- 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  $>1$
  - b. MoCA  $<16$
  - c. MMSE  $\leq 21$
- 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

**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: 11/2024.

**Review History**

Date of Last Annual Review: 1Q2025

Changes from previous policy version:

- Alzheimer's disease: Covered Doses - Updated to include monthly dosing

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