Drug Coverage Policy

Effective Date.....8/15/2026
Coverage Policy Number.....IP0796
Policy Title..... Leqembi IQLIK

Alzheimer's Disease – Amyloid Beta-Directed Antibodies – Leqembi IQLIK

- Leqembi® IQLIK™ (lecanemab-irmb subcutaneous injection – Eisai/Biogen)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

OVERVIEW
Leqembi IQLIK, an amyloid beta-directed antibody, is indicated for the **treatment of Alzheimer's disease.**[1] Treatment with Leqembi IQLIK 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 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
Leqembi IQLIK approval relied upon existing safety and efficacy information for Leqembi IV. Efficacy was assessed in pharmacokinetic and pharmacodynamic modeling using observed data from the CLARITY AD core study.[1]

Safety
Leqembi IQLIK has a Boxed Warning around amyloid related imaging abnormalities (ARIA).[1] Leqembi IQLIK 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 (within 1 year) MRI of the brain should be obtained prior to initiating treatment with Leqembi. The safety of Leqembi has not been evaluated in patients with prior cerebral hemorrhage > 1 cm in greatest diameter, more than four microhemorrhages, superficial siderosis, evidence of vasogenic edema, evidence of cerebral contusion, aneurysm, vascular malformation, infective lesions, multiple lacunar infarcts or stroke involving a major vascular territory, and severe small vessel or white matter disease. Enhanced clinical vigilance for asymptomatic amyloid related imaging abnormalities (ARIA) is recommended during the first seven doses of treatment with Leqembi, 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 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.

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POLICY STATEMENT
Prior Authorization is required for benefit coverage of Leqembi IQLIK. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Leqembi IQLIK as well as the monitoring required for adverse events and long-term efficacy, approval requires Leqembi IQLIK to be prescribed by a neurologist.

Documentation: Documentation is required for use of Leqembi IQLIK 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.

Leqembi IQLIK is considered medically necessary when the following is met:

FDA-Approved Indication

1. **Alzheimer's Disease.** Approve for the duration noted if the patient meets ONE of the following criteria (A or B):
   - **A)** Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, iv, v, and vi):
     - **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 ≤ 4 brain microhemorrhages, brain hemorrhage ≤ 1 cm, and ≤ 1 pre-treatment localized superficial siderosis; AND
     - **iv.** According to the prescriber, medical or neurological conditions, other than Alzheimer's disease, that may be contributing to the patient's cognitive impairment were ruled out; AND
     - **v.** 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
     - **vi.** The medication is prescribed by or under the supervision of a neurologist; OR
   - **B)** Patient is Currently Receiving Leqembi IQLIK or Leqembi IV. 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.

Conditions Not Covered

Leqembi IQLIK for any other use is considered not medically necessary. Criteria will be updated as new published data are available.

Coding Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
J0174	Injection, lecanemab-irmb, 1 mg

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. Eisai. Lecanemab subcutaneous formulation for maintenance dosing: the potential of a new and convenient option for ongoing treatment in early Alzheimer's disease [featured research session presentation]. Presented at: the Alzheimer's Association International Conference (AAIC) 2025; Toronto, Canada; July 27-31, 2025.

Revision Details

Summary of Changes	Review Date	Effective Date
New policy.	7/30/2026	8/15/2026

The policy effective date is in force until updated or retired.