Pharmacy Policy Bulletin: J-1458 Leqembi Iqlik (lecanemab-irmb) – Commercial and Healthcare Reform - Delaware	
Number: J-1458	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** Not applicable
Region(s): ☐ All ☒ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** Only applies to Delaware Fully Insured Commercial and Delaware Healthcare Reform Plans
Version: J-1458-001	**Original Date:** 06/25/2025
Effective Date: 09/11/2025	**Review Date:** 09/17/2025

Drugs Product(s):	• Leqembi Iqlik (lecanemab)
FDA-Approved Indication(s):	• Treatment of Alzheimer's disease (AD). Treatment with Leqembi should be initiated in patients with mild cognitive impairment (MCI) or mild dementia stage of disease, the population in which treatment was initiated in clinical trials.

Background:	• Leqembi is a humanized immunoglobulin gamma 1 (IgG1) monoclonal antibody directed against amyloid beta. The accumulation of amyloid beta plaques in the brain is a defining feature of AD.
	• AD is a degenerative brain disease caused by complex brain changes following cell damage. It leads to dementia symptoms that gradually worsen over time. The most common early symptom is difficulty remembering new information with more severe symptoms including disorientation, confusion, behavior changes, and difficulties with speaking, swallowing, and walking.
	• AD is the most common cause of dementia, accounting for 60-80% of dementia cases. In the United States, AD is estimated to be the seventh leading cause of death and affects over 6 million adults.
	• The Clinical Dementia Rating Scale (CDR) is a global assessment instrument of cognitive and behavioral performance. The CDR-global score (CDR-GS) is used regularly in clinical and research settings. The CDR-Sum of Boxes (CDR-SB) is a more detailed assessment than the CDR-GS and provides more information in patients with mild dementia. CDR-GS ranges from 0-3 and CDR-SB ranges from 0-18, with a higher score indicating increased severity for both scales.
	• The Mini-Mental State Examination (MMSE) is a screening tool that measures cognitive impairment. MMSE ranges from 0 to 30 with a lower score indicating more impairment.
	• Prescribing Considerations:
	  ○ Leqembi is available as an intravenous (IV) infusion and a subcutaneous (SC) injection. Patients begin treatment with the IV infusion. After 18 months of Leqembi IV 10 mg/kg every 2 weeks, patients may either continue IV Leqembi once every 2 or 4 weeks or start Leqembi Iqlik SC weekly.
	  ○ Leqembi has a black box warning for amyloid related imaging abnormalities (ARIA). Apolipoprotein E (ApoE) ε4 homozygotes have a

	higher incidence of ARIA. Testing for ApoE ε4 should be performed prior to initiation of treatment. If a patient experiences symptoms suggestive of ARIA, clinical evaluation should be performed, including an MRI if indicated. Dosing interruptions may be necessary based on clinical symptom severity. ○ Brain MRIs are required due to the risk of ARIA. Brain MRIs are required at baseline and prior to the 3rd, 5th, 7th, and 14th IV infusions. ○ The presence of amyloid beta pathology must be confirmed prior to initiating treatment.

Approval Criteria

I. Initial Authorization

When a benefit, coverage of Leqembi Iqlik may be approved when all of the following criteria are met **(A. through J.)**:

A. The member has a diagnosis of Alzheimer's disease (ICD-10: G30).

B. The member's disease is classified as one (1) of the following **(1. or 2.):**
- **1.** Mild cognitive impairment
- **2.** Mild dementia

C. The member has completed 18 months of IV infusions of Leqembi 10 mg/kg every two weeks.

D. Prior to initiation of Leqembi IV, the member had confirmed presence of amyloid beta pathology via Positron Emission Tomography (PET) imaging.

E. Prior to initiation of Leqembi IV, there was documentation of baseline functional and/or cognitive status including all of the following **(1. and 2.):**
- **1.** Clinical Dementia Rating (CDR)-Global score
- **2.** Mini-Mental State Examination (MMSE) score of greater than or equal to 19

F. Prior to initiation of Leqembi IV, the member obtained a brain MRI within the past year.

G. Prior to initiation of Leqembi IV, the member has not experienced any of the following with the previous year **(1., 2., and 3.):**
- **1.** Localized superficial siderosis
- **2.** Greater than or equal to ten (10) brain microhemorrhages
- **3.** Brain hemorrhage greater than one (1) cm

H. The member is not taking anticoagulant or antiplatelet agents (except aspirin for prevention of cardiovascular or thromboembolic events).

I. The prescriber has ruled out all other possible causes of cognitive impairment or dementia (for example, substance abuse, schizophrenia, vascular dementia, Parkinson's disease dementia, Huntington's disease).

J. Prior to initiation of Leqembi IV, the member has undergone ApoE ε4 genetic testing.

II. Reauthorization

When a benefit, reauthorization of Leqembi Iqlik may be approved when all of the following criteria are met **(A. and B.)**:

A. There is documentation that the member has stable or improved disease.

B. There is documentation that the member has not progressed to moderate or severe disease as indicated by both of the following **(1. and 2.):**
- **1.** MMSE score greater than or equal to 19
- **2.** CDR-Global score of less than or equal to 1.0 or CDR-Sum of Boxes less than or equal to 9

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None

References:

1. Leqembi [package insert]. Nutley, NJ: Eisai Inc.; August 2025.
2. O'Bryant SE, Waring SC, Cullum CM, et al; Texas Alzheimer's Research Consortium. Staging dementia using Clinical Dementia Rating Scale Sum of Boxes scores: a Texas Alzheimer's research consortium study. *Arch Neurol*. 2008 Aug;65(8):1091-5.
3. Eisai. Clinical Dementia Rating – Sum of Boxes (CDR-SB). Available at: https://www.understandingalzheimersdisease.com/-/media/Files/uAD/Clinical-Assessment/CDR-Brochure.pdf. Accessed May 14, 2025.