

Medical Pharmacy Drug Prior Authorization Criteria

Drug Trade Name:	Leqembi®	Drug Generic Name:	Lecanemab-Irmb
J Code:	JO174	1 billable unit =	1 mg
Original Date of Review:	12/11/2024	Last Reviewed:	12/11/2024
Revision Date History			

Leqembi® (lecanemab-irmb) is a humanized monoclonal antibody directed against aggregated soluble and insoluble forms of amyloid beta. Lecanemab reduces amyloid beta plaques, the accumulation of which is a defining pathological feature of Alzheimer's disease.

Criteria:

- **Length of authorization:** 6 months (initial), 6 months (renewal)
- **Age:** 50 years and older
- **Diagnoses [including ICD-10 codes]:**
- **Quantity Limit:**
 - 10mg/kg IV every 2 weeks
- **Initial Approval Criteria**
 - Patient is at least 50 years of age; AND
 - Prescribed by or in consultation with a neurologist, geriatric psychiatrist, or geriatrician who specializes in treating dementia; AND
 - Patient has a diagnosis of Alzheimer's disease with:
 - Mild cognitive impairment OR
 - Mild dementia AND
 - Clinical documentation demonstrates all of the following:
 - Global Clinical Dementia Rating (CDR) score of 0.5 or 1.0; AND
 - CDR Memory Box Score of 0.5 or greater; AND
 - One of the following:
 - Mini Mental State Examination (MMSE) score of 20 or greater OR
 - Montreal Cognitive Assessment (MoCA) score of 17 or greater OR
 - Saint Louis University Mental Status (SLUMS) score or 17 or greater AND
 - Patient's Alzheimer's disease is confirmed with beta amyloid pathology as evidenced by ONE of the following:
 - A positive amyloid PET scan interpreted by a radiologist or nuclear medicine specialist OR
 - Amyloid is detected in CSF from a lumbar puncture; AND
 - Patient has had a brain MRI within the past 12 months prior to initiating treatment to evaluate for pre-existing amyloid related imaging abnormalities (ARIA); AND
 - Patient has undergone a complete physical and neurological exam to comprehensively rule out all other possible causes of neurocognitive decline including but not limited to:
 - Any medication potentially causing cognitive impairment must have been stopped for at least 4 weeks with continued cognitive symptoms
 - Currently uncontrolled psychiatric condition (including alcohol or substance abuse)
 - Parkinson's disease
 - Lewy body dementia
 - Vascular dementia (such as from a stroke); AND

- Patient does not have risk factors for intracerebral hemorrhage (eg. prior cerebral hemorrhage greater than 1 cm diameter, more than 4 microhemorrhages, superficial siderosis, vasogenic edema, aneurysm, vascular malformation, presence of an ApoE e4 allele)
- Patient is not taking any blood thinners; AND
- Leqembi® will not be used in combination with other monoclonal antibodies to treat Alzheimer’s Disease; AND
- Prescriber attests that the patient and/or caregiver understands the risks and benefits of Leqembi® therapy will monitor for symptoms associated with amyloid related imaging abnormalities (ARIA-E and ARIA-H).
- **Renewal Criteria**
 - Patient continues to meet the criteria identified in the initial approval criteria; AND
 - Clinical documentation of follow-up MRIs to evaluate for ARIA-E, ARIA-H, and other structural changes after initiation of therapy, then at least once annually; AND
 - One of the following:
 - ARIA has NOT been observed on MRI; OR
 - All of the following:
 - ARIA has been observed on MRI; AND
 - Prescriber attests that continuation of therapy with Leqembi® is appropriate based on the severity of the patient’s clinical symptoms; AND
 - One of the following:
 - Follow-up MRI demonstrates resolution/stabilization; OR
 - Prescriber attests that Leqembi® remains appropriate based on radiographic severity of ARIA.
 - Documentation of current disease severity as demonstrated by current MMSE score (at least every 6 months)
 - Coverage authorization may be discontinued when Alzheimer's disease progresses rapidly into moderate to severe Alzheimer's disease unless the prescriber provides published peer-reviewed clinical research supporting continued use
 - Rapid decline is defined as a 4-point reduction in a 6-month period on the MMSE, with an additional 1-point reduction in the following 6 months

- **Dosage/Administration**

Leqembi®	
Indication	Dose
Alzheimer’s disease	IV Infusion 10mg/kg every 2 weeks

NDC: Leqembi® 500 mg/5 ml vial 62856-0215-01
Leqembi® 200 mg/2 ml vial 62856-0212-01

References:

- 1) Biogen, Inc. FDA grants traditional approval for Leqembi® (lecanemab-irmb) for the treatment of Alzheimer’s disease. News Release. Cambridge, MA; Biogen; July 6, 2023.
- 2) Cummings J, Aisen P, Apostolova LG, et al. Aducanumab; Appropriate use recommendations. J Prev Alzheimer’s Dis. 2021;8(4);398-410.
- 3) Institute for Clinical and Economic Review: Draft Evidence Report - Aducanumab for Alzheimer’s disease: Effectiveness and Value. May 5, 2021. Available at: https://icer.org/wp-content/uploads/2020/10/ICER_ALZ_Draft_Evidence_Report_050521.pdf. Accessed November 27, 2024

- 4) Van Dyck CH, Swanson CJ, Aisen P, et al. Lecanemab an early Alzheimer's disease. N Engl J Med. 2023.;338(1); 9-21.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
G30.0	Alzheimer's disease with early onset
G30.1	Alzheimer's disease with late onset
G30.8	Other Alzheimer's disease
G30.9	Alzheimer's disease, unspecified