blue california
Promise Health Plan

lecanemab-irmb (Leqembi®)

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:Inj, 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)

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

Alzheimer's Disease (AD)

1. Being prescribed by or in consultation with a neurologist, geriatrician, or relevant specialist, AND
2. Patient is 50 years of age or older, AND
3. One of the following:
    a. Positive for beta amyloid pathology based on PET scan, or
    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), AND
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, or
    b. Montreal Cognitive Assessment (MoCA) score ≥16, or
    c. Mini Mental State Exam (MMSE) score of 22-30, AND
5. Patient does not have a history of transient ischemic attack, stroke, or seizures within the past 12 months, AND
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, AND

7. Patient is not currently receiving anticoagulant therapy except for aspirin at a prophylactic dose or less (i.e., ≤ 325mg)

Covered Doses:
10 mg/kg given as an intravenous infusion every two weeks

Coverage Period:
Initial: 6 months

Reauthorization: 12 months if meets the below criteria

1. Prescribed by or in consultation with a neurologist, geriatrician, or relevant specialist, AND
2. Patient has not progressed beyond MCI or mild dementia related to AD as determined by one of the following:
    a. CDR-GS >1, or
    b. MoCA <16, or
    c. MMSE <21, AND
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, or
    b. Asymptomatic but moderate to severe radiographic findings of ARIA-E and/or ARIA-H, or
    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]. Nutley, NJ: Eisai Inc.; 1/2023

Review History

Date of Last Annual Review: 11/29/2023
Date of last revision: 11/29/2023
Changes from previous policy version:

- Added coverage for the treatment of early Alzheimer's disease
  Rationale: In July 2023, Leqembi received traditional approval for the treatment of early Alzheimer's disease following its accelerated approval.

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