UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Alzheimer's Disease – Amyloid Beta-Directed Antibodies – Leqembi Intravenous Utilization Management Medical Policy

- Leqembi® (lecanemab-irmb intravenous infusion – Eisai/Biogen)

REVIEW DATE: 02/18/2026; selected revision 04/15/2026, 06/10/2026, and 07/22/2026

OVERVIEW

Leqembi intravenous (IV), an amyloid beta-directed antibody, is indicated for the **treatment of Alzheimer's disease.**[1] Treatment with Leqembi IV 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.

Disease Overview

An estimated 7.2 million Americans ≥ 65 years of age are living with Alzheimer's dementia in 2025, with 74% of these people ≥ 75 years of age.[2] The number and proportion of older adults who have mild cognitive impairment due to Alzheimer's disease is difficult to estimate; however, a rough approximation suggests that 5 to 7 million older Americans may have mild cognitive impairment due to Alzheimer's disease. People with mild cognitive impairment due to Alzheimer's disease have biomarker evidence of brain changes due to the disease in addition to subtle problems with memory and thinking. Biomarker evidence includes abnormal levels of amyloid beta as evidenced on positron emission tomography (PET) scans and in analysis of cerebrospinal fluid, and decreased metabolism of glucose as shown on PET scans. These cognitive problems may be noticeable to the individual's family members and friends, but not to others, and they do not interfere with the person's ability to carry out everyday activities. The mild changes in cognitive abilities occur when the brain can no longer compensate for the damage and death of nerve cells due to Alzheimer's disease.

Clinical Efficacy

The efficacy of Leqembi IV was evaluated in one Phase III, randomized, double-blind, placebo-controlled, multicenter study (CLARITY AD) that included patients with mild cognitive impairment due to Alzheimer's disease and mild Alzheimer's disease dementia (n = 1,795).[3] In CLARITY AD, the adjusted mean change from baseline in the Clinical Dementia Rating-Sum of Boxes (CDR-SB) score at 18 months was 1.21 in the Leqembi IV arm and 1.66 in the placebo arm (treatment difference -0.45; $P < 0.001$). At 18 months, the adjusted mean change in amyloid burden from baseline was -55.48 Centiloids in the Leqembi IV arm and 3.64 Centiloids in the placebo arm (treatment difference -59.12 Centiloids [$P < 0.001$]).

Of the total 1,616 patients enrolled in the published 36 month CLARITY AD open label extension (OLE), 1,286 patients had ≥ 12 months of treatment with Leqembi IV, 872 patients had ≥ 24 months of treatment, and 464 patients had ≥ 36 months of treatment with Leqembi IV as of March 31, 2024 (data cutoff).[4] The baseline characteristics were similar between the early start Leqembi IV patients (Leqembi IV during the blinded period and continued through OLE) and the delayed start patients (placebo during the blinded period and switched to Leqembi IV for OLE). At 36 months, Leqembi IV treated patients continued to show benefit. The ADNI cohort showed about a -4.00 point change in CDR-SB compared with a -3.09 point change for the Leqembi IV early start group (a treatment difference of -0.95). The delayed start group did not catch up in CDR-SB (about -3.5 points) compared with the early start group. Leqembi IV resulted in a statistically meaningful delayed progression to the next Alzheimer's disease stage at 36 months (hazard

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ratio = 0.704). This represented a 30% reduction in the time to worsening for patients who started the blinded period on Leqembi IV vs placebo at 36 months. Quality of life data showed patient continued to benefit from Leqembi IV at Month 36. The mean change from baseline to Month 36 in the Quality of Life in Alzheimer's Disease (QoL-AD) total score showed a 0.944 decline for the early start group compared with 1.766 decline for the delayed start group. The Zarit Burden Interview (ZBI) total score adjusted mean change from baseline to Month 36 resulted in less increase of a care partner burden for the early start group (6.252) compared with the delayed start group (7.887).

Dosing Information

The recommended dose of Leqembi IV is 10 mg/kg administered as an IV infusion once every 2 weeks for 18 months.[1] After 18 months, the starting dosage may be continued or a transition to maintenance regimen may be considered, which can be administered as either a 10 mg/kg IV infusion once every 4 weeks. Leqembi IV must be administered by a healthcare professional at an infusion center.

Safety

Leqembi IV has a Boxed Warning regarding amyloid-related imaging abnormalities (ARIA).[1] Leqembi IV can cause amyloid-related imaging abnormalities-edema (ARIA-E) and amyloid-related imaging abnormalities-hemosiderin deposition (ARIA-H), which includes microhemorrhage and superficial siderosis, which can be observed on magnetic resonance imaging (MRI). A recent MRI of the brain should be obtained prior to initiating treatment with Leqembi IV. The safety of Leqembi IV has not been evaluated in patients with findings on neuroimaging that indicated an increased risk for intracerebral hemorrhage including prior cerebral hemorrhage > 1 cm in greatest diameter, more than four microhemorrhages, superficial siderosis, evidence of vasogenic edema, aneurysm, or vascular malformation. Enhanced clinical vigilance for asymptomatic ARIA is recommended during the first seven doses of treatment with Leqembi IV, particularly during titration, because the majority of ARIA was observed during this time. MRIs of the brain should be obtained prior to the third infusion, fifth infusion, seventh infusion, and 14th infusion of Leqembi IV to evaluate for the presence of asymptomatic ARIA. There is no experience in patients who continued dosing through symptomatic ARIA-E or through asymptomatic, but radiographically severe, ARIA-E. There is limited experience in patients who continued dosing through asymptomatic but radiographically mild to moderate ARIA-E. There are limited data in dosing patients who experienced recurrent ARIA-E. If a patient experiences symptoms suggestive of ARIA, clinical evaluation should be performed, including an MRI if indicated. Dosing interruptions may be needed for patients with ARIA-E or ARIA-H. In patients who develop intracerebral hemorrhage > 1 cm in diameter during treatment with Leqembi IV, suspend dosing until MRI demonstrates radiographic stabilization and symptoms, if present, resolve. Use clinical judgment in considering whether to continue treatment after radiographic stabilization and resolution of symptoms or permanently discontinue Leqembi IV.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Leqembi IV. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Leqembi IV as well as the monitoring required for adverse events and long-term efficacy, approval requires Leqembi IV to be prescribed by a neurologist.

Documentation: Documentation is required for use of Leqembi IV as noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, laboratory results, medical test results, claims records, prescription receipts, and/or other information. All documentation must include patient-specific identifying information.

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Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Leqembi IV is recommended in those who meet the following criteria:

FDA-Approved Indication

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1. Alzheimer's Disease. Approve for the duration noted if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, iv, and v):

i. According to the prescriber, the patient has mild cognitive impairment due to Alzheimer's disease or mild dementia due to Alzheimer's disease; AND
Note: Examples of confirmatory diagnostic evaluations include, but are not limited to, assessments performed using National Institute on Aging and Alzheimer's Association (NIA-AA) diagnostic criteria or the Clinical Dementia Rating-Global Score (CDR-GS).

ii. Patient has had ONE of the following baseline assessments (a, b, c, d, or e):
- **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); AND

iii. Patient meets BOTH of the following (a and b):
- **a)** Patient has had a magnetic resonance imaging (MRI) of the brain within the past 1 year **[documentation required]**; AND
- **b)** According to the prescriber; the MRI showed BOTH of the following [(1) and (2)]:
  - **(1)** ≤ 4 brain microhemorrhages, brain hemorrhage ≤ 1 cm, and ≤ 1 pre-treatment localized superficial siderosis; AND
  - **(2)** Medical or neurological conditions, other than Alzheimer's disease, that may be contributing to the patient's cognitive impairment were ruled out; AND

iv. Patient has had a positive test for amyloid beta based on ONE of the following (a or b):
- **a)** Positron Emission Tomography (PET) scan; OR
- **b)** Cerebrospinal fluid (CSF) beta-amyloid$_{1-42}$; AND

v. The medication is prescribed by or under the supervision of a neurologist; OR

B) Patient is Currently Receiving Leqembi IV or Leqembi IQLIK. Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):

i. According to the prescriber, the patient has not progressed beyond mild dementia due to Alzheimer's disease; AND
Note: Examples of confirmatory diagnostic evaluations include, but are not limited to, assessments performed using National Institute on Aging and Alzheimer's Association (NIA-AA) diagnostic criteria or the Clinical Dementia Rating-Global Score (CDR-GS).

ii. Patient has undergone MRI monitoring for amyloid related imaging abnormalities (ARIA) **[documentation required]** AND meets ONE of the following (a or b):
- **a)** Patient does not have ARIA; OR
- **b)** According to the prescriber, continuation of therapy is appropriate; AND

iii. The medication is prescribed by or under the supervision of a neurologist.

Dosing. Approve ONE of the following dosing regimens (A or B):

A) Initial dose: 10 mg/kg administered by intravenous infusion every 2 weeks; OR

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B) Maintenance dose: 10 mg/kg administered by intravenous infusion every 4 weeks after 18 months of initial dose.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Leqembi IV is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

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.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	01/24/2024
Annual Revision	No criteria changes.	02/05/2025
Selected Revision	**Policy Name:** Updated from "Neurology – Leqembi" to "Neurology – Leqembi Intravenous and Leqembi IQLIK". **Leqembi IQLIK:** Added to the policy with no Recommended Authorization Criteria.	9/24/2025
Update	11/03/2025: **Policy Name:** Updated from "Neurology – Leqembi Intravenous and Leqembi IQLIK" to "Alzheimer's Disease – Amyloid Beta-Directed Antibodies – Leqembi Intravenous and Leqembi IQLIK".	--
Annual Revision	**Policy Name:** Updated from "Alzheimer's Disease – Amyloid Beta-Directed Antibodies – Leqembi Intravenous and Leqembi IQLIK Utilization Management Medical Policy" to "Alzheimer's Disease – Amyloid Beta-Directed Antibodies – Leqembi Intravenous Utilization Management Medical Policy." Leqembi IQLIK was removed from the policy. **Policy Statement:** The Policy Statement was modified from "Due to safety concerns and the lack of clinically significant efficacy data, approval is not recommended for Leqembi IV or Leqembi IQLIK" to as listed. **Alzheimer's Disease:** This condition of approval was added. **Conditions Not Recommended for Approval:** Removed Alzheimer's Disease.	02/18/2026
Selected Revision	**Alzheimer's Disease:** The requirement that the patient is ≥ 50 years of age was removed.	04/15/2026
Selected Revision	**Alzheimer's Disease:** The requirement that the patient has a Mini-Mental State Examination (MMSE) score ≥ 20 was removed.	06/10/2026

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HISTORY (CONTINUED)

Type of Revision	Summary of Changes	Review Date
Selected Revision	**Alzheimer's Disease:** When the medication is being used as initial therapy, the requirement that the patient has a Clinical Dementia Rating-Global Score of 0.5 (very mild dementia) or 1 (mild dementia) was modified to according to the prescriber, the patient has mild cognitive impairment due to Alzheimer's disease or mild dementia due to Alzheimer's disease. A Note was added with examples of confirmatory diagnostic evaluations. A requirement was added that the patient has had ONE of the following baseline line assessments: Clinical Dementia Rating-Global Score (CDR-GS); Mini-Mental State Examination (MMSE); Montreal Cognitive Assessment (MoCA); Saint Louis University Mental Status (SLUMS); or Rowland Universal Dementia Assessment Scale (RUDAS). The requirement that the patient is currently receiving Leqembi IV was modified to the patient is currently receiving Leqembi IV or Leqembi Iqlik. The requirement that the patient has not progressed beyond a Clinical Dementia Rating-Global Score 1 was modified to according to the prescriber, the patient has not progressed beyond mild dementia due to Alzheimer's disease. A Note was added with examples of confirmatory diagnostic evaluations.	07/22/2026

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