Utilization Review Policy 305A

POLICY: Neurology – Leqembi Intravenous and Leqembi IQLIK Utilization Management Medical Policy

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

EFFECTIVE DATE: 7/17/2023
LAST REVISION DATE: 10/10/2025

COVERAGE CRITERIA FOR: UCare Medical Assistance Plans (PMAP, Connect, MSC+, MnCare) and UCare Health Exchange Plans (Individual and Family Plans)

OVERVIEW

Leqembi, an amyloid beta-directed antibody, is indicated for the **treatment of Alzheimer's disease** in patients with mild cognitive impairment or mild dementia stage of disease.[1] Leqembi intravenous (IV) can be used for initial and maintenance treatment. Leqembi IQLIK subcutaneous (SC) injection is only indicated for use as maintenance treatment after 18 months of Leqembi 10 mg/kg IV biweekly.

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

The current Leqembi IV and IQLIK efficacy information is insufficient to determine if the medication demonstrates any clinically meaningful benefits.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Leqembi. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. 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 as well as the monitoring required for adverse events and long-term efficacy, approval requires Leqembi to be prescribed by a neurologist or gerontologist.

Documentation: Documentation is required for use of Leqembi as noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, prescription claims records, prescription receipts, and/or other information.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

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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 EACH of the following (i through xv):

- **i.** Patient is ≥ 18 years of age; AND
- **ii.** Patient has a diagnosis of mild cognitive impairment (MCI) due to Alzheimer's disease (AD) or mild Alzheimer's dementia as evidenced by all of the following (a, b, c, d, and e):
  - **a)** Clinical Dementia Rating (CDR)-Global score of 0.5 to 1
  - **b)** Memory Box score ≥ 0.5
  - **c)** Mini-Mental State Examination (MMSE) score 22 to 30
  - **d)** Objective evidence of cognitive impairment at screening
  - **e)** Positron emission tomography (PET) scan or cerebrospinal fluid (CSF) assessment of amyloid beta (1-42) is positive for amyloid beta plaque; AND
- **iii.** Prescriber attests that other conditions causing similar symptoms have been ruled out (e.g., vascular dementia, dementia with Lewy bodies, frontotemporal dementia, normal pressure hydrocephalus); AND
- **iv.** Patient does not have risk factors for intracerebral hemorrhage (e.g., prior cerebral hemorrhage > 1 cm in greatest diameter, more than 4 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, severe small vessel or white matter disease); AND
- **v.** Patient has not had a stroke, transient ischemia attack (TIA), or seizure in the last 12 months; AND
- **vi.** Patient has not demonstrated clinically significant and unstable psychiatric illness in the last 6 months; AND
- **vii.** Testing for apolipoprotein E Ɛ4 (ApoE Ɛ4) carrier status has been conducted; AND
- **viii.** Prescriber attests to conducting a careful risk-benefit analysis prior to prescribing lecanemab-irmb for patients who are homozygous for ApoE Ɛ4, and for those receiving anti-platelet agents (with the exception of prophylactic aspirin or clopidogrel), anticoagulants (e.g., Factor Xa inhibitors), or anti-thrombins (e.g., heparin); AND
- **ix.** Brain magnetic resonance imaging (MRI) has been obtained prior to treatment initiation; AND
- **x.** Baseline disease severity has been assessed using an objective measure/tool (e.g., MMSE, Alzheimer's Disease Assessment Scale Cognitive Subscale [ADAS-Cog-13], Alzheimer's Disease Cooperative Study-Activities of Daily Living Inventory-Mild Cognitive Impairment version [ADCS-ADL-MCI], Clinical Dementia Rating-Sum of Boxes [CDR-SB]).
- **xi.** Will NOT be used concurrently with other anti-amyloid immunotherapies; AND
- **xii.** Prescriber attests that the patient and/or caregiver understands the risks and benefits of Leqembi therapy AND
- **xiii.** Prescriber attests that the patient and/or caregiver understands and is committed to receiving scheduled doses and enhanced clinical vigilance during the first 14 weeks of treatment
- **xiv.** The following documentation must be provided at time of requests (a and b):
  - **a)** Healthcare facility's written processes and procedures to support enhanced clinical vigilance during the first 14 weeks of treatment **[documentation required]**; AND

b) Patient's educational materials to empower patient and caregiver during the enhanced clinical vigilance period and thereafter including ways to contact prescriber and other relevant clinical staff **[documentation required]**; AND

xv. Prescribed by, or in consultation with, a specialist in neurology or gerontology

II. Coverage of Leqembi IV or Leqembi IQLIK is recommended in those who meet the following criteria:

B) Patient is Currently Receiving Leqembi. Approve for 1 year if the patient meets EACH of the following (i through vii):

i. Patient is ≥ 18 years of age; AND

ii. Scoring on an objective measure/tool (e.g., ADAS-Cog 13; ADCSADL-MCI; MMSE; CDR-SB) demonstrates improvement, stability, or slowing in cognitive and/or functional impairment; AND

iii. Patient has not experienced any treatment-restricting adverse effects (e.g., severe hypersensitivity reactions); AND

iv. Patient has undergone MRI prior to the 5th, 7th, and 14th infusions to monitor for ARIA with edema (ARIA-E) or ARIA with hemosiderin deposition (ARIA-H); AND

v. Leqembi administration will be suspended and not resumed until MRI demonstrates radiographic resolution and stabilization of symptoms in the event of any of the following (a, b, c, d, or e):

a) ARIA-E that is asymptomatic or mildly symptomatic with moderate to severe radiographic severity

b) ARIA-E with moderate to severe symptoms and any degree of radiographic severity

c) ARIA-H that is asymptomatic with moderate radiographic severity

d) ARIA-H with moderate to severe symptoms and any degree of radiographic severity

e) ARIA-E or ARIA-H with severe radiographic severity; AND

vi. If the request is for Leqembi IQLIK, at least 18 months of Leqembi IV has been completed and tolerated by the patient; AND

vii. The medication is prescribed by a neurologist or gerontologist.

Dosing. Approve if the dose meets ONE of the following (A or B):

A. Leqembi IV: Approve 10mg/kg administered intravenously not more frequently than once every 2 weeks.

B. Leqembi IQLIK: Approve 360mg administered subcutaneously not more frequently than once every 7 days.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Leqembi 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; August 2025.
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 September 22, 2025.
3. Swanson CJ, Zhang Y, Dhadda S, et al. A randomized, double-blind, phase 2b proof-of-concept clinical trial in early Alzheimer's disease with lecanemab, an anti-Aβ protofibril antibody. *Alzheimers Res Ther*. 2021;13(1):80.
4. van Dyck CH, Swanson CJ, Aisen P, et al. Lecanemab in early Alzheimer's disease. *N Engl J Med*. 2023;388(1):9-21.

5. Andrews JS, Desai U, Kirson NY, et al. Disease severity and minimal clinically important differences in clinical outcome assessments for Alzheimer's disease clinical trials. *Alzheimers Dement*. 2019;5:354-363.
6. 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.
7. Leqembi. MN Department of Human Services. March 2025. Available at: https://mn.gov/dhs/partners-and-providers/policies-procedures/minnesota-health-care-programs/provider/types/rx/pa-criteria/leqembi.jsp. Accessed October 10, 2025

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	01/25/2023
UCare Update	Created Medicaid specific policy as Leqembi now participates in the Medicaid Drug Rebate Program	06/26/2023
Update	7/19/2023: Leqembi received traditional approval by the FDA on July 6, 2023 based on results from the CLARITY AD trial. No criteria changes.	--
Annual Review	Updated for concurrent use with an anticoagulant. Added confirmation that there has been no stroke, TIA or seizure in the past 12 months. Added gerontologist as an appropriate prescribing specialist. Added that concurrent use with another Aβ monoclonal antibodies (mAbs) for Alzheimer's Disease (e.g., Aduhelm, Kisulna) is not allowed. Updated UCare plans that are targeted by this policy to include UCare Health Exchange Plans.	9/6/2024
UCare P&T Review	Policy reviewed and approved by UCare P&T committee. Annual review process.	9/16/2024
UCare P&T Review	Policy reviewed and approved by UCare P&T committee. Annual review process.	9/15/2025
Annual Review	**Policy Name:** Updated from "Neurology – Leqembi" to "Neurology – Leqembi Intravenous and Leqembi IQLIK". **Leqembi IQLIK:** Added to the policy and incorporated into the continuation of therapy criteria with validation of use of the intravenous product for at least 18 months. **Leqembi:** Updated criteria to align with the Minnesota Department of Human Services criteria requirement verbiage and approval durations.	10/10/2025