PARAGON HEALTHCARE

LEQEMBI® Payer Guide

Payer Coverage Criteria Updates

LEQEMBI® (lecanemab-irmb), with recent FDA approval, may be considered for the treatment of Alzheimer's Disease (AD) when ***all* of the following coverage criteria are met**.

Aetna insurance

Updated October 2023.

- Member is 50 years old or older
- Documentation of APOE genotype testing or documentation that it has been counseled to the member that it cannot be determined if they are APOE ε4 homozygous and may be at high rise for Amyloid-Related Imaging Abnormalities (ARIA)
- Diagnosed Mild Cognitive Impairment (MCI) due to AD or mild Alzheimer's dementia
- Objective evidence of MCI
- Requires *only one* cognitive assessment score: Clinical Dementia Rating (CDR) of 0.5–1, Mini Mental State Examination (MMSE) of 21–30, *or* Montreal Cognitive Assessment (MoCA) of ≥16
- Positive Positron Emission Tomography (PET) scan, *or* Cerebrospinal Fluid (CSF) testing
- Baseline MRI in past year to evaluate ARIA
- Member and/or provider must currently be participating in a provider-enrolled patient registry that collects information on treatments for AD (e.g., Alzheimer's Network for Treatment and Diagnostics [ALZ-NET])
- Approved diagnosis codes: G30.0–G30.9 and G31.84

Ambetter insurance

Published January 2023 with recent update July 2023.

- Diagnosed MCI due to AD or mild AD dementia
- Prescribed by or in consultation with a geriatrician or neurologist
- Presence of amyloid β plaques verified by *one* of the following: PET scan, *or* CSF testing
- Attestation that prescriber has discussed with the member the potentially increased risk of ARIA in those who are APOE ε4 genetic homozygotes, and in those who are currently taking (or may eventually need) concomitant anticoagulant or antithrombotic therapy
- Member must be enrolled in a randomized controlled trial conducted under an IND application *or* an NIH-supported trial

Medicare & Medicare Advantage patients must be enrolled in an approved study/registry that meets the Centers for Medicare and Medicaid Services (CMS) Coverage with Evidence Development (CED) criteria and is listed on the "Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (AD)" page of the CMS CED website (Available at: https://www.cms.gov/medicare/coverage-evidence-development/monoclonal-antibodies-directed-against-amyloid-treatment-alzheimers-disease-ad). A copy of the enrollment confirmation must be submitted.

Blue Cross Blue Shield Anthem insurance

Published July 2023, after recent FDA announcement.

- CO, CT, GA, IN, KY, ME, NV, NH, OH, VA, and MO (excluding 30 counties in the Kansas City area)
- Diagnosed MCI due to AD or mild AD dementia
- Member is 50–90 years old
- Documentation of APOE genotype testing or documentation that it has been counseled to the member that it cannot be determined if they are APOE ε4 homozygous and may be at high rise for ARIA
- Documentation of objective impairment in episodic memory according to memory tests, (i.e., Free & Cued Selective Reminding Test, Rey Auditory Verbal Learning Test, California Verbal Learning Test, or Logical Memory I, II or other versions of the Wechsler Memory Scale Revised)
- Requires *all three* cognitive assessment scores: CDR (0.5-1), MMSE (22-30), *and* Memory Box (≥0.5)
- Positive PET scan *or* CSF testing
- Baseline MRI in past year to evaluate ARIA
- No history of Transient Ischemic Attack (TIA) or stroke
- No uncontrolled bleeding disorder (including those with platelet count <50,000 or INR >1.5)
- Approved diagnosis codes: G30.0–G30.9 and F06.70–G06.71

Blue Cross Blue Shield of Alabama (BCBSAL) insurance

Published August 2023.

- LEQEMBI® is considered not medically necessary for all indications including treatment of AD
- Note: There is insufficient clinical evidence for demonstrated efficacy

Blue Cross Blue Shield of Tennessee (BCBSTN) insurance

Published May 2023, prior to recent FDA announcement.

- Diagnosed MCI due to AD or mild AD dementia
- Objective evidence of cognitive impairment at screening
- Requires *all three* cognitive assessment scores: CDR (0.5–1), MMSE (22–30), *and* Memory Box (≥0.5)
- Positive PET scan *or* CSF testing
- Baseline MRI in past year to evaluate ARIA
- Not receiving anti-platelet agents
- No stroke or TIA in the past 6 months
- No significant, unstable psychiatric illness in the past year
- No intracerebral hemorrhage risk factors

Blue Cross Blue Shield of Texas (BCBSTX) insurance

Published August 2023, after recent FDA announcement.

- Prescribed by or in consultation with a neurologist or neuropsychiatrist
- Diagnosed MCI due to AD or mild AD dementia
- Objective evidence of cognitive impairment at baseline
- Member is aged 50 years or older
- Individual has positive amyloid load as indicated by *one* of the following: Positive PET scan *or* CSF assessment of amyloid β (Aβ1-42), *and* a baseline brain MRI prior to initiating treatment (within one year), *and* one of the following assessment tool scores at baseline: Clinical Dementia Rating Global Score (CDR-GS) of 0.5-1, *or* MMSE of 21-30
- LEQEMBI® will not be used in combination with any other amyloid β-directed antibodies (e.g., aducanumab)

Humana Coverage Criteria

Published August 2023, after recent FDA announcement.

- Diagnosed with MCI or mild dementia due to Alzheimer's disease
- Documentation of APOE genotype testing or documentation that it has been counseled to the member that it cannot be determined if they are APOE ε4 homozygous and may be at high rise for ARIA
- Positive PET scan *or* CSF testing
- Member has a MMSE score of 22–30 (inclusive) and/or a MoCA score of 17–30 (inclusive) within the past 3 months, and a copy of the MMSE and/or MoCA test must be submitted
- Member must not currently be taking anticoagulant therapy
- Member has had a brain MRI in the past year
- Medical record (e.g., chart notes) from the most recent office visit must be submitted to support the requirements above

United Healthcare (UHC) insurance

Published November 2023.

- Diagnosed MCI due to AD or mild AD dementia
- Requires *all* of the following: CDR (0.5 or 1) *AND* CDR memory box (0.5 or greater), *AND* one of the following: MMSE (22 or greater, SLUMS (17 or greater) *or* MoCA (17 or greater)
- Documentation of APOE genotype testing or documentation that it has been counseled to the member that it cannot be determined if they are APOE ε4 homozygous and may be at high rise for ARIA
- Positive PET scan *or* CSF testing with attestation that patient does not have access to PET scan
- Baseline MRI in past year to evaluate ARIA
- Other differential diagnoses (e.g., dementia with Lewy bodies [DLB], frontotemporal dementia [FTD], vascular dementia, pseudodementia due to mood disorder, vitamin B12 deficiency, encephalopathy, etc.) have been ruled out
- No history of intracerebral hemorrhage
- Patient is not currently taking an anticoagulant, or is on an anticoagulant and has been counseled about risks of cerebral microhemorrhage. Provider must attest that patient has shared in decision-making to initiate LEQEMBI®
- Prescriber attests that the prescriber's site is currently registered or will seek registration with the Alzheimer's Network for Treatment and Diagnostics (ALZ-NET) or other comparable patient registry that collects information on treatments for AD, including LEQEMBI®
- Approved diagnosis codes: G30.0–G30.9

PARAGON HEALTHCARE

Bringing LEQEMBI® patients access to their infusion therapy *— anytime, anywhere.*

Download the LEQEMBI® order form.

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