UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2376-2
Program	Prior Authorization/Medical Necessity
Medication	*Leqembi® IQLIK™ (lecanemab-irmb) injection *This program applies to the subcutaneous formulations of Leqembi
P&T Approval Date	9/2025, 12/2025
Effective Date	2/1/2026

1. Background:

Leqembi is an amyloid beta-directed antibody indicated for the treatment of Alzheimer's disease. Treatment with Leqembi 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.

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Leqembi IQLIK** will be approved based on **all** of the following criteria:

   a. Diagnosis of Alzheimer's disease

   -AND-

   b. Presence of amyloid beta pathology has been confirmed

   -AND-

   c. Patient has been established on intravenous **Leqembi** therapy under an active UnitedHealthcare medical benefit prior authorization

   -AND-

   d. **Both** of the following:

      (1) Submission of medical records (e.g., chart notes) confirming follow-up brain magnetic resonance imaging (MRI) has been completed after the initiation of intravenous **Leqembi** therapy

      -AND-

      (2) **One** of the following:

         (a) Amyloid-related imaging abnormalities (ARIA) have not been observed on MRI

         -OR-

         (b) **All** of the following:

i. ARIA has been observed on MRI

-AND-

ii. Prescriber attests that continuation of therapy with **Leqembi IQLIK** is appropriate based on the severity of the patient's clinical symptoms

-AND-

iii. One of the following:

- Follow-up MRI demonstrates radiographic resolution and/or stabilization

-OR-

- Prescriber attests that continuation of therapy with **Leqembi IQLIK** is appropriate based on the radiographic severity of ARIA

-AND-

e. Not used in combination with other Aβ monoclonal antibodies (mAbs) for Alzheimer's Disease (e.g., Kisunla)

-AND-

f. Prescribed by a neurologist, geriatric psychiatrist, or geriatrician who specializes in treating dementia

Authorization will be issued for 12 months.

B. <u>Reauthorization</u>

1. **Leqembi IQLIK** will be approved based on **<u>both</u>** of the following criteria:

   a. Not used in combination with other Aβ monoclonal antibodies (mAbs) for Alzheimer's Disease (e.g., Kisunla)

   -AND-

   b. Prescribed by a neurologist, geriatric psychiatrist, or geriatrician who specializes in treating dementia

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Leqembi [Package insert]. Eisai, Inc. Nutley, NJ. August 2025.
2. Cummings J, Apostolova L, Rabinovici GD, et al. Lecanemab: Appropriate Use Recommendations. J Prev Alzheimers Dis. 2023;10(3):362-377. doi:10.14283/jpad.2023.30
3. Jack CR Jr, Andrews JS, Beach TG, Buracchio T, Dunn B, Graf A, Hansson O, Ho C, Jagust W, McDade E, Molinuevo JL, Okonkwo OC, Pani L, Rafii MS, Scheltens P, Siemers E, Snyder HM, Sperling R, Teunissen CE, Carrillo MC. Revised criteria for diagnosis and staging of Alzheimer's disease: Alzheimer's Association Workgroup. Alzheimers Dement. 2024 Jun 27. doi: 10.1002/alz.13859. Epub ahead of print. PMID: 38934362.

Program	Prior Authorization/Medical Necessity – Leqembi® IQLIK™ (lecanemab-irmb)
Change Control	
9/2025	New program
12/2025	Removed criteria for staging of dementia due to Alzheimer's disease.